

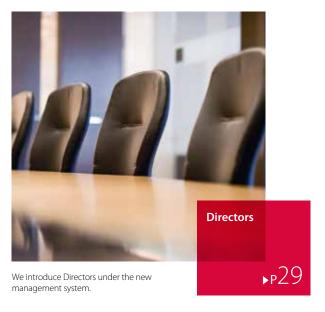
Changing tomorrow

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#### **Cautionary Note**

In this annual report, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this annual report is not intended to constitute an advertisement or medical advice

# **Business Philosophy**

#### Raison D'être

Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products

#### Mission

Sustainable enhancement of enterprise value

For details, please visit the following website:



#### **Editorial Policy**

To enable deeper stakeholder understanding of Astellas' efforts to continue to create value for sustainable growth, the Company has published this annual report as an integrated report.

In this report, we have attempted to provide disclosure while taking note of the Guiding Principles and Content Elements of the international integrated reporting framework of the International Integrated Reporting Council (IIRC). We have also referred to GRI Standards\* published by the Global Reporting Initiative and Environmental Reporting Guidelines (Fiscal Year 2012 Version) issued by Japan's Ministry of the Environment.

In creating the report, we have sought to make an effective tool for communicating with our many stakeholders. We have therefore used charts and photographs, and endeavored to use plain language that is easy to read.

Astellas has adopted the International Financial Reporting Standards (IFRS), effective from fiscal 2013. Information in this report is based on IFRS unless otherwise indicated. The monetary amounts stated in this report have been rounded off to the nearest unit, and the number of shares has been rounded down to the nearest whole number. Unless otherwise noted, percentage changes and other ratios involving the previous fiscal year have been rounded off to the second decimal place.

\* For the GRI Standards Content Index, please visit the following website: https://www.astellas.com/jp/en/investors/ir-library/annual-report

#### Scope of the Report

#### Period covered

Fiscal 2017 (April 1, 2017 - March 31, 2018)

- As much as possible, we have used the latest information available at the time of publication
- \* The period and scope of coverage may vary depending on the subject. We have noted each such case individually.
- \* The figures indicated in the field of Environment represent the results for fiscal 2017 (April 1, 2017 to March 31, 2018) in Japan and the calendar year 2017 (January 1 to December 31, 2017) for overseas operations as a combined total.

#### Organizations covered

Astellas Pharma Inc. and its consolidated subsidiaries in Japan and overseas (referred to in the report as "Astellas")

- \* The Americas includes North America and Latin America, and EMEA includes Europe, the Middle East, and Africa
- \* In the field of Environment, this report covers all the business sites in Japan and production sites overseas that are subject to the former Environmental Action Plan, and it covers all the business sites that are subject to the new Environmental Action Plan.

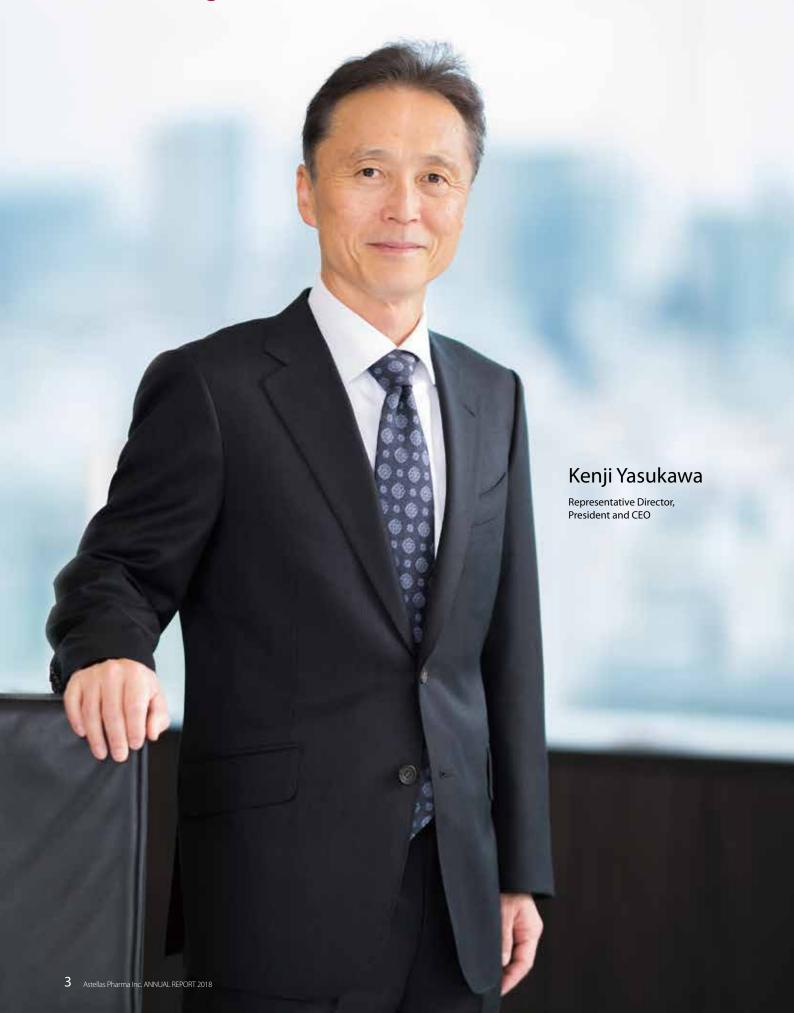
Note: In the information about pharmaceutical products in this report, market size, market share and product ranking are sourced from the following data.

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# **CEO** Message



# We will achieve sustainable growth by producing medical solutions that provide VALUE to patients.

#### Astellas' Evolution to Realize Its VISION

# Driving Transformation to Overcome the Patent Cliff and Achieve Sustainable Growth

In the next few years, Astellas will face the expiration of patents for several major products. I believe that the main responsibility handed to me as the new President and CEO of Astellas is to overcome the impact on business performance due to the expiration of patents for these products and return Astellas to a growth trajectory. The patent cliff is an issue that we cannot avoid as long as we remain specialized in the innovative drug business. Under these conditions, in order for Astellas to achieve sustainable growth, it will be crucial for us to continuously create VALUE by seeing changes in the environment as opportunities and driving evolution. In fiscal 2018, we launched a new strategic plan. By steadily executing the plan, we will seek to return Astellas to a trend of medium- to long-term core operating profit growth after reaching a low point in fiscal 2019.

# Continuously Create VALUE by Accurately Capturing Changes in the Environment

The business environment surrounding Astellas is changing at unprecedented speed. Changes in the environment that will have a negative impact on Astellas include higher hurdles for obtaining new drug approval and receiving insurance reimbursement, as well as increased pressure to reduce medical expenditures through measures such as reducing drug prices. Meanwhile, some changes in the environment will be positive for Astellas. Examples include the enhancement and expansion of systems to more quickly evaluate innovation, such as the priority review for new drugs, and an increase in modalities that can be applied to drug discovery in step with advances in science and technology. In addition, progress on digital technologies and engineering technologies will spur integration with different industries and provide new medical solutions for patients. In anticipation of these changes in the business environment, we will create medical solutions that leverage innovative medicines and Astellas' strengths. Moreover, we will continuously identify business opportunities from many different perspectives.

# Creating New Assets Based on the Focus Area Approach

Ever since I was appointed as Chief Strategy Officer (CSTO) in 2012, I have been involved in the formulation and execution of corporate strategy from medium- and long-term perspectives and promoting reforms in order to achieve Astellas' sustainable growth. When I was appointed as CSTO, we had adopted the "Global

Mid-Term Strategy ▶ P 1 1 Reference Feature: Focus ▶p15 Area Approach

Category Leader"\* (GCL) model. Under this business model, we sought to establish a competitive edge in key therapeutic areas such as urology, transplantation and immunology and inflammation. It is certainly true that this business model was instrumental in creating many products that have supported Astellas to this day. These achievements notwithstanding, the GCL model had kept Astellas narrowly focused on the same areas even after it had become difficult to create medicines that would surpass its existing drugs in those same areas. This made it difficult for Astellas to explore new opportunities. In addition, we had suffered setbacks such as missing out on valuable opportunities to make use of external resources due to our insistence on doing everything in-house. In order to put Astellas on a sustainable growth path, we needed to extensively revise the R&D strategy we had formulated based on the GCL model. As our first step, we decided to reform Astellas' research system in May 2013. Guided by the 3B philosophy of "Best Science, Best Talent, and Best Place," we developed a framework focused on proactively gaining access to external resources. In 2015, we formulated a new VISION, and shifted from our traditional approach of developing drugs only in a limited number of therapeutic areas to the new "Focus Area" approach of conducting drug discovery from multiple perspectives, irrespective of therapeutic area. Under the Focus Area approach, we will seek to understand the latest biology and intensively invest in areas backed by effective modalities for utilizing the latest biology. By doing so, we will build a portfolio where there is a high probability of success and where we can establish competitive superiority. This Focus Area approach is the foundation of Astellas' new R&D strategy. We have started to develop new assets based on the Focus Area approach including new technologies and modalities such as next-generation vaccines and cell therapy. These assets, which had previously been in the upstream research stage of the VALUE chain, have steadily advanced as a result of the activities of Strategic Plan 2015-2017, and some of those assets have now entered the development phase. To ensure that the Focus Area approach is implemented through to the downstream stages of our VALUE chain all at once, we have embraced "Evolving How We Create VALUE – With Focus Area Approach –" as one of the three strategic goals of the new Strategic Plan 2018 formulated this year. We have been making a Company-wide effort to drive the Focus Area approach forward. At the same time, we have identified the organizational capabilities that will be needed to push ahead with the Focus Area approach and have started taking steps to strengthen those capabilities.

\* A business model for establishing competitive advantage by creating medicines with innovative VALUE and delivering them to patients in therapeutic areas with high unmet medical needs. covering several areas such as urology, immunology and oncology.

### Strategic Plan 2018

# Strategic Plan 2018, a Clear Roadmap for Realizing Our VISION

With Strategic Plan 2018, we first clarified what we mean by "VALUE for patients" within our VISION and then presented a common definition of VALUE for all members of Astellas (please refer to the formula on the next page). In essence, our activities can be summarized as maximizing the "Outcomes that matter to patients," the numerator of the formula, and minimizing the "Cost to the healthcare system" of delivering those outcomes," the denominator of the formula. By gaining a true

eference	Mid-Term Strategy	▶p11
	Feature: Focus Area Approach	▶p15
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	Research and Development	▶P39

understanding of this system and its components, I believe that we will increase our understanding of all stakeholders in the healthcare sector, beginning with patients, and identify products and services that will most effectively and efficiently meet their needs, enabling us to prioritize efforts to deliver those kinds of products and services.

We then set strategic goals to bridge the gap between where we stand now and where we are headed.

#### Strategic Goal 1: Maximizing Product VALUE and Operational Excellence

We will continue to pursue operational excellence to establish competitive advantages, along with maximizing the VALUE of highly strategic products and late-stage pipeline projects. By doing so, we will free up funds for growth investments and direct those funds to the Focus Area approach, a strategic goal with a longer-term perspective.

We will strive to maximize sales of XTANDI and mirabegron. Concurrently, we will intensively allocate resources to six key post-POC\* pipeline projects (enzalutamide, gilteritinib, enfortumab vedotin, zolbetuximab, roxadustat, and fezolinetant), with the aim of obtaining approvals for these products as planned. In Japan, we will also endeavor to constantly launch and maximize the VALUE of new products.

By working to improve the quality and efficiency of operations, we will continue to build a business platform that can flexibly address the fast-changing business environment.

#### Strategic Goal 2: Evolving How We Create VALUE – With Focus Area Approach -

We will build a platform through the optimal combination of biology and modality, with the aim of obtaining POC for early-stage projects. Moreover, we will create high-quality assets by applying this platform to various diseases with high unmet medical needs. In addition, in order to acquire outstanding external innovation, we will strengthen our network with external innovators, through such means as partnerships with startups and academia, from our base in Boston, U.S.A.

#### Strategic Goal 3: Developing Rx+ Programs

We have established Rx+ Business Accelerator, a new department to promote the development of products and services (Rx+ programs) that combine Astellas' strengths in the prescription pharmaceutical (Rx) business developed over the years with technologies and knowledge from different fields. Going forward, this department will play a pivotal role in accelerating the commercialization of specific Rx+ programs, including collaboration with external partners.

#### Common Definition of VALUE

Outcomes that matter to patients

VALUE\* =

Cost to the healthcare system of delivering those outcomes

\* Source: BCG "Value in Healthcare" seminar

\* POC (Proof of Concept): Verification of clinical efficacy

#### **Human Resource Development, Compliance and CSR**

# Strengthening People and Organizations Is Essential to VALUE Creation

To realize our VISION, it is essential to strengthen our management strategies and the people and organizations that underpin those strategies.

I believe that it is crucial for every employee working at Astellas to take ownership of their duties based on an understanding of the Astellas Way and our HR Vision, which defines our aspirations for our human resources and for our organization, with a view to creating VALUE and earning the trust of society. In addition, guided by the Astellas Group Code of Conduct, we will undertake relevant issues in order to continue delivering VALUE to patients and gain the trust of the public.

Moreover, Astellas is a consistent supporter of the United Nations Global Compact, and has incorporated and implemented its 10 principles covering the four fields of human rights, labor, the environment and anti-corruption in its daily business activities.

Our People, Our Organization Ethics and

▶P56

Compliance

#### To Our Stakeholders

# Continuously Produce and Deliver Innovative Medical Solutions

Guided by Astellas' VISION of turning innovative science into VALUE for patients, Astellas aims to pursue cutting-edge science to produce medical solutions that provide VALUE to patients. Moreover, we will achieve sustainable growth by continuously generating VALUE for patients and society as a whole.

Kenji Yasukawa

Representative Director, President and CEO

# **Corporate Strategy and Corporate Governance**

# Pursuing Cutting-Edge Science to Realize Our VISION

Astellas' VISION is to turn innovative science into value for patients.

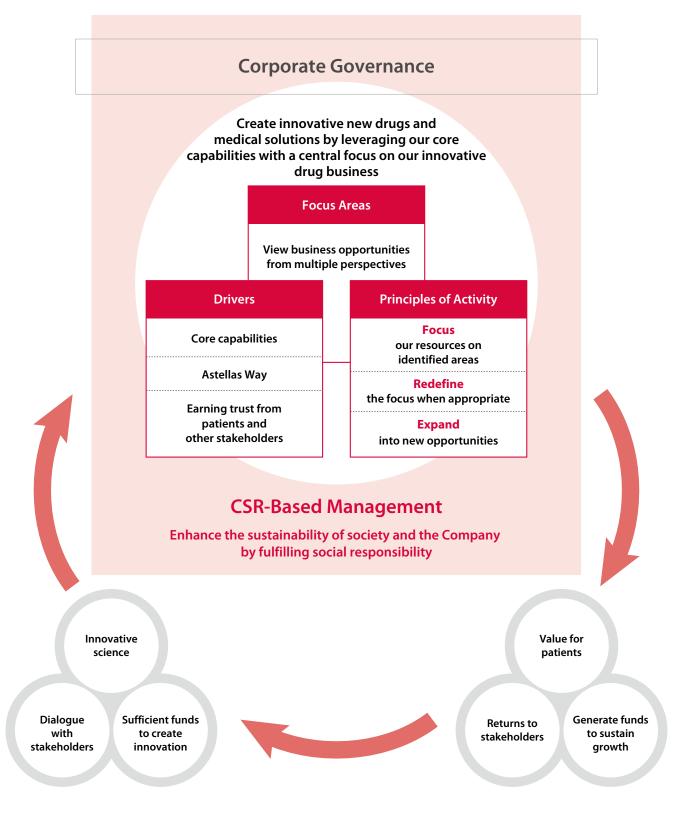
Strategic Plan 2018 will serve as a roadmap for realizing this VISION.

In order to realize sustainable growth, we will pursue cutting-edge science and create medical solutions that will provide value to patients.



# Astellas' Value Creation Process

Astellas stands on the forefront of healthcare change, turning innovative science into value for patients. By repeating this cycle continuously, we are pursuing the sustainable growth of enterprise value.



**Business Review** 

Financial Information and Data

#### Our Approach to the Value Creation **Process**

Astellas' raison d'être is to "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products."

Based on this, we aim to stand on the forefront of healthcare change, turning innovative science into value for patients. The keys to our success will be our Focus Areas, Principles of Activity, and Drivers, which describe where we should create value and how we should act to realize that value. Guided by this approach, we will create innovation with a central focus on the innovative drug business.

This process originates with advances in science, and Astellas then allocates sufficient funds and implements measures to satisfy the requests and expectations of stakeholders. By creating value for patients, through this process, we will generate funds to sustain the next phase of growth and provide returns to stakeholders.

Astellas will continue to follow this cycle to achieve sustainable growth of enterprise value.

#### **Focus Areas**

Amid continuing evolution in the healthcare industry, Astellas needs to identify business opportunities more flexibly and efficiently than ever in order to achieve further growth. We will define our Focus Areas by adding multiple perspectives to our conventional viewpoint of therapeutic areas. We will factor in a consideration of new technologies and treatment approaches, product development feasibility and new possibilities for commercialization, market trends and changes in pharmaceutical laws and regulations. Our goal is to identify areas of unmet need and find new business opportunities.

### **Principles of** Activity

In a fast-changing business environment, it is crucial to have the flexibility to reexamine business fields as needed—even those that have been carefully selected as opportunities at some point in the past. Astellas aims to drive further evolution by having all employees remain mindful of the three-step process of Focus our resources on identified areas, Redefine the focus when appropriate, and Expand the focus for the next generation of activity, as they carry out their activities.

#### **Drivers**

One of the drivers for Astellas to achieve sustainable growth is its core capabilities, which constitute the source of its competitive edge. It is vital to carefully identify our essential capabilities and enhance them until they are among the world's best. At the same time, when there are outstanding capabilities outside the Company, we will proactively form partnerships. By combining optimal capabilities, both internal and external, we enhance our productivity and creativity to maximize our value creation capabilities. Moreover, in the Astellas Way\*, we have defined a shared set of values to be embraced by all our employees as part of efforts to foster a corporate culture to help realize our business philosophy. At the same time, we remain committed to understanding the requests and expectations of a multitude of stakeholders, including patients, and transforming that understanding into value.

\* For details on the Astellas Way, Five Messages for One Astellas—Patient Focus, Ownership, Results, Openness, and Integrity—please refer to P56.

Astellas' Currently Identified Core Capabilities

Capability to create new drugs Capability to deliver new drugs

Commercial presence

Partnership

Operational foundation

Corporate Governance

Reference ▶ P23-P27

**CSR-Based** Management

Reference ▶ P19-P21

# Mid-Term Strategy

# Strategic Goals for Sustainable Growth



### **Review of Strategic Plan 2015-2017**

Under Strategic Plan 2015-2017, we produced solid results on three strategic priorities: Maximizing product VALUE, creating innovation and pursuing operational excellence.

With regard to maximizing product VALUE, we made three major achievements: (1) We increased sales of XTANDI, along with advancing the development of expanded indications; (2) We maximized the VALUE of the OAB franchise by driving early market penetration of mirabegron (Betanis/Myrbetriq/BETMIGA); and (3) We continuously launched new products in Japan.

In creating innovation, we produced results in three major areas: (1) We made steady progress on late-stage development programs such as gilteritinib, enfortumab vedotin, and roxadustat; (2) We upgraded and expanded the pipeline through the acquisition of Ganymed Pharmaceuticals AG and Ogeda SA; and (3) We advanced unique development programs that harness diverse treatment modalities and biology, such as cell therapy, to the clinical development stage.

In pursuing operational excellence, we transferred our global dermatology business and long-listed products manufactured and marketed in Japan. Meanwhile, we directed investments to priority areas, including establishing a global management structure.

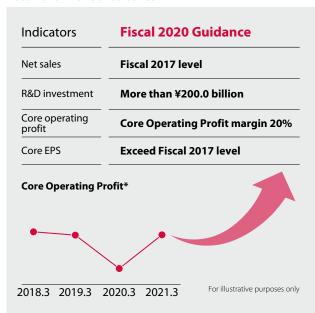
### Strategic Plan 2018

#### Basic Policy

In its VISION formulated in 2015, Astellas made a commitment to stand "on the forefront of healthcare change to turn innovative science into VALUE for patients." Guided by this VISION, Astellas seeks to create medical solutions that deliver VALUE to patients through the pursuit of cutting-edge science.

Under Strategic Plan 2018, Astellas will work to overcome the impact of the expiry of patents for core products that it will face from 2019 to 2020 to achieve sustainable growth. To this end, Astellas will strive to achieve three strategic goals: (1) Generate profit by maximizing product VALUE and operational excellence, along with using the funds generated through this process for (2) Evolving how we create VALUE through the Focus Area approach. Moreover, Astellas will (3) tackle the challenge of developing new businesses (Rx+ programs) that go beyond conventional prescription pharmaceuticals (Rx).

Fiscal 2020 Financial Guidance



<sup>\*</sup> For the definition of financial results on a core basis, please refer to P74.

#### Financial Guidance for Fiscal 2020

Astellas aims to return to a medium- to long-term core operating profit growth trend after fiscal 2019.

Net sales in fiscal 2020 are forecast to remain at mostly the same level as fiscal 2017. Astellas plans to allocate more than ¥200.0 billion a year to R&D investments for medium- and long-term growth, after setting clear priorities for those investments. In order to ensure both a certain level of profit and adequate R&D investment, we will thoroughly review the cost structure from a zero-basis, in addition to maximizing product VALUE. Through these measures, we are targeting a core operating profit margin of 20% in fiscal 2020. At the same time, we aim to achieve core EPS exceeding the fiscal 2017 level by working to enhance capital efficiency.

#### Strategic Goal 1

### **Maximizing Product VALUE and Operational** Excellence

#### Maximizing Product VALUE

Astellas will work to maximize product VALUE by intensively allocating resources to XTANDI, mirabegron and six key post-POC pipeline projects.

With regard to XTANDI, particularly its indication for metastatic castration-resistant prostate cancer, Astellas will strive to further increase penetration of XTANDI amongst urologists, along with establishing it as the first choice of therapy by utilizing extensive data based on the clinical experience accumulated since its launch. Moreover, we aim to expand the patient base and duration of therapy for XTANDI by expanding indications to earlier stages of prostate cancer.

In the OAB franchise, Astellas will work to mitigate the impact of the loss of exclusivity of VESIcare by shifting sales resources to mirabegron. We will continue to educate the public on mirabegron's clinical profile featuring a balance of efficacy and safety, with the aim of expanding market share.

In addition to maximizing the VALUE of these products, we will preferentially direct management resources to six key post-POC pipeline projects in order to obtain approval of these products as planned and support growth from fiscal 2020 onward.

#### Global Sales (March 2018 to March 2021)

XTANDI	
CAGR (%)	High single digit
Mirabegron (Be	tanis/Myrbetriq/BETMIGA)

#### Six Key Post-POC Pipeline Projects

- enfortumab vedotin
- enzalutamide (label expansion)
- fezolinetant
- gilteritinib zolbetuximab
- roxadustat

#### Pursuing Operational Excellence

Astellas will review all activities from a zero-basis from many different angles, without relying on past precedent.

Specifically, Astellas will preferentially allocate management resources to functions and activities that establish its competitive advantage over other companies, while terminating investment in areas that will not lead to growth or the establishment of competitiveness. In addition, Astellas will work to further evolve the operating model by leveraging cutting-edge technologies such as robotic process automation (RPA) and artificial intelligence (AI), and through globalization of organizations and functions and the standardization of operating processes.

Astellas anticipates an improvement of more than ¥30.0 billion in core operating profit to be generated from new initiatives in fiscal 2020.

#### Strategic Goal 2

### **Evolving How We Create VALUE** - With Focus Area Approach -

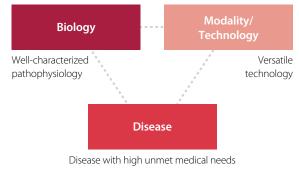
In order to achieve further growth, Astellas will need to identify business opportunities even more flexibly and efficiently than before. With this in mind, in its VISION, Astellas has established Focus Areas that reflect many different perspectives, without limiting itself to therapeutic areas, and has set out to find business opportunities in each of these areas.

Under Strategic Plan 2018, Astellas will evolve how it creates VALUE from the Therapeutic Area approach to the Focus Area approach. The goal of the Focus Area approach is to create innovative pharmaceuticals for diseases with high unmet medical needs by allocating management resources to fields that have been carefully narrowed from many different perspectives, including elucidation of pathophysiology through advances in science (biology) and the utilization of treatment modalities and

#### Our Approach to Operational Excellence



#### Focus Area Approach (Research to Pre-POC)

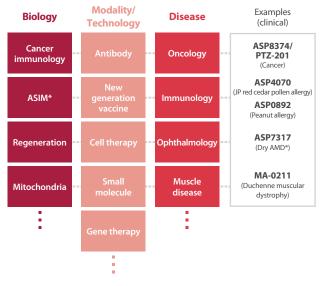


technologies (modality/technology). Astellas will identify unique combinations of biology and modality/technology based on emerging science and translate this into innovative solutions for patients with high unmet medical needs through continuous efforts to ensure development progress and market access. By doing so, Astellas will continuously identify innovative new drug candidates as it upgrades and expands its development pipeline.

In order to promote the Focus Area approach, Astellas will establish research sites that incorporate outstanding external innovation and bolster collaboration with biotechnology startups and academia, based on the concepts of Best Science, Best Talent and Best Place. At the same time, Astellas will also focus on developing human resources with a discerning eye for innovative science.

Astellas will generate high-quality programs by promoting the Focus Area approach, which seeks to drive innovation by flexibly combining biology, modality/technology and disease, while constantly embracing innovative science.

#### Pipeline Assets Based on the Focus Area Approach



 $<sup>\</sup>hbox{*} \ \, {\sf ASIM:} \, {\sf Antigen-specific immuno-modulation, AMD:} \, \, {\sf Age-related \, macular \, degeneration}$ 

#### Strategic Goal 3

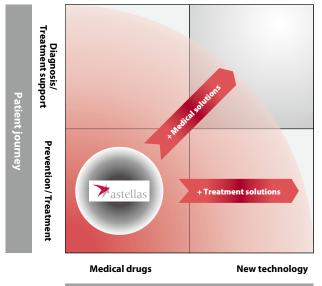
#### **Developing Rx+ Programs**

In addition to growth in the prescription pharmaceutical (Rx) business, Astellas recognizes that it is crucial to constantly look for new business opportunities where it can leverage its current strengths.

Mindful of this, Astellas has commenced initiatives to develop Rx+ programs. Rx+ programs refer to new products and services that create new revenue streams separate from Astellas' core prescription pharmaceutical products. Rx+ programs will be developed by combining Astellas' expertise and experience in medical drugs with technology and knowledge from different fields.

Through the Rx+ programs, Astellas will create new treatment solutions that replace conventional therapy or add new VALUE, and medical solutions that contribute positively to the entire patient journey, encompassing prevention, diagnosis, treatment and post-treatment care and management.

#### **Healthcare Solutions Beyond Rx Business**



Healthcare technology



\* Proof of Concept (POC): Verification of clinical efficacy

Case

# **Advancing Cell Therapy**

Astellas began its drug discovery initiatives through an approach combining the biology of regeneration and the modality of cell therapy, applying it to explore treatments in the field of ophthalmic diseases. We will expand this approach to other diseases in the future.

#### **Commenced R&D in Ophthalmology**

If cells abandon their original functions resulting in diseases, administering cells could be a treatment. In focusing on regeneration as biology closely related to pathophysiology and treatment, Astellas has commenced R&D based on the new modality of cell therapy.

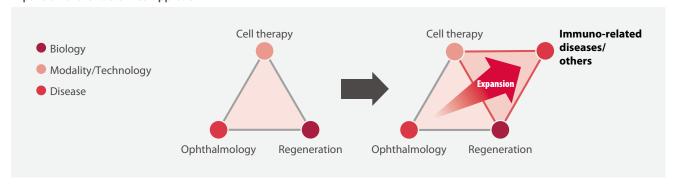
Astellas is first trying to apply this approach to the field of ophthalmology. In theory, the field of ophthalmology is suitable for cell therapy due to three main reasons: (1) The loss or dysfunction of cells is clearly connected with the resulting diseases, (2) The small size of eye tissue requires transfusion of only a relatively small number of cells, and (3) The intraocular region is isolated from immune reactions of the body. Notably, there are significant unmet medical needs for the treatment of diseases in the posterior segment of the eye, which can lead to vision loss. Currently, Astellas is developing ASP7317 for dry age-related macular degeneration (AMD) and Stargardt's macular degeneration. ASP7317 is a project derived from Ocata Therapeutics, Inc., which was acquired in 2015. ASP7317 is currently in the Phase 2 stage.

### **Introducing New Modalities to Expand Target Diseases**

Ocata Therapeutics was one of the world's frontrunners in the fundamental technology for establishing fully differentiated cells from pluripotent stem cells. Ocata Therapeutics has now changed its name to the Astellas Institute for Regenerative Medicine (AIRM) with further strengthened capabilities. We also plan to invest in manufacturing facilities at AIRM in anticipation of the commercialization of cell therapy.

Moving forward, Astellas will also expand its approach of combining regeneration and cell therapy to fields beyond ophthalmology. In the course of expanding into other therapeutic areas, one challenge will be to suppress the immunological rejection of transplanted cells. To resolve this issue, Astellas acquired Universal Cells, Inc. in February 2018. Universal Cells' proprietary Universal Donor Cell technology uses genome editing to prevent the expression of polymorphic human leukocyte antigen (HLA) molecules, thereby suppressing immune reactions caused by mismatched HLA at transplantation. By combining the technologies of AIRM and Universal Cells, Astellas will expand the scope of cell therapy from eye diseases to a variety of other diseases.

#### **Expansion of the Focus Area Approach**





# **Tackling the Challenge of Muscle Diseases**

Astellas is pursuing drug discovery in the field of muscle diseases based on a variety of approaches, beginning with improving the function of skeletal muscle by activating molecular motors and mitochondria.

# Targeting Muscle Diseases in Collaboration with Biopharmaceutical Companies

Recent scientific advances have identified new targets for drug development in the muscle disease area. It is also a field with high unmet medical needs. Aiming to alleviate declines in skeletal muscle function in muscle diseases, Astellas first focused on the approach of strengthening the function of molecular motors involved in muscle contractions from a perspective of biology.

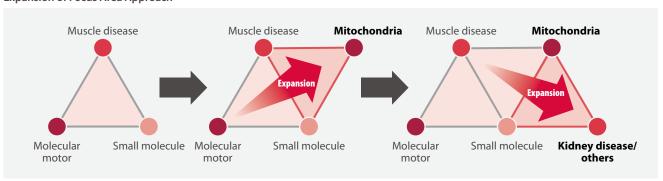
To advance R&D with this approach, Astellas is collaborating with Cytokinetics, Inc., a U.S.-based biopharmaceutical company that has been developing a compound called reldesemtiv. Reldesemtiv is expected to improve muscle contraction ability by activating troponin, which constitutes molecular motors in fast skeletal muscle. Currently, reldesemtiv is in Phase 2 clinical trials for spinal muscular atrophy (SMA), amyotrophic lateral sclerosis (ALS) and chronic obstructive pulmonary disease (COPD). A Phase 1b study in elderly subjects with limited mobility is also under way.

### **Expansion to Mitochondria-Related Diseases**

In the course of advancing research in muscle diseases, Astellas has also focused on mitochondria function. Mitochondria are vitally important organelles responsible for energy metabolism. They are found in almost every cell in the human body. Mitochondrial abnormalities are believed to play a role in various symptoms and diseases, such as muscle dysfunction, metabolic disorders, neurodegeneration, and visual disorders, as well as cancer, cardiovascular disorders, and renal failure.

In 2013, Astellas entered into an R&D collaboration with Mitokyne, Inc. (currently Mitobridge, Inc.), which conducts cutting-edge mitochondria research. MA-0211 for Duchenne muscular dystrophy and MA-0217 for acute kidney injury reached the Phase 1 clinical trial stage in only three years. In January 2018, Astellas acquired Mitobridge, which had generated many projects in the preclinical stage and achieved extensive results. Looking ahead, Astellas will accelerate R&D in mitochondria-related diseases, with the aim of delivering innovative new drugs to patients as early as possible.

#### **Expansion of Focus Area Approach**





#### **Pursuing Operational Excellence**

As with its previous three-year strategic plan, Astellas has adopted "maximizing operational excellence" as a crucial strategic theme for Strategic Plan 2018.

Together with taking steps to address various themes, we will also review all activities from a zero-basis. Activities that were assessed positively in the past are still subject to changes in the business environment and various assumptions underlying each of those activities. For example, we will strengthen activities and capabilities that differentiate Astellas from its competitors and lead to a competitive advantage. For activities that do not produce those results, we will explore options such as cancelling or outsourcing activities. In order to maximize effectiveness and efficiency, we will comprehensively review the operational process and organization as well as various rules and other operational aspects.

We will maximize the use of the latest technologies such as real-world data (RWD), robotic process automation (RPA), and artificial intelligence (AI). Concurrently, we will enhance our capabilities to take full advantage of those technologies.

In order to generate profits as we invest in growth, we will need to strictly prioritize our activities and allocate

management resources accordingly. Therefore, we will manage our activities even more strictly than before.

Let me present several recent examples of the numerous initiatives we have undertaken so far. We have reviewed Astellas' essential capabilities, organization and other attributes, with a focus on Japan and Europe, and have conducted a sizable reorganization of various functions. We have also been making preparations to develop a globally unified operating model centered on administrative functions. Naturally, this encompasses the use of technology. We have made initial investments and incurred expenses upon implementing these initiatives. However, over the medium and long terms, these initiatives will enable us to reap even greater benefits at a lower cost than now.

We have rigorously adopted a policy of preferentially allocating management resources to products in a growth phase and the key post-POC pipeline, as well as areas that offer prospects for future growth, in conjunction with reducing the allocation of management resources to areas such as products that have reached a mature phase. We have devised our plan for fiscal 2018 based on this blueprint.

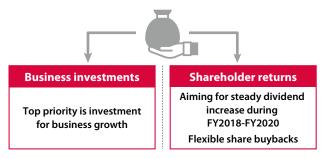
Guided by Strategic Plan 2018, we expect to deliver an improvement in core operating profit of over ¥30.0 billion in fiscal 2020 through future initiatives focused on raising the efficiency of operations.

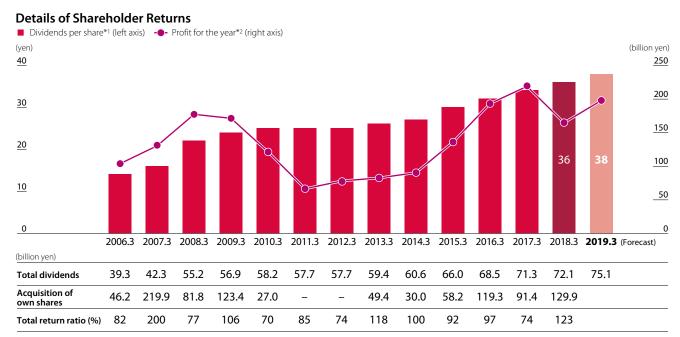
### **Capital Allocation**

I believe that our shareholders expect us to enhance Astellas' corporate value by investing in business opportunities. We will continue to preferentially allocate resources to business investments. At the same time, we are well aware that dividends are another important matter of concern for shareholders. With this in mind, we will strive to steadily increase dividends. During the three-year period from fiscal 2018, particularly fiscal 2019, our earnings performance is expected to come under pressure due to patent expiry of major products. However, we will seek to continuously increase dividends. Moreover, we will implement share buybacks flexibly as the occasion arises,

with the primary goal of enhancing capital efficiency and earnings per share. In May 2018, we announced plans to conduct our largest-ever share buyback by acquiring up to ¥100.0 billion of our own shares.

#### **Business Investments and Shareholder Returns**



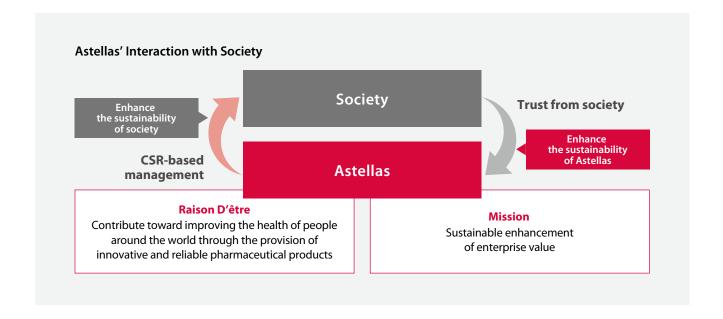


<sup>\*1</sup> The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014. Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal 2005.

<sup>\*2</sup> From fiscal 2013, figures are in accordance with International Financial Reporting Standards (IFRS).

# **CSR-Based Management**

Create and protect value for both Astellas and society by fulfilling social responsibility



# **Fulfilling Our Social Responsibility Means Realizing Our Business Philosophy**

Astellas recognizes its corporate social responsibility (CSR) is its responsibility for any impacts that its decisions and business activities have on society and the environment.

Astellas is helping to enhance the sustainability of society by fulfilling its social responsibilities as a pharmaceutical company by, for example, providing pharmaceutical products that satisfy unmet medical needs. We believe that we earn trust from society for both the Company and our products as a result of these activities, and that this trust enhances our sustainability. This positive cycle will lead to the realization of our mission, "sustainable enhancement of enterprise value" through fulfillment of our raison d'être "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products." For Astellas, fulfilling our social responsibility means realizing our business philosophy.

### Value Creation and Protection for Both Astellas and Society

CSR for Astellas has two aspects: value creation and value protection.

**Value Creation** Through its business activities, Astellas is creating value for society by addressing social issues such as unmet medical needs, and by returning profits to stakeholders. By reinvesting the profit we gain through business activities, we strengthen our capabilities in research and development. In addition, by winning trust from government and business partners in each country, we create new business opportunities. This process creates value for Astellas.

**Value Protection** Astellas seeks to preserve biodiversity by reducing the environmental burden associated with its business activities, while maintaining social order by ensuring compliance and preventing corruption. These activities will lead to the protection of value for society. In addition, Astellas protects its enterprise value by mitigating reputation risk and elevating its corporate brand through these activities.

### **Updating of the CSR Materiality Matrix**

Astellas discloses its CSR Materiality Matrix (see next page) that identifies and prioritizes material issues in CSR activities, and uses this materiality matrix to guide its CSR activities. In fiscal 2017, we reviewed the CSR Materiality Matrix in full in order to respond to the changing needs of society.

In conducting the review, we spoke with diverse stakeholders (investors, patient groups, doctors, employees, consultants, and academics) in Japan and overseas; examined their feedbacks from a variety of perspectives; deliberated on and approved matters at the CSR Committee\*, Executive Committee (EC) and Board of Directors; and decided to update the CSR Materiality Matrix.

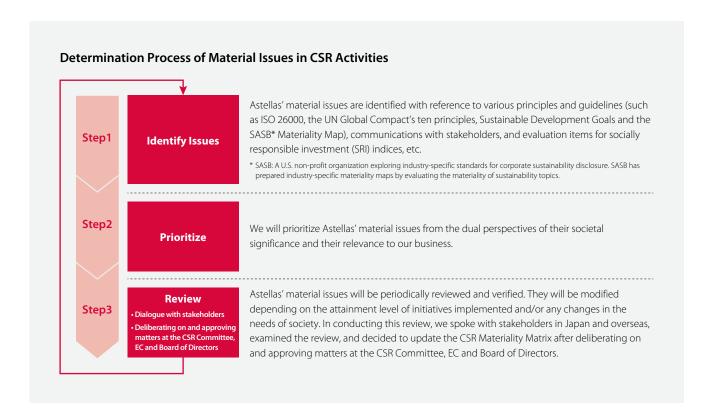
In this update, we have newly added "tax compliance" and "environmental impacts of pharmaceuticals" in order to respond to the needs of society. Moreover, based on their growing importance, we have moved "customer"

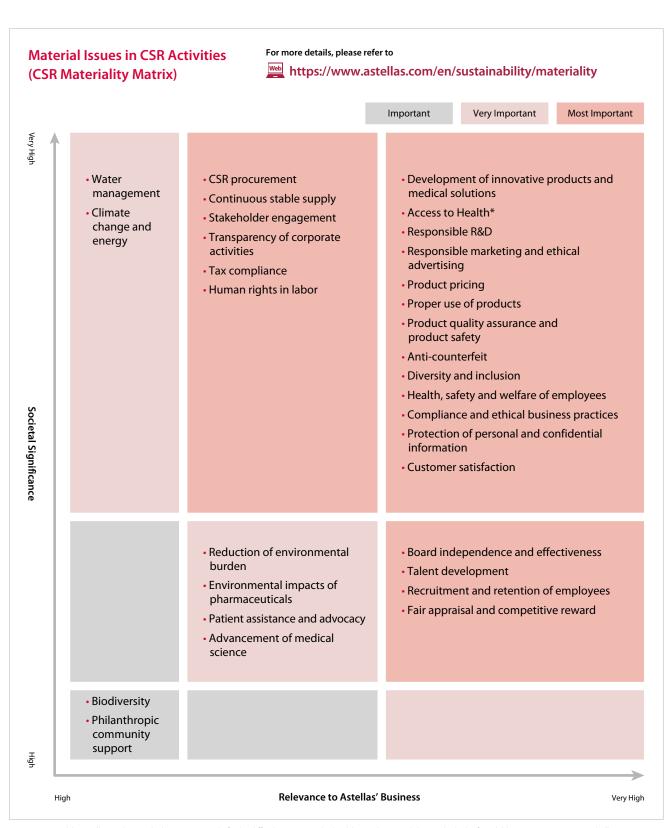
satisfaction" and "protection of personal and confidential information" to the upper-right quadrant. We have also renamed or combined material issues in order to properly express each material issue.

\* The CSR Committee discusses policies and plans for important activities in fulfilling the Company's social responsibilities. The committee is chaired by the Chief Administrative Officer & Chief Ethics & Compliance Officer, and comprises the heads of the relevant divisions in Japan, the Americas, EMEA and Asia & Oceania.

### **Activities and Monitoring of Material Issues**

In Astellas, divisions related to each material issue draw up annual and medium-term CSR-focused action plans, and work to resolve the material issues. The CSR Committee monitors activities and results, along with the status of progress made.





<sup>\*</sup> Access to Health: Astellas understands that some people find it difficult to receive the healthcare they need due to the lack of available treatments, poverty, challenges in healthcare systems and limited healthcare information. Astellas recognizes this problem as the Access to Health issue and is working to improve Access to Health by engaging in various initiatives.

# Contribution to the Sustainable Development Goals

Adopted by the United Nations General Assembly in 2015, the Sustainable Development Goals (SDGs) are a set of collective targets for the world to achieve by 2030.

Referring to the SDG Compass, Astellas identifies issues for priority action, based on the evaluation of SDG-related impacts across the entire value chain. Going forward, Astellas plans to contribute to the attainment of the SDGs through various business activities, focusing primarily on "Goal 3: Good Health and Well-Being."

#### Focus on Improving Access to Health in **Four Areas**

In regard to "Goal 3: Good Health and Well-Being" under the SDGs, Astellas is addressing this goal from the viewpoint of improving Access to Health. There are many people with insufficient access to the healthcare they need due to the lack of available treatments, poverty, challenges in healthcare systems and limited healthcare information. Astellas recognizes this problem as the Access to Health issue. Astellas has identified four areas where it is working to address Access to Health issues by making full use of the strengths and technology that it has. The four areas are (1) Creating innovation, (2) Enhancing availability, (3) Strengthening healthcare systems, and (4) Improving

health literacy. In doing so, Astellas will make maximum use of its partnerships in the manner of Goal 17.

In creating innovation, Astellas is working to create innovative medicines and medical solutions in disease areas with low treatment satisfaction and to deliver them. to patients around the world. Moreover, Astellas has been conducting collaborative research with partners aimed at creating drugs for the treatment of tuberculosis, malaria, and neglected tropical diseases (leishmaniasis and Chagas disease) and developing the rice-based oral vaccine MucoRice against infectious diseases such as cholera and enterotoxigenic Escherichia coli (E. coli). Astellas is also working closely with partners to develop a pediatric formulation of praziquantel tablets for the treatment of schistosomiasis.

To help enhance availability, we have established programs to assist patients facing severe financial constraints with the cost of dispensing pharmaceutical products. We also support patients by not filing or enforcing patents in countries facing significant economic challenges. As part of strengthening healthcare systems and improving health literacy, Astellas has participated in the Access Accelerated global partnership. This initiative aims to contribute to achieving the SDG of reducing premature mortality from non-communicable diseases by one-third by 2030. In other SDG-related initiatives, Astellas is supporting the ACTION ON FISTULATM program in Kenya.

#### Examples of Astellas' Activities for Achieving SDGs

#### Goals aimed at by contributions



#### Examples of activities to achieve each goal

	Lxamples	of activities to achieve each goal			
	SDGs	Theme	Examples of Astellas' activities		
	Goal 3	Good Health and Well-Being	Creation of innovative medicines and healthcare solutions; collaborative research and development into treatments and vaccines for tuberculosis, malaria, neglected tropical diseases, etc.		
	Goal 5	Gender Equality	Greater proportion of women in managerial roles in Japan		
	Goal 6	Clean Water and Sanitation	Reduced water usage; management of wastewater		
•	Goal 8	Decent Work and Economic Growth	Cultivation of productive workplaces; employee training and education; promotion of occupational health and safety		
	Goal 9	Industry Innovation and Infrastructure	Continuously executing a high level of investment in R&D		
	Goal 12	Responsible Consumption and Production	Eco-conscious production		
	Goal 13	Climate Action	Reduction of greenhouse gas emissions		
	Goal 15	Life on Land	Maintenance/preservation of biodiversity		
	Goal 17	Partnerships for the Goals	Participating partner in Global Health Innovative Technology (GHIT) Fund		

# **Corporate Governance**

The Company's raison d'être is to contribute to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The Company aims to sustainably enhance enterprise value as its mission.

With this business philosophy, we work to ensure and strengthen the effectiveness of corporate governance from the following perspectives:

- 1) Ensuring transparency, appropriateness and agility of management and
- 2) Fulfillment of our fiduciary duties and accountability to shareholders and appropriate collaboration with all stakeholders.

# Transition to a Company with an Audit & **Supervisory Committee**

Following a resolution of the June 2018 Annual Shareholders' Meeting, the Company transitioned from a Company with an Audit & Supervisory Board to a Company with an Audit & Supervisory Committee. As the management environment grows increasingly global and more complex, the Company is working to further enhance discussions of management strategy and other issues by its Board of Directors and to further strengthen the oversight function of the Board of Directors by transitioning to a company with an Audit & Supervisory Committee, which makes it possible to delegate a significant portion of the executive decision-making authority of the Board of Directors to the Executive Directors. Furthermore, the Company will improve the speed of decision-making in business execution and enhance management agility.

#### **Corporate Governance System**

#### **Characteristics**

- The Company adopts the organizational structure of a "Company with an Audit & Supervisory Committee." Outside Directors constitute the majority of the Board of Directors and the Audit & Supervisory Committee.
- The Board of Directors determines corporate management policies and corporate strategies, and serves a business execution oversight
- · As part of its business execution structure, the Company has established the Executive Committee to discuss material matters, and also appoints Executive Officers responsible for managing their respective divisions and functions. The Board of Directors established the Corporate Decision Authority Policy to clarify the responsibility and authority for the execution of business by the President and CEO and the Executive Officers.
- · As advisory bodies to the Board of Directors, the Company established the Nomination Committee and the Compensation Committee, each of which are composed of a majority of outside Directors.

#### **Corporate Governance System**

The Company recognizes the Annual Shareholders' Meeting as an important forum for constructive dialogue with shareholders.

Election/Dismissal Election/Dismissal Audit &

# Financial Auditor

 The Financial Auditor and the Company's Audit & Supervisory Committee Members maintain close cooperation by meeting regularly and as needed, verifying their annual auditing plans as well as sharing the results of audits and important audit information

(coordination)

# **Supervisory Committee**

The Audit & Supervisory Committee is the only deliberation and decision making body for forming opinions regarding the audits by Audit & Supervisory Committée Members. Where necessary, the Audit & Supervisory Committee provides its opinions to Directors or the Board of Directors

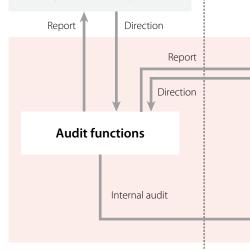
#### Composition

The Audit & Supervisory Committee is comprised entirely of Directors who are Audit & Supervisory Committee Members, with the Committee Chairman determined by a vote of the Audit & Supervisory Committee. To further enhance the independence and neutrality of the auditing system, outside Directors comprise a majority of Audit & Supervisory Committee Members. At least one of the Committee Members shall be an individual with appropriate knowledge regarding financial and accounting matters

<Structure as of the close of the June 2018 Annual Shareholders' Meeting> Five Directors who are Audit & Supervisory Committee Members, of whom a majority of three are independent outside Audit & Supervisory Committee Members (four male, one female).

### Administration

As a general rule, meetings are held once a month, with extraordinary meetings held as necessary



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#### Annual Shareholders' Meeting

The following measures are taken to invigorate the meeting for shareholders and encourage the exercise of voting rights.

- (1) Early dispatch of the Annual Shareholders' Meeting convocation notice.
- It is also published before dispatch on the Timely Disclosure Network (TDnet) provided by the Tokyo Stock Exchange and on the Company's website.
- (2) The date of the Annual Shareholders' Meeting is set to avoid dates when meetings of other companies are concentrated.
- (3) Adoption of an electronic voting platform (a platform run by ICJ, Inc., a firm in which the Tokyo Stock Exchange and others have invested).
- (4) Providing an English translation of the convocation notice.

Election/Dismissal

#### **Board of Directors**

#### Role

- By determining basic corporate management policies and corporate strategies, and performing an oversight function over business execution, the Board of Directors ensures that management is transparent and appropriate. By resolution of the Board of Directors, a significant portion of decision-making over important business execution matters has been delegated to the Executive Directors. The Board has also established the Corporate Decision Authority Policy, clarifying the business execution reponsibility and authority of the respective Executive Officers and ensuring management agility.

#### Composition

- The Board comprises an appropriate number of Directors, in consideration of diversity and balance from the perspectives of expertise and experience, and is chaired by the Director and Chairman of the Board.
- The Board is comprised of a majority of outside Directors to enable it to make decisions from a broader viewpoint and oversee business execution objectively.
- <Structure as of the close of the June 2018 Annual Shareholders' Meeting>

10 Directors, of whom a majority of 6 are independent outside Directors (eight male, two female).

#### Administration

- As a general rule, meetings are held once a month, with extraordinary meetings held as necessary.

#### Directors

Audit,

Audit

#### Responsibilities

- · As members of the Board of Directors, Directors participate in management decision-making through resolutions to the Board, in addition to overseeing the performance of duties of other Directors.
- To fully exercise their expected capabilities, Directors are expected to contribute to the sustained enhancement of the Company's corporate value by collecting the information necessary for the execution of their duties and engaging actively in discussions.
- Outside Directors are expected to enhance the appropriateness of management by overseeing the
  execution of business based on their independent standpoint, while utilizing their individual
  experience and knowledge to offer advice from a standpoint different from that of internal Directors.

#### Election

 Directors who are not Audit & Supervisory Committee Members are subject to election every year via resolution of the Annual Shareholders' Meeting. Directors who are Audit & Supervisory Committee Members are subject to election once every two years via resolution of the Annual Shareholders' Meeting.

#### **Nomination Committee**

#### Role

 Discusses matters concerning the election and dismissal of Executive Officers, etc., and reports the results to the Board of Directors.

#### Composition

- This committee is composed of members elected by the Board of Directors.
- The majority of members are outside Directors.
- This committee is chaired by an outside Director.

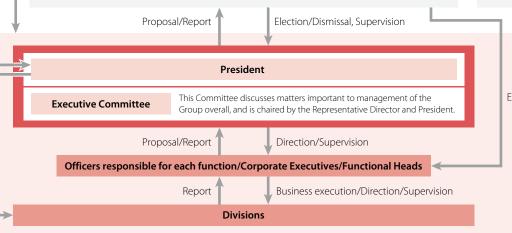
#### **Compensation Committee**

#### Role

 Discusses matters concerning remuneration, bonuses and other profits on assets received as compensation for the execution of duties of Directors, Executive Officers and others (excluding individual remuneration for Directors who serve as members of the Audit & Supervisory Committee), and reports the results to the Board of Directors.

#### Composition

- This committee is composed of members elected by the Board of Directors.
- The majority of members are outside Directors.
- This committee is chaired by an outside Director.



Election/Dismissal

Business execution

# **Progress in Enhancing Effectiveness of Corporate Governance**

Since Astellas' launch in April 2005, we have worked to increase the speed of execution by delegating authority to the management team, in the belief that prompt and accurate decision-making will result in the enhancement of enterprise value. In the year following our launch, the Company appointed a majority of outside Directors to its Board of Directors, and subsequently established the Nomination Committee and Compensation Committee, part of our ongoing efforts at structural reform.

With the implementation of Japan's Corporate Governance Code in June 2015, we also took the opportunity to further enhance the Company's corporate governance structure. In September 2015, the Company formulated its Corporate Governance Guidelines as the basis for implementing the individual principles of the Code.\* Beginning in June 2018, the Company has also transitioned to a Company with an Audit & Supervisory Committee. Through these efforts, the Company is working to enhance the effectiveness of its corporate governance.

\* By December 2018, the Company plans to disclose via its Corporate Governance Report the status of implementation of the Corporate Governance Code principles that were revised effective June 2018.

#### Start of Efforts to Evaluate the Effectiveness of the Board of Directors

As a means of considering issues and making improvements to further enhance the role of the Board of Directors, the Company has conducted an analysis and evaluation of the effectiveness of the Board of Directors since the fiscal year ended March 31, 2016. The results of the evaluation for the fiscal year ended March 31, 2018 are as shown below.

#### <Evaluation Method>

The Chairman of the Board of Directors conducted a survey based on a questionnaire to all Directors and Audit & Supervisory Board Members, primarily concerning the

### Major Corporate Governance Reforms Implemented to Date

Date	Change	Objective
April 2005 Launch of Astellas	New Board of Directors launched  Board of Directors comprised of 4 Executive Directors, 2 non-Executive Directors and 2 outside Directors  Board of Directors specialized in supervising the execution of business and decision-making regarding legal and most important matters	Ensure management transparency and appropriateness
Astellas	Authority delegated to the management team  • To the extent legally allowable, delegate as much authority as possible to the management team	Ensure management agility
June 2006	Outside Directors represent a majority of the Board of Directors  • 9 Directors, of whom 5 are outside Directors	Ensure management transparency and appropriateness
June 2007	Reduction in number of Directors  • 7 Directors, of whom 4 are outside Directors	Ensure management agility
June 2007	Established the Nomination Committee and the Compensation Committee  • 5 committee members, of whom 3 are outside Directors	Ensure management transparency and appropriateness
L 2010	Shortened term of appointment for Directors  • Term of appointment shortened from two years to one year	Clarify management responsibilities
June 2010	Elimination of advisor system • Prior to that, counselor system also eliminated	Ensure management transparency
June 2011	Change in chairmanship of the Nomination and the Compensation Committees  • Each Committee chaired by outside Director	Ensure management transparency and appropriateness
June 2015	Increase outside Audit & Supervisory Board Members From 2 to 3, resulting in outside members representing a majority of the total of 5 Audit & Supervisory Board Members	Strengthen independence and neutrality of the auditing system
June 2018	Transition to a Company with an Audit & Supervisory Committee  • 6 out of 10 Directors are outside Directors (3 out of the 5 Audit & Supervisory Committee Members are outside Directors)  • Delegation of decision-making authority for business execution from the Board of Directors to Executive Directors  • The Board of Directors discusses corporate management policies, strategies, etc.	Strengthen the supervisory function and ensure management mobility

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oversight function of the Board of Directors. Based on the results of this survey, the Board of Directors performed its analysis and evaluation.

#### <Conclusion>

The Board of Directors was found to function appropriately, with highly transparent and lively discussions by the Directors, including independent outside Directors. The overall effectiveness of the Board of Directors was assessed to be sufficiently ensured.

#### <Reasons for Assessment>

The Board of Directors consists of a majority of outside Directors and has engaged in free, open and constructive discussions, having fostered a climate in which those outside Directors are able to actively participate in discussion.

Aiming to achieve optimization of the Board of Directors' capabilities, which was recognized as an issue in the fiscal year ended March 31, 2017, the Company decided to transition to a Company with an Audit & Supervisory Committee structure, and by clearly distinguishing between oversight and execution, has established a framework for discussing matters that should be addressed by the Board of Directors.

To ensure that the process for selecting successors to the President and CEO maintains a high level of transparency and acceptability, the Board of Directors has been overseeing deliberations of the Nomination Committee and making appropriate resolutions based on proposals of the Nomination Committee.

#### <lssues>

To ensure it functions more effectively, the Board of Directors will continue to improve on the issues below which are present even in the new system.

- To carry out Strategic Plan 2018, the Board of Directors will monitor the constantly changing internal and external environmental trends and engage in more effective discussion of strategy.
- The Board of Directors will oversee whether appropriate measures have been taken against risks identified by the framework for systematic risk evaluation that were strengthened in the fiscal year ended March 31, 2018.

As an organ for discussing important matters regarding the business of the Astellas Group, the Company has established an Executive Committee, and has appointed Executive Officers responsible for managing their respective departments and functions. The responsibility and authority for the execution of business by the organ described above, the President and the Executive Officers are clearly stipulated in the Corporate Decision Authority Policy.

In order to build an optimal management system capable of speedy and precise decision-making, we have been promoting a system, under which we manage each division and function of Drug Discovery Research, Medical & Development, and Pharmaceutical Technology based on their respective functions from a global viewpoint across geographical regions, while the Sales & Marketing Divisions are managed on a regional basis.

Regarding staff functions also, Astellas is working to strengthen its global management functions. As part of these efforts, in April 2017, we established Legal and Intellectual Property functions in each region on a global level. Furthermore, in April 2018, we established Finance, Human Resources, and Internal Auditing functions in departments in the same manner.

In order to develop a system for more appropriate execution of business, the Company has established various committees comprising cross-functional members. These committees include the Corporate Disclosure Committee where matters including disclosure of corporate information are discussed, the CSR Committee that discusses policies and plans of important activities for the purpose of fulfilling the Company's social responsibilities (such as issues on the environment, health and safety, and social contribution activities), the Global Benefit Risk Committee to discuss benefit and risk information of products as well as measures to deal with such benefit and risk, the Global Compliance Committee where matters including global compliance policies and plans are discussed, and the Global Risk Management Office to promote identifying global risks and implementing optimum risk management.

#### **Efforts Aimed at Enhancing Business Execution**

The Company has established a global management structure, and continues to work to strengthen it.

Please refer to the following URL for the Corporate Governance Report and Corporate Governance Guidelines



https://www.astellas.com/jp/en/investors/ ir-library/governance

# A System of Remuneration for Directors That **Contributes to Sustainable Enhancement in Enterprise Value**

The compensation paid to Directors of the Company is designed to enable the Company to attract and retain talent, and maintain sufficient compensation standards and systems to meet the duties and responsibilities of the positions. The Company has improved the objectivity of decisions on remuneration levels by using survey data issued by outside research companies and other measures.

Remuneration for internal Directors who are not members of the Audit & Supervisory Committee is composed of fixed basic remuneration, bonuses and stock compensation. The Company appropriately links remuneration with business performance. To increase the awareness of contribution to the sustainable growth of business results and enterprise value, the Company has introduced a performance-linked stock compensation scheme which grants Company stock in line with the degree to which medium-term performance targets are achieved. Medium-term performance targets include predetermined goals for sales, core operating margin, core ROE, etc., over a three-year time span\*1.

Remuneration for outside Directors and internal Directors who serve as Audit & Supervisory Committee Members consists solely of fixed basic remuneration.

Remuneration for Directors who are not members of the Audit & Supervisory Committee\*2 is determined by resolution of the Board of Directors within a total ceiling amount approved by the Annual Shareholders' Meeting, while remuneration for Directors who serve as Audit & Supervisory Committee Members\*3 is determined through deliberations of the Audit & Supervisory Committee Members within a total ceiling amount approved by the Annual Shareholders' Meeting. Through the deliberations of the Compensation Committee, the Company enhances the transparency and objectivity of the deliberation process for remuneration for Directors (excluding individual remuneration for Directors who serve as Audit & Supervisory Committee Members).

- \*1 Regarding stock compensation, the Company has introduced a performancelinked stock compensation scheme, a medium- to long-term incentive plan known as the executive remuneration BIP (Board Incentive Plan) trust. Three consecutive business years are defined as a single eligible period, and for the first year of each eligible period, a ceiling of ¥5.5 million on the amount contributed to the BIP Trust as compensation to Directors (excluding outside Directors and Directors who serve as Audit & Supervisory Committee Members) was approved at the 13th Term Annual Shareholders' Meeting held on June 15,
- \*2 A ¥5.6 million annual ceiling on remuneration for Directors (excluding Directors who serve as Audit & Supervisory Committee Members) was approved at the 13th Term Annual Shareholders' Meeting held on June 15, 2018. This excludes, however, bonuses and stock compensation, the amount of and ceilings for which were approved separately at the Annual Shareholders' Meeting.
- \*3 An annual ceiling of ¥2.6 million on compensation for Directors who serve as members of the Audit & Supervisory Committee was approved at the 13th Term Annual Shareholders' Meeting held on June 15, 2018.

#### Remuneration for Directors in Fiscal 2018

Category	Total amount of Type of remuneration (¥ million) remuneration Basic Stock			Number of eligible	
	(¥ million)	remuneration	Bonus	compensation	Directors
Directors (excluding outside Directors)	358	159	124	74	3
Outside Directors	58	58	_	_	6
Total	415	217	124	74	9
Audit & Supervisory Board Members (excluding outside Audit & Supervisory Board Members)	88	88	_	_	2
Outside Audit & Supervisory Board Members	43	43	_	_	3
Total	131	131	_	_	5

<sup>\*1</sup> The above basic remuneration and stock compensation include amounts paid to three Directors (including two outside Directors) who resigned as of the conclusion of the 12th Term Annual Shareholders' Meeting held on June 19, 2017.

<sup>\*2</sup> The above stock compensation lists amounts recorded as expenses in the fiscal year ended March 31, 2018, based on J-GAAP.

# Risk Management

# Identifying and Mitigating Risks Relating to the Performance of Business Activities

Pharmaceutical companies that expand their business globally are expected to follow numerous regulations with a high level of compliance; Astellas must also address numerous risks that could impact our business results, performance and public perception. Astellas established a holistic approach to risk management through the creation of a Global Risk Management program. Separate Regional Risk Management programs in each of the Company's four regions support the Global Risk Management program. The purpose of these global and regional programs are to identify, prioritize and manage risks to the Company achieving its objectives from a preventive standpoint.

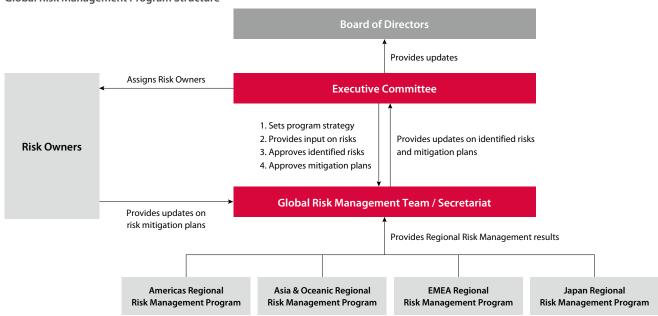
The Global Risk Management program are supervised by a global, cross-functional team. The Global Risk Management program utilizes a four-phased approach, which is repeated annually: 1. Risk Identification, 2. Risk Prioritization, 3. Risk Mitigation Plan Development, and 4. Risk Mitigation Plan Implementation.

The EC reviews and approves risks identified through the Global Risk Management program. The EC assigns risk owners to each identified global risk. The risk owners are responsible for developing and implementing risk mitigation plans. Risk owners update these plans throughout the year and mitigation plan progress is reported to the EC. The risks managed by the program are reflective of Astellas' footprint as global pharmaceutical company and the sector the Company operates in.

Through maintaining the Global Risk Management program, Astellas has a framework for identifying and addressing risk. This program has enhanced the Company's cross-functional awareness and transparency about the risks facing the Company as well as the activities being undertaken to mitigate these risks.

At the regional level, the Regional Risk Management programs operate in a similar format to the global program. The Global Risk Management program factors the results of the regional programs into its risk identification process to ensure regional concerns and priorities are considered appropriately. In addition, the Global Risk Management program takes on risks identified by the Regional Risk Management Program when necessary.

#### Global Risk Management Program Structure



# Directors

# **Directors who are not Audit & Supervisory Committee Members**



Yoshihiko Hatanaka Representative Director, Chairman of the Board

- 1980: Joined Fujisawa Pharmaceutical Co., Ltd.
- 2003: Director, Corporate Planning, Fujisawa Pharmaceutical Co., Ltd.
- 2005: Vice President, Corporate Planning Corporate Strategy Division, the Company
- 2005: Corporate Executive, Vice President, Corporate Planning, Corporate Strategy, the Company
- 2006: Corporate Executive of the Company and President & CEO, Astellas US LLC and President & CEO, Astellas Pharma US, Inc.
- 2008: Senior Corporate Executive of the Company and President & CEO, Astellas US LLC and President & CEO, Astellas Pharma US, Inc.
- 2009: Senior Corporate Executive, Chief Strategy Officer and Chief Financial Officer (CSTO & CFO), the Company
- 2011: Representative Director,
- President and CEO, the Company
- 2018: Representative Director, Chairman of the Board, the Company (present post)



Kenji Yasukawa Representative Director, President and CFO

- 1986: Joined the Company
- 2005: Vice President, Project Management, Urology, the Company
- 2010: Corporate Executive of the Company and Therapeutic Area Head, Urology, Astellas Pharma Europe B.V.
- 2010: Corporate Executive of the Company and Therapeutic Area Head, Urology, Astellas Pharma Global Development, Inc.
- 2011: Corporate Executive, Vice President, Product & Portfolio Strategy, the Company
- 2012: Corporate Executive, Chief Strategy Officer (CSTO), the Company
- 2012: Senior Corporate Executive, Chief Strategy Officer (CSTO), the Company
- 2017: Senior Corporate Executive, Chief Strategy Officer and Chief Commercial Officer (CSTO & CCO), the Company
- 2017: Representative Director, Executive Vice President, the
- 2018: Representative Director, President and CEO, the Company (present post)



Yoshiharu Aizawa **Outside Director** 

- 1975: Fellow, Department of Internal Medicine, School of Medicine, Keio University
- Assistant Professor, Department of Preventive Medicine and Public Health, School of Medicine, Kitasato University
- Associate Professor, Department of Preventive Medicine and Public Health, School of Medicine, Kitasato University
- Professor, Department of Preventive Medicine and Public Health, School of Medicine, Kitasato University
- 2004: Chairperson, School of Medicine, Kitasato University
- 2006: Dean, School of Medicine, Kitasato University 2009: Vice President, Kitasato University
- 2010: Executive Trustee, The Kitasato Institute
- 2012: Professor Emeritus, Kitasato University (present post)
- 2015: Director, the Company (present post)



Mamoru Sekiyama **Outside Director** 

- 1974: Joined Marubeni Corporation
- 1997: General Manager, Power Project Dept.-I. Marubeni Corporation
- 1998: General Manager, Power Project Dept.-III, Marubeni Corporation
- 1999: Deputy General Manager, Power Project Div.; General Manager, Power Project Dept. I, Marubeni Corporation
- 2001: Senior Operating Officer, Utility Infrastructure Div.; General Manager, Overseas Power Project Dept., Marubeni Corporation
- 2002: Corporate Vice President, Chief Operating Officer, Plant, Power & Infrastructure Div., Marubeni Corporation
- 2005: Corporate Senior Vice President, Chief Operating Officer, Plant, Power & Infrastructure Projects Div. Marubeni Corporation
- 2006: Corporate Senior Vice President, Member of the Board, Marubeni Corporation
- 2007: Corporate Executive Vice President, Member of the Board, Marubeni Corporation
- 2009: Senior Executive Vice President, Member of the Board, Marubeni Corporation
- 2013: Vice Chairman, Marubeni Corporation
- 2015: Corporate Adviser, Marubeni Corporation (present post) Chairman, Marubeni Power Systems Corporation
- 2017: Director, the Company (present post)

#### **Expected Role**

Yoshiharu Aizawa has been engaged in medical treatment while successively holding important posts at Kitasato University as a medical scientist, and has abundant specialized knowledge and experience. He currently plays a key role in the management of the Company from an independent standpoint as an outside Director. The Company is confident that he will draw on his abundant specialized knowledge and experience in management of the Company in the future as well.

#### **Expected Role**

Attendance at Meetings of the Board of Directors during Fiscal 2017: 16/17 times

Mamoru Sekiyama has been engaged in corporate management as a business manager of a general trading company over many years and has abundant global experience and extensive insight. He currently plays a key role in the management of the Company from an independent standpoint as an outside Director. The Company is confident that he will continue to apply his abundant specialized knowledge and experience to the management of the Company.

Attendance at Meetings of the Board of Directors during Fiscal 2017: 14/14 times



Keiko Yamagami **Outside Director** 

- 1987: Public Prosecutor, Yokohama District Public Prosecutors Office
- 2002: Coordinator, Legislative Division, Criminal Affairs Bureau, Ministry of Justice 2005: Counselor, Legislative Division, Criminal Affairs Bureau, Ministry of Justice
- 2005: Public Prosecutor, Supreme Public Prosecutors Office
- 2007: Deputy Director of Public Peace Department, Tokyo District Public Prosecutors Office
- 2008: Deputy Director of Trial Department, Tokyo District Public Prosecutors Office
- 2009: Trial Director, Yokohama District Public Prosecutors Office
- 2010: Registered as an attorney-at-law (Dai-ichi Tokyo Bar Association): Lawyer honorary member, Tokyo Seiwa Law Office (present post)
- 2017: Director, the Company (present post)

#### **Expected Role**

After successively holding important posts such as Public Prosecutor at the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors Office, Keiko Yamagami has been engaged in corporate legal affairs and the Supreme Public Prosecutors of the Supreme Public Prosecutors ofas an attorney-at-law. She currently plays a key role in the management of the Company from an independent standpoint as an outside Director. The Company is confident that she will continue to apply her abundant specialized knowledge and experience to the management of the Company.

Attendance at Meetings of the Board of Directors during Fiscal 2017: 14/14 times

# **Directors who are Audit & Supervisory Committee Members**



Tomokazu Fuiisawa Director who is an Audit & **Supervisory Committee** Member

1984: Joined Fujisawa Pharmaceutical Co., Ltd. 1999: Director of Planning, Medical Supply Business, Fujisawa Pharmaceutical Co., Ltd. 2006: Assistant to Senior Vice President,

Corporate Finance & Accounting and Project Leader of J-SOX Project, the Company 2013: Vice President, Internal Auditing, the Company

2014: Assistant to President and CEO, the Company 2014: Audit & Supervisory Board Member, the Company 2018: Director who is an Audit & Supervisory Committee Member, the Company (present post)



Hiroko Sakai Director who is an Audit & **Supervisory Committee** Member

1983: Joined the Company

2012: Vice President, Clinical and Research Quality Assurance, QA, RA and Pharmacovigilance Department, the Company

2016: Assistant to President & CEO, the Company 2016: Audit & Supervisory Board Member, the Company

2018: Director who is an Audit & Supervisory Committee Member, the Company (present post)



Hitoshi Kanamori Outside Director who is an Audit & Supervisory Committee Member

1984: Public Prosecutor. Tokyo District Public Prosecutors Office

1985: Public Prosecutor, Yamagata District Public Prosecutors Office

1988: Public Prosecutor. Niigata District Public Prosecutors Office

1990: Public Prosecutor,

Tokyo District Public Prosecutors Office 1992: Registered as an attorney-at-law (Tokyo Bar Association)

1993: Partner, SANNO LAW OFFICE (present post) 2005: Visiting Professor, University of Tsukuba Law School 2015: Audit & Supervisory Board Member, the Company 2018: Director who is an Audit & Supervisory Committee

Member, the Company (present post)





1997: Joined Deloitte Tohmatsu Consulting Co., Ltd. (current ABeam Consulting Ltd.)

1999: Global Partner for manufacturing industry and Managing Director in Kyushu area, Deloitte Tohmatsu Consulting Co., Ltd. (current ABeam Consulting Ltd.)

2003: Joined DENTSU INC.

2008: Established Uematsu & Co.: Managing Director, Uematsu & Co. (present post)

2011: President & Representative Director, SU Consultant Co., Ltd. (present post)

2015: Outside Audit & Supervisory Board Member, Kamakura Shinsho, Ltd.

2016: Outside Director and Audit & Supervisory Committee Member, Kamakura Shinsho, Ltd. (present post)

2016: Audit & Supervisory Board Member, the Company 2018: Director who is an Audit & Supervisory Committee

Member, the Company (present post)



Hitoshi Kanamori possesses expertise in corporate law by virtue of his long experience as an attorney-at-law. He currently plays a key role in the supervision and auditing of the Company's management from an independent standpoint as an outside Director who is an Audit & Supervisory Committee Member, The Company is confident that he will continue to leverage his abundant specialized knowledge and experience to supervise and audit the Company's management.

Attendance at Meetings of the Board of Directors during Fiscal 2017: 16/17 times Attendance at Meetings of the Audit & Supervisory Board during Fiscal 2017: 13/14 times

#### **Expected Role**

Noriyuki Uematsu has thorough knowledge of corporate consulting and auditing by virtue of his many years of experience as a certified public accountant and is also engaged in corporate management as a business manager of a consulting company relating to business accounting and tax accounting services. He currently plays a key role in the supervision and auditing of the Company's management from an independent standpoint as an outside Director who is an Audit & Supervisory Committee Member The Company is confident that he will continue to draw on his abundant specialized knowledge and experience in supervising and auditing the Company's management.

Attendance at Meetings of the Board of Directors during Fiscal 2017: 17/17 times Attendance at Meetings of the Audit & Supervisory Board during Fiscal 2017: 14/14 times



Hiroo Sasaki Outside Director who is an Audit & Supervisory Committee Member

1987: Assistant Professor, Faculty of Economics, Nagoya City University

1990: Associate Professor, Faculty of Economics, Nagoya City University

1993: Associate Professor, School of Commerce, Waseda University

1996: Professor, School of Commerce, Waseda University

1997: Senior Research Officer, Ministry of Finance, Institute of Fiscal and Monetary Policy (current Policy Research Institute); Special Officer for Research, Minister's Secretariat 1999: Professor, School of Commerce, Waseda University

2005: Professor, School of Commerce, Waseda University; Professor, Graduate School of Accountancy, Waseda University; Professor, Graduate School of Accountance, Waseda University; Prof2010: Professor, School of Commerce, Waseda University; Dean, Graduate School of Accountancy, Waseda University

2013: Dean, Graduate School of Accountancy, Waseda University

2016: Professor, Graduate School of Accountancy, Waseda University (present post)

2018: Director who is an Audit & Supervisory Committee Member, the Company (present post)

Hiroo Sasaki has held important positions at Waseda University, including at the graduate level, in economics and other fields. While Dean of Waseda University's Graduate School of Accountancy, he was also involved in the school's management. Having researched normative economics, he is deeply knowledgeable about vocational ethics and research ethics and has experience with practical handling of these ethical issues. The Company is confident that he will leverage his abundant specialized knowledge and experience to supervise and audit the Company's management from an independent standpoint as an outside Director who is an Audit & Supervisory Committee Member.

# Interview with an Outside Director

I will facilitate discussions to further enhance the effectiveness of Astellas' corporate governance, with an aim toward continuously evolving approach to the best possible form.

#### Mamoru Sekiyama **Outside Director**

Mr. Sekiyama joined Marubeni Corporation in 1974. After holding key posts including Senior Executive Vice President, Member of the Board and Vice Chairman, he currently serves as Corporate Adviser to Marubeni Corporation. He has served as an outside Director at Astellas since 2017.



Q: Could you please share your perspectives on the Strategic Plan 2018 from your standpoint as an outside Director?

# A: I believe that the key elements of Strategic Plan 2018 are the plan's transparent formulation process and its system for monitoring progress.

As an outside Director, I would like to discuss two key points concerning Astellas' Strategic Plan 2018. My first point concerns the process of formulating the management plan. Strategic Plan 2018 was formulated based on open discussions in meetings of the Board of Directors. My second point is that a system for monitoring progress regularly and in great detail has been embedded into meetings of the Board of Directors, in order to ensure that Astellas steadily achieves its strategic goals.

When formulating Strategic Plan 2018, the Board of Directors held a series of extensive discussions on the plan, beginning at the draft stage. The outside Directors were supplied with extensive information on external conditions and the business environment, which served as the basis for the discussions. Therefore, we, the outside Directors, were able to participate in the discussions based on a strong understanding of Astellas' current circumstances and the opportunities it should pursue. In addition, information on dialogues held between management and shareholders and investors in the fiscal year ended March 31, 2018 was shared with the outside Directors. Accordingly, the outside Directors were able to take the expectations and demands of the capital markets into consideration in the discussions, and the results of those discussions were reflected in Strategic Plan 2018 to the fullest extent possible. Enhancing the effectiveness of discussions in the Board of Directors is a priority shared by many companies. I believe that Astellas has been able to conduct in-depth discussions and formulate Strategic Plan 2018 based on a strong understanding of such priorities.

Under Strategic Plan 2018, Astellas has set three strategic goals and has developed a narrative for creating innovation by achieving each of those goals. With regard to the Focus Area approach and the Rx+ business philosophy, I believe that Astellas has developed a convincing narrative for attaining future asset growth underpinned by extensive discussion. Meanwhile, the success of Strategic Plan 2018 will depend on whether the management team is able to monitor progress and flexibly address new business issues that arise along the way. This is something I understand very well from my experience as a business leader. In those roles, I made various decisions on investments according to management strategies and monitored the progress of those investment projects.

**Business Review** 

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In this respect, with the start of Strategic Plan 2018, Astellas has adopted a system of monitoring the degree of achievement of its strategic goals for the business reports submitted to the Board of Directors. This clearly shows that Astellas understands the importance of monitoring progress toward the goals of Strategic Plan 2018. I have every expectation that Astellas will further enhance the reporting framework, thereby enabling it to monitor progress on Strategic Plan 2018 and identify new business issues in a more timely and accurate manner than before. In addition, even when there is a change in investment projects, I believe that the effectiveness of the Board of Directors will be increased further by enabling the Board to identify signs of changes as early as possible, make flexible decisions, and respond to those changes appropriately.

Q: What actions must Astellas take to further enhance the effectiveness of the Board of Directors?

# A: I believe that it is crucial for Astellas to further increase and enhance discussions on strategies and related matters amongst the Board of Directors.

The business environment is changing so rapidly that even a slight delay in decision-making can end up giving competitors an insurmountable lead. Business leaders must have the ability to make decisions rapidly and the execution skills needed to go all-out and get things done at critical moments. In these circumstances, the Board of Directors has an important role to play in enhancing discussions from many different points of view and supporting appropriate risk-taking by business leaders.

Meanwhile, a business environment in a state of constant flux can quickly render strategies obsolete—even strategies that appeared ideal when they were first approved. In such an environment, it is increasingly important to conduct monitoring in order to identify any signs of change at the earliest opportunity. I have already discussed this point earlier. When changes are identified, it is also important for the Board of Directors to hold discussions with a view to reexamining the risks and the appropriateness of strategies, and to flexibly revise the strategies as needed. This is another responsibility of the Board of Directors.

In the fiscal year ended March 31, 2018, Astellas evaluated the overall effectiveness of the Board of Directors. This evaluation identified the following two issues: (1) To carry out Strategic Plan 2018, the Board of Directors will monitor the constantly changing internal and external environmental trends and engage in more effective discussion of strategy, and (2) The Board of Directors will oversee whether appropriate measures have been taken against risks identified by the framework for systematic risk evaluation that were strengthened in the fiscal year ended March 31, 2018. I believe that it is crucial to enhance the effectiveness of the Board of Directors by giving consideration to those issues.

Q: In your view, what is the significance of Astellas' transition to a company with an Audit & Supervisory Committee?

# A: I believe that this is the best possible structure for improving discussions on strategies and related matters.

Pursuant to a resolution passed at the Annual Shareholders' Meeting held in June 2018, Astellas has transitioned to a company with an Audit & Supervisory Committee.

Operating as a company with an Audit & Supervisory Committee structure enables the delegation of a significant portion of the Board of Directors' decision-making authority for business execution to Executive Directors, and allows the agenda of Board of Directors meetings to be set more flexibly. This change in the organizational blueprint of the Company to further enhance discussions on management strategy and related issues amongst the Board of Directors is an initiative to address the issues identified in the evaluation of effectiveness.

In my view, the ideal corporate governance structure varies from company to company and with the company's circumstances. Astellas selected this structure as a corporate governance model that better fits its situation, after carefully considering various factors from many different angles, such as

# Corporate Strategy and Corporate Governance

the environment surrounding the Company, its VISION, the steady execution of Strategic Plan 2018, and accountability to stakeholders. I believe that this is a very positive change in structure.

Going forward, Astellas will continue to explore ways to further enhance its corporate governance. We, the outside Directors, will renew our awareness on a daily basis and continue to contribute positively to ensuring the effective functioning of this structure and its continued evolution and development.

Q: What kinds of attributes did you rate highly in nominating Kenji Yasukawa as the new President and CEO?

# A: I find great promise in Mr. Yasukawa's expansive perspective and expertise, as well as his ability to make decisions promptly and appropriately.

Every year, Astellas discusses successor candidates for president and succession planning in the Nomination Committee. The nomination of Mr. Yasukawa was made appropriately through a highly transparent and acceptable process.

Mr. Yasukawa has an expansive perspective that allows him to make decisions based on a holistic view of the entire Company, backed by his wide range of professional experience working in the development department and Product & Portfolio Strategy, as well as a strong understanding of science. He also has an extensive network both inside and outside the Company. Over the past few years, Mr. Yasukawa has demonstrated leadership in the execution of Strategic Plan 2015-2017 and the formulation of Strategic Plan 2018 as Chief Strategy Officer (CSTO) of the Company.

Therefore, I nominated Mr. Yasukawa as the successor to the President based on my belief that he will be able to make prompt and bold decisions guided by a strong understanding of Astellas as a whole. Another key reason for my nomination is that I believe Mr. Yasukawa will be able to fulfill Astellas' accountability to stakeholders on matters including decision-making processes. This is an attribute that was emphasized strongly by Chairman of the Board Yoshihiko Hatanaka, who previously served as President and CEO.

Q: What are your expectations for Astellas and Mr. Yasukawa going forward?

# A: I expect Astellas and Mr. Yasukawa to continuously transform the Company to realize its VISION.

Strategic Plan 2018 sets forth specific strategies for Astellas to overcome the impact of the expiry of the patent periods for core products from 2019 onward and to create a new growth trajectory. In the course of executing those strategies, Astellas will need to demonstrate an even greater ability to respond to change than before.

I believe that the ability to respond to change comes from diversity. Homogeneous groups tend to present risks when they are exposed to headwinds. However, organizations that can place their confidence in people who have completely different ways of thinking or people who may have different opinions than the views of decision makers, are able to surmount challenging situations with flexibility and strength.

Earlier, I noted that "Business leaders must have the ability to make decisions rapidly and the execution skills needed to go all-out and get things done at critical moments." In my view, Mr. Yasukawa possesses these qualities, as well as the flexibility needed to embrace different opinions.

Astellas is an enterprise that achieves growth through transformation. Guided by the leadership of Mr. Yasukawa, I expect Astellas to drive relentless evolution in order to achieve its strategic goals and make steady strides toward realizing its VISION: "Astellas is on the forefront of healthcare change to turn innovative science into value for patients."

### **Business Review**

# Achieve a Sustainable Increase in Enterprise Value and Fulfill Social Responsibilities through Business Activities

In all of its value chains, Astellas will make steady strides toward the strategic goals laid out in Strategic Plan 2018. By doing so, Astellas will seek to achieve a sustainable increase in enterprise value, while fulfilling its social responsibilities.



# Executive Committee (as of July 2018)

The Executive Committee discusses important matters of management across Astellas. It is chaired by the Representative Director, President and CEO, and comprises top management and General Counsel as standing members. Extended members include the officers responsible for research, development and pharmaceutical technology capabilities together with the officers responsible for each region, and these members participate in any necessary discussions at the request of the chairman.

### **Standing Members**



Fumiaki Sakurai

Chief Administrative Officer & Chief Ethics & Compliance Officer

> Bernhardt Zeiher, M.D. Chief Medical Officer

Linda Friedman General Counsel

Chikashi Takeda Chief Financial Officer

Kenji Yasukawa, Ph. D. Representative Director, President and CEO

Yukio Matsui Chief Commercial Officer

Naoki Okamura Chief Strategy Officer

#### **Extended Members**

Nobuaki Tanaka President, Japan Sales & Marketing

Masatoshi Kuroda President, Asia & Oceania Business

Percival Barretto-Ko President, Americas Operations

Dirk Kosche President, Europe, Middle East and Africa Operations

Akihiko Iwai President, Drug Discovery Research

Mitsunori Matsuda President, Pharmaceutical Technology

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# **Executive Messages**

Speaking with the CSTO Strategic Plan 2018

# **Delivering on Corporate Strategy by Setting Clear Priorities and Enhancing Monitoring**

Naoki Okamura Chief Strategy Officer (CSTO)



Q: How will you execute the strategies laid out in Strategic Plan 2018?

# A: We have started implementing systems to monitor our progress toward the achievement of our strategic goals.

Strategies are only meaningful when they are executed appropriately. Concurrently with the formulation of Strategic Plan 2018, Astellas has built and started implementing systems to monitor the degree of achievement of its three strategic goals.

We will track our progress toward those goals more comprehensively by monitoring the allocation of management resources against the strategic goals as well as the number of projects based on the Focus Area approach, which holds the key to realizing Astellas' vision. In order to succeed with the Focus Area approach, we must obtain the necessary resources to invest in this approach. To this end, we will continue to maximize product value and operational excellence, along with properly monitoring our progress toward these goals. In doing so, we intend to steadily deliver a higher level of performance.

Q: Why did you set forth "Developing Rx+ programs" as a strategic goal in Strategic Plan 2018?

# A: We believe that "Developing Rx+ programs" is a key element of driving sustainable growth and realizing Astellas' VISION.

Under Strategic Plan 2018, we have set clear management priorities. In the process, we have set forth "Developing Rx+ programs" as one of our strategic goals. This also signals how we view the current business environment.

Advances in digital technologies and other areas are rapidly and dramatically reshaping the structure of the industry and business environment. Against this backdrop, Astellas recognizes that it must establish new businesses and core business models from a long-term perspective by applying the strengths developed in its traditional core business, the prescription pharmaceutical (Rx) business. By pursuing innovative science, we will create optimal medical solutions (Rx+) that provide value to patients in fields beyond the Rx business, thereby achieving additional growth. Doing so is inseparable from realizing Astellas' VISION.

Speaking with the CMO Creating Future Value

# **Expanding Our Pipeline with a Transition** to the Focus Area Approach

Bernhardt Zeiher, M.D.

Chief Medical Officer (CMO)



Q: What were the key pipeline achievements from 2015-2017 and what are the key priorities for enhancing the pipeline moving forward?

# A: Astellas continues to progress our key mid- and late-stage projects while expanding our pipeline in line with our corporate strategy.

Under Strategic Plan 2015-2017, we significantly advanced our mid- to late-stage pipeline and built capabilities in new technology platforms and treatment modalities to support our future focus.

In oncology, we are delivering new value to patients across a spectrum of different cancers with additional indications for enzalutamide, potential new treatment options in acute myeloid leukemia, advanced bladder cancer, gastric cancer, and three early-phase immuno-oncology antibodies.

In medical specialties, we are exploring the biology underpinning many diseases, and our pipeline includes potential treatments in women's health, urology and nephrology, immunology and neuroscience, while also advancing new areas of discovery research in areas such as regenerative medicine, stem cell therapies and muscle diseases.

We are always exploring opportunities to grow our robust pipeline through business development activities that align with our strategy.

Q: How will a full transition to the Focus Area approach improve R&D productivity?

# A: We will improve R&D productivity by leveraging our strengths and investing new resources into innovative science.

We will create value for patients by focusing on the science of innovative biologies and modality/ technology platforms first, then seek to apply them across a broad range of diseases. This transition, however, requires us to change our mindset and capabilities.

Previously, most of our early development programs came from internal discovery research that we supplemented with later stage licensing or acquisitions. An increased emphasis on early stage collaborations with academia or biotechs requires a more flexible approach, including using external resources to perform some early-stage studies. An increased emphasis on novel biologies also requires deeper capability in translational science.

We will of course maintain a disciplined approach to early development, investing against key milestones or, in select programs, taking a more aggressive "fast track" approach.

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Speaking with the CAO & CECO Sustainable Enhancement of **Corporate Value and Compliance** 

# **Promoting Initiatives to Fulfill the Demands** and Expectations of Diverse Stakeholders

#### Fumiaki Sakurai

Chief Administrative Officer & Chief Ethics & Compliance Officer (CAO & CECO)



Q: What kinds of actions are you taking to solve social issues?

# A: We are focusing on improving Access to Health by making the most of Astellas' strengths.

Improving Access to Health is a particularly crucial social issue that we should be addressing as a pharmaceutical company. We continue to make contributions to improving Access to Health by harnessing our technologies, expertise and resources in each of the following four areas: (1) Creating innovation, which is the basis of our core business, (2) Enhancing availability of innovative medicines, (3) Strengthening healthcare systems, and (4) Improving health literacy. In the course of solving social issues, Astellas will make maximum use of partnerships as necessary.

Going forward, Astellas will continue to further expand opportunities to contribute to improving Access to Health, as it seeks to generate value for society and sustainably increase corporate value.

Q: What kinds of measures are you implementing to strengthen the compliance program?

# A: We are continuing to build a globally consistent compliance program encompassing emerging countries and continuing to foster a corporate culture based on the highest ethical standards and integrity.

Astellas is strongly committed to the ongoing strengthening of its compliance program, as highlighted by the globalization of the Ethics & Compliance function in April 2016.

The goal of strengthening the compliance program is to promote ethics and compliance in a globally consistent manner, including in emerging countries. Specific measures have included establishing the Astellas Group Code of Conduct and various global policies, as well as upgrading and expanding the internal whistleblowing system and online training system on a global basis. We have also increased personnel numbers by assigning full-time compliance staff independent of business departments to almost all countries where Astellas has a sales office. Moreover, we are doing more than merely establishing compliance policies and processes. We are also taking steps that continue to foster a corporate culture based on the highest ethical standards and integrity—one that serves as a strong foundation for those policies and processes.

# Research and Development

# Research and Development

Astellas aims to create a continuous stream of innovative medicines. We will focus on steady progress of six key post-POC pipeline projects that are expected to contribute to midterm growth, and will pursue cutting-edge science with efficient drug discovery approaches.

# **Core Strategy of Research and Development**

Astellas sets targets of research and development (R&D) from multiple perspectives through the Focus Area approach and works to create innovative medicines to fulfill high unmet medical needs based on the concepts of Best Science, Best Talent (optimal personnel), and Best Place (optimum environment).

We determine the priorities of development candidates at the early stages and optimize resource allocation according to priorities. These efforts have achieved results in reduction of the time for R&D and improvement of cost efficiency.

In late-stage development, we allocate management resources extensively to six key post-POC\* projects. We aim to characterize the therapeutic potential of these projects in development. In Strategic Plan 2018, the potential annual sales expected for these projects are described in the table below.

\* POC ("Proof of Concept"): Verification of clinical efficacy

# Potential Size of Key Post-POC Pipeline

Potential size*1 (at peak, billion yen)	Key post-POC pipeline*2	
400 – 500	XTANDI (enzalutamide)	
200 – 300	• fezolinetant	
100 – 200	zolbetuximab	
50 – 100	<ul><li>enfortumab vedotin</li><li>gilteritinib</li></ul>	

- \* Not disclosed for roxadustat
- \*1 Sales amount in the case of successful development in the patient segments currently being evaluated. Some patient segments under evaluation may not be included in the potential size because development is still in an early stage.
- \*2 Target diseases listed in the current pipeline list (P45) are included in the projection. XTANDI also includes sales for indications that have already been approved.

# **Key Post-POC Pipeline Projects**

# XTANDI (generic name: enzalutamide)

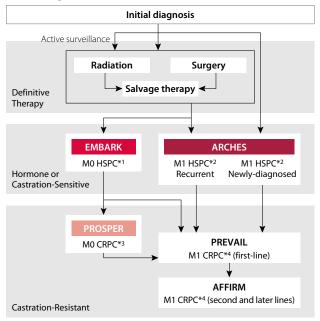
XTANDI is marketed worldwide for the treatment of metastatic castration-resistant prostate cancer (CRPC)\*. Development is ongoing to expand the indication to earlier stages of prostate cancer.

In September 2017, Phase 3 PROSPER trial in patients with non-metastatic CRPC had achieved its primary endpoint. Astellas submitted regulatory applications based on these data in the U.S. and Europe. The U.S. Food and Drug Administration (FDA) granted approval for nonmetastatic CRPC in July 2018.

Two Phase 3 trials (ARCHES and EMBARK) are also ongoing in patients with metastatic hormone-sensitive prostate cancer (HSPC) and non-metastatic HSPC.

\* In Japan, XTANDI has been approved for CRPC.

#### Maximizing the Value of Enzalutamide in Prostate Cancer



- \*1 M0 HSPC: Non-metastatic hormone-sensitive prostate cancer
- \*2 M1 HSPC: Metastatic hormone-sensitive prostate cancer
- \*3 M0 CRPC: Non-metastatic castration-resistant prostate cancer
- \*4 M1 CRPC: Metastatic castration-resistant prostate cancer

#### Gilteritinib

Gilteritinib is a FLT3/AXL inhibitor which is being developed for acute myeloid leukemia (AML). Gilteritinib inhibits both FLT3, a receptor-type tyrosine kinase known to be involved in cancer cell proliferation, and AXL, which is reported to be associated with resistance to some forms of chemotherapy.

AML is a cancer that is most commonly experienced in elderly people with the incidence rate increasing with age. In 2017, the numbers of newly diagnosed AML patients were around 17,500 in the U.S., 13,200 in western Europe, and 5,600 in Japan\*. The prognosis of relapsed or refractory FLT3-mutation positive (FLT3mut+) AML is poor with low response rates to salvage therapy. Resistance to current AML treatment and ineligibility of high-intensity induction chemotherapy for elderly patients due to an excessive physical burden also make challenges in AML treatment. A promising new treatment has been awaited in AML treatment landscape.

#### **Development Progress of Gilteritinib in Each Region**

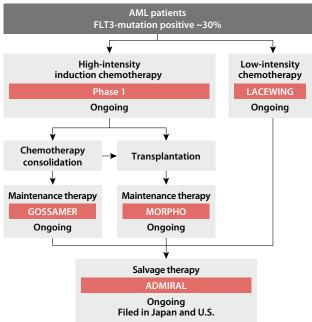
	Development stage	Regulatory designation
Japan	Filed in Mar. 2018	<ul><li>SAKIGAKE designation</li><li>Orphan Drug designation</li></ul>
U.S.	Filed in Mar. 2018 (PDUFA* date: Nov. 2018)	<ul><li>Fast Track designation</li><li>Orphan Drug designation</li></ul>
Europe	Phase 3	Orphan designation

<sup>\*</sup> PDUFA: Prescription Drug User Fee Act

Astellas is conducting the multiple Phase 3 trials to evaluate efficacy and safety of gilteritinib in AML patients at various therapeutic stages. In March 2018, a new drug application (NDA) for marketing approval of gilteritinib was submitted in Japan and the U.S. for the treatment of adult patients with FLT3mut+ relapsed and refractory AML based on the interim analysis data from the ongoing Phase 3 ADMIRAL trial. In this patient population, gilteritinib has been granted for SAKIGAKE designation in Japan and Fast Track designation in the U.S. Astellas has been working to accelerate development of gilteritinib by utilizing the various expedited regulatory pathways in each region. The status of filing and regulatory designation is shown in the table in this page.

\* Annual Incidence in 2017 in U.S., EU5 and JP. CancerMPact (Synix Inc./Kantar Health)

### Gilteritinib in AML Treatment Landscape



#### Enfortumab Vedotin

Enfortumab vedotin is an antibody drug conjugate\*1 (ADC) targeting Nectin-4, a cell adhesion molecule. While it is stable in blood, it is designed to kill only the targeted cancer cells after its internalization into cancer cells expressing Nectin-4.

Astellas is developing enfortumab vedotin as a treatment for urothelial cancer. In Japan, the U.S. and Europe, approximately 233,000\*2 new patients are diagnosed with urothelial cancer annually. It is reported that some patients are confirmed for metastasis at the time of initial diagnosis of urothelial cancer and the fiveyear survival rate is low. A high recurrence rate is reported even if diagnosed and treated at an early stage. A promising new treatment is awaited.

Currently, aiming for earlier approval in each region, Phase 2 and Phase 3 trials in patients with locally advanced or metastatic urothelial cancer previously treated with a checkpoint inhibitor (CPI) are ongoing. Enfortumab vedotin is also being evaluated for the various usage in urothelial cancer including combination therapy with a CPI or monotherapy.

The U.S. FDA has granted Breakthrough Therapy designation to enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who were previously treated with CPIs.

- \*1 Antibody drug conjugate (ADC): ADCs are monoclonal antibodies that are designed to selectively deliver cytotoxic agents to cancer cells.
- \*2 Annual Incidence in 2017 in U.S., EU5 and JP. CancerMPact (Synix Inc./Kantar

#### **Development Progress of Enfortumab Vedotin in Locally** Advanced or Metastatic Urothelial Cancer

Clinical trial	Patient segment	Progress
Phase 3	Patients with prior CPI treatment (platinum-pretreated)	Started in Jul. 2018
Phase 2	Patients with prior CPI treatment Cohort 1: Platinum-pretreated Cohort 2: Platinum naïve Cisplatin ineligible	Started in Oct. 2017
Phase 1b	Combination with CPI	Started in Nov. 2017
Phase 1	Metastatic urothelial cancer patients Patients with renal insufficiency Patients with prior CPI treatment	Ongoing Data presented at medical conferences

#### Zolbetuximab

Zolbetuximab is an antibody that targets Claudin 18.2, a transmembrane protein that forms a tight junction connecting and binding two adjoining cell membranes. Claudin 18.2 is expressed locally in stomach cells for normal cells. Claudin 18.2 is expressed in various cancer types including gastrointestinal adenocarcinomas and pancreatic, biliary duct, ovarian and lung cancers.

Gastric cancer is the fourth leading cause of cancer death worldwide\*1. Moreover, the overall five-year survival rate for metastatic gastric and gastroesophageal junction (GEJ) cancer is under 20%\*2. Gastric and GEJ cancer is one of the malignancies with the highest unmet medical needs. Chemotherapy and anti-HER2 antibodies are widely used for the treatment of metastatic or recurrent gastric and GEJ cancer. However, other therapeutic options are awaited especially in HER2-negative patients with a lack of effective targeted therapies.

Astellas is developing zolbetuximab as a treatment for gastric and GEJ cancer. Two Phase 3 trials are planned to evaluate zolbetuximab in combination with (1) mFOLFOX6\*3, which is commonly used as the first-line therapy in Europe and the U.S, and with (2) CAPOX\*4, the preferred regimen in Asia, including China. The former study was initiated first.

- \*1 World Health Organization Fact Sheet, 2018
- \*2 Pennathur et al, 2013; Sahin et al, 2008
- \*3 mFOLFOX6: Fluorouracil, leucovorin, oxaliplatin
- \*4 CAPOX: Capecitabine, oxaliplatin

## **Development Progress of Zolbetuximab**

Clinical trial	Trial overview	Progress	
	vs placebo Combination with mFOLFOX6	Started in Jun. 2018	
Phase 3	vs placebo Combination with CAPOX	Under preparation	
Phase 2	Monotherapy, Combination with mFOLFOX6	Started in Jun. 2018	

#### Roxadustat

Roxadustat is hypoxia-inducible factor (HIF) prolyl hydroxylase (PH) inhibitor with oral administration.

Roxadustat is thought to increase HIF involving in the production of red blood cells by inhibiting HIF-PH, thereby enhancing the production of red blood cells and improving anemia. Astellas is currently developing roxadustat for anemia associated with chronic kidney disease (CKD) in patients on dialysis and non-dialysis.

Anemia is one of the common complications of CKD. It is said that the progression of anemia in CKD leads to end-stage renal disease and increases the mortality rate. Therefore, managing the hemoglobin levels in patients with anemia in CKD is a crucial issue in the treatment of renal dysfunction.

Roxadustat has a different mechanism of action than the conventional treatments and can be administered orally. It is thus expected to become a new treatment option which could provide both effectiveness and convenience for patients.

For filing and reimbursement in Europe, a total of six Phase 3 trials are being conducted. In addition, six Phase 3 trials are being conducted in Japan. Four Japanese trials in patient with anemia in CKD on dialysis have all achieved their primary objectives. Astellas is planning to submit a

# Development Progress of Roxadustat Global

Treatment phase	Trial overview	Status
	HIMALAYAS: Incident dialysis, vs epoetin alfa	Enrollment completed
Dialysis	SIERRAS: Stable dialysis, vs epoetin alfa	Enrollment completed
	PYRENEES: Stable dialysis, vs epoetin alfa or darbepoetin	Enrollment completed
	DOLOMITES: vs darbepoetin	Enrollment completed
Non- dialysis	ALPS: vs placebo	Study completed
ululysis	ANDES: vs placebo	Enrollment completed

#### Japan

Treatment phase	Trial overview	Status	
	Hemodialysis: Conversion, vs darbepoetin	Study completed	
	Hemodialysis: Conversion, long-term	Study completed	
Dialysis	Hemodialysis: Correction (ESA*-naïve)	Study completed	
	Peritoneal dialysis	Study completed	
Non-	Conversion, vs darbepoetin	Recruiting	
dialysis	Correction (ESA*-naïve)	Enrollment completed	

<sup>\*</sup> ESA: Erythropoiesis-stimulating agents

NDA in Japan for anemia associated with CKD in patients on dialysis in 2018.

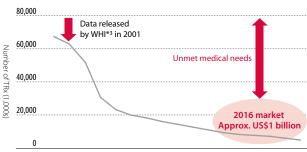
#### Fezolinetant

Fezolinetant is an antagonist of the G protein-coupled receptor (GPCR) known as NK3 receptor. Fezolinetant is expected to act on specific neurons that control body temperature in menopausal women, and is being developed for menopause-related vasomotor symptoms (MR-VMS: hot flashes and night sweats). It is reported that MR-VMS is recognized in nearly 80%\*1 of menopausal women. Given that existing hormone replacement treatments present safety concerns\*2, a safe and effective non-hormone therapy is awaited as a new treatment option.

In Phase 2a (POC) trial, fezolinetant showed positive results in terms of the improvement in the frequency and severity of hot flashes. Based on these results, Astellas expects fezolinetant to become a safe, first-in-class, non-hormonal treatment for MR-VMS. Phase 2b trial is currently ongoing in the U.S. with an expected data readout in 2018.

- \*1 UpToDate Clinical manifestations and diagnosis of menopause (Literature review current through: June 2017)
- \*2 JAMA 2013 Oct 2; 310(13): 1353-1368

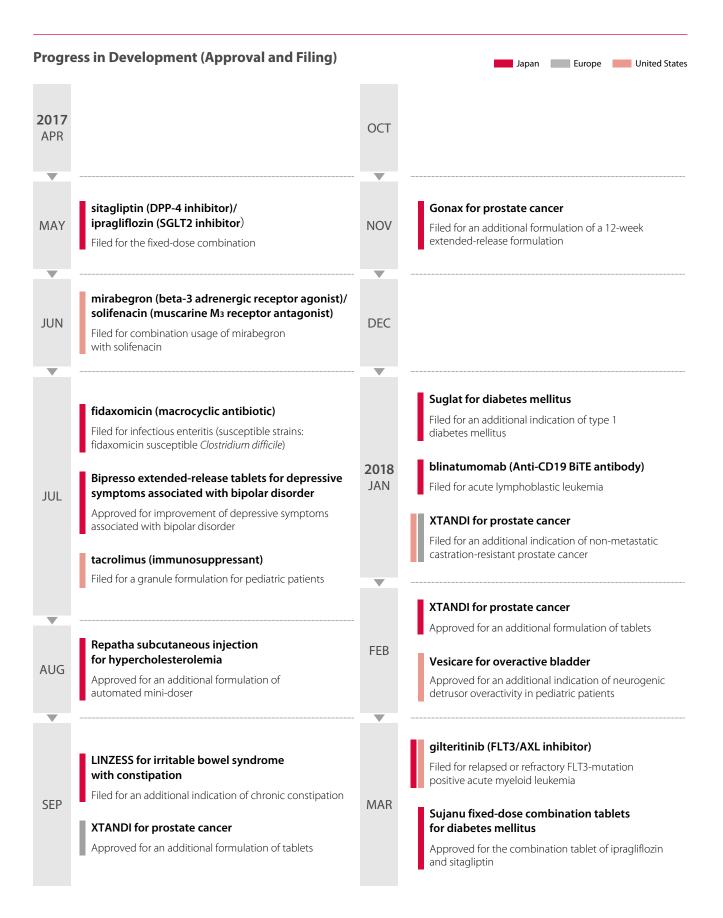
#### U.S. Annual Branded TRx\*1 Trends for MR-VMS\*2



2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

- \*1 TRx: Total prescriptions
- \*2 IQVIA NPA (2000-2016)/IQVIA NSP (2000-2016) (3HTs and SSRI), NAMS 2015 Position Statement
- \*3 WHI: Women's Health Initiative

# **R&D** Topics during the Year



# **Capturing New Opportunities**

# Modality/Technology

### Universal Donor Cell technology

In February 2018, Astellas acquired Universal Cells, Inc., which had proprietary Universal Donor Cell technology for producing pluripotent stem cells with the potential to reduce the risk of immunological rejection in cell therapy. This acquisition enables Astellas to strengthen and expand its research and development of cell therapy by combining this technology and the platform technologies of the Astellas Institute for Regenerative Medicine.

Reference | Focus Area Approach ▶ p15

## Biology

# Acquisition of Mitobridge, Inc.

In November 2017, Astellas exercised its exclusive option rights to acquire Mitobridge, Inc. into a wholly owned subsidiary and completed acquisition in January 2018. Mitobridge, Inc. was previously a R&D collaborator discovering and developing novel drugs that targets mitochondria function.

Reference | Focus Area Approach ▶ P 16

# Immunostimulatory gene-loading oncolytic virus

In February 2018, Astellas entered into an exclusive global licensing agreement with Tottori University on the development and commercialization of immunostimulatory gene-loading oncolytic virus. We expect to offer new opportunities in cancer immunotherapy with this virus via the induction of antitumor immunity in tumors not responding to currently available cancer immunotherapies.

#### Other

#### Alliance Station established

In April 2017, Astellas and Kyoto University established the Alliance Station as a new open innovation scheme with aim of delivering advanced medical treatments. In addition, the Alliance Laboratory for Advanced Medical Research in the Graduate School of Medicine Kyoto University was established as a framework for such activities.

# Acquisition of Ogeda SA

In May 2017, Astellas completed its acquisition of Ogeda SA, making it a wholly owned Astellas subsidiary with the aim of expanding the pipeline in clinical development. Besides fezolinetant, NK3 receptor antagonist developing for menopause-related vasomotor symptoms, Astellas acquired multiple small molecule compounds in the preclinical stage for inflammatory and autoimmune diseases.

Reference | Research and Development ▶ P42

## Rice-based oral vaccine MucoRice

In May 2017, Astellas and the Institute of Medical Science, the University of Tokyo (IMSUT) agreed to expand the scope of the collaborative research program for the ricebased oral vaccine MucoRice to include vaccines against cholera, enterotoxigenic E. coli, and viral gastroenteritis diarrhea. In February 2017, a new collaborative research agreement was signed with IMSUT, Chiba University and ASAHI KOGYOSHA CO., LTD. aiming for practical applications of MucoRice-CTB.

Reference | Access to Health ▶ P63

# New collaborative drug-discovery program

In October 2017, Astellas signed an agreement with Mitsubishi Tanabe Pharma Corporation and Daiichi Sankyo Co., Ltd. to conduct a joint program JOINUS to discover new therapeutic drugs using the drug-repositioning compound libraries.

<sup>\*</sup> Some rights relating to the fundamental technology are non-exclusive.

# Status of R&D Pipeline (as of July 2018)

Biology	Modality/Tecl	hnolo
Diology	iviodality/ icci	IIIIOIO

Code No. Generic Name (Brand Name)	Classification	Target Disease	Phase/Area	Dosage Form	Licensor* <sup>1</sup>	FA approach*2
Oncology						
MDV3100 enzalutamide	Androgen receptor inhibitor	Non-metastatic castration- resistant prostate cancer	Approved (Jul. 2018)/US Filed (Jan. 2018)/Europe	Oral	Pfizer	
(XTANDI)		Non-metastatic hormone- sensitive prostate cancer	P-III/US, Europe, Asia			
		Metastatic hormone-sensitive prostate cancer	P-III/US, Europe, Japan ,Asia			
ASP3550 degarelix (GONAX)	GnRH antagonist	Prostate cancer (3-month formulation)	Filed (Nov. 2017)/Japan	Injection	Ferring	
AMG 103 blinatumomab	Anti-CD19 BiTE antibody	Acute lymphoblastic leukemia	Filed (Jan. 2018)/Japan	Injection	Amgen (co-development with Amgen Astellas)	
ASP2215 gilteritinib	FLT3/AXL inhibitor	Relapsed or refractory acute myeloid leukemia	Filed (Mar. 2018)/US, Japan P-III/Europe, Asia	Oral	In-house	
		Post-chemo maintenance acute myeloid leukemia	P-III/US, Europe, Japan, Asia			
		Post-HSCT maintenance acute myeloid leukemia	P-III/US, Europe, Japan, Asia			
		Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	P-II/III/ US, Europe, Japan, Asia			
		Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	P-I/US, Japan			
IMAB362 zolbetuximab	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III/US, Europe, Japan, Asia	Injection	In-house (Ganymed)	
ASG-22ME enfortumab vedotin	ADC targeting Nectin-4	Urothelial cancer	P-III/US, Europe, Japan, Asia	Injection	In-house (co-development with Seattle Genetics)	
AGS-16C3F	ADC targeting ENPP3	Renal cell carcinoma	P-II/US, Europe	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
AGS67E		Lymphoid malignancies	P-I	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
AGS62P1		Acute myeloid leukemia	P-I	Injection	In-house (ADC technology, EuCODE license from Ambrx)	
ASP8374/PTZ-201		Cancer	P-I	Injection	Option agreement with Potenza Therapeutics	<ul><li>Cancer immunology</li></ul>
ASP1948/PTZ-329		Cancer	P-I	Injection	Option agreement with Potenza Therapeutics	<ul><li>Cancer immunology</li></ul>

# Immunology, Muscle disease and Ophthalmology

FK506 tacrolimus	Immunosuppressant	Prevention of rejection after organ transplantation (Granule formulation in pediatric use)	Approved (May 2018)/US	Oral	In-house	
ASP015K peficitinib	JAK inhibitor	Rheumatoid arthritis	Filed (May 2018)/Japan	Oral	In-house	
ASKP1240 bleselumab	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II/US	Injection	Kyowa Hakko Kirin	
ASP4070/ JRC2-LAMP-vax	DNA vaccine for Japanese red cedar	Pollinosis caused by Japanese red cedar	P-II/Japan	Injection	Immunomic Therapeutics	LAMP-vax technology
ASP5094	Anti-alpha-9 integrin monoclonal antibody	Rheumatoid arthritis	P-II/Japan	Injection	In-house	

■ Biology Modality/Technology

Code No. Generic Name (Brand Name)	Classification	Target Disease	Phase/Area	Dosage Form	Licensor* <sup>1</sup>	FA approach*2
CK-2127107	Fast skeletal troponin	Spinal muscular atrophy	P-II/US	Oral	Cytokinetics	<ul><li>Molecular</li></ul>
reldesemtiv	activator	Chronic obstructive pulmonary disease	P-II/US			motor
		Amyotrophic lateral sclerosis	P-II/US	Ì		
ASP7317	Cell therapy (Retinal pigment epithelium cell)	Dry age-related macular degeneration, Stargardt's macular degeneration	P-II/US	Injection	In-house (Astellas Institute for Regenerative Medicine)	Cell therapy
MA-0211		Duchenne muscular dystrophy	P-I	Oral	In-house (Mitobridge)	<ul><li>Mitochondria</li></ul>
ASP0892		Peanut allergy	P-I	Injection	Immunomic Therapeutics	LAMP-vax technology

# **Urology and Nephrology**

EB178 solifenacin/ mirabegron	Combination therapy of solifenacin and mirabegron	Overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	Approved (Apr. 2018)/US	Oral	In-house	
YM905 solifenacin	Muscarine M <sub>3</sub> receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	Filed (Feb. 2017)/US	Oral	In-house	
ASP1517/FG-4592 roxadustat	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	P-III/Europe P-III/Japan	Oral	FibroGen	
YM178 mirabegron	Beta-3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	P-III/Europe	Oral	In-house	
YM311/FG-2216	HIF stabilizer	Renal anemia	P-II/Europe P-I/Japan	Oral	FibroGen	
ASP6294	Nerve Growth Factor (NGF) neutralization antibody	Bladder pain syndrome / Interstitial cystitis	P-II/Europe	Injection	In-house	
ASP8302	Muscarine M <sub>3</sub> receptor positive allosteric modulator	Underactive bladder	P-II/Europe, Japan	Oral	In-house	
ASP7713		Underactive bladder	P-I	Oral	In-house	
MA-0217		Acute kidney injury	P-I	Injection	In-house (Mitobridge)	<ul><li>Mitochondria</li></ul>

# Others

fidaxomicin	Macrocyclic antibiotic	Infectious enteritis (bacterial target: Clostridium difficile)	Approved (Jul. 2018)/Japan	Oral	Merck
		Clostridium difficile infection in pediatric patients	P-III/Europe		
AMG 785 romosozumab	Anti-sclerostin monoclonal antibody	Osteoporosis for those at high risk of fracture	Filed (Dec. 2016)/Japan	Injection	Amgen (co-development with Amgen Astellas)
ASP1941 ipragliflozin (Suglat)	SGLT2 inhibitor	Type 1 diabetes	Filed (Jan. 2018)/Japan	Oral	In-house (co-development with Kotobuki)
ASP0456 linaclotide (LINZESS)	Guanylate cyclase-C receptor agonist	Chronic constipation	Filed (Sep. 2017)/Japan	Oral	Ironwood
ESN364 fezolinetant	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-II/US P-I/Japan	Oral	In-house (Ogeda)
ASP0819	Calcium2+-activated K+ channel opener	Fibromyalgia	P-II/US	Oral	In-house
ASP4345	Dopamine D <sub>1</sub> receptor positive allosteric modulator	Cognitive impairment associated with schizophrenia	P-II/US	Oral	In-house
ASP1807/CC8464		Neuropathic pain	P-I	Oral	Chromocell
ASP6981		Cognitive impairment associated with schizophrenia	P-I	Oral	In-house
MucoRice-CTB		Prophylaxis of diarrhea caused by Vibrio cholerae	P-I	Oral	The Institute of Medical Science, the University of Tokyo

<sup>\*1</sup> Compounds with "In-house" in this column include ones discovered by collaborative research.
\*2 Focus Area approach

# CSR Activities in Research and Development

#### Research

### Ethical Considerations in Research on Human **Subjects and Specimens Derived from Humans**

Astellas conducts research on human subjects, and obtains and conducts research on specimens derived from humans, after appropriately obtaining the consent of the subjects in accordance with the Declaration of Helsinki\* as well as the laws, regulations and guidelines of relevant countries.

In Japan, Astellas provides training for researchers in areas such as bioethics, genomic research and related clinical research based on a strong commitment to respecting the human rights of research subjects and protecting the privacy and confidentiality of their personal information.

The Astellas Research Ethics Committee has been established with outside members participating in the committee to determine the ethical acceptability and scientific propriety of research plans in a fair and impartial

\* Declaration of Helsinki: A statement of ethical principles for medical research involving human subjects, addressed to physicians and others who are involved in medical research on human subjects.

#### Ethical Considerations in Animal Testing

Astellas conducts animal testing based on its Policy on Animal Care and Use. We have established the Corporate Institutional Animal Care and Use Committee with outside members participating in the committee, to determine whether to conduct animal testing based on the 4R Principles\*1. All of Astellas' animal testing facilities have acquired accreditation from AAALAC international\*2.

- \*1 4R Principles: Developing non-animal testing alternatives and replacing animals of phylogenetically lower species (Replacement); reducing the number of animals involved to the minimum necessary to achieve the scientific purpose (Reduction); avoiding the infliction of distress on animals wherever possible (Refinement); and scientifically and ethically justifying animal use in light of their significance, necessity, predictability and other criteria (Responsibility).
- \*2 AAALAC International: The Association for Assessment and Accreditation of Laboratory Animal Care International. An international organization that promotes the humane treatment of animals through voluntary accreditation and assessment programs. Studies are undertaken from both scientific and ethical standpoints to verify the quality of animal control and use programs.

#### Biotechnology and Biohazard Control

Astellas handles genetically modified organisms and performs experiments using materials containing pathogens in compliance with the World Health Organization Laboratory Biosafety Manual\*1, the U.S. Centers for Disease Control (CDC) Biosafety Manual\*2 and the U.S. National Institutes of Health Guidelines\*3, as well as the laws of individual countries.

- \*1 Laboratory Biosafety Manual 3rd Edition
- \*2 Biosafety in Microbiological and Biomedical Laboratories 5th Edition
- \*3 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

#### Use of Genetic Resources

Astellas has published its Position on Genetic Resources, and is committed to full compliance with the relevant laws and regulations of countries supplying genetic resources, and to the fair distribution of profits derived from the use of such resources according to the conditions mutually agreed upon with each country. This commitment is based on the concept of genetic resource utilization and the associated distribution of profits set out in the Nagoya Protocol\*1 adopted by the Conference of the Parties to the Convention on Biological Diversity\*2. The impacts of the use of new genetic modification technologies on the environment, biodiversity, and human health are not fully known. Therefore, Astellas will proceed cautiously when using these technologies while remaining mindful of the need to preserve biodiversity and consider ethical issues.

- \*1 Nagoya Protocol: Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization
- \*2 The Convention on Biological Diversity: International convention on the sustainable use and conservation of biological diversity

#### Treatment of Intellectual Property

Appropriate protection of intellectual property is critical to addressing unmet medical needs and maintaining a competitive advantage. With this in mind, Astellas has established a Policy on Intellectual Property. In view of the importance of improving people's access to health, Astellas participates in the Patent Information Initiative for Medicines (Pat-INFORMED) implemented by the World International Patent Organization (WIPO) to ensure easy access to Astellas' patent information on medicines by health agencies tasked with the procurement of medicines in various countries.

Moreover, we are committed to not filing or enforcing patents in countries facing significant economic challenges. These select countries are decided by referring to those designated as Least Developed Countries (LDCs) defined by the United Nations or Low Income Countries (LICs) defined by the World Bank.

Financial Information and Data

# **Clinical Development**

Respect for Human Rights, Protection of the Privacy and Confidentiality of the Personal Information of Clinical Trial Subjects, and Assurance of Reliability in Clinical Trials

Astellas conducts clinical trials to assess the efficacy and safety of new drug candidates in patients under the Declaration of Helsinki, Good Clinical Practice (GCP) and all relevant laws and regulations with full consideration to protecting human rights and the privacy and confidentiality of clinical trial subjects' personal information. Clinical study protocols developed by Astellas are evaluated and approved for ethical acceptability and scientific validity by internal and external evaluation committees.

In conducting clinical trials, Astellas confirms that clinical trial subjects have provided informed consent, having received a full explanation of the purpose and methods of the trial, its expected benefits and disadvantages, matters related to compensation for health impairment and other details. Moreover, we implement education and training for any employees or staff members involved in clinical trials, and monitor medical institutions that perform clinical trials to ensure full GCP compliance.

In addition, we manage trial data appropriately to protect the privacy and confidentiality of the personal information of clinical trial subjects. Periodic assessments are also made to check that any outsourced clinical trials are conducted in accordance with the same standards.

### Disclosure of Information on Clinical Trials and Trial Results

Astellas is committed to increasing transparency and providing disclosure of clinical trial data. Maximizing the value of clinical trial data, and putting it to good use in driving scientific advancement and increasing innovation, requires that the clinical trial data be appropriately accessible to the research community and others who might utilize it. The Policy on Disclosure of Clinical Trial Data has been published on the Company website to present Astellas' position on this matter.

Specifically, Astellas provides patient-level data that have been anonymized in accordance with applicable laws and regulations through an external website\*1 to those scientists and healthcare professionals requesting it. Doctors and the public can confirm summaries of clinical trial findings via the website for clinical trial data disclosure. This website also gives patients access to plain language summaries of study results prepared for non-experts\*2.

- \*1 Patient-level data are provided through the following website: http://www.clinicalstudydatarequest.com
- \*2 Results of the clinical trials are provided through the following website: https://www.astellasclinicalstudyresults.com/Welcome.aspx

# Patient Centricity in Clinical Drug Development

Real-world considerations in clinical trials are increasingly important in ensuring that our studies address current medical practices and patient needs.

Patient centricity is now a focus for regulatory authorities and the pharmaceutical industry. The patient-centric approach is being discussed at all points in the drug development value chain, from discovery through to commercialization.

We are pursuing patient centricity in clinical development. To do so, we are trying to incorporate insights from real-world data into the planning of clinical trials by understanding how healthcare is provided to patients. Efforts are being made to include patient input in how to optimally design clinical trials, recruit participants, and identify relevant endpoints that patients care most about.

For example, we use patient-reported outcomes (PROs) such as questionnaires and patient diaries to monitor and assess patients' health conditions. In addition, we use real-world data for estimation of target populations based on the morbidity rate and ineligible cases in screening, and feasibility of studies in clinical trial facilities. As a pilot project, we established a patient-friendly website for an investigational drug to support patient/caregiverfocused recruitment and health literacy recommendations. Especially in the muscle disease field, we are working with patient organizations. Working closely with those organizations, we are striving to reflect valuable insights from patients and caregivers in clinical trial designs. Through these activities, we try to make it easier for patients to participate in clinical trials, as we work to obtain trial results with greater clinical significance.

Please refer to the URL below for information about the following CSR activities in research and development.

- Ethical Considerations in Stem Cell Research and Development
- Expanded Access to Investigational Medicines

https://www.astellas.com/en/sustainability/ business-activities/

Please refer to the following URL for information about our policies and position statements.

https://www.astellas.com/en/about/policies-and-position-statements/

# Manufacturing to Sales and Procurement

# **Overview of Main Products**

Astellas is focused on maximizing the value of the main products that will drive growth in each region, such as XTANDI and Betanis/Myrbetriq/BETMIGA.

# **Prostate Cancer Treatments XTANDI**

# Business Environment and Basic Strategy

According to the American Cancer Society, more than 164,000 men are expected to be diagnosed with prostate cancer in the U.S. in 2018. In Europe, it is estimated that approximately 365,000 people were diagnosed with prostate cancer in 2015.

XTANDI is a once-daily oral androgen receptor inhibitor. It was launched in the U.S. in 2012 to treat patients with metastatic castration-resistant prostate cancer who had previously received chemotherapy through docetaxel. In 2014, XTANDI obtained an additional indication for the treatment of patients with chemotherapy-naïve metastatic castration-resistant prostate cancer. As of March 2018, XTANDI is sold in more than 70 countries and regions around the world, including Japan, the Americas, EMEA and Asia & Oceania. It has so far been used in the treatment of more than 310,000 patients.

XTANDI stands out as a significant growth driver for Astellas. We aim to establish the position of XTANDI as the first choice of therapy for metastatic castration-resistant prostate cancer\*, for which it is currently indicated. To reach this goal, we will leverage our solid presence in the urology field and our abundant data based on extensive

clinical experience to further increase penetration of this drug among urologists.

In the U.S., Astellas and the Pfizer Group co-promote XTANDI and share profits equally. In all countries excluding the U.S., Astellas commercializes XTANDI, while paying the Pfizer Group royalties based on sales.

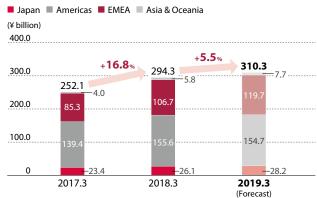
\* In Japan, XTANDI has been approved for the treatment of castration-resistant prostate cancer.

#### Fiscal 2017 Performance and Outlook

Sales of XTANDI were ¥294.3 billion, an increase of 16.8% year on year.

Looking at regional sales of XTANDI, sales in Japan increased 11.4% to ¥26.1 billion. Sales in the Americas rose 9.2% to US\$1,404 million. In this region, U.S. sales increased 7.2% to US\$1,303 million. In EMEA, sales rose by 14.6% to €823 million. In Asia & Oceania, sales increased 47.3% to ¥5.8 billion, marking overall growth. Sales increased across all regions as XTANDI steadily gained traction among chemotherapy-naïve patients.

#### Sales of XTANDI by Region



As part of efforts to maximize the product value of XTANDI, Astellas drove development forward with a focus on expanding indications. In January 2018, Astellas submitted applications in Europe and the U.S. for approval of an additional indication of XTANDI for non-metastatic castration-resistant prostate cancer based on data from the PROSPER trial. In July 2018, Astellas obtained approval for this additional indication in the U.S. In Japan, Astellas obtained approval for XTANDI tablets as additional dosage forms. Sales of XTANDI tablets were launched in June 2018.

Moreover, Astellas is pushing ahead with additional clinical studies such as the EMBARK trial for patients with non-metastatic hormone-sensitive prostate cancer and the ARCHES trial for patients with metastatic hormone-sensitive prostate cancer, with the aim of expanding the indications of XTANDI to patients with prostate cancer in earlier stages.



In the area of prostate cancer, Astellas also sells Eligard and Gonax, both of which are treatments for prostate cancer, in addition to XTANDI. Eligard, a luteinizing hormone-releasing hormone (LHRH) agonist, is sold in EMEA and Asia & Oceania, while Gonax, a gonadotrophin-releasing hormone (GnRH) antagonist with a subcutaneously injectable formulation, is sold in Japan.

# Overactive Bladder (OAB) Treatments

Betanis/Myrbetrig/BETMIGA and Vesicare

# Business Environment and Basic Strategy

OAB can trigger urinary urgency issues (involving cases where urge urinary incontinence is present and others where it is not), and it is often associated with urinary frequency and nocturia. By 2018, approximately 546 million people worldwide are expected to contract OAB\*.

Astellas sells Vesicare and Betanis/Myrbetriq/BETMIGA as treatments that help to relieve symptoms associated with OAB such as urgency, urinary frequency, and urge urinary incontinence. Vesicare has earned a position as the first choice among anticholinergic drugs—the standard therapy for OAB. As of March 2018, Vesicare is sold in over 80 countries and regions worldwide.

Betanis/Myrbetriq/BETMIGA is a beta-3 adrenergic receptor agonist that helps to relieve symptoms associated with OAB through a different mechanism of action from Vesicare. As of March 2018, it is sold in around 50 countries and regions worldwide under the brand name of Betanis in Japan, Myrbetriq in the Americas, and BETMIGA in EMEA and Asia & Oceania.

Patent protection for Vesicare will expire in various regions from 2019 onward. In this environment, we will allocate resources to Betanis/Myrbetriq/BETMIGA as we focus on achieving further market penetration, in order to maximize the value of the OAB franchise as a whole.

\* Irwin DE, Kopp ZS, Agatep B, Milsom I, Abrams P. Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction. BJU Int. 2011, vol.108, no.7, p.1132-1138.

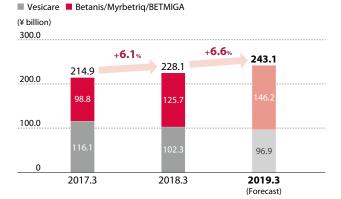
#### Fiscal 2017 Performance and Outlook

In fiscal 2017, aggregate sales of our OAB franchise, including Vesicare and Betanis/Myrbetrig/BETMIGA, increased by 6.1% to ¥228.1 billion.

Astellas focused on increasing the market penetration of Betanis/Myrbetrig/BETMIGA by promoting it as an OAB treatment with well-balanced effectiveness and tolerability based on a new mechanism of action. As a result, in fiscal 2017, aggregate sales increased in every region, with sales growing by 27.2% to ¥125.7 billion. In Japan, sales of Betanis increased by 13.7% to ¥29.5 billion. Betanis' annual share of the OAB treatment market was approximately 37% (on a value basis). In the Americas, Myrbetriq sales rose 28.7% to US\$657 million. In this region, Myrbetriq's annual share of the U.S. OAB treatment market reached approximately 41% (on a value basis). In EMEA, sales of BETMIGA increased by 18.5% to €141 million. In EMEA, BETMIGA's annual share of the OAB treatment market reached approximately 16% (on a value basis). In Asia & Oceania, BETMIGA sales increased sharply by 47.7% to ¥5.2 billion.

Meanwhile, in fiscal 2017, sales of Vesicare decreased by 11.9% to ¥102.3 billion. Looking at regional sales of Vesicare, sales in Japan decreased 6.8% to ¥23.9 billion, sales in the Americas declined 24.0% to US\$372 million, sales in EMEA decreased 9.5% to €244 million, and sales in Asia & Oceania rose 0.4% to ¥5.0 billion.

Total Sales of the OAB Franchise (By Product)



As a result of the foregoing, sales of Betanis/ Myrbetriq/BETMIGA in fiscal 2017 surpassed sales of Vesicare for the first time. Additionally, Betanis/Myrbetriq/ BETMIGA's share of the total sales of the OAB franchise reached approximately 55%, compared with approximately 46% in fiscal 2016, on a yen basis.

Concomitant use of Betanis/Myrbetriq/BETMIGA and Vesicare, which was approved in the U.S. in May 2018, is expected to contribute positively to sales. Moreover, Astellas will make effective use of additional data that will be obtained from post-marketing clinical trials, with the aim of driving further growth in sales of Betanis/Myrbetrig/BETMIGA.



# Other Main Products and New Products

# Overview of Main Products (Global Products) Prograf and Advagraf/Graceptor/ASTAGRAF Prograf and Advagraf/Graceptor/ASTAGRAF are a vital earnings base for Astellas.

This drug is an immunosuppressant used to suppress organ transplant rejection. Although the patent for this drug has already expired in major countries, it is sold in approximately 100 countries and regions and has made a significant global contribution to the field of transplantation. Sales of Prograf increased 6.6% to ¥198.5 billion in fiscal 2017. Looking at regional sales, sales in Japan decreased 1.1% to ¥48.3 billion, and sales in the Americas declined 8.0% to US\$232 million. However, sales in EMEA via in-house distribution channels rose 2.8% to

€607 million, mainly supported by an increase of 8.0% in sales of Advagraf. Sales in Asia & Oceania rose 14.0% to ¥42.5 billion, with sales growing primarily in China.

# Overview of New Products (Japan)

**Suglat/Sujanu** Suglat, a type 2 diabetes treatment, is Japan's first selective sodium-glucose co-transporter 2 (SGLT2) inhibitor. In Japan, Astellas is co-promoting Suglat with Kotobuki Pharmaceutical Co., Ltd. Sales of Suglat grew 22.5% to ¥11.6 billion in fiscal 2017. Suglat's share of the market for selective SGLT2 inhibitors in Japan was around 22% (on a value basis).

In May 2018, Astellas launched sales in Japan of Sujanu Combination Tablets, a combination drug of Suglat and the DPP-4 inhibitor sitagliptin phosphate hydrate, with the indication of type 2 diabetes. Sujanu is co-promoted with Kotobuki Pharmaceutical Co., Ltd. and MSD K.K.

In addition, in January 2018, Astellas filed an application in Japan for approval of an additional indication of Suglat for type 1 diabetes.

Repatha In April 2016, Astellas launched Repatha, the first proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor in Japan, indicated for the treatment of familial hypercholesterolemia or hypercholesterolemia\*. It is being co-promoted by Astellas and Amgen Astellas BioPharma K.K. in an effort to steadily increase market penetration. In May 2017, limits on the prescription period were removed and the self-injectable formulation of Repatha became eligible for National Health Insurance coverage. In fiscal 2017, sales of Repatha were ¥1.6 billion. In January 2018, Astellas launched sales of Repatha SC Injection 420 mg Auto Mini-Doser, an additional dosage formulation of Repatha.

\* The approved indication is as follows: "Familial hypercholesterolemia, Hypercholesterolemia, only when patients who have high risk of cardiovascular events and do not adequately respond to HMG-CoA reductase inhibitors.

**Linzess** Linzess was launched in March 2017 as Japan's first drug indicated for the treatment of irritable bowel syndrome with constipation (IBS-C). In fiscal 2017, sales of Linzess were ¥1.4 billion. We will continue working to increase market penetration of this drug, which provides a new option for treating IBS-C. In August 2018, Astellas obtained approval in Japan for the additional indication of chronic constipation (other than constipation associated with organic disorders).



Linzess

<sup>\*</sup> Official guidance on points to consider regarding the use of Repatha under National Health Insurance coverage was issued by the Medical Affairs Division of the Ministry of Health, Labour and Welfare (Medical Affairs Division 1215 No.12; December 15, 2017).

# **CSR Activities from Manufacturing to Sales**

# **Quality and Reliability Assurance**

# Anti-Counterfeiting Activities

The distribution of counterfeit medicines in legitimate supply chains not only leads to the loss of opportunities for patients to receive medical treatment but could also have adverse health consequences. This has become a serious problem worldwide.

Astellas operates the Anti-Counterfeit Committee, led by the supply chain management and quality assurance divisions, and has a product security division. These parts of Astellas conduct monitoring and surveys, and implement countermeasures targeting not only counterfeit medicines, but also diversion, smuggling, theft and related activities. When selling products, Astellas systematically introduces effective anti-counterfeit technologies, including product serialization of secondary product packaging as stipulated by regulations, based on pharmaceutical laws and regulations and risks in each market where products are sold, as well as product characteristics. In addition, Astellas carries out educational activities to prevent the spread of counterfeit medicines in collaboration with members of the pharmaceutical industry and organizations such as the World Health Organization (WHO), the PSI\* and the Transported Asset Protection Association. We also proactively endeavor to support and cooperate with national governments and judicial authorities to crack down on counterfeit medicines.

Astellas publishes its Position on Counterfeit Medicines on its website.

#### Product Recalls

Astellas has a recall system in place that is activated when the safety, efficacy or quality of a product is brought into question. The system ensures relevant information is promptly passed on to medical institutions and other affected parties, and that a recall of the product in question is instigated. Astellas voluntarily initiated three product recalls in fiscal 2017. As of March 2018, no reports of any related health impairments had been received.

#### Improving the Pharmacovigilance (PV) System

Astellas is continuously improving its PV system by strengthening collaboration between the internal PV function and other relevant departments, affiliates and licensing partners. This is to support the provision of

trustworthy product information and proper product use, along with regulatory compliance.

Astellas regularly provides product safety awareness training not only to staff closely involved with the PV function but also to all employees and contractors including affiliate staff, to maintain and strengthen swift and appropriate collection of product safety information. For external service providers outsourced by departments other than the PV division, Astellas updates their contracts to add requirements for safety management information collection as necessary. Through these measures, Astellas is building a system for collecting information over a wide scope.

In addition, Astellas is exploring utilizing real-world data such as large healthcare databases for safety signal detection of Astellas products to help minimize risk by enhancing collaboration between PV and other functions. Furthermore, Astellas PV has started exploring and assessing automation technologies and artificial intelligence technologies that can be used for safety data monitoring, processing and reporting, and earlier identification and analysis of safety signals. We plan to use these technologies to strengthen our safety data management systems.

### **Technology Development & Manufacturing**

### Stable Supply and Quality Control

Astellas places highest priority on ensuring stable manufacture and supply of safe and effective pharmaceuticals to patients. To ensure this, we have established our own Good Manufacturing Practice (GMP)compliant quality standards as the basis for consistently achieving high levels of quality control. We apply these standards to manufacturing facilities and equipment, and to all stages from raw material procurement and storage to production and shipment.

#### Relationship with Local Communities

To promote sustainable pharmaceutical manufacturing, Astellas arranges opportunities for dialogue with local residents and communities near its manufacturing sites. By proactively disclosing its initiatives, Astellas is working to build good relationships with them.

At the Kerry Plant in Ireland, Astellas is launching annual events with the local community to protect the environment, ensure health and safety, and save energy. Each year, the event themes revolve around environmental protection, health and safety, and energy conservation,

<sup>\*</sup> PSI: The Pharmaceutical Security Institute (PSI) is a not-for-profit organization. established to strengthen global anti-counterfeiting efforts. A total of 33 pharmaceutical manufacturers are currently members of the PSI.

Financial Information and Data

and local children draw pictures with the themes. These are made into a calendar which is sold locally, with all proceeds donated to the Irish Kidney Association. Every year, over 1,000 entries are received from 12 schools, and the event is now being developed into a regular community event. In 2017, we received the SEAI\* Award as one of Ireland's leading companies.

\* SEAI: Sustainable Energy Authority of Ireland is an Irish government-affiliated organization supporting the reduction of CO2 emissions.

#### **Provision of Product Information**

#### Ensuring Proper Use

Astellas' Medical Representatives (MRs) provide information on appropriate usage based on on-label information to healthcare professionals to ensure that Astellas pharmaceutical products are used safely and effectively. In promotion of Astellas products, MRs observe high ethical standards and strictly observe the Astellas Group Code of Conduct, local codes of conduct, and the relevant laws and regulations in each country.

Medical Science Liaisons (MSLs) engage with healthcare professionals to exchange scientifically based information to advance their understanding and the safe and effective use of our products in patient care. MSLs observe high ethical standards and provide reliable, clear, fair, balanced and unbiased medical and scientific information. MSLs refrain from promotion of products, and observe high ethical standards, making compliance their top priority.

#### Responding to Inquiries

Astellas has a responsibility to provide truthful, balanced and unbiased medical information in response to inquiries regarding our products. By fulfilling this responsibility, Astellas supports the safe and effective use of our products.

In countries throughout the globe, we have Medical Information Call Centers that respond to a variety of inquiries. In our larger call centers, we have systems that allow for 24-hour responses to urgent inquiries, even on business holidays. In fiscal 2017, we responded to approximately 160,000 inquiries.

Astellas makes continuous efforts to improve its medical information services, with the aim of providing accurate, appropriate and consistent information. As part of these efforts, a global medical information system is used where medical responses from Group companies around the world are documented. This enables the

responses to be communicated to our customers in a simple, swift and accurate manner. At the same time, we can analyze feedback from patients and medical professionals and inform the life cycle management of our products.

#### **Procurement**

# Promoting CSR Procurement

Astellas considers it important to fulfill its social responsibilities across the entire supply chain, including suppliers. To achieve this goal, Astellas has formulated the Astellas Business Partner Code of Conduct, which requires business partners to do their business in accordance with CSR measures. We also conduct global questionnairebased surveys based on the code, along with requesting our business partners to sign the Acknowledgement of Astellas Business Partner Code of Conduct. As of March 31, 2018, we had obtained survey responses from approximately 900 companies, covering suppliers of direct materials, as well as major suppliers of indirect materials and major facility and equipment suppliers. In fiscal 2017, we widened the scope of the survey to include pharmaceutical wholesalers, licensees, distributors and banks. Furthermore, we conduct on-site audits of suppliers in countries that pose a high CSR procurement risk.

Please refer to the following URL for information about related CSR activities from manufacturing to sales.

- · Anti-Doping Measures
- Strengthening of Quality Assurance Systems at Affiliates
- Quality Assurance Policies
- Measures to Prevent Medical Malpractice and Improve the Distinguishability of Pharmaceuticals
- Introduction of Universal Design into Product Packaging



https://www.astellas.com/en/sustainability/ business-activities

Please refer to the following URL for information about our policies and



https://www.astellas.com/index.php/en/about/ policies-and-position-statements

# Improvement in the Quality and Efficiency of Operations

# **Recent Initiatives**

Astellas will pursue further improvements in both the quality and efficiency of operations, as well as reallocating management resources in fields that promise growth and a superior position competitively, further strengthening its operational foundation.

With regard to the organizational structure, Astellas is working to strengthen its global management functions. In April 2017, we integrated legal and intellectual property functions in each region by newly establishing Legal and Intellectual Property functions on a global level. Furthermore, in April 2018, we established the new global functions Finance, Human Resources, and Internal Auditing to integrate the finance, human resources, and internal auditing functions in each region.

We are also promoting optimization of management resource allocation. Our agreement to transfer assets to LTL Pharma Co., Ltd. regarding marketing authorization for 16 long-listed products in Japan, bulk supply business of active pharmaceutical ingredients to third parties in and outside of Japan, and the royalty business took effect in April 2017. Accordingly, in the fiscal year ended March 31, 2018, manufacturing and marketing authorization for several products was also succeeded to LTL Pharma Co., Ltd., and we transferred the distribution rights of the products in Japan. Furthermore, in October 2017, we succeeded the manufacturing and marketing approvals in Japan for Protopic, a treatment for atopic dermatitis, to Maruho Co., Ltd.

In addition, Astellas implemented the following initiatives.

### Outsourcing of Operational and Management Support

As part of an initiative to promote efficiency by outsourcing operational and management support duties, in December 2017, Astellas dissolved Astellas Business Services Co., Ltd., which undertook operational and management support duties for Astellas Pharma Inc. and its subsidiaries in Japan, completing the liquidation in March 2018.

### Termination of Research Activities at Agensys, Inc.

Astellas terminated its research activities at U.S. consolidated subsidiary Agensys, Inc. in March 2018 and transferred the research facilities and related assets to Kite, a Gilead Company in the United States, in April 2018.

Astellas will advance its strategy in the oncology field by reducing its investments in Antibody-Drug Conjugate (ADC) research and expanding its investments in new technologies and modalities that will give us an even stronger competitive advantage.

#### Optimization of Organizational Structure in Europe

Astellas is taking steps to optimize our organizational structure in Europe, aiming to evolve our operating model with changes in the operating environment. As part of this, we decided to consolidate our Netherlands R&D functions in Japan and the U.S.

Moreover, in EMEA, we are working to further improve the efficiency of our finance function through outsourcing, and to enhance the quality and efficiency of our sales and marketing activities by optimizing the sales and marketing organization and structure.

### Restructuring of Operations in Japan and **Introduction of Early Retirement Incentive Program**

As part of optimization of organizational capabilities under Strategic Plan 2018, Astellas decided to reorganize itself and its Group companies within Japan, focusing not only on back-office divisions, but also frontline divisions such as R&D and Sales & Marketing.

In conjunction with the restructuring of operations in Japan, an early retirement incentive program is planned to be introduced for Astellas Pharma Inc., Astellas Marketing and Sales Support Co., Ltd., Astellas Research Technologies Co., Ltd., and Astellas Learning Institute Co., Ltd. in the fiscal year ending March 31, 2019.

We will strive to strengthen the operational foundation even further by streamlining our organizational structure and secure the necessary resources for growth investment by pursuing Operational Excellence while utilizing advanced technologies.

# Our People, Our Organization

Astellas recognizes employees as important stakeholders. Astellas employees play the most valuable role in transforming the Company and in achieving enhanced levels of enterprise value. We are working to train employees and strengthen their competitiveness. Astellas is fostering a corporate culture that aims to align the aspirations of its diverse employees in one direction to realize its business philosophy.

languages, conducting training and meetings for managers, and even reflecting the vision in personnel measures.

Astellas will increase the competitiveness of its human resources and organization by spreading and implementing the HR Vision and the Astellas Way. Moreover, Astellas will bring together individuals from diverse backgrounds within the Company to surmount national, regional and organizational barriers, foster mutual respect, and unite our people to continuously achieve innovation.

#### **HR Vision**

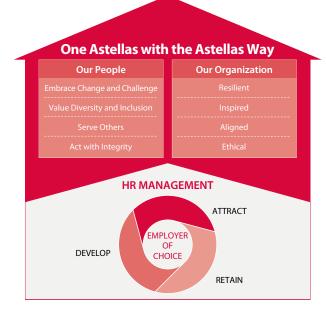
Astellas has formulated a Human Resources (HR) Vision, which represents its approach to "Our People, Our Organization," and this vision is shared globally to define its aspirations for its human resources and its organization. Making Astellas' VISION a reality requires individual employees to understand the HR Vision and to act based on the Astellas Way.

As part of its activities to achieve these goals, Astellas is focusing on activities to disseminate the HR Vision.

Specifically, this involved translating the HR Vision into various

# Overview of the HR Vision

**Towards Realizing the Corporate VISION** 





# Providing Opportunities for Employees to Succeed Globally

Astellas provides employees with opportunities to succeed globally in a variety of ways. In Japan, we have established an internal recruitment system to revitalize our organization and support employees in developing their own abilities and growing, while encouraging our people to succeed in roles at various overseas bases by proactively appointing employees from each division to be assigned abroad. In addition, we accept long-term and short-term assignees from Group companies outside Japan. In these and other ways, we are working to promote global interaction among our people at the divisional level.

# **Diversity Management**

Astellas is working to promote diversity so that diverse people can play a role in our Company, irrespective of race, nationality, gender, or age. Respecting the diverse values of our employees and reflecting their various perspectives in our business activities not only heightens creativity in our organization but also helps to attract talented people as employees and enhances our competitiveness.

Based on this recognition, Astellas implements measures to promote diversity in line with the current situation in the region. For Astellas, promoting the career advancement of women in Japan is a high priority, particularly because the country has a low ratio of women in management positions compared to other regions. In 2007, therefore, Astellas launched the Diversity Promotion Project. By 2020, the Company aims to develop a work environment in which life events do not hinder career advancement, and it has established a target to raise its ratio of female managers in Japan to 10% or higher (at Astellas Pharma Inc.) on a non-consolidated basis.

In fiscal 2017, Astellas disseminated information twice a year by e-learning to encourage employees to understand other matters in addition to promoting women's activities in the workplace, and publicized the themes of male participation in childcare and caregiving and of LGBTQ.

In addition, Astellas is promoting nationality diversity to further advance the globalization of its business, and in Japan, the Company has been hiring non-Japanese graduates since 2014.

Astellas is implementing initiatives for upgrading the work environment it provides for people with disabilities. It has established the Green Supply Support Office\*1 and been a participating member of Japan's Accessibility Consortium for Enterprises (ACE)\*2. Astellas is supporting hearing-impaired employees to overcome their disabilities by utilizing an app that instantaneously converts voice data into written words.

Male/Female Employee Ratio per Region and Ratio of Female Managers (Fiscal 2017)

	Japan	Americas	EMEA	Asia & Oceania	Average
Male	70.8%	45.4%	41.7%	46.8%	55.0%
Female	29.2%	54.6%	58.3%	53.2%	45.0%
Ratio of female managers	8.5%	49.3%	51.5%	48.8%	33.2%

# **Promoting Health Management**

If each employee realizes a high level of productivity and creativity and practices a workstyle that enables selffulfillment, this will revitalize the organization and lead to its growth as One Astellas. The underlying condition for realizing these ways of working is the good health of the employees. Based on this thinking, in Japan, Astellas is promoting a health management that encourages employees to take control of looking after their health. Specifically, in cooperation with the health insurance association ("collaboration health"), the Company is promoting improving employee health and disease prevention, and developing measures that include supporting mental health, preventing overwork, and countering second-hand smoking.

# **Occupational Health & Safety**

We have the Astellas Environment, Health & Safety Policy in place to prevent work-related accidents and minimize those caused by workplace mishaps and hazards. Under this policy, each facility is independently building Environment, Health & Safety management systems and promoting associated initiatives. We are also working to ensure occupational safety from many different perspectives based on the information we share on accidents and near misses that have occurred at our workplaces around the world.

From 2017, Astellas expanded its scope of management and began global consolidation\*1.

Between January and December 2017, there were 0 fatalities and 11 work-related injuries requiring time off work. Of these 11 injuries, the longest leave of absence was 61 days due to a traffic accident.

Frequency rate of work-related injuries\*2 was 0.33 and severity rate of work-related injuries\*3 was 0.007 on a global basis. We will strive to reduce our occupational

<sup>\*1</sup> Green Supply Support Office: An organization established within a Group company in 2011 that is mainly comprised of employees with intellectual disabilities. It engages in activities such as enhancing greenery by cultivating flowers, resource recycling, and carrying out various cleaning activities.

<sup>\*2</sup> Accessibility Consortium of Enterprises (ACE): A general incorporated association that was formed to conduct activities such as the establishment of a new employment model for people with disabilities who contribute to the growth of companies.

safety risks with the goal of holding our severity rate of work-related injuries under 0.005 on a global basis.

- \*1 In addition to the previous scope, Astellas began aggregating data for overseas offices and research bases. The totals by region for global and outside Japan have been disclosed since 2017.
- \*2 Frequency rate of work-related injuries: This rate shows the number of employee deaths or injuries resulting from work-related accidents causing leaves of absence per million hours of work. The larger the number, the more frequently work-related injuries occur.
- \*3 Severity rate of work-related injuries: This rate shows the number of days absent from work due to work-related injuries per thousand hours of work. The larger the number, the more serious the injury.

# **Respect for Human Rights**

The Astellas Charter of Corporate Conduct clearly states that members of the Astellas Group shall respect human rights and the personality and individuality of all its employees, observe all applicable international rules and local regulations, and embrace all cultures and customs. The recognition of the importance of respecting human rights is shared by Group companies worldwide.

Astellas disclosed its Position on Human Rights in April 2017. Wherever we operate, Astellas is committed to complying with internationally recognized basic human rights and labor standards as well as applicable local labor and employment laws, and to implementing and upholding the UN Guiding Principles on Business and Human Rights. Also, Astellas conducted a human rights

impact assessment and has identified four human rights issues to which we pay particular attention as human rights in clinical trials and other research and development activities, product safety and counterfeit drugs, Access to Health and human rights in the workplace. Under the U.K. Modern Slavery Act 2015, we publish a Slavery and Human Trafficking Statement for each fiscal year, describing what steps we have taken to address this risk in our own operations or our supply chains.

We have established a system for swiftly responding to human rights issues that includes the setting up of external and internal helplines, as well as conducting training sessions for employees. Moreover, we have been globally confirming the awareness of human rights issues in the workplace and the status of human rights activities at our Group companies by conducting written surveys. In fiscal 2017, there were no critical human rights issues or other issues of common, worldwide concern reported in the survey.

For details on our people, our organization, please visit the following website:



https://www.astellas.com/en/sustainability/employees/

For details on the incidence of work-related injuries, please visit the following website:



https://www.astellas.com/index.php/en/responsibility/ Occupational-Health-And-Safety

# TOPIC | Improving Employee Satisfaction

# **Engagement Survey**

Astellas is continuously pursuing initiatives to improve employee satisfaction. As part of these, in January 2018, the Company conducted an engagement survey in Japan, the Americas, EMEA and Asia & Oceania. This was the first survey to be conducted that targeted the approximate 16,000 employees of the Astellas Group and was based on common questions that were asked on a global basis. The response rate was about 90%, which is very high compared to the average response rate of global pharmaceutical companies.

Of the 13 categories, 11 categories received favorable answers from over 70% of answers. Of these, the five categories entitled Customer Focus, Ethics and Compliance, Goals and Targets, Immediate Superior, and Sustainable Engagement received more than 80% favorable answers. From these results, the Company determined that Astellas' strengths include its support of employees' vision for Astellas, their significant pride and recognition in the vision's implementation, and their high evaluation of the trustworthy work environment.

Regarding the opinions about needed improvements that Astellas has gained from employees through this survey, the Company will reflect them in the course of carrying out the new Corporate Strategic Plan and will implement appropriate actions to make the needed improvements.

# **Ethics and Compliance**

Astellas believes that acting in accordance with the highest ethical standards, which includes obeying the letter and spirit of the law, is the cornerstone of all its activities. Based on this belief, the Astellas Charter of Corporate Conduct, which is shared globally, expresses the Company's ethical business philosophy in terms of corporate behavior. In addition, the Astellas Group Code of Conduct is a global code for all agents, directors, officers and employees around the world, establishing that they are expected to perform their duties ethically and in compliance with laws and regulations.

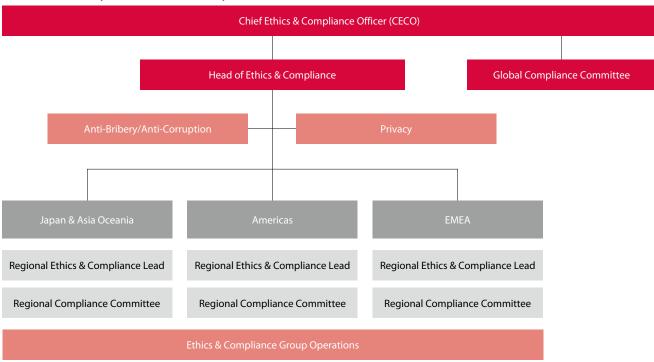
Astellas promotes compliance and maintains the highest ethical standards through the development, implementation and continuous enhancement of its policies, processes, and global compliance structures and thereby maintains the trust of patients and other stakeholders and enhances enterprise value.

# **Structured to Promote Ethics and Compliance**

Astellas has been continuously enhancing the global organizational structure for the Ethics & Compliance function at the global, regional and local levels. In fiscal 2017, Astellas increased the number of Ethics & Compliance personnel to enhance support in high-risk markets and activities. Ethics & Compliance professionals partner with the business to continue to reinforce the importance of integrating ethics, integrity and compliance into business processes as doing so is critical to the sustainable success of Astellas.

The Group Operations team in the Ethics & Compliance function continues to coordinate compliancerelated activities such as training, communications, risk assessment, monitoring, investigations, and policy management, thereby driving consistency on a global basis.





# **Initiatives to Promote Compliance**

## Compliance Training and Communications

Compliance training and communications targeted at the business are important to conducting business activities grounded on high ethical standards and integrity. Astellas regularly educates employees on both existing and emerging compliance risks as well as policies and processes that help manage those risks. These educational activities help to foster compliance awareness and understanding among employees. Training and communication materials share Astellas Way values and a patient-focused mindset, so employees can see how policies and procedures help them live the Astellas mission.

In fiscal 2017, the Ethics & Compliance function began deploying online training through a single global system, enhancing the ability to provide access to important training initiatives to all employees globally. Global online training allows for enhanced tracking and monitoring of timely completion of training requirements and has resulted in improvements in completion rates across a wide range of training topics. All employees, including new employees, are required to complete compliance training on topics such as the Astellas Group Code of Conduct, data privacy, anti-bribery and anti-corruption compliance, and conflicts of interest.

### Integrity in Action Program

As one of the pillars of the Astellas Way, the Integrity in Action program is designed to reinforce for all employees the importance of taking responsibility and being accountable for their actions, acting ethically and with integrity, and leading by example.

As of the end of fiscal 2017, the Integrity in Action program was adopted by almost all affiliates and functions globally.

During Integrity in Action events, both business and Ethics & Compliance leaders at the local, regional, and global levels delivered messages to employees that reinforced how critical it is to incorporate Integrity in Action in all their business activities. The events also raised awareness about the importance of speaking up about potential compliance issues and how acting ethically and with a high sense of integrity can create a competitive advantage for Astellas.

### Compliance Risk Assessments

The ability to effectively assess compliance risk at local, regional and global levels is a foundational element of Astellas' compliance program. These assessments enable Astellas to more quickly identify and better respond to existing and emerging compliance risks.

In fiscal 2017, Astellas conducted compliance risk assessments (CRAs), based on a globally consistent process, in a number of countries around the globe. The CRAs involved both the assessment of external environmental risk in each of the countries as well as assessment of internal risks within the affiliate.

The internal activities assessed included transfers of value in any form to healthcare professionals, market access activities, interactions between the Company and government officials or healthcare professionals, and meals, gifts or hospitality. The findings of the CRAs helped Astellas to enhance compliance programs in each country and monitor trends in risks at the regional and global levels. The Ethics & Compliance function works closely with the business throughout the assessment process and helps develop and support any risk mitigation plans developed to address the identified risks.

#### Compliance Monitoring

Compliance monitoring is a foundational component of any compliance program. Astellas monitors existing and emerging compliance risks and trends across a variety of activities. Doing so allows us to better anticipate potential issues before they become actual problems for the Company. In fiscal 2017, Astellas continued to enhance its monitoring program and activities in each region. The compliance monitoring yielded results that not only enhanced the compliance program, but also provided management with insights to inform their decisionmaking on various process improvements. One of the many positive outcomes of the monitoring program this year was that monitoring helped identify areas where Astellas could optimize systems functionality to provide both compliance and business utility.

# Increasing Understanding of the Global Conflict of **Interest Policy**

Another core element of an effective ethics and compliance program is how a company approaches its own conflicts of interest, because the foundation of an effective and robust ethics and compliance program is based on how a company manages its own internal behavior.

Conflicts of interest refer to situations where outside activities or other personal interests impair an employee's objectivity or judgment when performing their duties. Conflicts of interest also encompass situations where there is a potential conflict between the interests of an employee and Astellas. The Astellas Global Conflict of Interest Policy and accompanying training reinforces for employees that they are expected to conduct their business activities with ethics and integrity even when no one is observing or there are no potential legal violations. Astellas believes that establishing this baseline expectation regarding internal conflicts of interest contributes to employees conducting their business with ethics and integrity when engaging with stakeholders outside the Company and where legal risks are involved.

#### Transparency

More and more countries and government organizations are requiring transparency with respect to pharmaceutical company relationships with healthcare professionals and organizations. Astellas is committed to engaging in appropriate relationships with healthcare professionals and organizations throughout the world. The disclosure of relevant financial relationships with healthcare professionals and organizations reflects the commitment

to corporate accountability to both internal and external stakeholders. Astellas is committed to fulfilling its transparency requirements through the work of its global transparency team in coordination and collaboration with multiple business functions across the organization.

In Japan, Astellas has continued to make public financial relationships with healthcare professionals and organizations and patient organizations in accordance with the Transparency Guideline published by the Japan Pharmaceutical Manufacturers Association. In the U.S., Astellas adheres to reporting requirements set forth by the federal Sunshine Act and state laws. Across Europe, we disclose transfers of value to healthcare professionals and organizations based on the disclosure requirements established by the European Federation of Pharmaceutical Industries and Associations.

# Helpline for Employees and Encouraging a **Speak-Up Culture**

In fiscal 2017, Astellas upgraded its existing regional external compliance reporting helplines by deploying a global version of its external helpline that is available in local languages. Employees can use the helpline to report and receive advice on how to react in the event they discover actual or suspected misconduct. Reports may be made by employees or third parties and may be made anonymously where permitted by local law. In Japan, Astellas has established internal helplines in addition to the global external helpline, including one dedicated to sexual harassment.

Astellas continues to foster an environment that encourages employees to use the helplines and speak up to report potential or actual violations of the Astellas Group Code of Conduct, as well as any other illegal or unethical behavior or business practices. In addition, Astellas strictly prohibits any retaliation against those who raise a concern or report a suspected compliance violation in good faith, even if the concern or report is not substantiated.

Having the ability to centrally manage the reports of suspected non-compliance and the corresponding investigations also enhances Astellas' ability to analyze compliance trends both regionally and globally. In fiscal 2017, Astellas' helplines received reports in each region. Matters raised included potential harassment and promotional code violations. In response, thorough investigations were conducted and appropriate action was taken.

# **Anti-Bribery and Anti-Corruption Compliance**

Astellas strictly prohibits bribery and corruption in any aspect of its business. One critically important compliance priority is to identify those activities that have high bribery and corruption risks for the Company and establish the processes needed to appropriately manage those risks. Examples of activities identified as high risk for which we have developed processes include support for healthcare professional education and the engagement of healthcare professionals to provide necessary services on behalf of the Company. The development and implementation of policies and procedures targeted at these kinds of highrisk activities as well as the regular training of employees and business partners on how to comply with these policies and procedures helps Astellas mitigate the risks associated with these activities.

Astellas monitors the bribery and corruption risk environment at the global, regional and local levels and enhances its compliance governance activities to appropriately manage these risks, including the use of effective and impactful training and communication activities.

# **Ensuring Fair Competition**

Astellas is committed to conducting its business in a fair and competitive environment and does not reach any agreements with its competitors regarding sales conditions, such as prices, sales plans and strategies, and market and customer shares. Astellas limits engagement with competitors and avoids any conversation concerning these topics when engagement is necessary, so that such interactions are not construed to reflect the existence of such an agreement.

In fiscal 2017, there were no incidences of government authorities taking legal action against Astellas for anti-competitive, anti-trust, or monopolistic practices, or of authorities levying significant fines or other sanctions due to non-compliance with laws and regulations.

For further information on Astellas' ethics and compliance activities, please visit the following website:



https://www.astellas.com/en/about/ compliance-initiatives/

#### Message from the Privacy Lead

#### **Enhancing Our Data Privacy Program**

Protecting the personal information of patients, healthcare professionals, suppliers, employees and other stakeholders has been and continues to be an extremely important priority for Astellas.

Astellas has established a global team made up of experts from the Ethics & Compliance, Information Systems, and Legal functions in order to address the European Union's new General Data Protection Regulation (GDPR). Astellas has introduced crucial program elements to comply with GDPR requirements.

In addition, Astellas has implemented the Information Security Enhancement Program led by the Information Systems function. This program has strengthened our security controls around data privacy and cybersecurity.

In Japan, Astellas has revised the local privacy policy and supporting internal guidelines in response to the amended Act on the Protection of Personal

Information, which came into force in May 2017.

Astellas is committed to complying with GDPR and data privacy laws around the world in order to maintain the trust of stakeholders. Astellas will continue to enhance transparency and fulfill our obligation of corporate accountability with respect to the personal information entrusted to us.

**Karen Lowney** Executive Director, Privacy Lead, **Ethics & Compliance** Astellas US LLC



# Access to Health

Astellas is committed to solving Access to Health issues. We believe that the relationships of trust developed with governments and local partners through these initiatives will generate synergies with business activities over the long term.

# **Collaborative Research on New Drugs for the Treatment of Tuberculosis and Malaria**

Astellas is pursuing collaborative research to discover new drugs for the treatment of tuberculosis and malaria, which are infectious diseases that cause tremendous suffering among people in developing countries

In 2016, 10.4 million people fell ill with tuberculosis, while more than 200 million people contracted malaria. 1.7 million people\* died of tuberculosis while 445,000 people died of malaria. Both tuberculosis and malaria have led to serious social problems, underscoring the urgent need for innovative drugs to treat these diseases.

Considering these backgrounds, in October 2017, Astellas entered into a new collaborative research agreement with TB Alliance for the exploration of new drugs for the treatment of tuberculosis and a screening collaboration agreement with Medicines for Malaria Venture (MMV) to discover new drugs for malaria. Under these agreements, Astellas will provide its original library of compounds, while TB Alliance and MMV will conduct screenings of the library to discover hit compounds to be used in the research and development of new tuberculosis and malaria drugs, respectively.

These research programs are funded by the Global Health Innovative Technology Fund ("GHIT Fund").

# **Collaborative Research to Identify Lead Compounds for New Antiparasitic Drugs**

In March 2018, Astellas participated in the Neglected Tropical Diseases Drug Discovery Booster\*1, a consortium whose purpose is to identify lead compounds\*2 for leishmaniasis and Chagas disease, both of which are neglected tropical diseases (NTDs). The consortium is supported by funding from the GHIT Fund.

NTDs are mainly parasitic, bacterial, viral or fungal infections prevalent among people living in poverty in developing nations in tropical and subtropical regions. At least 1 billion people worldwide are reported to be infected with the 20 NTDs listed by the World Health Organization (WHO), many of which cause serious social difficulties.

Through the consortium, Astellas will contribute to the discovery of new drugs for patients suffering from leishmaniasis and Chagas disease.

The collaborative research concerning Chagas disease undertaken by Astellas with the National Institute of Advanced Industrial Science and Technology has been concluded following the expiry of the term of the collaborative research agreement. As a part of this project, basic technology for the discovery of molecules essential for the protozoan parasite survival were developed using genome editing technology, thereby making it possible to select highly suitable target molecules for drug discovery.

- \*1 Neglected Tropical Diseases Drug Discovery Booster: A consortium launched by the Drugs for Neglected Diseases initiative (DNDi), a not-for-profit organization engaged in the development of new treatments for neglected diseases. In addition to Astellas, seven pharmaceutical companies, specifically Eisai Co., Ltd., Shionogi & Co., Ltd., Takeda Pharmaceutical Company Limited, AstraZeneca plc., Celgene Corporation, Merck KGaA, and AbbVie, also participate in the consortium as partners.
- \*2 Lead compound: A compound with confirmed pharmacological activity against a target disease. Optimization research (for improvement of activity, physical properties, pharmacokinetics, toxicity, etc.) is conducted based on lead compounds.

# Collaborative Research on a Rice-Based **Oral Vaccine**

Astellas has been conducting collaborative research with the Institute of Medical Science, the University of Tokyo (IMSUT) on the rice-based oral vaccine MucoRice against diarrheal diseases caused by cholera, enterotoxigenic Escherichia coli (E. coli), norovirus, etc. In developing countries, diarrhea caused by pathogenic bacteria, such as Vibrio cholera and enterotoxigenic E. coli, is a major cause

<sup>\*</sup> Figure includes 0.4 million people infected with HIV.

of death among infants and young children. However, vaccines present several issues, such as the need to store and transport existing cholera vaccines at a constant low temperature, and the fact that vaccines against enterotoxigenic E. coli have not been approved in developing countries.

There are high hopes that MucoRice could be stored at room temperature. Therefore, if the challenges are overcome, it will not require the strict temperature management that is usual for the storage of biopharmaceuticals. The establishment of cultivation techniques that enable efficient production should help reduce medical expenditures for the vaccine.

In December 2017, Astellas, IMSUT, Chiba University and ASAHI KOGYOSHA CO., LTD. signed a collaborative research agreement aimed at the practical application of MucoRice-CTB, a rice-based oral vaccine that expresses the Cholera Toxin B subunit (CTB) in the rice storage protein. Under the agreement, Astellas will examine the conditions for production and formulation of MucoRice-CTB. Meanwhile, IMSUT, Chiba University, and ASAHI KOGYOSHA will develop the production system for the vaccine. This research program has been designated as a project under Cyclic Innovation for Clinical Empowerment and will be supported by the Japan Agency for Medical Research and Development.

Through these collaborative research projects, Astellas will attempt to develop new platform technology to create innovative new drugs to address unmet medical needs.

# **Development of Pediatric Formulation** for Schistosomiasis

Schistosomiasis is one of the most prevalent parasitic diseases in developing countries centered on Africa and South America. The disease has a particularly high incidence rate among children. The existing "gold standard" treatment for schistosomiasis is praziquantel. However, one challenge is that praziquantel tablets are difficult to administer to preschool-age children, including infants and toddlers, mainly due to the risk of choking stemming from the tablets' large size and the drug's bitter taste.

Having set up a consortium with other pharmaceutical companies, research institutions and international non-profit organizations, Astellas is developing a pediatric formulation of praziguantel.

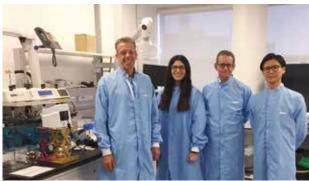
The pediatric formulation newly developed by Astellas

uses its own drug formulation technology. The pediatric formulation was designed to be smaller than the existing tablet and orally dispersible so that it can be taken even without water, due to a reduction of bitterness. In addition, the pediatric formulation can be manufactured using simple production technology, while holding down production costs, and the tablets are stable even in the hot and humid environment of tropical areas. Astellas has transferred the technology and expertise needed to develop the pediatric formulations to consortium partners in Brazil and Germany, thereby helping to produce drug products used for clinical trials and to build local pharmaceutical manufacturing capabilities.

The consortium is conducting a Phase 2 clinical trial and preparing to start Phase 3 clinical trials including the receipt of funding from the GHIT Fund and the European & Developing Countries Clinical Trials Partnership. Astellas continues to provide its expertise and technology to the consortium.



Newly developed pediatric formulation (top) and existing formulation (bottom)



Members of the consortium developing the pediatric formulation of praziquantel

# **Contribution to Access Accelerated and Related Progress**

Astellas has participated in Access Accelerated\*1 since its launch in January 2017. Access Accelerated is a global initiative aimed at improving access to non-communicable disease prevention, diagnosis and treatment in low and middle income countries. More than 20 international pharmaceutical companies are partners in the program, working alongside organizations such as the World Bank and the Union for International Cancer Control.

Non-communicable diseases (NCDs) are any diseases not caused by human-to-human transmission of an infectious agent. Leading NCDs include cancer, cardiovascular disease, chronic respiratory disease and diabetes. Many NCDs are caused by unhealthy eating, lack of exercise, smoking or excessive drinking, and could be prevented by lifestyle improvement. NCDs are not just on the increase in developed countries, but the number of patients suffering from NCDs is also increasing in developing countries. The rising incidence of NCDs not only puts pressure on the healthcare budgets of developing countries, but also leads to economic losses when patients cannot work due to illness.

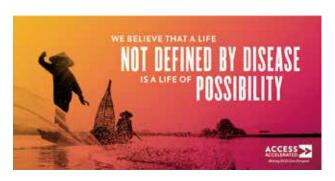
Under Access Accelerated, Astellas supports ACTION ON FISTULA<sup>TM</sup>, a pioneering program which has transformed the lives of over 3,400\*2 women in Kenya who are suffering with obstetric fistula. As part of this program, Astellas worked to present its activities and raise public awareness of obstetric fistula by opening a booth at a special side event at the United Nations General Assembly held in September 2017 and at a stakeholder collaboration event held in Kenya in March 2018.

Moreover, in 2017, Astellas launched a new initiative in India structured according to patients' income levels, with the aim of improving their access to its anticancer products. Astellas will continue to push ahead with activities that improve patients' access to the prevention, diagnostics, and treatment of NCDs in low and middle income countries.

Furthermore, in December 2017, the Japan Pharmaceutical Manufacturers Association and Access Accelerated hosted a side event titled "Accelerating Sustainable Universal Health Coverage by Improving Access to NCD Care" at the 2017 Universal Health Coverage Forum. Astellas was involved in the planning and

management of this event. Participants included members of pharmaceutical companies, academia, United Nations organizations, non-governmental organizations, and government institutions. Through keynote addresses and panel discussions by experts, the event confirmed the importance of collaboration between the private and public sectors and facilitated discussion on activities, issues and prospects for driving widespread adoption of universal health coverage and achieving the United Nations' Sustainable Development Goals.

- \*1 For details about Access Accelerated, please visit the following website: http://www.accessaccelerated.org/
- \*2 As of March 2018



#### **ACTION ON FISTULATM**

ACTION ON FISTULA<sup>TM\*1</sup> was conceived, built and is run by the Fistula Foundation. It was started in 2014 by a grant given to the Fistula Foundation from an affiliate of Astellas, Astellas Pharma Europe Ltd. Since 2014, the program has transformed the lives of 3,417\*2 women in Kenya who are suffering with obstetric fistula\*3. By 2020, ACTION ON FISTULA™ aims to help more than 4,500 patients in total to access fistula treatment.

The Fistula Foundation and Astellas jointly funded the first phase of the program, which ran from 2014 to 2017. Astellas provided funding of €1.5 million (approximately 50% of the total) and the remaining was provided by the Fistula Foundation. In this phase, the program improved the lives of patients with obstetric fistula while simultaneously training doctors who will be able to provide surgical treatment in Kenya. The program also set up the Fistula Treatment Network to extend access to services, with six hospitals enrolled and providing fistula surgeries on a routine basis.

The second phase of ACTION ON FISTULA<sup>TM</sup> is scheduled to run from 2017 to 2020. Astellas has committed to supporting the Fistula Foundation for this phase. Astellas is funding €0.75 million (approximately 25% of the total) and the remaining was funded by the Fistula Foundation. In the second phase of the program, ACTION ON FISTULA<sup>TM</sup> aims to build capacity to deliver ongoing treatment and provide surgeries to even more patients with obstetric fistula. Specifically, the program aims to increase the number of hospitals enrolled in the Fistula Treatment Network to 8 hospitals, train an additional 6 surgeons specializing in fistula, and train an additional 10 fistula nurses. In addition, ACTION ON FISTULA<sup>TM</sup> wants to help fistula patients who have undergone treatment with emotional assistance, economic empowerment and employment support so that they can return to their communities. To this end, the program plans to establish 20 support groups that will be enrolled in the Fistula Treatment Network.

On WHO's Universal Health Coverage Day in December 2017, Astellas hosted a meeting titled "Act for UHC, ACTION ON FISTULA - Transforming the Lives of Women in Kenya." Members of the Fistula Foundation and the United Nations Population Fund (UNPFA) were invited to speak at the event, in an effort to raise awareness of obstetric fistula in Japan.

- \*1 For more information about the program visit the following website: https://www.astellas.com/index.php/en/sustainability/action-on-fistula
- \*2 As of March 2018
- \*3 An obstetric fistula is a hole between the vagina and rectum or bladder that is caused by prolonged obstructed labor when emergency care is unavailable, causing fecal and/or urinary incontinence. Although it has been virtually eradicated in developed countries, the UNFPA estimates 3,000 new cases of obstetric fistula occur annually in Kenya. Women with obstetric fistula are often subject to severe social stigma due to odor, which is constant and humiliating. often driving the patients' family, friends and neighbors away. Stigmatized, these women are also often denied access to education and employment and live in isolation and poverty.



Astellas employees visit the Gynocare Women's and Fistula Hospital ©Georgina Goodwin 2017



Astellas employees visit the home of an obstetric fistula patient who has received treatment ©Georgina Goodwin 2017

#### Progress in ACTION ON FISTULA™ (May 2014-March 2018)

Patients successfully treated with reconstructive surgery	3,417 patients
Trained and certified doctors to the standard level of competency	6 Kenyan doctors
Centers in the Fistula Treatment Network	6 centers
FIGO-accredited fistula training center	Established Gynocare Women's and Fistula Hospital in Eldoret, Kenya
Kenyan counties* reached	45 counties
Trained community outreach workers	295 outreach workers
Conducted outreach activities	10,093 activities
Community members reached with fistula messages	845,578 community members

<sup>\*</sup> Kenya is divided into 47 counties. There are several units of governance below the county level. These units include subcounties, wards, and villages.

# Social Contribution

Astellas is cooperating with a range of stakeholders in an effort to address social issues that affect people throughout the world.

# **AECEP Overseas Volunteer Program**

In fiscal 2016, Astellas launched a new social contribution program called the Astellas Emerging Countries Empowerment Program (AECEP).

AECEP is a program for addressing social issues in emerging countries in partnership with enterprises and non-governmental organizations (NGO) in which Astellas employees utilize their respective expertise, skills and experience. Volunteer employees participating in the program ("participants") travel to an emerging country after a preparation period of one and half months. They then carry out initiatives in the country for a limited time of three and a half months at an assigned partner enterprise or NGO that works toward solutions that should meet the expectations of society.

Partners are selected from among enterprises and NGOs involved in addressing medical, health and safety issues or environmental problems. Participants get directly involved in local social issues and learn many things through collaborating with leaders and community members who are strongly committed to solving the issues. Participants maximize their use of the experience and abilities they have cultivated through work at Astellas to help make the partner activities more effective, and to build or improve their systems. Engaging in social contributions in this kind of equal, interactive relationship is the major characteristic of AECEP.

In fiscal 2017, the second year of the program, two employees were selected as participants. One participant was assigned to an organization in Cambodia, where they contributed to efforts to promote better health for the needy and children through the manufacture and sale of highly nutritious food and beverage products. The other participant was assigned to an organization in Vietnam where they managed an art classroom, selling miscellaneous goods printed with the children's illustrations primarily to support children with disabilities. The participants cooperated with the local organizations while overcoming various difficulties, and managed to successfully generate results in improving the nutritional value of numerous products, developing new products,

expanding sales channels, and improving the level of customer service. They received warm words of gratitude from members of their assigned organizations.

The invaluable experiences that can be obtained through AECEP—getting away from daily work and pursuing one's own potential in an emerging country while newly creating value for society—also have major significance for Astellas from the standpoint of human resource development.

"Embrace Change and Challenge" is included in the "Our People" section of our HR Vision, and Astellas will also continue promoting AECEP for this reason: to help develop human resources with a long-term, strategic thinking ability who are truly capable of taking on challenges with a sense of ownership.



An Astellas employee (right) meets with a member of an organization in Cambodia to discuss making products with high nutritional value



An Astellas employee (second from the left) selling miscellaneous goods crafted from artwork created by children in Vietnam

# **Support for Patients**

Astellas conducts a variety of activities to provide assistance to patients fighting illnesses, and to their family members, on a global basis. Astellas promotes Peer Support Training Sessions in Japan as part of efforts to support the self-reliance and development of patient associations. Peer Support Training Sessions are held for a wide range of participants, including patients and their families, along with those who have recently formed patient associations. In these training sessions, activities include programs for participants to learn attentive listening skills, which enable colleagues who have faced the same issues or have experienced the same problems to serve as consulting partners to one another. In fiscal 2017, Peer Support Training Sessions were held in 3 locations across Japan, and were attended by 19 organizations and 31 people.

Astellas also supports local Ronald McDonald House Charities (RMHC) Chapters in the United States, helping the global organization provide comfort and care to millions of families with sick children who have to travel far from home for the care they need. Last year alone, RMHC helped families save almost US\$900 million in out-of-pocket lodging and meal expenses, due in large part to more than 508,000 volunteers who provide services like meal preparation at Ronald McDonald Houses around the world.

Astellas employees in the U.S. have supported this organization for three years in a row, volunteering to cook for patients' families staying at local Ronald McDonald Houses. These activities offer Astellas employees in the U.S. the opportunity to lead local volunteer programs. Employees are responsible for scheduling events, recruiting team members to participate, purchasing supplies and leading teams in preparing and serving meals. The events have served as an engaging teambuilding experience that contributes to the organization's activities to support patients and their families. In fiscal 2017, 379 Astellas US employees prepared and served 2,623 meals to patients' families at 62 Ronald McDonald House events across the U.S. to comfort families caring for a sick child.

# Mentor Volunteers in the Science WoRx® Program

Astellas employees in the U.S. are dedicated to mentoring students as part of the Science WoRx® mentor program to promote science education. In 2017, Science WoRx® mentors shared their experiences in science, technology, engineering, and math (STEM) fields and encouraged more than 200 young women to take an interest in sciencerelated careers at iBIO Institute's STEMGirls camp, a weeklong STEM summer camp for girls.

Employees who volunteer as mentors through Science WoRx® also serve as judges and presenters at science fairs, sharing their love of science with students to inspire the next generation of innovators.

# **Group-Wide Volunteer Activities for Changing Tomorrow Day**

Astellas Group employees around the world are encouraging a diverse range of volunteer activities as part of Changing Tomorrow Day based on the themes of promoting healthcare and maintaining the environment, thereby contributing to their local communities. In fiscal 2017, more than 6,400 employees participated.

## Changing Tomorrow Day Held in Fiscal 2017

Region	Participants	Volunteering hours	Number of locations	Number of countries
Japan	3,445	4,542	117	1
Americas	2,060	7,178	81	4
EMEA	325	2,449	20	13
Asia & Oceania	641	2,173	11	6
Total	6,471	16,342	229	24

# **Environmental Preservation**

Astellas believes that maintaining a healthy global environment is an essential theme for maintaining sound business activities and building a sustainable society.

Going forward, Astellas will strive to realize its VISION for being a responsible corporation based on a long-term timeframe that keeps future generations in mind and a global perspective. At the same time, we will continue efforts to address regional social issues and pursue corporate activities in harmony with the global environment.

#### **Environmental Action Plan**

Having determined the Astellas Environment, Health & Safety Policy, Astellas identified its aspirations in the Astellas Environment, Health & Safety Guidelines. As appropriate, we review the Environmental Action Plan, which outlines short- to medium-term activity targets based on various factors, including progress status and social circumstances, and add new initiatives and/or set more challenging targets.

Fiscal 2017 results are as shown in the table below. The Environmental Action Plan involving Climate-Related Measures was formulated using fiscal 2005 as the base year, but we have revised the plan to take into account the significant changes that have occurred to the environments within and outside of the Company since the time the plan was formed. The main background to the changes and the new plan are below.

#### Main Background to Changes in the Climate-Related Action Plan

- Increase of overseas offices
- In Japan's electricity usage, there is a divergence between the volume of GHG emissions based on the Environmental Action Plan and the volume of actual emissions
- Transfer of the Fuji Plant, Norman Plant, etc., to other companies, etc.

New Environmental Action Plan Reduce greenhouse gas (GHG) emissions (scope 1+2\*) by 30% by fiscal 2030 (Base year: Fiscal 2015)

- \* Scope 1 Direct emissions
- \* Scope 2 Indirect emissions

# **Initiatives for Realizing a Low-Carbon Society**

- Promotion Framework and Initiatives for Climate-Related Measures
  - Setting Science Based Targets (SBT)

Astellas endeavors to reduce the GHG emissions accompanying its activities to help realize a low-carbon society. The Global EHS Sub-Committee comprised of members from each regional base has been organized to develop ways to conserve energy and reduce GHG emissions for the entire Group and analyze the risks and opportunities that climate change presents to the business. The sub-committee reports to top management

#### **Environmental Action Plan Performance in Fiscal 2017 (Summary)**

Environmental Action Plan		Fiscal 2017 (Summary)	
Measures to Address Climate Change (Base year: Fiscal 2005)	Reduce GHG emissions by 35% or more by the end of fiscal 2020 Japan: Reduce GHG emissions by 30% or more Overseas plants: Reduce GHG emissions by 45% or more	Global: Reduced 30% Japan: Reduced 29% Overseas plants: Reduced 37%	
Measures for the Conservation of Natural Resources (Research and production sites) (Base year: Fiscal 2005)	1) Enhance water resource productivity by around 2.5 times the fiscal 2005 result by the end of fiscal 2020 Indicator: Sales (¥ billion)/Water resources withdrawn (1,000 m³) 2) Improve waste generated per unit of sales to around 20% of the fiscal 2005 result by the end of fiscal 2020 Indicator: Volume of waste generated (tons)/Sales (¥ billion)	<ol> <li>Achieved; 2.9 times the fiscal 2005 result</li> <li>Almost achieved; 21% the fiscal 2005 result</li> </ol>	
3. Biodiversity (Base year: Fiscal 2005)	Triple the biodiversity index by fiscal 2020	Improved to 2.6 times	

Note: GHG emissions generated through electricity usage are calculated using the following coefficients:

(1) A coefficient of 0.330 kg-CO2/kWh is used to calculate results needed to evaluate progress against the Environmental Action Plan and make investment decisions and implement countermeasures to bridge the gap between results and targets. The figures shown in the table above represent the results calculated using this coefficient.

(2) GHG emissions (actual emissions) for electricity use are calculated using the CO2 emission coefficient of electric power suppliers. In Japan, the latest adjusted emission coefficient for each power supplier announced by the Ministry of the Environment and METI is applied. If the coefficient of the electric power supplier is not available in other regions, the country-specific emission coefficient provided by the International Energy Agency (IEA) is applied.

on their discussions and decisions at the CSR Committee.

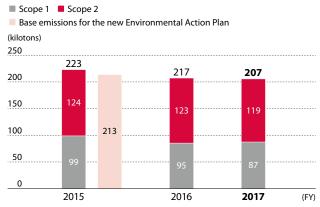
In the new Environmental Action Plan from fiscal 2018, Astellas has newly set our targets that are consistent with the Science Based Targets (SBT), which recommended that private companies set reduction targets aligned with the Paris Agreement, which entered into force in 2016, with all business activities being evaluated. In February 2018, we submitted a commitment letter to the SBT Initiative. We expect that our fiscal 2030 targets (base year: fiscal 2015) will be verified and approved by the SBT Initiative by the end of fiscal 2018.

### Reducing GHG Emissions

The GHG emissions volume for fiscal 2017, based on the new action plan, was 207 kilotons (Scope 1: 87 kilotons; Scope 2: 119 kilotons).

For reductions under Scope 2, which accompany energy supply from external sources such as electricity, Astellas employs a market-based method calculated using an emission coefficient for each power company that supplies us. Emissions in regions where it is difficult to use the emission coefficients for each electric power company are calculated with country-specific emission coefficients provided in the CO<sub>2</sub> EMISSIONS FROM FUEL COMBUSTION 2017 EDITION published by the International Energy Agency. Furthermore, we also purchase electricity obtained from renewable energy sources for plants in the European region and other areas.

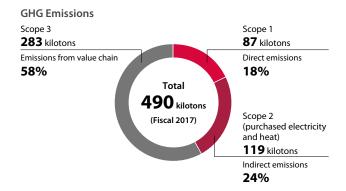
#### **GHG Emissions (Actual Emissions)**



# Monitoring GHG Emissions in the Value Chain

The Environmental Action Plan applies to emissions in its business activities related to climate change (Scope 1, 2), but Astellas also strives to monitor emissions across the entire value chain (Scope 3).

We have also set SBT for GHG emissions from important emissions sources in Scope 3 and are working to reduce these.



#### Status of GHG Emissions (Fiscal 2017)

**Scope 1 Direct emissions** 

(tons)

Scope 2 Indirect emissions

87,429 (Sales fleets 24,203)		119,499		
Scope	3 Other ir	ndirect emissions		
Upstream activities		Downstream activities		
Purchased goods and services	144,418	9. Transportation and distribution (downstream)*	Not relevant	
2. Capital goods	68,203	10. Processing of sold products	Not relevant	
3. Fuel- and energy-related activities (not included in Scope 1 or 2)	26,002	11. Use of sold products	No emissions results	
4. Transportation and	3,781	12. End-of-life treatment of sold products	668	
distribution (upstream)* Raw materials transported	(244)	13. Leased assets (downstream)	Not relevant	
by tanker trucks	(244)		N	
Plant → Warehouse	(286)	14. Franchises	Not relevant	
Distribution warehouse	(853)			
Distribution warehouse → Wholesaler	(2,398)	15. Investments	Not relevant	
5. Waste generated in operations	4,753			
6. Business travel (aircraft use)	32,572			
7. Employee commuting	2,542			
8. Leased assets (upstream)	Not relevant			

<sup>\*</sup> Product shipments are handled by outside contractors.

### Using Renewable Energy

Using renewable energy is one of the most effective climate-related measures. Astellas actively installs equipment for photovoltaic panels, wind turbine generators, and biomass boilers, and consumes the energy produced at its business sites.

Additionally, by purchasing renewable-sourced electricity and carbon-neutral city gas, we also indirectly suppress GHG emissions.

#### Status of Renewable Energy Use (Fiscal 2017)

Business site	Types of renewable energy	Energy volume	
Kerry Plant	Wind power generation (Power capacity: 800 kW)     Woodchip biomass boiler (Power capacity: 1.8 MW)     Purchases renewable-sourced electricity	1,692 37,211 6,650	MWh GJ MWh
Dublin Plant	<ul> <li>Purchases renewable-sourced electricity</li> </ul>	5,855	MWh
Meppel Plant	Purchases renewable-sourced electricity	12,896	MWh
Leiden (Netherlands)	Purchases renewable-sourced electricity     Purchases carbon-neutral city gas     Geothermal heat	2,305 146 1,491	MWh GJ GJ
U.S. regional headquarters	- Geothermal heat	3	GJ
Tsukuba Research Center	Photovoltaic generation	49	MWh
Yaizu Technology Center	- Geothermal heat (immeasurable)	_	

# **Initiatives for Resource Recycling**

Astellas seeks to contribute solutions to the social issues involved in establishing a recycling-oriented society. We have therefore been striving to reduce water withdrawal and landfill waste. We established a management indicator called water resource productivity and have been working to improve on this front.

We are also moving ahead on reducing landfill waste to as close to zero as possible by actively recycling and reusing, and have set improvement targets for waste generated per unit of sales.

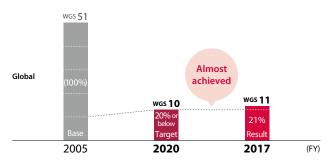
#### **Environmental Action Plan (Resource Recycling)**

Water resource productivity (For research and production sites)		
Indicator	Sales (¥ billion)/Water resources withdrawn (1,000 m³)	
Numerical targets	Enhance water resource productivity by around 2.5 times the fiscal 2005 result by the end of fiscal 2020	
Waste gene	rated per unit of sales (For research and production sites)	
Indicator	Volume of waste generated (tons)/Sales (¥ billion)	
Numerical	Improve waste generated per unit of sales to around	



\* Water Resource Productivity (WRP) =  $\frac{\text{Sales (\$ DIIIION)}}{\text{Water resources withdrawn (1,000 m}^3)}$ 

# Waste Generated per Unit of Sales\*



\* Waste Generated per unit of Sales (WGS) =  $\frac{\text{Volume of waste generated (tons)}}{\text{Sales (¥ billion)}}$ 

# Ongoing Water Risk Evaluation

Astellas uses the Global Water Tool™ provided by the World Business Council for Sustainable Development to analyze water risks specific to the operating regions where its plants and other facilities are located.

The Astellas Group on a global basis does not currently withdraw water from water bodies in areas concerned with water resource depletion. As water risks may emerge in the future as a result of climate change, we are taking steps to minimize our dependence on such resources, and also regard this as an effective means of ensuring business continuity.

## **Initiatives for Biodiversity**

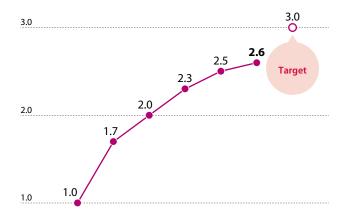
Astellas understands its business activities in all fields have an impact on ecosystems. We will make a positive contribution to the preservation of biodiversity by working to lessen that impact. Furthermore, we will actively contribute to the creation of a society that coexists with the natural world, enabling the preservation of biodiversity and the sustainable use of the benefits of healthy ecosystems.

Astellas has created a Biodiversity Index\* by assessing the three main factors responsible for the deterioration of biodiversity, categorized as environmental pollution, resource consumption and climate change. Going forward, we will continue improving in each category while working toward achieving the target for fiscal 2020, which is a ratio three times the fiscal 2005 level.

The Biodiversity Index for fiscal 2017 came in at 2.6 times the fiscal 2005 level. As the scope of the Environmental Action Plan has expanded regarding climate change, so has the scope of each index used to calculate the Biodiversity Index. The following graph has been recalculated from past indices. Beyond the region, Astellas believes that by minimizing the impact of its business activities on the environment, the Company will help suppress the deterioration of biodiversity and realize an environment in which sustainable business activities may be continued.

#### **Biodiversity Index**

-O- Ratio to fiscal 2005 level





For details on environmental preservation, please visit the following



https://www.astellas.com/en/responsibility/environment

#### Message from the Kerry Plant Vice President & General Manager

## Protecting the Natural Ecosystem Inside the Plant

Kerry Plant manufactures a range of products including the immunosuppressant Prograf, which are supplied globally. A significant portion of the plant is located in a designated nature reserve, and the plant has a nature reserve plan to protect and enhance ecological value and biodiversity. The plan aims to conserve and enhance the ecological environment of all plant and animal habitats, protect notable plant and animal species, encourage sustainable recreational and educational use and improve public awareness.

We take part in various Killorglin Tidy Towns sustainability initiatives, providing a leisure walkway through the nature reserve, erecting information boards on the local flora and fauna, and educating local

students on environmental awareness.

Astellas will continue to contribute to the creation of a community with a strong environmental conscience and a clear commitment to a sustainable relationship

with our environment that will lead to the preservation of biodiversity and protection of our ecosystem.

Patricia Quane Vice President & General Manager, Kerry Plant Astellas Ireland Co., Limited



<sup>\*</sup> For details on the calculation method, please visit the following website: https://www.astellas.com/responsibility/preserving-biodiversity

## **Stakeholder Engagement**

Astellas conducts business activities within a diverse network of relationships, including with patients and many others, and our activities are supported by these relationships. We regard stakeholders such as patients and healthcare professionals, employees, and shareholders and investors as particularly important stakeholders because they are significantly impacted by our business activities.

Interacting with these stakeholders who support the business activities of Astellas in good faith, and understanding their expectations and needs, is essential to acquiring their trust and sustainably

increasing our enterprise value.

We therefore use various opportunities to communicate with stakeholders. In addition, to promote constructive dialogue with our stakeholders, we appropriately disclose information to all groups in a way that is both timely and impartial.

By continuing to conduct communication through disclosure and engagement, we will further raise our transparency as a company and strive to sustainably increase the enterprise value of Astellas while simultaneously raising the overall sustainability of society.

For details, please visit the following website:



https://www.astellas.com/en/sustainability/stakeholder-communications

#### **Patient Engagement**

## Achieving "Even Better" Communication with Patients

Astellas defines Patient Focus as one of our five messages of the Astellas Way. To improve our implementation of patient focus, Astellas assesses its day-to-day efforts continuously and improves how it interacts with patients.

Astellas made changes in the U.S. such as establishing a system to give a quicker response to inquiries about its clinical trials to patients, and implementing a patient support survey to assess the responses of Astellas to patients, and to better understand patients' perceptions about our customer services.

Furthermore, taking into consideration the levels

of patients' knowledge and understanding about health, Astellas revises the descriptions of important safety information together with the informed consent form. Moreover, Astellas strives to have better communications with patients by providing training to all staff who have the chance of coming into contact with patients, on themes such as the knowledge and understanding of health, the consideration of patients, and interpersonal skills.

These improvements that started in the U.S. will be adapted for other regions, helping to fulfill our VISION of turning innovative science into value for patients.

## **Financial Information and Data**

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#### **Definition of Financial Results on a Core Basis**

We disclose our financial results under IFRS on a core basis to help provide an accurate indication of the Group's recurring profitability. Certain items reported in financial results under IFRS on a full basis that are deemed to be non-recurring items by the Company are excluded as non-core items on a core basis.

## Consolidated Financial Results (Full Basis)

## Sales

Cost of sales

### Gross profit

Selling, general and administrative expenses

R&D expenses Amortisation of

intangible assets

Share of profits of associates and joint ventures

#### Other income Other expense

Operating profit

Finance income Finance expense

Profit before tax Income tax expense

Profit for the year

Non-recurring other income and other expense within IFRS-based operating profit are excluded (for example, items such as impairment losses or restructuring expenses)

### Core operating profit

Adjustments for finance income and finance expense (for example, gain (loss) on sale of available-for-sale (AFS) financial assets and impairment losses on AFS financial assets are excluded)

Core profit for the year

## **Financial Summary**

Astellas has adopted the International Financial Reporting Standards (IFRS), effective from fiscal 2013 (March 2014). Results for each category and earnings per share are presented on a core basis for the fiscal years since March 2014.

					(¥ billion)	
	2008.3	2009.3	2010.3	2011.3	2012.3	
	J-GAAP	J-GAAP	J-GAAP	J-GAAP	J-GAAP	
For the year						
Sales	¥972.6	¥965.7	¥974.9	¥953.9	¥969.4	
Cost of sales	279.3	264.4	289.2	296.0	318.6	
SG&A expenses*2	417.3	450.9	499.2	538.8	519.2	
R&D expenses*2	134.5	159.1	195.6	217.3	189.8	
R&D ratio (%)	13.8	16.5	20.1	22.8	19.6	
Operating income/profit	275.9	250.4	186.4	119.2	131.5	
Operating margin (%)	28.4	25.9	19.1	12.5	13.6	
Net income/Profit for the year	177.4	171.0	122.3	67.7	78.2	
At year-end						
Total assets	1,439.2	1,348.4	1,364.2	1,335.1	1,400.6	
Total net assets/Total equity	1,110.9	1,030.2	1,053.9	1,021.1	1,018.1	
Per share data* <sup>3</sup>					(¥)	
Net income/Profit for the year	¥349.89	¥356.11	¥261.84	¥146.49	¥169.38	
Total net assets/Total equity	2,228.34	2,189.26	2,278.77	2,207.70	2,200.64	
Dividends	110.00	120.00	125.00	125.00	125.00	
Major indicators						
ROE (%)	16.1	16.0	11.7	6.5	7.7	
DOE (%)	5.0	5.4	5.6	5.6	5.7	
Equity ratio (%)	77.1	76.3	77.1	76.4	72.6	
Free cash flow						
(¥ billion, US\$ million)	178.5	168.8	118.6	(142.0)	146.7	
Average exchange rate (US\$/¥)	114	101	93	86	79	
(€/¥)	162	143	131	113	109	

<sup>\*1</sup> U.S. dollars have been converted at the rate of ¥106 to US\$1, the approximate exchange rate on March 31, 2018.

<sup>\*2</sup> SG&A expenses under J-GAAP (from fiscal 2007 to fiscal 2012) include R&D expenses.

<sup>\*3</sup> Astellas conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014. Net income/profit for the year per share and total net assets/total equity per share are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal 2012. Moreover, the number of shares outstanding has also been calculated on the assumption that the stock split was conducted at the beginning of fiscal 2012.

					(¥ billion)	(US\$ million)*1
2013.3	2014.3	2015.3	2016.3	2017.3	2018.3	2018.3
J-GAAP	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
¥1,005.6	¥1,139.9	¥1,247.3	¥1,372.7	¥1,311.7	¥1,300.3	\$12,267
324.1	330.6	333.2	335.6	320.5	294.2	2,776
527.6	397.0	452.5	500.4	470.8	478.3	4,513
182.0	191.5	206.6	225.7	208.1	220.8	2,083
18.1	16.8	16.6	16.4	15.9	17.0	_
153.9	186.3	216.5	267.5	274.6	268.7	2,535
15.3	16.3	17.4	19.5	20.9	20.7	_
82.9	132.8	153.2	198.8	213.3	204.3	1,928
1,445.6	1,653.1	1,793.6	1,799.3	1,814.1	1,858.2	17,530
1,062.0	1,268.5	1,317.9	1,259.2	1,271.8	1,268.3	11,965
					(¥)	(US\$)
¥36.08	¥59.11	¥69.37	¥92.12	¥101.15	¥100.64	\$0.95
469.92	568.53	600.93	592.58	615.89	641.80	6.05
130.00	135.00	30.00	32.00	34.00	36.00	0.34
8.0	7.4	10.5	15.0	17.3	13.0	_
5.7	5.0	5.1	5.4	5.6	5.7	_
73.3	76.7	73.5	70.0	70.1	68.3	_
95.5	187.4	116.2	166.7	162.2	190.8	1,800
83	100	110	120	108	111	_
107	134	139	133	119	130	_

## **Financial Review**

## Overview of the Year Ended March 31, 2018 (Fiscal 2017)

In its consolidated operating results (core basis) for fiscal 2017, Astellas posted decreases in the three items of sales, core operating profit and core profit for the year.

#### **Consolidated Financial Results (Core Basis)**

		(¥ billion	
	2017.3	2018.3	
Sales	1,311.7	1,300.3	
Operating profit	274.6	268.7	
Profit for the year	213.3	204.3	

Astellas discloses financial results on a core basis as an indicator of its recurring profitability. Certain items reported in financial results on a full basis that are deemed to be non-recurring items by Astellas are excluded as non-core items from these financial results on a core basis.

These adjusted items include impairment losses, gain (loss) on sales of property, plant and equipment, restructuring costs, loss on disaster, a large amount of losses on compensation or settlement of litigation and other legal disputes, and other items that we judge should be excluded.

#### Foreign Exchange Impact for Fiscal 2017

The exchange rates for yen in fiscal 2017 are shown in the table below. Movements in the rates led to a ¥43.3 billion increase in the value of sales and a ¥13.1 billion increase in core operating profit.

#### Foreign Exchange Rates (Average)

		(¥)
	2017.3	2018.3
US\$1	108	111
€1	119	130

#### Fluctuation in Foreign Exchange Rates from April to March

	2017.3	2018.3
US\$1	¥0 (Strengthening of yen)	¥6 (Strengthening of yen)
E1	¥8 (Strengthening of yen)	¥11 (Weakening of yen)

#### Sales

In fiscal 2017, consolidated sales declined 0.9% year on year to ¥1,300.3 billion. Despite strong sales of core products, sales decreased mainly due to the impact of generics in Japan, the transfer of the global dermatology business in 2016, and the transfer of long-listed products in Japan in 2017.

In global products, sales of XTANDI for the treatment of prostate cancer increased in all regions—Japan, the Americas, EMEA, and Asia & Oceania. In addition, combined sales of overactive bladder (OAB) treatments Vesicare and Betanis/Myrbetrig/BETMIGA grew, and sales of the immunosuppressant Prograf increased.

Turning to products in Japan, sales continued to grow for the anti-inflammatory analgesic Celecox, the adult bronchial asthma treatment Symbicort, the type 2 diabetes treatment Suglat, and the adult rheumatoid arthritis treatment Cimzia. Further, sales rose in the Americas for the azole antifungal CRESEMBA and the pharmacologic stress agent Lexiscan.

#### Sales by Region

		(¥ billion)
	2017.3	2018.3
Consolidated	1,311.7	1,300.3
Japan	480.8	421.2
Americas	412.4	433.3
EMEA	330.8	343.8
Asia & Oceania	87.7	102.0

Note: Sales by geographical area are calculated according to the location of sellers.

## Americas/EMEA (Foreign Currency)

	2017.3	2018.3
Americas (US\$ million)	3,805	3,909
EMEA (€ million)	2,785	2,651

#### Sales of Main Products

			(¥ billion)
	2017.3	2018.3	Change
XTANDI	252.1	294.3	16.8%
OAB products in Urology	214.9	228.1	6.1%
Vesicare	116.1	102.3	-11.9%
Betanis/Myrbetriq/BETMIGA	98.8	125.7	27.2%
Prograf	186.2	198.5	6.6%

## Cost of Sales and Gross Profit

Cost of sales decreased 8.2% to ¥294.2 billion. The cost of sales ratio stood at 22.6%, 1.8 percentage points lower from the previous fiscal year, mainly due to changes in the product mix.

Gross profit increased by 1.5% to ¥1,006.1 billion in line with the decrease in the cost of sales.

#### Cost of Sales and Gross Profit

		(¥ billion)
	2017.3	2018.3
Sales	1,311.7	1,300.3
Cost of sales	320.5	294.2
Cost of sales ratio (%)	24.4	22.6
Gross profit	991.2	1,006.1
Gross profit ratio (%)	75.6	77.4

## Selling, General and Administrative (SG&A) Expenses, Research and Development (R&D) **Expenses and Amortization of Intangible Assets**

SG&A expenses increased 1.6% year on year to ¥478.3 billion. Despite effective use of expenses and optimization of resource allocation, there was an increase due largely to impact from foreign exchange rates.

R&D expenses rose 6.1% year on year to ¥220.8 billion, owing primarily to a rise in costs associated with expanded investment in new fields and technologies, and progress on late-stage development projects. The ratio of R&D expenses to sales increased 1.1 percentage points year on year to 17.0%.

Amortization of intangible assets was ¥35.8 billion, unchanged year on year.

#### SG&A Expenses, R&D Expenses and Amortisation of Intangible Assets

		(¥ billion)
	2017.3	2018.3
SG&A expenses	470.8	478.3
SG&A ratio (%)	35.9	36.8
Advertising and sales promotional expenses	144.1	152.1
Personnel expenses	177.0	178.5
Other	149.7	147.7
R&D expenses	208.1	220.8
R&D ratio (%)	15.9	17.0
Amortisation of intangible assets	35.8	35.8

#### Operating Profit (Core Basis)

As a result of the above mentioned factors, core operating profit decreased 2.1% to ¥268.7 billion. The operating margin decreased 0.2 of a percentage point to 20.7%.

#### **Operating Profit (Core Basis)**

	(¥ billion	
	2017.3	2018.3
Sales	1,311.7	1,300.3
Operating profit	274.6	268.7
Operating margin (%)	20.9	20.7

#### Profit for the Year (Core Basis)

Core profit for the year decreased by 4.2% to ¥204.3 billion. Basic core earnings per share decreased by 0.5% year on year to ¥100.64.

## Profit for the Year (Core Basis)

		(¥ billion)
	2017.3	2018.3
Profit before tax	274.9	269.4
Income tax expense	61.6	65.1
Profit for the year	213.3	204.3
Ratio of profit for the year to sales (%)	16.3	15.7

#### Consolidated Financial Results (Full Basis)

In its consolidated operating results on a full basis for fiscal 2017, Astellas posted decreases in the four items of sales, operating profit, profit before tax, and profit for the year. The full basis financial results include "other income," "other expense" (including impairment losses, net foreign exchange losses, etc.), and gain on sales of available-forsale financial assets (included in "finance income") which are excluded from the core basis financial results.

Under "other income," Astellas posted a gain from remeasurement relating to business combinations associated with the acquisition of Mitobridge, Inc. Items posted under "other expense" included impairment losses in connection with the termination of research operations of Agensys, Inc. and revision of plans for the development project involving Ganymed Pharmaceuticals AG, in addition to net foreign exchange losses. As a result, "other income" for FY2017 was ¥11.9 billion (¥9.6 billion in the previous fiscal year). "Other expense" for FY2017 was ¥67.3 billion (¥23.3 billion in the previous fiscal year). Gain on sales of available-for-sale financial assets for FY2017 was ¥4.7 billion (¥21.3 billion in the previous fiscal year).

#### Consolidated Financial Results (Full Basis)

		(¥ billion)
	2017.3	2018.3
Sales	1,311.7	1,300.3
Operating profit	260.8	213.3
Profit before tax	281.8	218.1
Profit for the year	218.7	164.7

#### Reconciliation of Full Basis to Core Basis

Reconciliation of Full Basis to Core Basis						
_						(¥ billion)
		2017.3			2018.3	
Account item	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Sales	1,311.7	_	1,311.7	1,300.3	_	1,300.3
Cost of sales	320.5	_	320.5	294.2	_	294.2
Gross profit	991.2	_	991.2	1,006.1	_	1,006.1
SG&A expenses	470.8	_	470.8	478.3	_	478.3
R&D expenses	208.1	_	208.1	220.8	_	220.8
Amortisation of intangible assets	35.8	_	35.8	35.8	_	35.8
Share of losses of associates and joint ventures	(1.9)	_	(1.9)	(2.4)	_	(2.4)
Other income*1	9.6	(9.6)	_	11.9	(11.9)	_
Other expense*1	23.3	(23.3)	_	67.3	(67.3)	_
Operating profit	260.8	13.7	274.6	213.3	55.4	268.7
Finance income*2	22.9	(21.3)	1.7	6.6	(4.7)	1.9
Finance expense*2	2.0	(0.7)	1.3	1.8	(0.6)	1.2
Profit before tax	281.8	(6.9)	274.9	218.1	51.3	269.4
Income tax expense	63.1	(1.5)	61.6	53.4	11.6	65.1
Profit for the year	218.7	(5.4)	213.3	164.7	39.6	204.3

<sup>\*1 &</sup>quot;Other income" and "other expense" are excluded from core basis results. "Other income" and "other expense" include gain (loss) on sale and disposal of property, plant and equipment, impairment losses for other intangible assets, loss on restructuring and foreign exchange gains (losses), etc.

<sup>\*2</sup> Gain (loss) on sale of available-for-sale (AFS) financial assets and impairment losses on AFS financial assets included in "finance income" and "finance expense" are excluded from core basis results as non-core items.

## **Consolidated Forecasts for the Year Ending** March 31, 2019 (Fiscal 2018) (Announced in **April 2018)**

Consolidated business forecasts for fiscal 2018 are presented on a core basis in the table below.

#### Fiscal 2018 Forecasts (Core Basis)

		(¥ billion)
	2018.3	2019.3 (Forecast)
Sales	1,300.3	1,278.0
Operating profit	268.7	262.0
Profit for the year	204.3	210.0

		(¥)
	2018.3	2019.3 (Forecast)
Average exchange rate (US\$)	111	105
(€)	130	130

We project decreases in sales and core operating profit but an increase in core profit for the year, compared with fiscal 2017. We expect negative impacts on sales and profits from foreign exchange rates and a decline in the amount of deferred income recognized in connection with the transfer of long-listed products and the global dermatology business. Excluding the impact from business transfers and foreign exchange rates, we project sales and core operating profit on par with fiscal 2017, despite negative impact from NHI drug price revisions in Japan.

We assume the yen will strengthen against the U.S. dollar and stay at the same level against the euro compared with fiscal 2017. Accordingly, we expect foreign exchange factors to have a ¥23.9 billion negative impact on sales and a ¥1.9 billion negative impact on core operating profit.

#### Sales

In fiscal 2018, we forecast a 1.7% year-on-year decrease in sales to ¥1,278.0 billion. Despite anticipating ongoing growth for the mainstay global products XTANDI and Betanis/Myrbetriq/BETMIGA, we expect lower sales due mainly to impact from NHI drug price revisions taking effect in April 2018 in Japan and generic versions of longlisted products such as the hypertension treatment Micardis.

**Reference** | Overview of Main Products ▶ P49

#### **Forecast by Region**

		(¥ billion)
	2018.3	2019.3 (Forecast)
Consolidated	1,300.3	1,278.0
Japan	421.2	396.8
Americas	433.3	424.4
EMEA	343.8	343.9
Asia & Oceania	102.0	112.9

Note: Sales by geographical area are calculated according to the location of sellers.

## Americas/EMEA (Foreign Currency)

	2018.3	2019.3 (Forecast)
Americas (US\$ million)	3,909	4,042
EMEA (€ million)	2,651	2,645

### Sales of Main Products

			(¥ billion)
	2018.3	2019.3 (Forecast)	Change
XTANDI	294.3	310.3	5.5%
OAB products in Urology	228.1	243.1	6.6%
Vesicare	102.3	96.9	-5.2%
Betanis/Myrbetriq/BETMIGA	125.7	146.2	16.3%
Prograf	198.5	190.7	-3.9%

## **Sales of Main Products by Region**

## Japan

			(¥ billion)
	2017.3	2018.3	2019.3 (Forecast)
Sales in the Japanese market*	452.7	383.4	365.3
XTANDI	23.4	26.1	28.2
Vesicare	25.6	23.9	22.7
Betanis	25.9	29.5	32.0
Harnal	9.2	7.4	5.1
Prograf	48.8	48.3	46.3
Funguard	11.2	10.6	7.8
Micardis	93.2	46.3	17.7
Micombi	9.4	4.9	
Micamlo	26.2	13.8	
Celecox	47.6	48.3	49.4
Symbicort	39.3	39.5	
Bonoteo	13.8	13.3	10.4
Geninax	10.1	9.2	8.7
Vaccines	34.5	29.4	36.8
ARGAMATE	5.8	5.8	5.3
Gonax	4.5	4.7	5.1
Cimzia	7.7	9.0	9.8
Suglat	9.5	11.6	13.3
Repatha		1.6	
LINZESS		1.4	9.2
Lipitor	23.2	19.6	15.3
Myslee	14.7	13.3	10.9
Seroquel	7.5	6.2	4.5

#### Americas

			(US\$ million)
	2017.3	2018.3	2019.3 (Forecast)
Sales in the Americas	3,805	3,909	4,042
XTANDI	1,286	1,404	1,474
US	1,215	1,303	1,355
Outside of the US	71	102	119
Tarceva	325	268	
US	238	194	
Outside of the US	87	74	
VESIcare	490	372	377
Myrbetriq	510	657	806
Prograf	252	232	191
Scan	660	664	661
MYCAMINE	113	111	94
AmBisome	97	102	109
CRESEMBA	53	87	100

#### **EMEA**

			(€ million)
	2017.3	2018.3	2019.3 (Forecast)
Sales in EMEA	2,785	2,651	2,645
XTANDI	718	823	921
Eligard	132	125	126
Vesicare	270	244	229
BETMIGA	119	141	169
Omnic	138	138	130
Sales by Astellas	118	121	121
Bulk and royalties	19	17	9
Prograf and Advagraf	612	632	598
Sales by Astellas	590	607	584
Advagraf	252	272	
Exports to third parties	22	25	14
MYCAMINE	91	90	70

## Asia & Oceania

			(¥ billion)
	2017.3	2018.3	2019.3 (Forecast)
Sales in Asia & Oceania	87.7	102.0	112.9
Prograf	37.3	42.5	46.5
Harnal	21.1	23.2	23.8
Vesicare	5.0	5.0	4.5
BETMIGA	3.5	5.2	7.5
MYCAMINE	6.0	6.4	7.9
XTANDI	4.0	5.8	7.7
Eligard	0.2	0.4	0.6

<sup>\*</sup> Sales of products in Japan are shown on a gross sales basis.

#### Operating Profit and Profit for the Year (Core Basis)

We project a decline in gross profit due to a decrease in sales.

We expect SG&A expenses to remain mostly unchanged from fiscal 2017 as a result of ongoing efforts to streamline expenses and a reduction in negative impact from foreign exchange rates, although the ratio of SG&A expenses to sales is expected to rise due mainly to a decline in sales.

We forecast a 3.1% year-on-year decline in R&D expenses to ¥214.0 billion, chiefly reflecting the concentration of resources including investments in key post-POC pipeline projects and new technology such as cell therapy. The ratio of R&D expenses to sales is projected at 16.7% (compared with 17.0% in fiscal 2017).

As a result, we forecast a 2.5% year-on-year decrease in core operating profit to ¥262.0 billion.

Core profit for the year is expected to increase 2.8% year on year to ¥210.0 billion. Basic core earnings per share is projected to increase 5.6% year on year to ¥106.27.

#### **Number of Employees**

As of March 31, 2018, Astellas employed 16,617 people worldwide, a year-on-year decrease of 585.

Looking at each region, in Japan, the number of employees was 6,825, down 204 from the previous fiscal year-end. In the Americas, the regional head count was 2,840 employees, down 176 from the previous fiscal yearend. In EMEA, we had 4,490 employees, down 182 year on year. In Asia & Oceania, we had 2,462 employees, down 23 from the previous fiscal year-end.

#### Number of Employees by Region

1 , , ,	<u></u>	
		(persons)
	2017.3	2018.3
Total	17,202	16,617
Japan	7,029	6,825
Americas	3,016	2,840
EMEA	4,672	4,490
Asia & Oceania	2,485	2,462

#### Number of MRs

		(persons)
	2017.3	2018.3
Total (Global)	5,750	5,330

## **Assets, Liabilities and Equity**

An overview of the consolidated statement of financial position as of March 31, 2018 and the main changes from the end of the previous fiscal year are shown below.

#### Assets

Total assets as of March 31, 2018 amounted to ¥1,858.2 billion, up ¥44.1 billion from a year earlier.

Non-current assets increased ¥75.2 billion to ¥1,012.6 billion at the fiscal year-end. Goodwill and other intangible assets increased, owing mainly to the acquisitions of Ogeda SA and Mitobridge, Inc. As a result, goodwill was ¥213.0 billion, up ¥44.5 billion from the previous fiscal year-end, and other intangible assets were ¥416.9 billion, up ¥29.5 billion from the previous fiscal year-end.

Current assets decreased ¥31.0 billion to ¥845.6 billion. Cash and cash equivalents were ¥331.7 billion, down ¥9.2 billion from the previous fiscal year-end.

## Equity

Total equity as of March 31, 2018 was ¥1,268.3 billion, a decrease of ¥3.5 billion from a year earlier. While profit for the year stood at ¥164.7 billion, Astellas paid ¥71.6 billion in dividends of surplus and acquired ¥130.7 billion in treasury shares.

We cancelled treasury shares worth ¥132.2 billion (85 million shares) in May 2017.

#### Liabilities

Total liabilities as of March 31, 2018 amounted to ¥589.9 billion, up ¥47.7 billion from a year earlier.

Total non-current liabilities rose ¥25.9 billion to ¥168.3 billion. Current liabilities increased ¥21.8 billion to ¥421.6 billion.

## **Liquidity and Financing**

Astellas is making strategic business investments to enhance innovation and add greater breadth to its product and development pipelines, targeting sustainable enhancement of enterprise value.

Regarding the liquidity of funds, liquidity is maintained to enable Astellas to target a certain amount of strategic investment opportunities, while also supplying working capital. As outlined in the section on business risks (P85), Astellas' operations face various risks unique to the ethical pharmaceutical business. The Group's financial policy is to maintain a healthy balance sheet at all times so that it can finance smoothly at low costs, especially in the event that funding requirements exceed Astellas' internal funding capacity in the course of developing business.

#### **Cash Flows**

#### Cash flows from Operating Activities

Net cash flows from operating activities amounted to ¥312.6 billion, an increase of ¥77.0 billion in year-on-year terms. The main components included income tax paid of ¥65.0 billion.

## Cash Flows from Investing Activities

Net cash flows used in investing activities totaled ¥121.8 billion, up ¥48.4 billion from the previous fiscal year.

Looking at the main outflows, acquisition of subsidiaries used cash of ¥83.7 billion mainly due to the acquisition of Ogeda SA, purchases of property, plant and equipment used cash of ¥25.1 billion, and purchases of intangible assets used cash of ¥15.2 billion. On the other hand, proceeds from sales of available-for-sale financial assets provided cash of ¥7.0 billion.

#### Cash Flows from Financing Activities

Net cash flows used in financing activities totaled ¥203.4 billion, up ¥37.3 billion from the previous fiscal year.

Dividends paid to owners of the parent totaled ¥71.6 billion, an increase in outflow of ¥1.5 billion year on year. Other outflows included ¥130.7 billion used for the acquisition of Astellas' own shares.

As a result of the above, the balance of cash and cash equivalents as of March 31, 2018 amounted to ¥331.7 billion, a decrease of ¥9.2 billion compared with the previous fiscal year-end.

#### Business Acquisitions

Astellas is investing to capture new business opportunities and working to create innovation, as we are enhancing our capabilities to deliver innovative medicines.

As part of these initiatives, Astellas acquired Ogeda SA, a drug discovery company in Belgium, for €0.5 billion and made it a wholly owned subsidiary in May 2017 to further expand its pipeline. Ogeda shareholders will be eligible to receive up to €0.3 billion in further contingent payments based on progress in the development of fezolinetant, Ogeda's clinical program.

Additionally, in January 2018, Astellas paid \$225 million\*1 to acquire 100% of the equity in Mitobridge, Inc., previously a U.S. equity-method company, and made it a wholly owned subsidiary. Mitobridge shareholders will be eligible to receive up to \$225 million\*2 in further contingent payments based on progress of various programs in clinical development. The purpose of the acquisition is to strengthen Astellas' networks and knowledge related to mitochondrial drug development, along with acquiring several programs involving patients with mitochondrial dysfunctions.

Moreover, in February 2018, Astellas acquired Universal Cells, Inc., a bioventure company in the U.S., for up to \$102.5 million of upfront and milestones depending on achievement of clinical milestones. Through the acquisition, Astellas gained technology to produce pluripotent stem cells with the potential to lower immunological rejection, an issue in cell therapy.

- \*1 The actual payment excluding the amount equivalent to Astellas' equity is
- \*2 The actual payment excluding the amount equivalent to Astellas' equity is \$165.5 million

Reference | R&D Topics during the Year ▶ P43

## **Capital Expenditures**

Astellas made capital expenditures with the aim of augmenting and renewing its research facilities and equipment as well as production facilities and equipment. Capital expenditures in fiscal 2017 totaled ¥24.1 billion, up 0.9% year on year (accrual basis).

In fiscal 2018, capital expenditures are forecast to increase 12.0% to ¥27.0 billion.

## **Earnings per Share, Dividends and Equity Attributable to Owners of the Parent**

#### **Per Share Data**

		(¥)
	2017.3	2018.3
Earnings per share		
Basic	103.69	81.11
Diluted	103.55	81.02
Basic (core basis)	101.15	100.64
Dividends	34.00	36.00
Equity per share attributable to owners of the parent	615.89	641.80

#### Policy on Shareholder Returns

Astellas is working to achieve sustained enhancement in enterprise value, and actively pursuing shareholder returns.

While prioritizing the reinvestment of funds in the business to foster growth, Astellas strives to achieve stable and sustained growth in dividends, based on medium- to longterm consolidated earnings growth. Furthermore, Astellas will flexibly purchase treasury stock as necessary to improve capital efficiency and the level of returns to shareholders.

#### Common Stock

#### Common Stock

	(thousands of share					
	2017.3	2018.3				
Total number of issued shares*	2,153,823	2,068,823				
Treasury shares*	88,817	92,670				

#### **Treasury Shares**

	2017.3	2018.3
Number of shares bought back*	60,000 thousand	88,870 thousand
Acquisition cost	¥91.4 billion	¥129.9 billion
Cancellation of treasury shares*	68,000 thousand	85,000 thousand

<sup>\*</sup> Excludes purchases of shares constituting less than a trading unit

As a part of profit distribution to its shareholders and as measures of its capital policy, Astellas implemented acquisition of its own shares from the stock market, purchasing 88.87 million shares, worth ¥129.9 billion, during the fiscal year ended March 31, 2018.

Furthermore, we cancelled 89 million shares of treasury stock in May 2018.

#### ROE

Return on equity (ROE) was 13.0%, down 4.3 percentage points from fiscal 2017.

#### **Business Risks**

The main risks that could significantly impact the business results and financial position of the Astellas Group are outlined below.

#### Inherent Uncertainties in Pharmaceutical R&D

In general, the probability of discovering a promising compound through drug discovery research is not high. Further, it takes a large amount of investments and a great deal of time to successfully launch a new product after discovery of a new compound. However, it may be necessary to discontinue clinical development if the effectiveness of a drug is not proven as initially expected, or if safety issues arise. In addition, pharmaceuticals are subject to legal restrictions in each country, so that authorization from local regulatory authorities is a prerequisite for a product launch in each country. It is difficult to accurately foresee if and when approvals for new products can be obtained.

The Astellas Group's R&D activities are subject to these inherent risks.

#### Sales-Related Risk

The pharmaceutical industry operates in a highly competitive environment characterized by rapid technological innovation. The Astellas Group faces fierce competition from drug makers and generics manufacturers based in Japan or overseas. The launch of competitive products by rivals could impact the Astellas Group's business results significantly.

## Intellectual Property (IP) Risk

The Astellas Group's ethical pharmaceuticals business benefits from the protection of many patents. Although the Astellas Group manages IP rights properly and is vigilant against third-party violation of such rights, the adverse impact on the Astellas Group's business results of actual IP violations may still be substantial. The Astellas Group's business results are also subject to the outcome of litigation undertaken by the Astellas Group to protect patents where infringement has occurred.

While the Astellas Group strives to ensure that its actions do not infringe the IP rights of other parties, there is a risk of litigation in the event of any inadvertent violations. Such litigation could also impact the Astellas Group's business results significantly.

#### Risks Relating to Product Side Effects and Safety

Any problems arising due to serious side effects or other safety issues that are caused by the Astellas Group's products could impact the Astellas Group's business results significantly.

#### Environment, Health and Safety-Related Risks

The Astellas Group is careful to observe laws and regulations relating to environmental or health and safety issues and has instituted internal standards that aim to exceed most statutory requirements. Despite such precautions, the costs involved in the unlikely event of a business-related incident causing a serious breach of compliance in this area could impact the Astellas Group's business results significantly.

#### Foreign Exchange Rate Fluctuations

The Astellas Group's business results and financial position are subject to the impact of exchange rate fluctuations due to the Astellas Group's extensive international operations.

In addition to the risks outlined above, the Astellas Group is exposed to a wide range of business-related risks, including but not limited to (1) general commercial litigation, (2) delays or suspension of manufacturing activities due to natural disasters or other factors, and (3) partial dependence on licensing or sales agreements relating to pharmaceuticals developed by other companies.

## **Consolidated Financial Statements**

## **Consolidated Statement of Income**

Astellas Pharma Inc. and Subsidiaries For the year ended 31 March 2018

		(Millions of	(Millions of U.S. dollars			
	Note	2017	2018	2018		
Sales	6	¥1,311,665	¥1,300,316	\$12,267		
Cost of sales		(320,503)	(294,250)	(2,776)		
Gross profit		991,162	1,006,066	9,491		
Selling, general and administrative expenses		(470,777)	(478,330)	(4,513)		
Research and development expenses		(208,129)	(220,781)	(2,083)		
Amortisation of intangible assets	17	(35,837)	(35,838)	(338)		
Share of losses of associates and joint ventures		(1,864)	(2,419)	(23)		
Other income	7	7 9,594 <b>11,872</b>				
Other expense	8	(23,318)	(67,311)	(635)		
Operating profit		260,830	213,258	2,012		
Finance income	10	22,916	6,637	63		
Finance expense	11	(1,976)	(1,782)	(17)		
Profit before tax		281,769	218,113	2,058		
Income tax expense	12	(63,069)	(53,434)	(504)		
Profit for the year		¥ 218,701	¥ 164,679	\$ 1,554		
Profit attributable to:						
Owners of the parent		¥ 218,701 <b>¥ 164,679</b>		\$ 1,554		
		(Yen)				
Earnings per share	_					
Basic	13	¥ 103.69	¥ 81.11	\$ 0.77		
Diluted	13	103.55	81.02	0.76		

## Consolidated Statement of Comprehensive Income

Astellas Pharma Inc. and Subsidiaries For the year ended 31 March 2018

		(Millions of	(Millions of U.S. dollars)						
	Note	2017	2018	2018					
Profit for the year		¥218,701	¥164,679	\$1,554					
Other comprehensive income									
Items that will not be reclassified subsequently to profit or loss									
Remeasurements of defined benefit plans		2,962	1,611	15					
Subtotal		2,962	1,611	15					
Items that may be reclassified subsequently to profit or loss									
Foreign currency translation adjustments	14	(32,544)	28,590	270					
Fair value movements on available-for-sale financial assets	14	(14,474)	3,660	35					
Subtotal		(47,018)	32,250	304					
Other comprehensive income, net of tax		(44,056)	33,860	319					
Total comprehensive income		¥174,644	¥198,539	\$1,873					
Total comprehensive income attributable to:									
Owners of the parent		¥174,644	¥198,539	\$1,873					

## **Consolidated Statement of Financial Position**

Astellas Pharma Inc. and Subsidiaries As of 31 March 2018

	AS OF 31 March 2018			
		(Millions o	of yen)	(Millions of U.S. dollars)
	Note	2017	2018	2018
Assets				
Non-current assets				
Property, plant and equipment	15	¥ 191,115	¥ 181,295	\$ 1,710
Goodwill	16	168,521	212,976	2,009
Other intangible assets	17	387,419	416,912	3,933
Trade and other receivables	22	22,263	25,282	239
Investments in associates and joint ventures		2,988	3,138	30
Deferred tax assets	18	90,349	97,237	917
Other financial assets	19	61,597	67,375	636
Other non-current assets	20	2017 2018 2018  ¥ 191,115	79	
Total non-current assets		937,407	1,012,587	9,553
Current assets				
Inventories	21	182,537	147,626	1,393
Trade and other receivables	22	309,817	319,512	3,014
Income tax receivable		10,986	8,412	79
Other financial assets	19	13,554	13,517	128
Other current assets	20	18,849	14,448	136
Cash and cash equivalents	23	340,923	331,731	3,130
Subtotal		876,665	835,245	7,880
Assets held for sale	24		10,374	98
Total current assets		876,665	845,619	7,978
Total assets		¥1,814,072	¥1,858,205	\$17,530

		(Millions of	(Millions of U.S. dollars)	
	Note	2017	2018	2018
Equity and liabilities				
Equity				
Share capital	25	¥ 103,001	¥ 103,001	\$ 972
Capital surplus	25	177,091	177,219	1,672
Treasury shares	25	(138,207)	(135,951)	(1,283)
Retained earnings		1,013,923	976,076	9,208
Other components of equity	25	116,002	147,945	1,396
Total equity attributable to owners of the parent		1,271,810	1,268,289	11,965
Total equity		1,271,810	1,268,289	11,965
Liabilities				
Non-current liabilities				
Trade and other payables	32	440	3,515	33
Deferred tax liabilities	18	18,514	26,426	249
Retirement benefit liabilities	28	36,614	36,673	346
Provisions	29	4,921	4,891	46
Other financial liabilities	30	28,389	49,422	466
Other non-current liabilities	31	53,528	47,370	447
Total non-current liabilities		142,406	168,296	1,588
Current liabilities				
Trade and other payables	32	182,826	140,909	1,329
Income tax payable		10,900	25,184	238
Provisions	29	96,589	126,231	1,191
Other financial liabilities	30	2,992	7,559	71
Other current liabilities	31	106,548	121,737	1,148
Total current liabilities		399,856	421,620	3,978
Total liabilities		542,262	589,916	5,565
Total equity and liabilities		¥1,814,072	¥1,858,205	\$17,530

## **Consolidated Statement of Changes in Equity**

Astellas Pharma Inc. and Subsidiaries For the year ended 31 March 2018

						(N	lillions of ye	en)				
		Equity attributable to owners of the parent										
		Other components of equity										=
	Note	Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Foreign currency translation adjustments	Fair value movements on available-for-sale financial assets	Remeasurements of defined benefit plans	Total	Total	Total equity
As of 1 April 2016		¥103,001	¥176,903	¥ (157,111)	¥ 973,054	¥2,126	¥132,134	¥29,103	¥ —	¥163,363	¥1,259,209	¥1,259,209
Comprehensive income												
Profit for the year		_	_	_	218,701	_	_	_	_	_	218,701	218,701
Other comprehensive income		_	_	_	_	_	(32,544)	(14,474)	2,962	(44,056)	(44,056)	(44,056)
Total comprehensive income		_	_	_	218,701	_	(32,544)	(14,474)	2,962	(44,056)	174,644	174,644
Transactions with owners of the parent												
Acquisition of treasury shares	25	_	_	(92,193)	_	_	_	_	_	_	(92,193)	(92,193)
Disposals of treasury shares	25	_	(78)	877	(456)	(342)	_	_	_	(342)	1	1
Cancellation of treasury shares	25	_	_	110,219	(110,219)	_	_	_	_	_	_	_
Dividends	26	_	_	_	(70,119)	_	_	_	_	_	(70,119)	(70,119)
Share-based payments	27	_	266	_	_	_	_	_	_	_	266	266
Transfers		_	_	_	2,962	_	_	_	(2,962)	(2,962)	_	_
Total transactions with owners of the parent		_	188	18,903	(177,831)	(342)	_	_	(2,962)	(3,304)	(162,044)	(162,044)
As of 31 March 2017		103,001	177,091	(138,207)	1,013,923	1,784	99,590	14,629	_	116,002	1,271,810	1,271,810
Comprehensive income												
Profit for the year		_	_	_	164,679	_	_	_	_	_	164,679	164,679
Other comprehensive income		_	_	_	_	_	28,590	3,660	1,611	33,860	33,860	33,860
Total comprehensive income		_	_	_	164,679	_	28,590	3,660	1,611	33,860	198,539	198,539
Transactions with owners of the parent												
Acquisition of treasury shares	25	_	_	(130,712)	_	_	_	_	_	_	(130,712)	(130,712)
Disposals of treasury shares	25	_	(159)	819	(353)	(307)	_	_	_	(307)	1	1
Cancellation of treasury shares	25	_	_	132,150	(132,150)	_	_	_	_	_	_	_
Dividends	26	_	_	_	(71,634)	_	_	_	_	_	(71,634)	(71,634)
Share-based payments	27	_	286	_	_	_	_	_	_	_	286	286
Transfers		_	_	_	1,611	_	_	_	(1,611)	(1,611)	_	_
Total transactions with owners of the parent		_	127	2,257	(202,526)	(307)	_	_	(1,611)	(1,918)	(202,060)	(202,060)
As of 31 March 2018		¥103,001	¥177,219	¥(135,951)	¥ 976,076	¥1,477	¥128,179	¥18,289	¥ —	¥147,945	¥1,268,289	¥1,268,289

wners	tributable to	Equity att				
Other components of eq						
oreign curre translation	Subscription	Retained				

	Note	Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Foreign currency translation adjustments	Fair value movements on available-for-sale financial assets	Remeasurements of defined benefit plans	Total	Total	Total equity
As of 31 March 2017		\$972	\$1,671	\$(1,304)	\$9,565	\$17	\$ 940	\$138	\$ —	\$1,094	\$11,998	\$11,998
Comprehensive income												
Profit for the year		_	_	_	1,554	_	_	_	_	_	1,554	1,554
Other comprehensive income		_	_	_	_	_	270	35	15	319	319	319
Total comprehensive income		_	_	_	1,554	_	270	35	15	319	1,873	1,873
Transactions with owners of the parent												
Acquisition of treasury shares	25	_	_	(1,233)	_	_	_	_	_	_	(1,233)	(1,233)
Disposals of treasury shares	25	_	(2)	8	(3)	(3)	_	_	_	(3)	0	0
Cancellation of treasury shares	25	_	_	1,247	(1,247)	_	_	_	_	_	_	_
Dividends	26	_	_	_	(676)	_	_	_	_	_	(676)	(676)
Share-based payments	27	_	3	_	_	_	_	_	_	_	3	3
Transfers		_	_	_	15	_	_	_	(15)	(15)	_	_
Total transactions with owners of the parent		_	1	21	(1,911)	(3)	_	_	(15)	(18)	(1,906)	(1,906)
As of 31 March 2018		\$972	\$1,672	\$(1,283)	\$9,208	\$14	\$1,209	\$173	\$ —	\$1,396	\$11,965	\$11,965

(Millions of U.S. dollars)

## **Consolidated Statement of Cash Flows**

Astellas Pharma Inc. and Subsidiaries For the year ended 31 March 2018

		(Millions of	yen)	(Millions of U.S. dollars)
	Note	2017	2018	2018
Cash flows from operating activities				
Profit before tax		¥281,769	¥218,113	\$2,058
Depreciation and amortisation		63,791	64,863	612
Impairment losses and reversal of impairment losses		16,340	42,398	400
Finance income and expense		(20,940)	(4,854)	(46)
(Increase) decrease in inventories		(26,644)	37,830	357
(Increase) decrease in trade and other receivables		5,057	(6,634)	(63)
Increase (decrease) in trade and other payables		15,651	(43,804)	(413)
Other		(27,409)	69,723	658
Cash generated from operations		307,616	377,635	3,563
Income tax paid		(72,004)	(65,021)	(613)
Net cash flows from operating activities		235,612	312,614	2,949
Cash flows from investing activities				
Purchases of property, plant and equipment		(29,010)	(25,077)	(237)
Proceeds from sales of property, plant and equipment		1,262	1,209	11
Purchases of intangible assets		(19,638)	(15,208)	(143)
Purchases of available-for-sale financial assets		(484)	(693)	(7)
Proceeds from sales of available-for-sale financial assets		28,642	6,970	66
Acquisition of subsidiaries, net of cash acquired	37	(50,915)	(83,723)	(790)
Interest and dividends received		1,618	1,849	17
Other		(4,858)	(7,125)	(67)
Net cash flows used in investing activities		(73,383)	(121,799)	(1,149)
Cash flows from financing activities				
Acquisition of treasury shares	25	(92,193)	(130,712)	(1,233)
Dividends paid to owners of the parent	26	(70,119)	(71,634)	(676)
Other		(3,841)	(1,083)	(10)
Net cash flows used in financing activities		(166,153)	(203,429)	(1,919)
Effect of exchange rate changes on cash and cash equivalents		(15,183)	3,421	32
Net increase (decrease) in cash and cash equivalents		(19,107)	(9,192)	(87)
Cash and cash equivalents at the beginning of the year	23	360,030	340,923	3,216
Cash and cash equivalents at the end of the year	23	¥340,923	¥331,731	\$3,130

## Notes to Consolidated Financial Statements

Astellas Pharma Inc. and Subsidiaries For the year ended 31 March 2018

### 1. Reporting Entity

Astellas Pharma Inc. and its subsidiaries (collectively, the "Group") are engaged in the manufacture and sales of pharmaceutical products. The parent company of the Group, Astellas Pharma Inc. (the "Company"), is incorporated in Japan, and the registered address of headquarters and principal business offices are available on the Company's website (https://www.astellas.com/en/). Also, shares of the

Company are publicly traded on the Tokyo Stock Exchange (First Section).

The Group's consolidated financial statements for the year ended 31 March 2018 were authorised for issue on 15 June 2018 by Kenji Yasukawa, Representative Director, President and Chief Executive Officer, and Chikashi Takeda, Senior Corporate Executive and Chief Financial Officer.

## 2. Basis of Preparation

## (1) Compliance with IFRS

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards ("IFRS") issued by the International Accounting Standards Board.

#### (2) Basis of measurement

The Group's consolidated financial statements have been prepared on a historical cost basis, except for financial instruments measured at fair value.

#### (3) Presentation currency

The Group's consolidated financial statements are presented in Japanese yen, which is also the Company's functional currency, and figures are rounded to the nearest million yen, except as otherwise indicated.

For the convenience of readers outside Japan, the accompanying consolidated financial statements are also presented in U.S. dollars by translating Japanese yen amounts at the exchange rate of ¥106 to U.S. \$1, the approximate rate of exchange at the end of 31 March 2018. Such translations should not be construed

as representations that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

## (4) New or amended IFRS standards and interpretations not yet adopted

The following is a list of the major new or amended IFRS standards and interpretations that the Group has not adopted among those issued by the date of the approval of the Group's consolidated financial statements. The effects on the Group's consolidated financial statements for the year ending 31 March 2019 due to the application of IFRS 9 *Financial Instruments* and IFRS 15 *Revenue from Contracts with Customers* are immaterial. Financial assets classified as available-for-sale financial assets under IAS 39 will be classified as financial assets measured at fair value through other comprehensive income under IFRS 9.

The effects on the Group's consolidated financial statements due to the application of IFRS 16 *Leases* are still under consideration and cannot be estimated at this time

	IFRSs	Effective date (fiscal years beginning on or after)	The Group's application date (fiscal year ending)	Summaries of new or amended IFRS standards and interpretations
IFRS 9	Financial Instruments	1 January 2018	31 March 2019	Amendments related to classification and measurement of financial assets and financial liabilities, impairment, and hedge accounting
IFRS 15	Revenue from Contracts with Customers	1 January 2018	31 March 2019	Comprehensive framework for revenue recognition
IFRS 16	Leases	1 January 2019	31 March 2020	Amendments related to accounting treatment for leases

## 3. Significant Accounting Policies

The significant accounting policies of the Group set forth below are applied continuously to all periods indicated in the consolidated financial statements.

#### (1) Basis of consolidation

## (i) Subsidiaries

Subsidiaries are entities controlled by the Group. The Group controls an entity when the Group has power over the entity, is exposed to, or has rights, to variable returns from its involvement with the entity, and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group, and they are deconsolidated from the date on which the Group loses control.

All intragroup assets and liabilities, transactions and unrealised gains or losses arising from intragroup transactions are eliminated on consolidation.

#### (ii) Associates

Associates are entities over which the Group has significant influence on their financial and operating policies but does not have control or joint control. If the Group owns between 20% and 50% of the voting power of an entity, it is presumed that the Group has significant influence over the entity. The Group accounts for investments in associates using the equity method.

#### (iii) Joint arrangements

A joint arrangement is an arrangement in which the Group has joint control. Joint control is the contractually

agreed sharing of control of an arrangement, which exists only when decisions about the activities that significantly affect the returns of the arrangement require the unanimous consent of the parties sharing control. Joint arrangements in which the Group has an interest are classified and accounted for as follows:

- Joint operation—when the Group has rights to the assets and obligations for the liabilities relating to an arrangement, it accounts for each of its assets, liabilities, revenue and expenses, in relation to its interest in the joint operation.
- Joint venture—when the Group has rights only to the net assets of the arrangement, it accounts for its interest in the joint venture using the equity method in the same way as associates.

## (2) Business combinations

Business combinations are accounted for using the acquisition method.

The consideration transferred is measured at fair value and calculated as the aggregate of the fair values of the assets transferred, liabilities assumed, and the equity interests issued by the Group. The consideration transferred also includes any assets or liabilities resulting from a contingent consideration arrangement.

The identifiable assets acquired, the liabilities and contingent liabilities assumed that meet the recognition principles of IFRS 3 "Business Combinations" are measured at their acquisition-date fair values, except:

- Deferred tax assets or liabilities, liabilities (or assets, if any) related to employee benefits, and liabilities related to share-based payment transactions are recognised and measured in accordance with IAS 12 "Income Taxes", IAS 19 "Employee Benefits", and IFRS 2 "Share-based Payment", respectively; and
- Non-current assets and disposal groups classified as held for sale are measured in accordance with IFRS 5 "Non-current Assets Held for Sale and Discontinued Operations".

The excess of the aggregate of the consideration transferred and the amount recognised for non-controlling interest in the acquiree over the acquisition-date fair value of the identifiable net assets acquired is recorded as goodwill. If the excess is negative, then a gain is immediately recognised in profit or loss.

Acquisition-related costs incurred in connection with business combinations, such as finder's fees and advisory fees, are expensed when incurred.

## (3) Foreign currency translation (i) Functional and presentation currency

The financial statements of an entity of the Group are prepared using the functional currency of the entity. The consolidated financial statements of the Group are presented in Japanese yen, which is the functional currency of the Company.

#### (ii) Transactions in foreign currencies

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions or an approximation of the rate.

At the end of each reporting period, monetary assets and liabilities denominated in foreign currencies are translated into the functional currency using the exchange rates at the closing date and exchange differences arising from translation are recognised in profit or loss.

#### (iii) Foreign operations

Assets and liabilities of foreign operations are translated into Japanese yen using the exchange rate at the end of fiscal year. Income and expenses are translated into Japanese yen using the average exchange rate for the period.

Exchange differences arising on translating the financial statements of foreign operations are recognised in other comprehensive income. On the disposal of the interest in a foreign operation, the cumulative amount of the exchange differences is reclassified to profit or loss.

#### (4) Sales

#### (i) Sale of goods

Sales are measured at the fair value of the consideration received or receivable, less discounts, charge-backs and other rebates, excluding sales taxes and value added taxes. Also, the Group recognises the sales amount of transactions in which the Group is acting as an agent on a net basis.

Revenue from the sale of goods is recognised when all of the following conditions have been satisfied, namely, the significant risks and rewards of ownership of the goods have been transferred to the buyers, the Group retains neither continuing managerial involvement which normally can be associated with ownership nor effective control over the goods sold, it is probable that the economic benefits will flow to the Group, and the amount of revenue and costs associated with the transaction can be reliably measured. Therefore, revenue is usually recognised at the time of delivery of goods to customers.

Sales discounts, charge-backs and other rebates are recognised upon the recognition of underlying revenue as accounts payable, provisions or as deductions from accounts receivable.

#### (ii) Royalty income

Some of the Group's revenues are generated from the agreements under which third parties have been granted rights to produce or market products or rights to use technologies. Royalty income is recognised on an accrual basis in accordance with the substance of the relevant agreement. Revenue associated with milestone agreements is recognised upon achievement of the milestones defined in the respective agreements. Upfront payments and licence fees received for agreements where the rights or obligations still exist are initially recognised as deferred income and then

recognised in income as earned over the period of the development collaboration or the manufacturing obligation.

#### (5) Research and development expenses

Expenditure on research and development of an internal project is fully expensed as "Research and development expenses" in the consolidated statement of income when incurred.

Internally generated development expenses are recognised as an intangible asset only if the capitalisation criteria under IAS 38 are satisfied. Therefore, internal expenditure incurred for ongoing internal development projects is not capitalised until marketing approval is obtained from the regulatory authorities in a major market, which is considered the time at which the criteria of capitalisation under IAS 38 are met.

In addition to the Group's internal research and development activities, the Group has entered into research and development collaboration agreements with some alliance partners. The expenses and income associated with the settlement of the expenditure incurred for the research and development collaboration activities are accounted for as research and development expenses on an accrual basis in the same way as research and development expenses incurred within the Group.

## (6) Finance income and finance expense

Finance income mainly comprises interest income, dividend income, and gain on sales of financial instruments. Interest income is recognised using the effective interest method. Dividend income is recognised when the right to receive payment is established.

Financial expenses mainly comprise interest expense, fees, loss on sales of financial instruments, and impairment losses for financial assets.

#### (7) Income tax

Income tax expense is comprised of current and deferred taxes, and recognised in profit or loss, except for taxes related to business combinations and to items that are recognised in other comprehensive income or directly in equity.

Current taxes are calculated at the amount expected to be paid to or recovered from the taxation authority by applying the statutory tax rate and tax laws enacted or substantially enacted at the end of the fiscal year.

Deferred tax assets and deferred tax liabilities are recognised for temporary differences between the carrying amounts of certain assets or liabilities in the consolidated statement of financial position and their tax base. However, deferred tax assets and liabilities are not recognised for:

- taxable temporary differences arising from the initial recognition of goodwill.
- taxable or deductible temporary differences arising from the initial recognition of assets and liabilities in a transaction other than a business combination that affects neither accounting profit nor taxable profit (tax loss).
- deductible temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements when it is not probable that the temporary difference will reverse in the foreseeable future or there will not be sufficient taxable profits against which the deductible temporary differences can be utilised.
- taxable temporary differences associated with investments in subsidiaries, associates, and interests in joint arrangements when the Group is able to control the timing of the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets are recognised to the extent that it is probable that taxable profits will be available against which deductible temporary differences, unused tax losses, and unused tax credits can be utilised.

Deferred tax assets and deferred tax liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates and tax laws that have been enacted or substantively enacted by the end of the fiscal year.

Deferred tax assets and deferred tax liabilities are offset if the Group has a legally enforceable right to offset current tax assets against current tax liabilities, and they are related to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend to settle current tax assets and current tax liabilities on a net basis.

## (8) Earnings per share

Basic earnings per share are calculated by dividing profit for the year attributable to owners of the parent by the weighted-average number of ordinary shares outstanding during the year, adjusting treasury shares. For the purpose of calculating diluted earnings per share, profit for the year attributable to owners of the parent and the weighted average number of shares outstanding, adjusting treasury shares, is calculated for the effects of all dilutive potential ordinary shares.

#### (9) Property, plant and equipment

Property, plant, and equipment is measured by using the cost model and is stated at cost less accumulated depreciation and accumulated impairment losses.

The cost of items of property, plant and equipment includes costs directly attributable to the acquisition and the initial estimate of costs of dismantling and removing the items and restoring the site on which they are located.

Costs incurred after initial recognition are recognised as an asset, as appropriate, only when it is probable that future economic benefits associated with the asset will flow to the Group and its cost can be reliably measured. Costs of day-to-day servicing for items of property, plant and equipment, such as repairs and maintenance, are expensed when incurred.

When an item of property, plant and equipment has a significant component, such component is accounted for as a separate item of property, plant and equipment. Depreciation of an asset begins when it is available for use. The depreciable amount of items of property, plant and equipment is depreciated on a straight-line basis over the estimated useful lives of each component. The

depreciable amount of an asset is determined by deducting its residual value from its cost.

The estimated useful lives of major classes of property, plant and equipment are as follows:

Buildings and structures	2 to 60 years
Machinery and vehicles	2 to 20 years
Tools, furniture and fixtures	2 to 20 years

The useful lives, residual values, and depreciation methods of property, plant and equipment are reviewed at the end of fiscal year, and changed, if any.

#### (10) Leases

Leases are classified as finance leases whenever substantially all the risks and rewards incidental to ownership of an asset are transferred to the Group. All other leases are classified as operating leases.

Under finance lease transactions, leased assets and lease obligations are initially recognised at the lower of the fair value of the leased property or the present value of the minimum lease payments, each determined at the inception of the lease. Leased assets are depreciated on a straight-line basis over the shorter of their estimated useful lives or lease terms. Minimum lease payments made under finance leases are allocated to finance expense and the repayment amount of the lease obligations. The finance expense is allocated to each period during the lease term so as to produce a constant periodic rate of interest on the remaining balance of liabilities.

Under operating lease transactions, lease payments are recognised as an expense on a straight-line basis over the lease term.

The Group determines whether an arrangement is, or contains a lease, based on the substance of the arrangement at the date of commencement of the lease. The substance of the arrangement is determined based on the following factors:

- (a) whether the fulfillment of the arrangement is dependent on the use of a specific asset or assets and,
- (b) whether the arrangement conveys a right to use the asset.

#### (11) Goodwill

Measurement of goodwill on initial recognition is described in "(2) Business combinations". After initial recognition, goodwill is carried at cost less any accumulated impairment losses.

Impairment of goodwill is described in "(13) Impairment of property, plant and equipment, goodwill, and other intangible assets".

#### (12) Other intangible assets

Other intangible assets are identifiable non-monetary assets without physical substance, other than goodwill, including patents and technologies, marketing rights, and in-process research and development (IPR&D) acquired in a business combination or acquired separately.

Other intangible assets acquired separately are measured at cost upon initial recognition, and those acquired in a business combination are measured at fair value at the acquisition date. After initial recognition, the Group applies the cost model and other intangible assets are carried at cost less any accumulated amortisation and accumulated impairment losses.

Other intangible assets are amortised over their estimated useful lives (2-25 years) on a straight-line basis beginning at the time when they are available for use. Amortisation of other intangible assets acquired through business combinations or through the inlicensing of products or technologies is presented in the consolidated statement of income under "Amortisation of intangible assets". The estimated useful life of other intangible assets is the shorter of the period of legal protection or its economic life, and it is also regularly reviewed.

Among rights related to products or research and development through the in-licensing of products or technologies or acquired through business combinations, those that are still in the research and development stage or have not yet obtained marketing approval from the regulatory authorities are recognised under "Other intangible assets" as IPR&D.

Subsequent expenditure, including initial upfront and milestone payments to the third parties, on an acquired IPR&D is capitalised if, and only if, it is probable that the

expected future economic benefits that are attributable to the asset will flow to the Group and the asset is identifiable.

An intangible asset recognised as IPR&D is not amortised because it is not yet available for use, but instead, it is tested for impairment whenever there is an indication of impairment or at least on an annual basis irrespective of whether there is any indication.

Once marketing approval from the regulatory authorities is obtained and the asset is available for use, IPR&D is transferred to "Patents and technologies" or "Marketing rights" and amortisation begins from that time on a straight-line basis over its useful life.

# (13) Impairment of property, plant and equipment, goodwill, and other intangible assets

## (i) Impairment of property, plant and equipment and other intangible assets

At the end of each quarter, the Group assesses whether there is any indication that its property, plant and equipment and other intangible assets may be impaired.

If there is an indication of impairment, the recoverable amount of the asset is estimated. Other intangible assets not yet available for use or with indefinite useful lives are tested for impairment annually irrespective of whether there is any indication of impairment.

When it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs. A cash-generating unit is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

The recoverable amount is the higher of fair value less costs of disposal and value in use. In measuring the value in use, the estimated future cash flows are discounted to the present value using a discount rate that reflects the time value of money and the risks specific to the asset. The discount rate used for calculating the recoverable amount is set at a rate appropriate to each geographical area of operations.

If the recoverable amount of an asset or a cashgenerating unit is less than its carrying amount, the carrying amount of the asset or the cash-generating unit is reduced to its recoverable amount, and the reduction is recognised in profit or loss as an impairment loss.

#### (ii) Impairment of goodwill

Goodwill is allocated to each of the cash-generating units, or groups of cash-generating units, that is expected to benefit from the synergies of the business combination, and it is tested for impairment annually and whenever there is an indication that the cash-generating unit may be impaired. If, at the time of the impairment test, the recoverable amount of a cash-generating unit is less than its carrying amount, the carrying amount of the cash-generating unit is reduced to its recoverable amount, and the reduction is recognised in profit or loss as an impairment loss.

Impairment loss is allocated to reduce the carrying amount of any goodwill allocated to the cash-generating unit or group of cash-generating units and then to the other assets on a pro rata basis of the carrying amount of each asset in the cash-generating unit or group of cash-generating units.

## (iii) Reversal of impairment loss

At the end of each quarter, the Group assesses whether there is any indication that an impairment loss recognised in prior years for other intangible assets may no longer exist or may have decreased. If such indication exists, the recoverable amount of the asset or the cash-generating unit is estimated. If the recoverable amount of the asset or the cash-generating unit is greater than its carrying amount, a reversal of an impairment loss is recognised, to the extent the increased carrying amount does not exceed the lower of the recoverable amount or the carrying amount (net of depreciation or amortisation) that would have been determined had no impairment loss been recognised in prior years.

Any impairment loss recognised for goodwill is not reversed in a subsequent period.

#### (14) Financial instruments

#### (i) Initial recognition

Financial assets and financial liabilities are recognised on the trade date when the Group becomes a party to the contractual provisions of the instrument.

Financial assets and financial liabilities are measured at fair value at initial recognition. Transaction costs directly attributable to the acquisition of financial assets or issuance of financial liabilities, other than financial assets measured at fair value through profit or loss ("financial assets at FVTPL") and financial liabilities measured at fair value through profit or loss ("financial liabilities at FVTPL"), are added to the fair value of the financial assets or deducted from the fair value of financial liabilities on initial recognition. Transaction costs directly attributable to the acquisition of financial assets at FVTPL and financial liabilities at FVTPL are recognised in profit or loss.

#### (ii) Non-derivative financial assets

Non-derivative financial assets are classified into "financial assets at FVTPL", "held-to-maturity investments", "loans and receivables" and "available-forsale financial assets". The classification is determined based on the nature and purpose of the financial assets at the time of initial recognition.

## (a) Financial assets at FVTPL

The Group classifies financial assets as FVTPL when the financial assets are either held for trading or designated as FVTPL at initial recognition.

Financial assets at FVTPL are measured at fair value, and any gain or loss resulting from changes in fair value, dividends, and interest income are recognised in profit or loss.

## (b) Held-to-maturity investments

Non-derivative financial assets with fixed or determinable payments and fixed maturity dates that the Group has the positive intent and ability to hold to maturity are classified as held-to maturity investments.

Subsequent to initial recognition, held-to-maturity investments are measured at amortised cost using the effective interest method, less any impairment loss. Interest income using the effective interest method is recognised in profit or loss.

#### (c) Loans and receivables

Non-derivative financial assets with fixed or determinable payments not quoted in an active market are classified as loans and receivables.

Subsequent to initial recognition, loans and receivables are measured at amortised cost using the effective interest method, less any impairment loss. Amortisation incurred under the effective interest method is recognised in profit or loss.

#### (d) Available-for-sale financial assets

Non-derivative financial assets designated as availablefor-sale financial assets or not classified as FVTPL, held-to-maturity investments or loans and receivables are classified as available-for-sale financial assets.

Subsequent to initial recognition, available-for-sale financial assets are measured at fair value, and any gain or loss resulting from changes in fair value is recognised in other comprehensive income. Dividends on available-for-sale financial assets are recognised in profit or loss. When available-for-sale financial assets are derecognised or determined to be impaired, the cumulative gain or loss that had been recognised in other comprehensive income is reclassified to profit or loss.

## (iii) Impairment of financial assets other than FVTPL

Financial assets, other than those at FVTPL, are assessed for any objective evidence of impairment at the end of each quarter. Financial assets are impaired when there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the financial assets and these events have adversely affected the estimated future cash flows of the financial assets that can be reliably estimated.

Objective evidence of impairment of financial assets includes:

- · significant financial difficulty of the issuer or obligor;
- breach of contract, such as a default or delinquency in interest or principal payments;
- probability that the borrower will enter bankruptcy or other financial reorganisation; or
- disappearance of an active market for the financial assets.

In the case of equity instruments classified as available-for-sale, a significant or prolonged decline in the fair value of the equity instrument below its cost would be considered as objective evidence of impairment.

The Group assesses the existence of objective evidence of impairment for loans and receivables and held-to-maturity financial assets, individually for separately significant assets or collectively for assets with no individual significance. When there is objective evidence of impairment on those financial assets, the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the financial asset's original effective interest rate is recognised in profit or loss as an impairment loss.

The impairment loss for loans and receivables are recognised through the allowance for doubtful accounts, and the carrying amount of a loan and receivable is written off against the allowance account when it is subsequently considered uncollectible. When an event occurring after the impairment was recognised causes the amount of the impairment loss to decrease, a reversal of the impairment loss is recognised in profit or loss.

When there is objective evidence that an availablefor-sale financial asset is impaired, the cumulative loss that had been recognised in other comprehensive income is transferred to profit or loss. Any subsequent recovery in the fair value of impaired equity instruments classified as available-for-sale financial assets is recognised in other comprehensive income.

### (iv) Derecognition of financial assets

When the contractual rights with respect to the cash flows from a financial asset expire or the contractual rights to receive the cash flows from a financial asset have been transferred and substantially all the risks and rewards of ownership of the financial asset are transferred, the Group derecognises the financial asset.

#### (v) Non-derivative financial liabilities

Non-derivative financial liabilities are classified into "Financial liabilities at FVTPL" and "Financial liabilities measured at amortised cost". The classification is determined based on the nature and purpose of the financial liabilities at the time of initial recognition.

#### (a) Financial liabilities at FVTPL

The Group classifies financial liabilities as FVTPL when the financial liabilities are designated as FVTPL at initial recognition.

Financial liabilities at FVTPL are measured at fair value, and any gain or loss resulting from changes in fair value and interest expense are recognised in profit or loss

**(b) Financial liabilities measured at amortised cost**Non-derivative financial liabilities not classified as
FVTPL are classified as financial liabilities measured at amortised cost.

Subsequent to initial recognition, financial liabilities measured at amortised cost are measured at amortised cost using the effective interest method.

#### (vi) Derecognition of financial liabilities

The Group derecognises financial liabilities when the obligations of the financial liabilities are fulfilled or when the obligations are discharged, cancelled, or expired.

#### (vii) Derivatives

The Group is engaged in derivative transactions and mainly uses forward foreign exchange contracts to manage its exposure to risks from changes in foreign exchange rates.

Derivatives are initially recognised at fair value of the date when the derivative contracts are entered into and are subsequently measured at their fair values at the end of each guarter.

Changes in the fair value of derivatives are recognised in profit or loss, except for the following. If the hedging relationship qualifies for hedge accounting, the gain or loss on the hedging instrument of cash flow hedges or hedges of a net investment in a foreign operation that are determined to be effective hedges are recognised in other comprehensive income. The amounts that had been recognised in other comprehensive income for cash flow hedges and hedges of a net investment in a foreign operation shall be reclassified from equity to profit or loss in the same period or periods during which the hedged items affect

profit or loss and on the disposal or partial disposal of the foreign operation, respectively.

Financial assets and financial liabilities arising from derivatives are classified as either financial assets at FVTPL or financial liabilities at FVTPL.

#### (15) Cash and cash equivalents

Cash and cash equivalents comprise cash on hand, demand deposits, and highly liquid short-term investments with maturities of three months or less from the date of acquisition which are subject to an insignificant risk of changes in value.

#### (16) Inventories

Inventories are measured at the lower of cost and net realisable value. The cost of inventories includes costs of purchase, costs of conversion and all other costs incurred in bringing the inventories to their present location and condition. Net realisable value is calculated as the estimated selling price in the ordinary course of business less the estimated costs of completion and estimated costs necessary to sell. Cost of inventories is calculated mainly using the first-in, first-out (FIFO) method.

## (17) Assets held for sale

Non-current assets or disposal groups are classified as "Assets held for sale" if their carrying amounts will be recovered principally through a sale transaction rather than through continuing use. To be classified as assets held for sale, the asset must be available for immediate sale in its present condition, and the sale must be highly probable. Specifically, management of the Group must have a firm commitment to execute the plan to sell the asset and the sale is expected to be completed within one year from the date of classification, as a general rule. Assets held for sale are measured at the lower of their carrying amounts and fair values less costs to sell, and they are not depreciated or amortised while they are classified as held for sale.

#### (18) Equity

#### (i) Ordinary shares

Proceeds from the issuance of ordinary shares by the Company are included in share capital and capital surplus. Transaction costs of issuing ordinary shares (net of tax) are deducted from capital surplus.

#### (ii) Treasury shares

When the Company reacquires its own ordinary shares, the amount of the consideration paid including transaction costs is deducted from equity. When the Company sells treasury shares, the difference between the carrying amount and the consideration received from the sale is recognised in equity.

#### (19) Share-based payment

The Group operates an equity-settled share-based payment plan and a cash-settled share-based payment plan as share-based payment plans.

#### (i) Equity-settled share-based payment plan

Under the equity-settled share-based payment plan, services received are measured at the fair value of the equity instruments at the grant date, and are recognised as expenses from the grant date over the vesting period, with a corresponding increase in equity.

#### (ii) Cash-settled share-based payment plan

Under the cash-settled share-based payment plan, services received are measured at the fair value of the liabilities incurred and recognised as expenses over the vesting period, with a corresponding increase in liabilities. Until the liabilities are settled, the fair value of liabilities are remeasured at the end of each quarter and at the settlement date, with changes in fair value recognised in profit or loss.

#### (20) Employee benefits

## (i) Retirement benefits

The Group operates defined benefit and defined contribution retirement plans for its employees.

#### (a) Defined benefit plans

Net defined benefit assets or liabilities are calculated as the present value of the defined benefit obligation less the fair value of plan assets and they are recognised in the consolidated statement of financial position as assets or liabilities. The defined benefit obligation is calculated by using the projected unit credit method. The present value of the defined benefit obligation is calculated by the expected future payments using discount rate. The discount rate is determined by reference to market yield on high-quality corporate bonds having maturity terms consistent with the estimated term of the related pension obligations.

Service cost and net interest expense (income) on the net defined benefit liabilities (assets) are recognised in profit or loss.

Actuarial gains and losses, the return on plan assets, excluding amounts included in net interest, and any change in the effect of the asset ceiling are recognised immediately in other comprehensive income under "Remeasurements of defined benefit plans", and transferred from other components of equity to retained earnings immediately.

#### (b) Defined contribution plans

Contributions paid for defined contribution plans are expensed in the period in which the employees provide the related service.

## (ii) Short-term employee benefits

Short-term employee benefits are expensed when the related service is provided. Bonus accrual is recognised as a liability when the Group has present legal or constructive obligations resulting from past service rendered by the employees and reliable estimates of the obligations can be made.

#### (21) Provisions

Provisions are recognised when the Group has present legal or constructive obligations as a result of past events, it is probable that outflows of resources embodying economic benefits will be required to settle the obligations, and reliable estimates of the obligations can be made.

When the effect of the time value of money is material, provisions are measured at the present value of the expenditures expected to be required to settle the obligations.

#### (22) Government grants

Government grants are recognised and measured at fair value, if there is reasonable assurance that the Group will comply with the conditions attached to them and that the grants will be received. Government grants that are intended to compensate for specific costs are

recognised as income in the period in which the Group recognises the corresponding expenses. Government grants related to assets are recognised as deferred income and then recognised in profit over the expected useful life of the relevant asset on a regular basis.

### 4. Significant Accounting Estimates, Judgments and Assumptions

The preparation of the consolidated financial statements requires management of the Group to make estimates, judgments and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income, and expenses.

Given their nature, actual results may differ from those estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis, and the effects resulting from revisions of accounting estimates are recognised in the period in which the estimates are revised and in future periods affected by the revision.

Estimates and underlying assumptions representing

a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities in the next fiscal year are as follows:

- Impairment of property, plant and equipment, goodwill and other intangible assets (Notes 15, 16 and 17)
- Provisions (Note 29)
- · Retirement benefits (Note 28)
- · Recoverability of deferred tax assets (Note 18)
- · Income tax expense (Note 12)
- Financial instruments measured at fair value which have no market price in active markets (Notes 33 and 37)

## 5. Segment Information

The main activities of the Group are the manufacture and sale of pharmaceutical products, and there are no separate operating segments. Therefore, the Group has a single reporting segment, "Pharmaceutical".

## Information about products and services

Sales by type of product and service are as follows:

		(Millions of yen)	
	2017	2018	
XTANDI	¥ 252,078	¥ 294,302	
Prograf	186,156	198,471	
Betanis/Myrbetriq/BETMIGA	98,844	125,745	
Vesicare	116,075	102,306	
Other	658,512	579,492	
Total	¥1,311,665	¥1,300,316	

(Note) Sales of "Betanis/Myrbetriq/BETMIGA" previously included in "Other" are presented separately from the fiscal year ended 31 March 2018 since those have become material. In accordance with this change, sales of "Betanis/Myrbetriq/BETMIGA" for the fiscal year ended 31 March 2017 of ¥98,844 million, which had been included in "Other," have been reclassified to conform to the current period presentation.

## Information about geographical areas

Sales and non-current assets by geographical areas are as follows:

#### Sales by geographical areas

		(Millions of yen)	
	2017	2018	
Japan	¥ 464,082	¥ 406,414	
Americas	412,625	435,108	
U.S.A. (included in Americas)	388,539	404,409	
EMEA	343,401	351,280	
Asia and Oceania	91,558	107,513	
Total	¥1,311,665	¥1,300,316	

(Note) Sales by geographical areas are categorised by country or areas based on the geographical location of customers.

## Non-current assets by geographical areas (Property, plant and equipment, goodwill and other intangible assets)

		(Millions of yen)
	2017	2018
Japan	¥356,907	¥424,603
Americas	253,277	240,566
U.S.A. (included in Americas)	252,943	240,313
EMEA	132,715	141,952
Asia and Oceania	4,155	4,061
Total	¥747,055	¥811,183

(Note) Due to the completion of the purchase price allocation for the acquisition of Ganymed Pharmaceuticals AG, the Group retrospectively revised the corresponding balances in the above non-current assets by geographical areas table as of 31 March 2017. For details, please refer to Note "37.

Business Combinations".

#### Information about major customers

External customer that accounts for 10% or more of consolidated sales of the Group is as follows:

		(Millions of yer		
	Segment	2017	2018	
McKesson Corporation	Pharmaceutical	¥150,184	¥148,962	

## 6. Sales

The breakdown of sales is as follows:

		(Millions of yen)	
	2017	2018	
Sales of pharmaceutical products	¥1,225,070	¥1,231,839	
Royalty income	57,433	43,254	
Other	29,162	25,223	
Total sales	¥1,311,665	¥1,300,316	

## 7. Other Income

The breakdown of other income is as follows:

	(Millions of yen)		
	2017	2018	
Gain from remeasurement relating to business combinations	¥ -	¥ 5,877	
Net foreign exchange gains	6,946	_	
Other	2,649	5,995	
Total other income	¥9,594	¥11,872	

<sup>(</sup>Notes) 1. The amount of "Net foreign exchange gains" for the year ended 31 March 2017 includes foreign exchange losses resulting from forward foreign exchange contracts (¥10,285 million).

<sup>2. &</sup>quot;Gain from remeasurement relating to business combinations" for the year ended 31 March 2018 was due to Mitobridge, Inc. becoming a wholly owned subsidiary of the Company.

## 8. Other Expense

The breakdown of other expense is as follows:

(Mil	lions	of	yen

	2017	2018
Impairment losses for property, plant and equipment	¥ 7,877	¥ 2,533
Impairment losses for goodwill	_	7,200
Impairment losses for other intangible assets	10,188	32,665
Restructuring costs	3,117	9,151
Net foreign exchange losses	_	10,468
Other	2,136	5,294
Total other expense	¥23,318	¥67,311

- (Notes) 1. "Impairment losses for property, plant and equipment" for the year ended 31 March 2017 mainly resulted from the recognition of impairment losses for buildings and certain other assets held by a U.S. subsidiary in connection with the sale of shares of this subsidiary to another company.
  - 2. "Impairment losses for other intangible assets" for the year ended 31 March 2017 were principally due to an impairment loss on patents due to lower-than-expected profitability and to the discontinuation of development activities for projects.
  - 3. "Impairment losses for goodwill" for the year ended 31 March 2018 were due to impairment of the goodwill resulting from the acquisition of U.S. subsidiary Agensys, Inc., in connection with the termination of research operation of Agensys.
  - 4. "Impairment losses for other intangible assets" for the year ended 31 March 2018 were principally due to reviewing development project plans for IMAB362.
  - 5. "Restructuring costs" for the year ended 31 March 2018 were principally due to the consolidation of the R&D activities in EMEA into Japan and the
  - 6. The amount of "Net foreign exchange losses" for the year ended 31 March 2018 includes foreign exchange gains resulting from forward foreign exchange contracts (¥2,147 million).

## 9. Employee Benefit Expenses

The breakdown of employee benefit expenses is as follows:

(Millions of yen)

	2017	2018
Rewards and salaries	¥143,538	¥152,523
Bonuses	56,341	55,654
Social security and welfare expenses	30,600	31,117
Retirement benefit expenses—Defined contribution plan	14,243	14,411
Retirement benefit expenses—Defined benefit plan	6,804	6,302
Restructuring and termination benefits	8,064	6,230
Other employee benefit expenses	2,821	2,664
Total employee benefit expenses	¥262,411	¥268,902

(Note) Employee benefit expenses are included in "Cost of sales", "Selling, general and administrative expenses", "Research and development expenses" and "Other expenses" in the consolidated statement of income.

## 10. Finance Income

The breakdown of finance income is as follows:

		(Millions of yen)
	2017	2018
Interest income		
Cash and cash equivalents	¥ 906	¥1,575
Other	72	73
Dividend income		
Available-for-sale financial assets	618	227
Gain on sales		
Available-for-sale financial assets	21,265	4,744
Other	13	2
Other	41	14
Total finance income	¥22,916	¥6,637

## 11. Finance Expense

The breakdown of finance expense is as follows:

		(Millions of yen)	
	2017	2018	
Impairment losses			
Available-for-sale financial assets	¥ 642	¥ 474	
Other	1,334	1,309	
Total finance expense	¥1,976	¥1,782	

## 12. Income Tax Expense

The breakdown of income tax expense recognised in profit or loss is as follows:

	(Millions of yen)	
	2017	2018
Current income tax expense	¥ 68,322	¥ 81,409
Deferred income tax expense	(5,253)	(27,975)
Income tax expense reported in the consolidated statement of income	¥ 63,069	¥ 53,434

(Note) Deferred income tax expense increased by ¥9,800 million for the year ended 31 March 2018, due to the effect of the U.S. Tax Cuts and Jobs Act, which came into force in December 2017.

Income tax recognised in other comprehensive income is as follows:

						(Millions of yen)
	2017		2018			
		Tax benefit		Tax benefit		
	Before tax	(expense)	Net of tax	Before tax	(expense)	Net of tax
Remeasurements of defined						
benefit plans	¥ 4,211	¥(1,249)	¥ 2,962	¥ 2,271	¥ (661)	¥ 1,611
Foreign currency translation						
adjustments	(32,544)	_	(32,544)	28,590	_	28,590
Fair value movements on						
available-for-sale financial assets	(20,931)	6,457	(14,474)	5,168	(1,508)	3,660
Total other comprehensive						
income	¥(49,264)	¥ 5,208	¥(44,056)	¥36,029	¥(2,169)	¥33,860

## Reconciliation of effective tax rate

The Company is subject mainly to corporate tax, inhabitant tax, and enterprise tax on its income and the effective statutory tax rates calculated based on those taxes for the years ended 31 March 2017 and 2018

were 30.7% in both years. Foreign subsidiaries are subject to income taxes on their income in their respective countries of domicile.

	2017	2018
Effective statutory tax rate	30.7%	30.7%
Tax credit for research and development expenses	(1.7)	(3.9)
Non-deductible expenses	2.6	4.3
Difference in tax rates applied to foreign subsidiaries	(7.8)	(12.6)
Undistributed earnings of foreign subsidiaries	0.3	(0.3)
Effect of U.S. tax reforms	_	3.9
Other	(1.8)	2.4
Actual tax rate	22.4%	24.5%

## 13. Earnings per Share

The basis of calculation of basic earnings per share and diluted earnings per share is as follows:

	(Millions of yen, except as otherwise indicated)	
	2017	2018
Basis of calculating basic earnings per share		
Profit attributable to owners of the parent	¥ 218,701	¥ 164,679
Profit not attributable to ordinary shareholders of the parent	_	_
Profit used to calculate basic earnings per share	218,701	164,679
Weighted average number of shares during the year (Thousands of shares)	2,109,149	2,030,203
Basis of calculating diluted earnings per share		
Profit used to calculate basic earnings per share	¥ 218,701	¥ 164,679
Adjustment	_	_
Profit used to calculate diluted earnings per share	218,701	164,679
Weighted average number of shares during the year (Thousands of shares)	2,109,149	2,030,203
Subscription rights to shares (Thousands of shares)	2,830	2,268
Weighted average number of diluted ordinary shares during the year		
(Thousands of shares)	2,111,979	2,032,472
Earnings per share (attributable to owners of the parent):		
Basic (Yen)	¥ 103.69	¥ 81.11
Diluted (Yen)	103.55	81.02

## 14. Other Comprehensive Income

Reclassification adjustments of other comprehensive income are as follows:

_		(Millions of yen)
	2017	2018
Other comprehensive income that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments		
Amount arising during the year	¥(32,615)	¥28,563
Reclassification adjustment	71	27
Subtotal	(32,544)	28,590
Fair value movements on available-for-sale financial assets		
Amount arising during the year	(94)	9,860
Reclassification adjustment	(20,836)	(4,692)
Subtotal	(20,931)	5,168
Other comprehensive income that may be reclassified subsequently to		
profit or loss before tax effect	(53,475)	33,758
Tax effect	6,457	(1,508)
Other comprehensive income that may be reclassified subsequently to profit or loss, net of tax	¥(47,018)	¥32,250

# 15. Property, Plant and Equipment

# Movement of cost, accumulated depreciation and impairment losses for property, plant and equipment

The movement of property, plant and equipment for the year ended 31 March 2017 is as follows:

_						(Millions of yen)
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Total
Cost						
Balance at 1 April 2016	¥211,164	¥ 154,051	¥ 79,235	¥18,023	¥ 18,124	¥ 480,597
Acquisitions	2,599	2,712	4,591	_	14,001	23,903
<b>Business combinations</b>	_	258	14	_	_	272
Disposals	(1,302)	(3,658)	(5,383)	(0)	(65)	(10,408)
Loss of control of subsidiaries	(8,775)	(8,696)	(289)	(144)	(1,457)	(19,360)
Reclassification from						
construction in progress	3,228	12,481	1,083	_	(16,792)	_
Other	(2,193)	(2,456)	(565)	(116)	(485)	(5,816)
Balance at 31 March 2017	204,722	154,692	78,687	17,762	13,325	469,188
Accumulated depreciation and						
accumulated impairment losses						
Balance at 1 April 2016	(92,416)	(123,360)	(63,811)	_	(54)	(279,642)
Depreciation	(7,520)	(8,753)	(5,598)	_	_	(21,872)
Impairment losses						
(or reversal of impairment losses)	(4,375)	(2,030)	(46)	(128)	(1,298)	(7,877)
Disposals	1,228	3,062	5,297	_	52	9,639
Loss of control of subsidiaries	8,249	8,448	283	128	1,298	18,407
Other	927	1,894	449	_	2	3,272
Balance at 31 March 2017	(93,907)	(120,739)	(63,427)	_	_	(278,073)
Carrying amounts						_
Balance at 1 April 2016	118,748	30,691	15,423	18,023	18,069	200,955
Balance at 31 March 2017	¥110,815	¥ 33,953	¥ 15,260	¥17,762	¥ 13,325	¥ 191,115

<sup>(</sup>Notes) 1. The increase due to business combinations reflected the acquisition of Ganymed Pharmaceuticals AG. For details on this business combination, please refer to Note "37. Business Combinations".

<sup>2. &</sup>quot;Other" mainly includes exchange differences.

The movement of property, plant and equipment for the year ended 31 March 2018 is as follows:

						(Millions of yen)
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Total
Cost						
Balance at 1 April 2017	¥ 204,722	¥ 154,692	¥ 78,687	¥17,762	¥13,325	¥ 469,188
Acquisitions	3,765	4,646	3,624	_	12,071	24,107
<b>Business combinations</b>	488	155	21	36	_	700
Disposals	(8,473)	(5,939)	(4,159)	_	(7)	(18,577)
Reclassification from						
construction in progress	5,979	3,301	432	_	(9,712)	_
Reclassification to assets						
held for sale	(10,149)	(4,102)	(127)	_	(95)	(14,473)
Other	687	3,502	470	24	(920)	3,764
Balance at 31 March 2018	197,020	156,254	78,949	17,822	14,664	464,709
Accumulated depreciation and						
accumulated impairment losses						
Balance at 1 April 2017	(93,907)	(120,739)	(63,427)	_	_	(278,073)
Depreciation	(7,468)	(8,780)	(5,792)	_	_	(22,039)
Impairment losses						
(or reversal of impairment losses)	(1,837)	(319)	(21)	_	_	(2,177)
Disposals	8,277	5,407	4,086	_	_	17,771
Reclassification to assets						
held for sale	1,933	3,056	87	_	_	5,076
Other	(628)	(2,856)	(488)	_	_	(3,972)
Balance at 31 March 2018	(93,629)	(124,231)	(65,554)	_	_	(283,414)
Carrying amounts						
Balance at 1 April 2017	110,815	33,953	15,260	17,762	13,325	191,115
Balance at 31 March 2018	¥ 103,390	¥ 32,023	¥ 13,395	¥17,822	¥14,664	¥ 181,295

(Notes) 1. The increase due to business combinations reflected the acquisitions of Ogeda SA, Mitobridge, Inc., and Universal Cells, Inc. For details on these business combinations, please refer to Note "37. Business Combinations".

The Group recognised impairment losses (or reversal of impairment losses) of  $\pm 7,877$  million for the year ended 31 March 2017 and  $\pm 2,177$  million for the year ended 31 March 2018, and they are included in "Other expense" in the consolidated statement of income.

Impairment losses (or reversal of impairment losses) of ¥7,877 million for the year ended 31 March 2017

mainly resulted from the transfer of a U.S. subsidiary to another company. The recoverable amount of the assets, including buildings, of ¥944 million is calculated with reference to fair value based on the price agreed upon for the transfer.

<sup>2. &</sup>quot;Other" mainly includes exchange differences.

The carrying amounts of the assets held under finance leases included in "Property, plant and equipment" are as follows:

				(Millions of yen)
	<b>Buildings and</b>	Machinery and	Tools, furniture and	
	structures	vehicles	fixtures	Total
Balance at 1 April 2016	¥-	¥95	¥1,133	¥1,228
Balance at 31 March 2017	¥37	¥ 6	¥1,630	¥1,672
Balance at 31 March 2018	¥41	¥ 1	¥1,344	¥1,386

# 16. Goodwill

The movement of cost and accumulated impairment losses for goodwill is as follows:

			(Millions of yen)		
	Accumulated				
	Cost	impairment losses	Carrying amount		
Balance at 1 April 2016	¥153,121	¥ –	¥153,121		
Business combinations	16,360	_	16,360		
Exchange differences	(960)	_	(960)		
Balance at 31 March 2017	168,521	_	168,521		
Business combinations	58,288	_	58,288		
Impairment losses	_	(7,200)	(7,200)		
Disposals	(7,200)	7,200	_		
Exchange differences	(6,632)	_	(6,632)		
Balance at 31 March 2018	¥212,976	¥ —	¥212,976		

<sup>(</sup>Notes) 1. The increase due to business combinations in the year ended 31 March 2017 reflected the acquisition of Ganymed Pharmaceuticals AG. The movement in the year ended 31 March 2017 was retrospectively revised due to the completion of the purchase price allocation in the year ended 31 March 2018. For details on this business combination, please refer to Note "37. Business Combinations".

<sup>2.</sup> The increase due to business combinations in the year ended 31 March 2018 reflected the acquisitions of Ogeda SA, Mitobridge, Inc., and Universal Cells, Inc. For details on these business combinations, please refer to Note "37. Business Combinations".

Goodwill recognised in the consolidated statement of financial position mainly resulted from the acquisition of OSI Pharmaceuticals, Inc. in 2010.

The Group, in principle, regards the geographical business units, which are managed for internal reporting purposes, as cash-generating units.

For the year ended 31 March 2017, the majority of goodwill is mainly allocated to the Americas cashgenerating unit, and the carrying amount of goodwill was ¥152,455 million.

For the year ended 31 March 2018, goodwill is allocated to the Americas cash-generating unit and the whole pharmaceutical business, and the carrying amounts of goodwill allocated were ¥113,632 million and ¥68,571 million, respectively. In addition, the Group has not yet completed the allocation to cash-generating units of goodwill amounting to ¥30,773 million acquired through business combinations in the year ended 31 March 2018.

For the impairment test, the value in use, which is calculated based on the three-year business plan approved at the board of directors meeting, is used as the recoverable amount. The Group uses a discount rate calculated based on a weighted average cost of capital (WACC) determined for each geographical area. The after-tax discount rates used for the impairment test of the Americas cash-generating unit and the whole

pharmaceutical business are 8.0% and 6.0%, respectively. The pre-tax discount rates used for the impairment test of the Americas cash-generating unit and the whole pharmaceutical business are 10.4% and 7.7%, respectively.

Also, a growth rate of 2.0% for the Americas cashgenerating unit and 1.0% for the whole pharmaceutical business is reflected in calculating the terminal value after the three-year business plan. The growth rate reflects the status of the country and the industry to which the cash-generating unit belongs.

The value in use sufficiently exceeds the carrying amount of the cash-generating unit. Therefore, even if the key assumptions used in the calculation of the value in use fluctuate within a reasonable range, the Group assumes that the possibility that the value in use will be lower than the carrying amount is remote.

The Group recognised impairment losses of ¥7,200 million for the year ended 31 March 2018 and they are included in "Other expense" in the consolidated statement of income. The impairment losses for the year ended 31 March 2018 were recognised on the goodwill resulting from the acquisition of U.S. subsidiary Agensys, Inc., in connection with the termination of research operation of Agensys, deeming the recoverable amount to be zero.

#### 17. Other Intangible Assets

# Movement of cost, accumulated amortisation and impairment losses for other intangible assets

The movement of other intangible assets for the year ended 31 March 2017 is as follows:

(Millions of yen) Patents and Marketing technologies rights IPR&D **Software** Other **Total** Cost Balance at 1 April 2016 ¥ 341,371 ¥ 57,081 ¥145,876 ¥ 43,697 ¥ 319 ¥ 588,344 163 10,416 1,550 **Acquisitions** 99 7,400 19,628 **Business combinations** 86,020 11 86,033 **Disposals** (5,127)(2,184)(3) (7,314)Reclassification 7,728 (7,728)Other (770)(1,599)(404)(23)(4,433)(1,636)Balance at 31 March 2017 348,492 50,454 232,949 48,520 1,843 682,258 Accumulated amortisation and accumulated impairment losses Balance at 1 April 2016 (166, 192)(42,493)(16,258)(26,931)(208)(252,083)Amortisation (32,304)(3,533)(6,073)(9)(41,919)Impairment losses (or reversal of impairment losses) (4,064)(6,054)1,725 (8,463)(70)**Disposals** 3,402 2,140 3 5,545 Other (224)1,459 8 829 10 2,082 Balance at 31 March 2017 (204,775)(39,441)(20,315)(30,104)(204)(294,839)Carrying amounts Balance at 1 April 2016 175,179 14,588 129,617 16,766 111 336,261 Balance at 31 March 2017 ¥ 143,717 ¥ 11,013 ¥212,634 ¥ 18,416 ¥1.639 ¥ 387,419

<sup>(</sup>Notes) 1. The increase due to business combinations reflected the acquisition of Ganymed Pharmaceuticals AG. For details on this business combination, please refer to Note "37. Business Combinations".

<sup>2. &</sup>quot;Other" mainly includes exchange differences.

The movement of other intangible assets for the year ended 31 March 2018 is as follows:

(Millions of yen)

	Patents and	Marketing				
	technologies	rights	IPR&D	Software	Other	Total
Cost						
Balance at 1 April 2017	¥ 348,492	¥ 50,454	¥232,949	¥ 48,520	¥ 1,843	¥ 682,258
Acquisitions	569	602	3,365	10,641	21	15,198
<b>Business combinations</b>	1,052	_	79,846	_	2	80,899
Disposals	(1,360)	_	_	(1,344)	_	(2,704)
Reclassification to assets						
held for sale	_	_	_	(93)	_	(93)
Other	(9,343)	1,469	9,509	1,315	6	2,956
Balance at 31 March 2018	339,410	52,525	325,669	59,039	1,871	778,514
Accumulated amortisation and						
accumulated impairment losses						
Balance at 1 April 2017	(204,775)	(39,441)	(20,315)	(30,104)	(204)	(294,839)
Amortisation	(32,802)	(3,037)	_	(6,975)	(11)	(42,824)
Impairment losses						
(or reversal of impairment losses)	(529)	_	(30,592)	(0)	(1,520)	(32,642)
Disposals	1,359	_	_	1,319	_	2,678
Reclassification to assets						
held for sale	_	_	_	70	_	70
Other	7,626	(1,371)	(56)	(237)	(6)	5,955
Balance at 31 March 2018	(229,121)	(43,849)	(50,964)	(35,927)	(1,742)	(361,602)
Carrying amounts						
Balance at 1 April 2017	143,717	11,013	212,634	18,416	1,639	387,419
Balance at 31 March 2018	¥ 110,289	¥ 8,676	¥274,705	¥ 23,112	¥ 130	¥ 416,912

(Notes) 1. The increase due to business combinations reflected the acquisitions of Ogeda SA and Universal Cells, Inc. For details on these business combinations, please refer to Note "37. Business Combinations".

Amortisation of other intangible assets related to the rights of product or research and development arising from in-licensing agreements is recognised in the consolidated statement of income under "Amortisation of intangible assets".

Impairment losses (or reversal of impairment losses) for other intangible assets are recognised in the consolidated statement of income under "Other expense" and "Other income."

# Impairment test and impairment losses for other intangible assets

For the intangible assets other than goodwill, the Group assesses the necessity of impairment mainly by individual asset. Also, intangible assets not yet being amortised are tested for impairment annually whether or not there is any indication of impairment. For the

impairment test, the value in use is mainly used as the recoverable amount. The discount rate is calculated based on the WACC, and the range of post-tax discount rate used for the calculation of the value in use is 6.0%

<sup>2. &</sup>quot;Other" mainly includes exchange differences.

to 10.0%, and that of the pre-tax discount rate is 7.7% to 14.3%.

As a result of the impairment test, the Group recognised the following impairment losses for the years ended 31 March 2017 and 2018.

For the year ended 31 March 2017, impairment losses (or reversal of impairment losses) recognised for other intangible assets were ¥8,463 million, and details of the main items are as follows:

- (1) The Company recognised an impairment loss of ¥6,054 million, deeming the recoverable amount as zero, due to lower-than-expected profitability of patents for products sold in Japan. The recoverable amount represented the value in use, calculated based on discounted future cash flows.
- (2) The Company recognised an impairment loss of ¥4,000 million, deeming the recoverable amount as zero, due to the exercise of its right to terminate its

agreement with UMN Pharma Inc. and the discontinuation of development activities with respect to IPR&Ds for ASP7374 and ASP7373, cell culture based influenza vaccine programs that had been licensed from UMN Pharma Inc.

For the year ended 31 March 2018, impairment losses (or reversal of impairment losses) recognised for other intangible assets were ¥32,642 million, and details on the main item are as follows:

The Company recognised an impairment loss of \$27,548 million on IPR&D pertaining to IMAB362, resulting from the acquisition of Ganymed Pharmaceuticals AG, due to reviewing development project plans. The recoverable amount represented the value in use, calculated based on discounted future cash flows. The post-tax and pre-tax discount rates used for the calculation of the value in use are 10.0% and 14.3%, respectively.

#### Significant intangible assets

Significant intangible assets recognised in the consolidated statement of financial position as of 31 March 2017 are mainly composed of the rights related to IMAB362 resulting from the acquisition of Ganymed Pharmaceuticals AG in 2016, the rights related to the research and development of enzalutamide (XTANDI) acquired through the licence agreement with Medivation, Inc., the rights related to the research and development of YM311/roxadustat acquired through the licence agreement with FibroGen, Inc., and the rights related to "Tarceva" resulting from the acquisition of OSI Pharmaceuticals, Inc. in 2010. The carrying amounts of those intangible assets were ¥84,476 million, ¥67,231 million, ¥51,656 million, and ¥44,698 million, respectively.

Significant intangible assets recognised in the consolidated statement of financial position as of 31 March 2018 are mainly composed of the rights related to fezolinetant resulting from the acquisition of Ogeda SA in 2017, the rights related to IMAB362 resulting from the

acquisition of Ganymed Pharmaceuticals AG in 2016, the rights related to the research and development of enzalutamide (XTANDI) acquired through the licence agreement with Medivation, Inc., and the rights related to the research and development of YM311/roxadustat acquired through the licence agreement with FibroGen, Inc. The carrying amounts of those intangible assets were ¥77,609 million, ¥64,017 million, ¥60,930 million and ¥51,656 million, respectively. The carrying amount of the rights related to fezolinetant resulting from the acquisition of Ogeda SA represents provisional fair value, as the allocation of the fair value of purchase consideration transferred had not been completed. For details, please refer to Note "37. Business Combinations".

For intangible assets already starting amortisation, the remaining amortisation period was 2 to 12 years in the year ended 31 March 2017 and 1 to 11 years in the year ended 31 March 2018. The intangible assets not yet being amortised are tested for impairment annually.

# 18. Deferred Taxes

The breakdown and movement of deferred tax assets and deferred tax liabilities are as follows:

# For the year ended 31 March 2017

_						(Millions of yen)
			Recognised in			
	As of	Recognised	other			As of
	1 April	in profit or	comprehensive	e Business		31 March
	2016	loss	income	combinations	Other	2017
Available-for-sale financial assets	¥(11,067)	¥ (263)	¥ 6,457	¥ –	¥ 66	¥ (4,807)
Retirement benefit assets and liabilities	10,448	315	(1,249)	_	(172)	9,343
Property, plant and equipment	2,506	(1,469)	_	_	(40)	996
Intangible assets	(47,540)	2,881	_	(25,806)	1,199	(69,266)
Accrued expenses	25,792	(1,572)	_	_	(214)	24,007
Inventories	52,116	3,843	_	_	(736)	55,223
Tax loss carry-forwards	8,637	(270)	_	6,954	(920)	14,401
Other	39,841	1,788	_	_	310	41,939
Total	¥ 80,733	¥ 5,253	¥ 5,208	¥(18,852)	¥ (506)	¥ 71,836

(Note) The increase in deferred tax assets and deferred tax liabilities due to business combinations reflected the acquisition of Ganymed Pharmaceuticals

AG. The movement in the year ended 31 March 2017 was retrospectively revised due to the completion of the purchase price allocation in the year ended 31 March 2018. For details on this business combination, please refer to Note "37. Business Combinations".

## For the year ended 31 March 2018

						(Millions of yen)
			Recognised in			
	As of	Recognised	other			As of
	1 April	in profit or	comprehensive	Business		31 March
	2017	loss	income	combinations	Other	2018
Available-for-sale financial assets	¥ (4,807)	¥ 73	¥(1,508)	¥ –	¥ (41)	¥ (6,283)
Retirement benefit assets and liabilities	9,343	809	(661)	_	63	9,553
Property, plant and equipment	996	1,376	_	(20)	132	2,484
Intangible assets	(69,266)	36,805	_	(26,615)	(2,303)	(61,380)
Accrued expenses	24,007	(4,452)	_	1	(433)	19,123
Inventories	55,223	7,556	_	3	967	63,749
Tax loss carry-forwards	14,401	(11,821)	_	1,406	386	4,372
Other	41,939	(2,371)	_	209	(584)	39,193
Total	¥ 71,836	¥ 27,975	¥(2,169)	¥(25,016)	¥(1,814)	¥ 70,812

(Note) The increases in deferred tax assets and deferred tax liabilities due to business combinations reflected the acquisitions of Ogeda SA, Mitobridge, Inc., and Universal Cells, Inc. For details on these business combinations, please refer to Note "37. Business Combinations".

Deductible temporary differences, tax loss carry-forwards, and unused tax credits for which no deferred tax asset is recognised are as follows:

		(Millions of yen)
	2017	2018
Deductible temporary differences	¥31,527	¥33,446
Tax loss carry-forwards	3,350	13,423
Unused tax credits	2,182	2,708
Total	¥37,059	¥49,577

(Note) The amounts for the year ended 31 March 2017 were retrospectively revised due to the completion of the purchase price allocation for Ganymed Pharmaceuticals AG in the year ended 31 March 2018.

The expiration date and amount of tax loss carry-forwards for which no deferred tax asset is recognised are as follows:

(Millions of yen) 2017 2018 Year 1 ¥ 632 72 Year 2 62 271 378 Year 3 356 Year 4 471 152 1,807 Year 5 or later 12,571 Total ¥3,350 ¥13,423

(Note) The amounts for the year ended 31 March 2017 were retrospectively revised due to the completion of the purchase price allocation for Ganymed Pharmaceuticals AG in the year ended 31 March 2018.

## 19. Other Financial Assets

The breakdown of other financial assets is as follows:

		(Millions of yen)
	2017	2018
Other financial assets (non-current)		
Financial assets at FVTPL	¥10,762	¥13,334
Loans and other financial assets	10,421	10,745
Allowance for doubtful accounts	(14)	(13)
Available-for-sale financial assets	40,428	43,308
Total other financial assets (non-current)	61,597	67,375
Other financial assets (current)		
Loans and other financial assets	13,554	13,517
Total other financial assets (current)	13,554	13,517
Total other financial assets	¥75,151	¥80,891

# 20. Other Assets

The breakdown of other assets is as follows:

	(Millions of yen		
	2017	2018	
Other non-current assets			
Long-term prepaid expenses	¥10,063	¥ 5,155	
Retirement benefit assets	2,372	2,544	
Other	720	673	
Total other non-current assets	13,154	8,372	
Other current assets			
Prepaid expenses	10,763	9,149	
Other	8,087	5,299	
Total other current assets	¥18,849	¥14,448	

# 21. Inventories

The breakdown of inventories is as follows:

	(Millions of yen		
	2017	2018	
Raw materials and supplies	¥ 36,225	¥ 39,302	
Work in progress	15,389	15,512	
Merchandise and finished goods	130,922	92,813	
Total	¥182,537	¥147,626	

The carrying amounts of inventories are measured at the lower of cost and net realisable value.

The cost of inventories recognised as an expense in "Cost of sales" for the years ended 31 March 2017 and 2018 amounted to ¥274,048 million and ¥237,717 million, respectively.

The write-down of inventories recognised as an expense for the years ended 31 March 2017 and 2018 amounted to ¥3,414 million and ¥6,737 million, respectively.

## 22. Trade and Other Receivables

The breakdown of trade and other receivables is as follows:

		(Millions of yen)
	2017	2018
Notes and accounts receivable	¥297,094	¥305,930
Other accounts receivable	44,792	48,711
Allowance for doubtful accounts	(9,806)	(9,848)
Total trade and other receivables	332,080	344,794
Non-current assets	22,263	25,282
Current assets	¥309,817	¥319,512

# 23. Cash and Cash Equivalents

The breakdown of cash and cash equivalents is as follows:

<u> </u>	(Millions of yen	
	2017	2018
Cash and deposits	¥331,801	¥328,669
Short-term investments (cash equivalents)	9,122	3,062
Cash and cash equivalents in the consolidated statement of financial position	340,923	331,731
Cash and cash equivalents in the consolidated statement of cash flows	¥340,923	¥331,731

#### 24. Assets Held for Sale

The breakdown of assets held for sale is as follows:

		(Millions of yen)
	2017	2018
Assets		
Property, plant and equipment		
Buildings and structures	¥—	¥ 7,789
Other tangible assets	_	164
Other	_	2,422
Total	¥-	¥10,374

Assets held for sale as of 31 March 2018 mainly represented facilities and leasehold rights connected with the research operations of Agensys, Inc., a U.S.

consolidated subsidiary. The Company completed the sale of those assets in April 2018.

# 25. Equity and Other Components of Equity

## (1) Share capital and capital surplus

The movement of the number of issued shares and share capital is as follows:

	Number of	Number of ordinary		
	authorised shares	issued shares	Share capital	Capital surplus
	(Thousands of shares)	(Thousands of shares)	(Millions of yen)	(Millions of yen)
As of 1 April 2016	9,000,000	2,221,823	¥103,001	¥176,903
Increase	_	_	_	266
Decrease	_	(68,000)	_	(78)
As of 31 March 2017	9,000,000	2,153,823	103,001	177,091
Increase	_	_	_	286
Decrease	_	(85,000)	_	(159)
As of 31 March 2018	9,000,000	2,068,823	¥103,001	¥177,219

(Note) Decrease in the number of ordinary issued shares during the years ended 31 March 2017 and 2018 resulted from the cancellation of treasury shares.

## (2) Treasury shares

The movement of treasury shares is as follows:

	Number of shares	Amount
	(Thousands of shares)	(Millions of yen)
As of 1 April 2016	96,844	¥ 157,111
Increase	60,513	92,193
Decrease	(68,540)	(111,096)
As of 31 March 2017	88,817	138,207
Increase	89,379	130,712
Decrease	(85,526)	(132,969)
As of 31 March 2018	92,670	¥ 135,951

## (3) Other components of equity

## Subscription rights to shares

The Company had adopted share option plans through the year ended 31 March 2015, and has issued subscription rights to shares under the former Commercial Code and the Companies Act of Japan. Contract conditions and amounts are described in Note "27. Share-based Payment".

## Foreign currency translation adjustments

These amounts represent foreign currency translation differences that occurred when consolidating financial statements of foreign subsidiaries prepared in a foreign currency.

#### Fair value movements on available-for-sale financial assets

These amounts represent valuation differences between the fair value and acquisition cost of available-for-sale financial assets, which are measured at fair values.

## 26. Dividends

# For the year ended 31 March 2017

#### (1) Dividends paid

Resolution	Class of shares	Amount of dividends (Millions of yen)	Dividends per share (Yen)	Record date	Effective date
Ordinary general meeting of	Ordinary			31 March	21 June
shareholders held on 20 June 2016	shares	¥34,007	¥16.00	2016	2016
Board of directors meeting	Ordinary			30 September	1 December
held on 28 October 2016	shares	36,134	17.00	2016	2016

<sup>(</sup>Notes) 1. The amount of dividends approved by resolution of the ordinary general meeting of shareholders on 20 June 2016 includes dividends of ¥7 million corresponding to the Company's shares held in the executive compensation BIP trust.

<sup>2.</sup> The amount of dividends approved by resolution of the board of directors meeting on 28 October 2016 includes dividends of ¥15 million corresponding to the Company's shares held in the executive compensation BIP trust.

(2) Dividends whose record date is in the fiscal year ended 31 March 2017 but whose effective date is in the following fiscal year are as follows:

Population	Class of shares	Amount of dividends (Millions of yen)	Dividends per share (Yen)	Record date	Effective date
Resolution Ordinary general meeting of	Ordinary	(Willions of yell)	(Tell)	31 March	20 June
shareholders held on 19 June 2017	shares	¥35,120	¥17.00	2017	2017

<sup>(</sup>Note) The amount of dividends above includes dividends of ¥15 million corresponding to the Company's shares held in the executive compensation BIP trust.

## For the year ended 31 March 2018

(1) Dividends paid

Resolution	Class of shares	Amount of dividends (Millions of yen)	Dividends per share (Yen)	Record date	Effective date
Ordinary general meeting of	Ordinary			31 March	20 June
shareholders held on 19 June 2017	shares	¥35,120	¥17.00	2017	2017
Board of directors meeting	Ordinary			30 September	1 December
held on 31 October 2017	shares	36,552	18.00	2017	2017

- (Notes) 1. The amount of dividends approved by resolution of the ordinary general meeting of shareholders on 19 June 2017 includes dividends of ¥15 million corresponding to the Company's shares held in the executive compensation BIP trust.
  - 2. The amount of dividends approved by resolution of the board of directors meeting on 31 October 2017 includes dividends of ¥23 million corresponding to the Company's shares held in the executive compensation BIP trust.
- (2) Dividends whose record date is in the fiscal year ended 31 March 2018 but whose effective date is in the following fiscal year are as follows:

		Amount of dividends	Dividends per share		
Resolution	Class of shares	(Millions of yen)	(Yen)	Record date	Effective date
Ordinary general meeting of	Ordinary			31 March	18 June
shareholders held on 15 June 2018	shares	¥35,594	¥18.00	2018	2018

<sup>(</sup>Note) The amount of dividends above includes dividends of ¥23 million corresponding to the Company's shares held in the executive compensation BIP trust.

# 27. Share-based Payment

## (1) Performance-linked Stock Compensation Scheme

# (i) Outline of the Performance-linked Stock Compensation Scheme

From the fiscal year ended 31 March 2016, the Group has introduced a Performance-linked Stock Compensation Scheme for directors (excluding outside directors and directors who are Audit & Supervisory Committee members) and corporate executives for the purpose of increasing their awareness of contributing to the sustainable growth in business results and corporate value.

The Scheme employs a framework referred to as the executive compensation BIP (Board Incentive Plan) trust (hereinafter the "BIP Trust") for directors and corporate executives other than those residing overseas. The BIP Trust acquires the Company's shares and delivers those shares to directors and other executives based on the

level of attainment of the medium-term management targets. The Performance-linked Stock Compensation Scheme under which the Company's shares are delivered from the BIP Trust is accounted for as an equity-settled share-based payment transaction.

In addition, the Company will provide cash benefits determined based on stock price of the Company to corporate executives residing overseas based on the level of attainment of the medium-term management targets. The Performance-linked Stock Compensation Scheme that provides cash benefits from the Company is accounted for as a cash-settled share-based payment transaction.

## (ii) Expenses recognised in the consolidated statement of income

		(Millions of yen)
	2017	2018
Total expenses recognised for the Performance-linked		
Stock Compensation Scheme	¥290	¥304

# (iii) Measurement approach for the fair value of the Company's shares granted during the fiscal year based on the Performance-linked Stock Compensation Scheme

The weighted average fair value of the Company's shares granted during the period is calculated based on the following assumptions.

	2017	2018
Share price at the grant date	1,603.5 yen	1,383.0 yen
Vesting period (Note 1)	3 years	3 years
Expected annual dividend (Note 2)	34 yen/share	36 yen/share
Discount rate (Note 3)	(0.3)%	(0.1)%
Weighted average fair value	1,501 yen	1,275 yen

(Notes) 1. Refers to the number of years from the grant date until the shares are expected to be delivered.

- 2. Calculated based on the latest dividends paid.
- 3. Based on the yield on Japanese government bonds corresponding to the vesting period.

## (2) Share option plans

## (i)Outline of share option plans

The Company had adopted share option plans through the year ended 31 March 2015, and has granted share options to directors and corporate executives of the Company. The purpose of share option plans is to improve the sensitivity to the share price and the Group's financial results and also increase the value of the Group by motivating the members to whom share options are granted.

After obtaining approval at the meeting of shareholders, share options are granted as subscription

rights to shares to individuals approved at the Company's board of directors meeting.

Holders of subscription rights to shares can exercise their share subscription rights only from the day following the date of resignation from their position as director or corporate executive of the Company.

Share options not exercised during the exercise period defined in the allocation contract will be forfeited.

The Company accounts for those share option plans as equity-settled share-based payment transactions.

## (ii) Movement of the number of share options outstanding and their weighted average exercise price

	2017		2018	
	Weighted average		Weighted average	
	exercise price	Number of	exercise price	Number of
	(Yen)	shares	(Yen)	shares
Outstanding, beginning of the period	¥1	3,022,900	¥1	2,531,500
Granted	_	_	_	_
Exercised	1	(491,400)	1	(423,500)
Forfeited or expired	_	_	_	_
Outstanding, end of the period	1	2,531,500	1	2,108,000
Options exercisable, end of the period	¥1	2,531,500	¥1	2,108,000

<sup>(</sup>Notes) 1. The number of share options is presented as the number of underlying shares.

<sup>2.</sup> The weighted average share prices of share options at the time of exercise during the years ended 31 March 2017 and 2018 are ¥1,525 and ¥1,415, respectively.

#### (iii) Expiration dates and exercise prices of share options outstanding at the end of the period

	Exercise price		Number of shares	
	Expiration date	per share (Yen)	2017	2018
Granted on August 2005	24 June 2025	¥1	46,000	46,000
Granted on February 2007	27 June 2026	1	56,500	16,500
Granted on August 2007	26 June 2027	1	121,500	27,500
Granted on September 2008	24 June 2028	1	129,000	50,500
Granted on July 2009	23 June 2029	1	263,500	143,000
Granted on July 2010	23 June 2030	1	396,000	332,000
Granted on July 2011	20 June 2031	1	485,000	460,500
Granted on July 2012	20 June 2032	1	498,000	498,000
Granted on July 2013	19 June 2033	1	318,500	316,500
Granted on July 2014	18 June 2034	1	217,500	217,500
Total	·	_	2,531,500	2,108,000

(Note) There are vesting conditions in which share subscription rights are vested according to the service record over approximately one year from the grant date of the share option to the vesting date.

## 28. Retirement Benefits

The Group, excluding a part of foreign subsidiaries, offers post-employment benefits such as defined benefit plans and defined contribution plans. Among the defined

benefit plans offered, the defined benefit plan adopted in Japan is a major one, accounting for approximately 80% of the total defined benefit obligations.

#### (i) Defined benefit plan adopted in Japan as post-employment benefit

The Company and its domestic subsidiaries offer corporate pension plans and retirement lump-sum payment plans as defined benefit plans.

The benefits of the defined benefit plan are determined based on the base compensation calculated by accumulated points earned by the time of retirement and promised rate of return based on the yield of 10 year government bonds. Also, the option of receiving benefits in the form of a pension is available for plan participants with 15 years or more enrollments.

Defined benefit plans are administered by the Astellas Corporate Pension Fund. Directors of the pension fund are jointly liable for damages to the fund due to their neglect of duties about management of the funds.

Contributions of the employer are made monthly and also determined as 4.0% of standard salary, which is calculated based on the estimate of the points granted during a year to each participant. When the plan assets are lower than the minimum funding standard at the end of the period, the employer will make additional contributions.

Defined benefit plans are exposed to actuarial risks. The Astellas Corporate Pension Fund assigns staff with professional knowledge and expertise about the composition of plan asset to determine the asset mix ratio and manages risks by monitoring on a quarterly basis.

# (ii) Defined benefit plans of overseas subsidiaries as post-employment benefits

Among foreign subsidiaries, ones located in the United Kingdom, Germany, Ireland, and some other countries offer defined benefit plans as post-employment benefits.

Assets and liabilities of defined benefit plans recognised in the consolidated statement of financial position are as follows:

Δs	of	31	Mai	rch	201	7

				(Millions of yen)
	Pension a	and lump-sum	payment	
	Japan	Overseas	Total	Other
Present value of defined benefit obligations	¥ 123,118	¥ 30,816	¥ 153,934	¥2,608
Fair value of plan assets	(111,926)	(10,374)	(122,300)	_
Net defined benefit liability (asset)	11,192	20,442	31,634	2,608
Amounts in the consolidated statement of financial				
position				
Assets (other non-current assets)	(2,372)	_	(2,372)	_
Liabilities (retirement benefit liabilities)	¥ 13,564	¥ 20,442	¥ 34,006	¥2,608

#### As of 31 March 2018

(Millions of yen)

				,
	Pension a	Pension and lump-sum payment		
	Japan	Overseas	Total	Other
Present value of defined benefit obligations	¥ 123,513	¥ 36,386	¥ 159,899	¥1,787
Fair value of plan assets	(114,280)	(13,278)	(127,557)	_
Net defined benefit liability (asset)	9,233	23,109	32,342	1,787
Amounts in the consolidated statement of financial				
position				
Assets (other non-current assets)	(2,544)	_	(2,544)	_
Liabilities (retirement benefit liabilities)	¥ 11,777	¥ 23,109	¥ 34,886	¥1,787

The movement of the present value of defined benefit obligations is as follows:

_				(Millions of yen)
	Pension a	and lump-sum p	ayment	
_	Japan	Overseas	Total	Other
Balance at 1 April 2016	¥125,717	¥31,128	¥156,845	¥2,788
Current service cost	5,110	919	6,029	255
Interest cost	558	637	1,195	59
Remeasurements of defined benefit obligations				
-actuarial gains arising from changes in				
demographic assumptions	(5)	(360)	(365)	(6)
-actuarial (gains)/losses arising from changes in				
financial assumptions	(1,722)	850	(873)	1
-other	(139)	271	131	(100)
Past service cost, and gains and losses arising from				
settlements	_	(28)	(28)	_
Contributions to the plan by plan participants	_	72	72	_
Payments from the plan	(6,400)	(768)	(7,168)	(51)
Effect of changes in foreign exchange rates	_	(1,905)	(1,905)	(337)
Balance at 31 March 2017	123,118	30,816	153,934	2,608
Current service cost	4,875	1,048	5,923	218
Interest cost	1,001	677	1,677	61
Remeasurements of defined benefit obligations				
-actuarial gains arising from changes in				
demographic assumptions	(5)	(144)	(149)	(2)
-actuarial (gains)/losses arising from changes in				
financial assumptions	1,915	1,023	2,937	(126)
-other	(720)	466	(254)	(186)
Past service cost, and gains and losses arising from				
settlements	_	_	_	(431)
Contributions to the plan by plan participants	_	79	79	_
Payments from the plan	(6,671)	(1,082)	(7,753)	(43)
Effect of changes in foreign exchange rates	_	3,504	3,504	(310)
Balance at 31 March 2018	¥123,513	¥36,386	¥159,899	¥1,787

The movement of fair value of plan assets is as follows:

				(Millions of yen)	
	Pension a	Pension and lump-sum payment			
	Japan	Overseas	Total	Other	
Balance at 1 April 2016	¥111,799	¥ 9,820	¥121,620	¥—	
Interest income	494	211	706	_	
Remeasurements of the fair value of the plan					
assets					
-return on plan assets	2,080	525	2,605	_	
-actuarial gains/(losses) arising from changes					
in financial assumptions	411	(17)	394	_	
Contributions to the plan					
-by employer	2,756	648	3,404	_	
-by plan participants	_	63	63	_	
Payments from the plan	(5,614)	(198)	(5,812)	_	
Effect of changes in foreign exchange rates	_	(679)	(679)	_	
Balance at 31 March 2017	111,926	10,374	122,300	_	
Interest income	905	241	1,146	_	
Remeasurements of the fair value of the plan					
assets					
-return on plan assets	4,637	(11)	4,626	_	
-actuarial losses arising from changes in					
financial assumptions	(111)	(25)	(135)	_	
Contributions to the plan					
-by employer	2,746	901	3,647	_	
-by plan participants	_	70	70	_	
Payments from the plan	(5,824)	(333)	(6,157)	_	
Effect of changes in foreign exchange rates	_	2,060	2,060	_	
Balance at 31 March 2018	¥114,280	¥13,278	¥127,557	¥-	

The Group expects to contribute ¥3,852 million to its defined benefit plans in the fiscal year ending 31 March 2019.

The breakdown of the fair value of plan assets is as follows:

		(Millions of yen)
	2017	2018
Japan		
Equity	¥ 22,724	¥ 21,498
Bonds	37,396	36,292
Cash and other investments	51,806	56,489
Total	111,926	114,280
Overseas		
Equity	4,337	4,267
Bonds	2,420	2,936
Cash and other investments	3,617	6,075
Total	10,374	13,278
Total fair value of plan assets	¥122,300	¥127,557

#### (i) Japanese plan assets

Equity comprises mainly investment trust funds and it is categorised as Level 2 within the fair value hierarchy. The fair values of bonds are measured using quoted prices for identical or similar assets in markets that are

not active, and they are categorised as Level 2 within the fair value hierarchy. Cash and other investments include alternative investments.

# (ii) Overseas plan assets

Equity is mainly composed of investments with quoted prices in active markets or with measured value using quoted prices for identical or similar assets in markets that are not active, and they are mainly categorised as Level 1 or Level 2 within the fair value hierarchy. The

fair values of bonds are measured using quoted prices for identical or similar assets in markets that are not active, and they are categorised as Level 2 within the fair value hierarchy. Cash and other investments include alternative investments.

Significant actuarial assumptions and sensitivity analysis for each significant actuarial assumption are as follows:

	2017	2018
Discount rate (%)		
Japan	0.6%-0.8%	0.5%-0.7%
Overseas	1.8%-2.5%	1.7%-2.5%

The impact of a 0.5% increase or decrease in the discount rate as significant actuarial assumption used on the defined benefit obligations as of 31 March 2018 would result in a ¥11,659 million decrease and ¥13,128 million increase, respectively, in the defined benefit obligation.

The sensitivity analysis does not consider correlations between assumptions, assuming that all

other assumptions are held constant. In practice, changes in some of the assumptions may occur in a correlated manner. When calculating the sensitivity of the defined benefit obligations, the same method has been applied as calculating the defined benefit obligations recognised in the consolidated statement of financial position.

The weighted-average duration of the defined benefit obligations is as follows:

	2017	2018
Japan	13.7 years	13.6 years
Overseas	18.6 years	18.4 years

## 29. Provisions

The movement of provisions for the year ended 31 March 2017 is as follows:

				(Millions of yen)
	Trade-related	Asset retirement		
	provisions	obligations	Other	Total
Balance at 1 April 2016	¥ 83,531	¥1,948	¥11,462	¥ 96,941
Increase during the year	81,742	7	3,648	85,397
Decrease due to intended use	(71,488)	(7)	(9,282)	(80,777)
Reversal during the year	(2,429)	_	(634)	(3,063)
Other	2,378	(11)	646	3,013
Balance at 31 March 2017	93,734	1,938	5,839	101,511
Non-current	2,214	1,938	769	4,921
Current	91,520	_	5,070	96,589
Total provisions	¥ 93,734	¥1,938	¥ 5,839	¥101,511

The movement of provisions for the year ended 31 March 2018 is as follows:

				(Millions of yen)
	Trade-related	Asset retirement		
	provisions	obligations	Other	Total
Balance at 1 April 2017	¥ 93,734	¥1,938	¥ 5,839	¥101,511
Increase during the year	110,251	5	9,944	120,201
Decrease due to intended use	(81,511)	(1)	(3,261)	(84,772)
Reversal during the year	(947)	_	(1,518)	(2,465)
Other	(3,155)	24	(221)	(3,352)
Balance at 31 March 2018	118,372	1,966	10,783	131,122
Non-current	1,931	1,966	993	4,891
Current	116,441	_	9,791	126,231
Total provisions	¥118,372	¥1,966	¥10,783	¥131,122

Details of provisions are as follows:

# (i) Trade-related provisions

The Group recognises provisions for expenditures expected to be incurred after the end of the period related to sales rebates, discounts, Medicare and Medicaid of the United States, and other price

adjustments to customers, based on the conditions of contracts and past experience.

The outflow of economic benefits is expected within one year from the end of the reporting period.

# (ii) Asset retirement obligations

The Group recognises asset retirement obligations based on past performance in order to provide for the restoration of rented offices.

The outflow of economic benefits is expected more than one year after the end of the reporting period.

# 30. Other Financial Liabilities

The breakdown of other financial liabilities is as follows:

		(Millions of yen)
	2017	2018
Other financial liabilities (non-current)		
Financial liabilities at FVTPL		
Contingent consideration	¥27,253	¥48,226
Financial liabilities measured at amortised cost		
Finance lease liabilities	1,136	904
Other	_	293
Total other financial liabilities (non-current)	¥28,389	¥49,422
Other financial liabilities (current)		
Financial liabilities at FVTPL		
Forward foreign exchange contracts	¥ 626	¥ 481
Contingent consideration	1,196	5,946
Financial liabilities measured at amortised cost		
Finance lease liabilities	499	444
Other	671	688
Total other financial liabilities (current)	¥ 2,992	¥ 7,559
Total other financial liabilities	¥31,381	¥56,981

The maturity and the present value of finance lease liabilities are as follows:

		(Millions of yen		
	2017	2018		
Minimum lease payments				
Not later than one year	¥ 499	¥ 444		
Later than one year and not later than five years	1,110	886		
Later than five years	26	18		
Present value of finance lease liabilities	¥1,635	¥1,348		

16,443

4,156

¥106,548

(Millions of yen)

18,020

7,946

¥121,737

#### 31. Other Liabilities

**Deferred income** 

Other

The breakdown of other liabilities is as follows:

2017 2018 Other non-current liabilities Other long-term employee benefits ¥ 17,727 ¥ 18,759 **Deferred income** 34,153 22,301 Other 1,648 6,309 Total other non-current liabilities ¥ 53,528 ¥ 47,370 Other current liabilities **Accrued bonuses** ¥ 30,665 ¥ 29,991 11,792 Accrued paid absences 12,017 Other accrued expenses 43,493 53,763

(Note) Deferred income under other non-current liabilities and deferred income under other current liabilities include deferred income of ¥30,593 million and ¥14,877 million, respectively, in the year ended 31 March 2017, and ¥19,584 million and ¥12,539 million, respectively, in the year ended 31 March 2018, in connection with the transfer of the global dermatology business to LEO Pharma A/S.

# 32. Trade and Other Payables

Total other current liabilities

The breakdown of trade and other payables is as follows:

		(Millions of yen)
	2017	2018
Accounts payable-trade	¥115,188	¥ 75,683
Other payables	68,078	68,741
Total trade and other payables	¥183,266	¥144,424
Non-current	¥ 440	¥ 3,515
Current	182,826	140,909

## 33. Financial Instruments

## (1) Capital management

The Group's capital management principle is to maintain an optimal capital structure by improving capital efficiency and ensuring sound and flexible financial conditions in order to achieve sustained improvement in the enterprise value, which will lead to improved return to shareholders.

The Group monitors financial indicators in order to maintain an optimal capital structure. Credit ratings are monitored for financial soundness and flexibility, and so is return on equity attributable to owners of the parent (ROE) for capital efficiency.

The Group is not subject to material capital regulation.

# (2) Classification of financial assets and financial liabilities

The breakdown of financial assets and financial liabilities is as follows:

		(Millions of yen)
	2017	2018
Financial assets		
Financial assets at FVTPL		
Other	¥ 10,762	¥ 13,334
Loans and receivables		
Trade and other receivables	332,080	344,794
Loans and other financial assets	23,961	24,249
Available-for-sale financial assets	40,428	43,308
Cash and cash equivalents	340,923	331,731
Total financial assets	748,153	757,416
Financial liabilities		
Financial liabilities at FVTPL		
Forward foreign exchange contracts	¥ 626	¥ 481
Contingent consideration	28,450	54,172
Financial liabilities measured at amortised cost		
Trade and other payables	183,266	144,424
Other	2,306	2,328
Total financial liabilities	¥214,647	¥201,405

<sup>(</sup>Notes) 1. Financial assets at FVTPL, loans and other financial assets, and available-for-sale financial assets are included in "Other financial assets" in the consolidated statement of financial position.

# (3) Financial risk management policy

The Group is exposed to financial risks such as credit risks, liquidity risks, and foreign exchange risks in operating businesses, and it manages risks based on its policy to mitigate them.

The Group limits the use of derivatives to transactions for the purpose of hedging financial risks and does not use derivatives for speculation purposes.

<sup>2.</sup> Financial liabilities at FVTPL and financial liabilities at amortised cost are included in "Other financial liabilities" in the consolidated statement of financial position.

#### (i) Credit risk

## (a) Credit risk management

Receivables, such as trade receivables, resulting from the business activities of the Group are exposed to the customer's credit risk. This risk is managed by grasping the financial condition of the customer and monitoring the trade receivables balance. Also, the Group reviews collectability of trade receivables depending on the credit conditions of customers and recognises an allowance for doubtful accounts as necessary.

Securities held by the Group are exposed to the issuer's credit risk, and deposits are exposed to the credit risk of banks. Also, derivative transactions that the Group conducts in order to hedge financial risks are exposed to the credit risk of the financial institutions which are counterparties of those transactions. In regard to securities transactions and deposit transactions in fund management, the Group only deals with banks and issuers with certain credit ratings and manages investments within the defined period and credit limit, in accordance with Global Cash Investment Policy. In addition, regarding derivative transactions, the Group only deals with financial institutions with certain credit ratings in accordance with Astellas Global Treasury Policy.

## (b) Concentrations of credit risk

In Japan, like other pharmaceutical companies, the Group sells its products through a small number of wholesalers. Sales to the four largest wholesalers accounted for approximately 75% of the Group's sales in Japan, and the amount of trade receivables due from those four wholesalers are ¥106,464 million at 31 March 2017 and ¥94,410 million at 31 March 2018.

# (c) Maximum exposure to credit risk

Other than guaranteed obligations, the Group's maximum exposure to credit risks without taking into account any collateral held or other credit enhancements is the carrying amount of financial instruments less impairment losses in the consolidated statement of financial position. The Group's maximum exposure to credit risks of guaranteed obligations as of 31 March 2017 and 2018 were ¥444 million and ¥343 million, respectively.

#### (d) Collateral

The Group has securities and deposits received as collateral for certain trade and other receivables. The carrying amount of securities held as collateral is ¥1,420 million at 31 March 2018 (¥1,088 million at 31 March 2017), and the carrying amount of deposits received is ¥72 million at 31 March 2018 (¥72 million at 31 March 2017).

The analysis of aging of financial assets that are past due but not impaired is as follows:

							(Millions of yen)
			Past due but	not impaired			
	Neither past due nor impaired	Within three months	Between three months and six months	Between six months and one year	Over one year	Allowance for doubtful accounts	Total
Balance at 31 March 2017							
Trade and other							
receivables	¥296,263	¥12,563	¥1,187	¥1,076	¥858	¥(1,250)	¥310,697
Loans and other							
financial assets	23,955	1		_	6	_	23,961
Total	¥320,218	¥12,564	¥1,187	¥1,076	¥864	¥(1,250)	¥334,658
Balance at 31 March 2018							
Trade and other							
receivables	¥305,165	¥12,570	¥1,253	¥1,250	¥914	¥ (483)	¥320,669
Loans and other							
financial assets	24,241	1	0	_	6	_	24,249
Total	¥329,406	¥12,571	¥1,254	¥1,250	¥920	¥ (483)	¥344,917

Financial assets that are individually determined to be impaired are as follows:

_			(Milli	ons of yen)
	2017	,	20	18
Trade and other receivables (gross)	¥29	,939	¥;	33,489
Allowance for doubtful accounts	8)	3,556)		(9,365)
Trade and other receivables (net)	¥21	,383	¥ź	24,125
Loans and other financial assets (gross)	¥	14	¥	13
Allowance for doubtful accounts		(14)		(13)
Loans and other financial assets (net)	¥	_	¥	_

The movement of the allowance for doubtful accounts is as follows:

		(Millions of yen)
	2017	2018
Balance at the beginning of the year	¥ 2,873	¥9,820
Increase during the year	9,704	1,629
Decrease due to intended use	(229)	(961)
Reversal during the year	(2,351)	(748)
Other	(176)	120
Balance at the end of the year	¥ 9,820	¥9,861

# (ii) Liquidity risk

# Liquidity risk management

The Group is exposed to liquidity risk that the Group might have difficulty settling financial obligations. However, the Group is maintaining the liquidity on hand that enables the Group to meet the assumed repayment

of financial obligations and respond flexibly to strategic investment opportunities. Also, the balance is reported monthly to the Chief Financial Officer (CFO).

Financial liabilities by maturity date are as follows:

#### As of 31 March 2017

										(Millions of yen)
							Between	Between	Between	
	Ca	rrying	Con	tractual	Withi	n six	six months	one year and	two years	Over
	an	nount	cas	h flows	mon	ths	and one year	two years	and five years	five years
Financial liabilities at FVTPL										
Forward foreign exchange										
contracts	¥	626	¥	626	¥	_	¥ 626	¥ —	¥ —	¥ —
Subtotal		626		626		_	626	_	_	_
Financial liabilities measured										
at amortised cost										
Trade and other payables	18	3,266	18	3,266	181,	507	1,319	313	127	_
Other		2,306		2,306		927	245	405	703	26
Subtotal	18	5,571	18	5,571	182,	433	1,564	718	830	26
Total	¥18	6,197	¥18	6,197	¥182,	433	¥2,190	¥718	¥830	¥26
							Maximum		Between	
					Carry	/ing	payment	Within one	one year	Over
					amo	unt	amount	year	and five years	five years
Contingent consideration					¥28,	450	¥103,019	¥1,198	¥14,543	¥13,241

#### As of 31 March 2018

												(Millions	of yen)
							Between	Betwee	n	Betwe	en		
	Carr	ying	Con	tractual	Withi	n six	six months	one year	and	two ye	ears	Ov	er
	amo	ount	cas	h flows	mon	iths	and one year	two yea	's	and five	years	five y	ears
Financial liabilities at FVTPL													
Forward foreign exchange													
contracts	¥	481	¥	481	¥	_	¥481	¥	_	¥	_	¥	_
Subtotal		481		481		_	481		_		_		_
Financial liabilities measured													
at amortised cost													
Trade and other payables	144	,424	14	4,424	140	,677	232	42	21	1,	313	1	,780
Other	2	,328		2,328		925	209	38	34		511		299
Subtotal	146	,752	14	6,752	141	,603	441	80	)4	1,	824	2	,079
Total	¥147	,232	¥14	7,232	¥141	,603	¥922	¥80	)4	¥1,	824	¥2	,079

		Maximum		Between	
	Carrying	payment	Within one	one year	Over
	amount	amount	year	and five years	five years
Contingent consideration	¥54,172	¥172,969	¥5,981	¥40,130	¥9,756

# (iii) Foreign exchange risk

## Foreign exchange risk management

The Group operates globally and the Group's business results and financial position are exposed to foreign exchange risks.

The Group's long-term basic policy is to mitigate the foreign exchange risks by controlling the amount of the Group's net assets denominated in foreign currencies to the level corresponding to the business scale of each area. In the short term, the Group uses derivatives such as forward foreign exchange contracts to reduce the impact of exchange rate fluctuations arising from import and export transactions denominated in foreign

currencies. Also, the balance of derivative transactions is reported monthly to the CFO.

## Foreign exchange sensitivity analysis

The financial impact on profit before tax for the years ended 31 March 2017 and 2018 in the case of a 10% appreciation of Japanese yen, which is the Company's functional currency, against the U.S. dollar and euro is as follows.

Also, it is based on the assumption that currencies other than the ones used for the calculation do not fluctuate and other change factors are held constant.

(Millions of yen)

		, ,
	2017	2018
Profit before tax		
U.S. dollar	¥ (34)	¥(908)
Euro	(745)	329

(Note) The above negative amounts represent the negative impact on profit before tax in the event of a 10% appreciation in Japanese yen.

#### (4) Fair values of financial instruments

#### (i) Fair value calculation of financial instruments

#### Financial assets at FVTPL

Financial assets at FVTPL comprise mainly debt securities and forward foreign exchange contracts. The fair value of those financial instruments is measured based on prices provided by counterparty financial institutions.

#### Loans and receivables

The carrying amount approximates fair value due to the short period of settlement terms.

#### Available-for-sale financial assets

The fair value of marketable securities is based on quoted market prices at the end of the period. The fair value of unquoted equity shares is measured mainly based on the discounted cash flows.

## Cash and cash equivalents

The carrying amount approximates fair value due to the short maturities of the instruments.

#### Financial liabilities at FVTPL

Financial liabilities at FVTPL comprise contingent consideration for business combinations and forward foreign exchange contracts.

The fair value of contingent consideration for business combinations is calculated based on the estimated success probability of development activities and the time value of money.

The fair value of forward foreign exchange contracts is measured based on prices provided by counterparty financial institutions.

#### Financial liabilities measured at amortised cost

Financial liabilities measured at amortised cost comprise trade and other payables and other financial liabilities. The carrying amount approximates fair value due to the short period of settlement terms.

# (ii) Financial instruments measured at fair value on a recurring basis

#### Fair value hierarchy

The levels of the fair value hierarchy are as follows:

- Level 1: Fair value measured using quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2: Fair value measured using inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly; and

 Level 3: Fair value measured using significant unobservable inputs for the assets or liabilities.

The level of the fair value hierarchy is determined based on the lowest level of significant input used for the measurement of fair value.

The Group accounts for transfers between levels of the fair value hierarchy as if they occurred at the end of each quarter. The breakdown of financial assets and liabilities measured at fair value on a recurring basis, including their levels in the fair value hierarchy, is as follows:

## As of 31 March 2017

				(Millions of yen)
	Level 1	Level 2	Level 3	Total
Financial assets				
Financial assets at FVTPL				
Other	¥ —	¥7,864	¥ 2,897	¥10,762
Subtotal	_	7,864	2,897	10,762
Available-for-sale financial assets				
Quoted equity shares	26,170	_	_	26,170
Unquoted equity shares	_	_	14,258	14,258
Other equity securities	_	_	0	0
Subtotal	26,170	_	14,258	40,428
Total financial assets	26,170	7,864	17,156	51,190
Financial liabilities				_
Financial liabilities at FVTPL				
Forward foreign exchange contracts	_	626	_	626
Contingent consideration	_	_	28,450	28,450
Subtotal	_	626	28,450	29,076
Total financial liabilities	¥ -	¥ 626	¥28,450	¥29,076

<sup>(</sup>Note) Financial assets at FVTPL and available-for-sale financial assets, and financial liabilities at FVTPL are included in "Other financial assets" and "Other financial liabilities" in the consolidated statement of financial position, respectively.

## As of 31 March 2018

				(Millions of yen)
	Level 1	Level 2	Level 3	Total
Financial assets				
Financial assets at FVTPL				
Other	¥ —	¥9,197	¥ 4,137	¥13,334
Subtotal	_	9,197	4,137	13,334
Available-for-sale financial assets				
Quoted equity shares	28,732	_	_	28,732
Unquoted equity shares	_	_	14,576	14,576
Other equity securities	_	_	0	0
Subtotal	28,732		14,576	43,308
Total financial assets	28,732	9,197	18,714	56,643
Financial liabilities				
Financial liabilities at FVTPL				
Forward foreign exchange contracts	_	481	_	481
Contingent consideration	_	_	54,172	54,172
Subtotal	_	481	54,172	54,653
Total financial liabilities	¥ —	¥ 481	¥54,172	¥54,653

<sup>(</sup>Note) Financial assets at FVTPL and available-for-sale financial assets, and financial liabilities at FVTPL are included in "Other financial assets" and "Other financial liabilities" in the consolidated statement of financial position, respectively.

The movement of fair value of financial instruments categorised within Level 3 of the fair value hierarchy is as follows:

# For the year ended 31 March 2017

## 1. Financial assets

_			(Millions of yen)
	Financial assets at FVTPL	Available-for- sale financial assets	Total
Balance at 1 April 2016	¥2,005	¥13,861	¥15,866
Realised or unrealised gains (losses)			
Recognised in profit or loss (Note)	(60)	(150)	(211)
Recognised in other comprehensive income	_	280	280
Purchases, issues, sales, and settlements			
Purchases	952	482	1,434
Sales	_	(10)	(10)
Other	1	(204)	(203)
Balance at 31 March 2017	¥2,897	¥14,258	¥17,156
Gains or losses recognised during the year in profit or loss			
attributable to the change in unrealised gains or losses relating			
to those assets held at the end of the period (Note)	¥ (60)	¥ (135)	¥ (196)

(Note) This is included in "Finance income" and "Finance expense" in the consolidated statement of income.

# 2. Financial liabilities

	(Millions of yen)
	Financial liabilities at FVTPL
Balance at 1 April 2016	¥ -
Realised or unrealised gains (losses)	
Recognised in profit or loss (Note)	(484)
Business combinations	28,934
Balance at 31 March 2017	¥28,450
Gains or losses recognised during the year in profit or loss	
attributable to the change in unrealised gains or losses relating	
to those assets held at the end of the period (Note)	¥ (484)

(Note) This is included in "Other income" and "Other expense" in the consolidated statement of income.

# For the year ended 31 March 2018

# 1. Financial assets

			(Millions of yen)
	Financial assets at FVTPL	Available-for- sale financial assets	Total
Balance at 1 April 2017	¥2,897	¥14,258	¥17,156
Realised or unrealised gains (losses)			
Recognised in profit or loss (Note)	(332)	(450)	(782)
Recognised in other comprehensive income	_	345	345
Purchases, issues, sales, and settlements			
Purchases	1,577	693	2,269
Sales	_	(5)	(5)
Other	(4)	(265)	(269)
Balance at 31 March 2018	¥4,137	¥14,576	¥18,714
Gains or losses recognised during the year in profit or loss			
attributable to the change in unrealised gains or losses relating			
to those assets held at the end of the period (Note)	¥ (332)	¥ (452)	¥ (784)

(Note) This is included in "Finance income" and "Finance expense" in the consolidated statement of income.

# 2. Financial liabilities

	(Millions of yen)
	Financial liabilities at FVTPL
Balance at 1 April 2017	¥28,450
Realised or unrealised gains (losses)	
Recognised in profit or loss (Note)	2,889
Business combinations	22,958
Other	(125)
Balance at 31 March 2018	¥54,172
Gains or losses recognised during the year in profit or loss	
attributable to the change in unrealised gains or losses relating	
to those assets held at the end of the period (Note)	¥ 2,889

(Note) This is included in "Other income" and "Other expense" in the consolidated statement of income.

# Financial Information and Data

The financial assets categorised within Level 3 are composed mainly of unquoted equity shares.

The fair value of significant unquoted equity shares is measured using discounted cash flows. The fair value of unquoted equity shares is categorised within Level 3 because unobservable inputs such as estimates of future net operating profit after tax and WACC are used for the measurement. The WACC used for the measurement of fair value depends on region or industry. In the years ended 31 March 2017 and 2018, the WACC used for measurement was 8.0%. Generally, the fair value would decrease if the WACC capital were higher.

The fair value of unquoted equity shares is measured by relevant departments of the Company and each Group company in accordance with the Group accounting policy every quarter. The results with evidences of changes in fair value are reported to a superior and, if necessary, to the Executive Committee as well.

The financial liabilities categorised within Level 3 are composed of contingent considerations arising from business combinations.

Contingent considerations represent certain milestone payments based on progress in the development of the clinical programs possessed by the acquirees. The fair value of the contingent consideration is calculated based on the estimated success probability of the clinical program adjusted for the time value of money. The fair value of contingent considerations increase if the success probability of the clinical program, which is the significant unobservable input, is raised.

In regards to financial instruments categorised within Level 3, there would be no significant change in fair value when one or more of the unobservable inputs is changed to reflect reasonably possible alternative assumptions.

# 34. Operating Leases

Future minimum lease payments under non-cancellable operating leases are as follows:

(Millions of yen)

	2017	2018
Not later than one year	¥13,237	¥12,636
Later than one year and not later than five years	20,776	30,385
Later than five years	3,167	24,255
Total	¥37,179	¥67,275

Future minimum sublease payments expected to be received under non-cancellable subleases is as follows:

	(Millions of yen)	
	2017	2018
Future minimum sublease payments expected to be received	¥1,819	¥1,486

Minimum lease payments and sublease payments received recognised as expenses are as follows:

 Minimum lease payments
 ¥17,050
 ¥17,113

 Sublease payments received
 (211)
 (221)

 Total
 ¥16,839
 ¥16,891

The Group leases buildings, vehicles and other assets under operating leases.

The significant leasing arrangements have terms of renewal and escalation clauses, but there exist no

contingent rents payable and terms of purchase options. In addition, there are no material restrictions imposed by the lease arrangements.

#### 35. Commitments

The breakdown of commitments for the acquisition of property, plant and equipment and intangible assets is as follows:

		(Millions of yen)	
	2017	2018	
Intangible assets			
Research and development milestone payments	¥299,099	¥248,706	
Sales milestone payments	290,749	272,990	
Total	589,848	521,696	
Property, plant and equipment	¥ 5,114	¥ 4,804	

## Commitments for the acquisition of intangible assets

The Group has entered into research and development collaborations and in-license agreements of products and technologies with a number of third parties. These agreements may require the Group to make milestone

payments upon the achievement of agreed objectives or when certain conditions are met as defined in the agreements. "Research and development milestone payments" represent obligations to pay the amount set out in an individual contract agreement upon achievement of a milestone determined according to the stage of research and development.

"Sales milestone payments" represent obligations to pay the amount set out in an individual contract agreement upon achievement of a milestone determined according to the target of sales. The amounts shown in the table above represent the maximum payments to be made when all milestones are achieved, and they are undiscounted and not risk adjusted. Since the achievement of the conditions for payment is highly uncertain, it is unlikely that they will all fall due and the amounts of the actual payments may vary considerably from those stated in the table.

# 36. Related Party Transactions

## (1) Major companies the Group controls

A list of major companies the Group controls is presented in "Principal Subsidiaries and Affiliates".

#### (2) Compensation of key management personnel

The table below shows, by the type, the compensation of key management personnel:

		(Millions of yen)	
	2017	2018	
Rewards and salaries	¥1,353	¥1,312	
Share-based payment	164	206	
Other	430	932	
Total compensation	¥1,947	¥2,450	

Key management personnel consist of 22 people (21 during 2017) including Directors, Corporate Audit & Supervisory Board Members and members of the Executive Committee.

## 37. Business Combinations

For the year ended 31 March 2017

## **Acquisition of Ganymed Pharmaceuticals AG**

# (1) Outline of business combination

## (i) Name and business description of the acquiree

Name of the acquiree: Ganymed Pharmaceuticals AG ("Ganymed") Business description: Development of antibodies against cancer

#### (ii) Acquisition date

20 December 2016

## (iii) Percentage of voting equity interests acquired

100%

### (iv) Acquisition method

Acquisition of all shares of common stock in cash with contingent consideration to be paid when certain milestones are achieved in the future.

### (v) Primary reasons for the business combination

Ganymed is a formerly privately-held biopharmaceutical company founded in 2001 and focuses on the development of a new class of cancer drugs. Ganymed has several pipeline assets in pre-clinical and clinical stages including IMAB362. Through the acquisition, the

Group will expand its oncology pipeline with an antibody program in the late-stage to build upon its leading oncology franchise as a platform for sustainable growth.

# (2) The fair values of assets acquired, liabilities assumed and purchase consideration transferred as at the acquisition date are as follows:

	(Millions of yen)
Property, plant and equipment	¥ 272
Other intangible assets	86,033
Cash and cash equivalents	629
Other assets	1,103
Deferred tax liabilities	(18,852)
Other liabilities	(5,066)
Fair value of assets acquired and liabilities assumed (net)	64,118
Goodwill	16,360
Total	80,478
Cash	51,544
Contingent consideration	28,934
Total fair value of purchase consideration transferred	¥ 80,478

Certain items had reflected provisional amounts as of 31 March 2017, however, the Group completed the purchase price allocation during the fiscal year ended 31 March 2018. Along with this, the Group retrospectively revised the corresponding balances in the consolidated statement of financial position as of 31 March 2017. As

a result, "Goodwill" and "Deferred tax liabilities" each decreased by ¥6,829 million.

Goodwill mainly comprises the value of expected synergies arising from the acquisition and future economic benefits, which is not separately recognisable.

### (3) Contingent consideration

The contingent consideration represent certain milestone payments based on progress in the development of IMAB362, Ganymed's clinical program.

Maximum potential future cash outflows associated with the contingent consideration total 860 million euros (¥103,019 million).

### (4) Cash flow information

	(Millions of yen)
Total fair value of purchase consideration transferred	¥ 80,478
Fair value of contingent consideration included in purchase consideration transferred	(28,934)
Cash and cash equivalents held by the acquiree	(629)
Acquisition of subsidiaries, net of cash acquired	¥ 50,915

### (5) Acquisition-related costs

Acquisition-related costs: ¥101 million

Acquisition-related costs were recognised in selling, general and administrative expenses in the consolidated statement of income.

### (6) Effect on the consolidated statement of income

(i) Profit (loss) before tax of the acquiree since the acquisition date included in the consolidated statement of income for the year ended 31 March 2017:

¥(1,151) million

(ii) Profit (loss) before tax of the combined entity for the year ended 31 March 2017 assuming the acquisition date had been at the beginning of the fiscal year (unaudited):

¥(3,825) million

(Note) This effect is calculated based on the business results of Ganymed from 1 April 2016 to the acquisition date.

For the year ended 31 March 2018

### Acquisition of Ogeda SA

### (1) Outline of business combination

### (i) Name and business description of the acquiree

Name of the acquiree: Ogeda SA ("Ogeda")

Business description: Development of small molecule drugs targeting G-protein coupled receptors (GPCR)

### (ii) Acquisition date

16 May 2017

### (iii) Percentage of voting equity interests acquired

100%

### (iv) Acquisition method

Acquisition of all shares of common stock in cash with contingent consideration to be paid when certain milestones are achieved in the future.

### (v) Primary reasons for the business combination

Ogeda is a formerly privately owned drug discovery company founded in 1994 and focuses on the discovery

and development of small molecule drug candidates targeting GPCRs. Ogeda has fezolinetant in the clinical

development stage. In addition, Ogeda has several small molecules targeting GPCRs in pre-clinical development in multiple therapeutic areas including inflammatory and autoimmune diseases. Through the

acquisition, the Group will expand its late stage pipeline, thereby further solidifying its medium- to long-term growth prospects.

# (2) The fair values of assets acquired, liabilities assumed and purchase consideration transferred as at the acquisition date are as follows:

	(Millions of yen)
Property, plant and equipment	¥ 560
Other intangible assets	74,415
Cash and cash equivalents	519
Other assets	513
Deferred tax liabilities	(25,256)
Other liabilities	(1,883)
Fair value of assets acquired and liabilities assumed (net)	48,868
Goodwill	26,145
Total	75,014
Cash	62,086
Contingent consideration	12,928
Total fair value of purchase consideration transferred	¥ 75,014

Certain items above reflect provisional fair values based on reasonable information obtained at 31 March 2018 as the purchase price allocation is incomplete.

Goodwill mainly comprises the value of expected synergies arising from the acquisition and future economic benefits, which is not separately recognisable.

### (3) Contingent consideration

The contingent consideration represent certain milestone payments based on progress in the development of fezolinetant, Ogeda's clinical program. Maximum potential future cash outflows associated with

the contingent consideration total 300 million euros (¥39,156 million).

### (4) Cash flow information

	(Millions of yen)
Total fair value of purchase consideration transferred	¥ 75,014
Fair value of contingent consideration included in purchase consideration transferred	(12,928)
Cash and cash equivalents held by the acquiree	(519)
Acquisition of subsidiaries, net of cash acquired	¥ 61,567

### (5) Acquisition-related costs

Acquisition-related costs: ¥60 million

Acquisition-related costs were recognised in selling, general and administrative expenses in the consolidated statement of income.

### (6) Effect on the consolidated statement of income

(i) Profit (loss) before tax of the acquiree since the acquisition date included in the consolidated statement of income for the year ended 31 March 2018:

Dislosure is omitted due to immateriality.

(ii) Profit (loss) before tax of the combined entity for the year ended 31 March 2018 assuming the acquisition date had been at the beginning of the fiscal year (unaudited):

Dislosure is omitted due to immateriality.

### Acquisition of Mitobridge, Inc.

### (1) Outline of business combination

### (i) Name and business description of the acquiree

Name of the acquiree: Mitobridge, Inc. ("Mitobridge")

Business description: Research and development in diseases associated with mitochondrial dysfunctions

### (ii) Acquisition date

23 January 2018

### (iii) Percentage of voting equity interests

The Company had owned 26.4% of voting equity interests before the acquisition. As a result of the acquisition, the Company owns 100% of voting equity interests.

### (iv) Acquisition method

Acquisition of all shares of common stock in cash with contingent consideration to be paid when certain milestones are achieved in the future.

### (v) Primary reasons for the business combination

Mitobridge is a biotechnology company founded in 2011 and is discovering and developing compounds that target mitochondrial function. These drug candidates have the potential to treat genetic, metabolic or neurodegenerative disorders as well as conditions of

aging. The transaction accelerates the Group's research and development in diseases associated with mitochondrial dysfunctions and will enable the delivery of innovative new treatment options to patients.

## (2) The fair values of assets acquired, liabilities assumed and purchase consideration transferred as at the acquisition date are as follows:

	(Millions of yen)
Property, plant and equipment	¥ 71
Deferred tax assets	1,594
Cash and cash equivalents	27
Other assets	27
Other liabilities	(339)
Fair value of assets acquired and liabilities assumed (net)	1,380
Goodwill	29,329
Total	30,708
Cash	17,951
Contingent consideration	7,048
Fair value of previously held equity interests in Mitobridge	5,709
Total fair value of purchase consideration transferred	¥30,708

Certain items above reflect provisional fair values based on reasonable information obtained at 31 March 2018 as the purchase price allocation is incomplete.

Goodwill mainly comprises the value of expected synergies arising from the acquisition and future economic benefits, which is not separately recognisable.

As a result of the remeasurement of the Company's previously held equity interests in Mitobridge at fair

value as of the acquisition date, the Company recognised a ¥5,877 million gain on remeasurement related to a business combination achieved in stages. This gain was included as a component of "Other income" in the consolidated statement of income.

### (3) Contingent consideration

The contingent consideration represent certain milestone payments depending on the progress of various programs in clinical development of Mitobridge. Maximum potential future cash outflows associated with

the contingent consideration total 165 million U.S. dollars (¥17,582 million).

### (4) Cash flow information

	(Millions of yen)
Total fair value of purchase consideration transferred	¥ 30,708
Fair value of contingent consideration included in purchase consideration transferred	(7,048)
Fair value of previously held equity interests in Mitobridge included in purchase consideration	
transferred	(5,709)
Cash and cash equivalents held by the acquiree	(27)
Acquisition of subsidiaries, net of cash acquired	¥ 17,924

### (5) Acquisition-related costs

Dislosure is omitted due to immateriality.

### (6) Effect on the consolidated statement of income

(i) Profit (loss) before tax of the acquiree since the acquisition date included in the consolidated statement of income for the year ended 31 March 2018:

Dislosure is omitted due to immateriality.

(ii) Profit (loss) before tax of the combined entity for the year ended 31 March 2018 assuming the acquisition date had been at the beginning of the fiscal year (unaudited):

Dislosure is omitted due to immateriality.

### Acquisition of Universal Cells, Inc.

### (1) Outline of business combination

### (i) Name and business description of the acquiree

Name of the acquiree: Universal Cells, Inc. (Universal Cells)

Business description: Research and development of stem cell therapies that overcome immune rejection

### (ii) Acquisition date

9 February 2018

### (iii) Percentage of voting equity interests acquired

100%

### (iv) Acquisition method

Acquisition of all shares of common stock in cash with contingent consideration to be paid when certain milestones are achieved in the future.

### (v) Primary reasons for the business combination

Universal Cells is a biotechnology company founded in 2013, which has a proprietary Universal Donor Cell technology to create cell therapy products that do not require Human Leukocyte Antigen (HLA) matching, potentially overcoming a huge treatment challenge by reducing the risk of rejection. The acquisition combines the Group's capability of establishing differentiated

functional cells from pluripotent stem cells with Universal Cells' ability to produce pluripotent stem cells that have lower immunological rejection to further enable investigation of innovative cell therapy treatments for various diseases that currently have few or no treatment options.

# (2) The fair values of assets acquired, liabilities assumed and purchase consideration transferred as at the acquisition date are as follows:

	(Millions of yen)
Other intangible assets	¥ 6,485
Cash and cash equivalents	915
Other assets	82
Deferred tax liabilities	(1,354)
Other liabilities	(812)
Fair value of assets acquired and liabilities assumed (net)	5,315
Goodwill	2,814
Total	8,130
Cash	5,148
Contingent consideration	2,982
Total fair value of purchase consideration transferred	¥ 8,130

Certain items above reflect provisional fair values based on reasonable information obtained at 31 March 2018 as the purchase price allocation is incomplete. Goodwill mainly comprises the value of expected synergies arising from the acquisition and future economic benefits, which is not separately recognisable.

### (3) Contingent consideration

The contingent consideration represent certain specified clinical milestone payments. Maximum potential future cash outflows associated with the contingent

consideration total 38 million U.S. dollars (¥3,984 million).

### (4) Cash flow information

	(Millions of yen)
Total fair value of purchase consideration transferred	¥ 8,130
Fair value of contingent consideration included in purchase consideration transferred	(2,982)
Cash and cash equivalents held by the acquiree	(915)
Acquisition of subsidiaries, net of cash acquired	¥ 4,233

### (5) Acquisition-related costs

Acquisition-related costs: ¥64 million

Acquisition-related costs were recognised in selling, general and administrative expenses in the consolidated statement of income.

### (6) Effect on the consolidated statement of income

(i) Profit (loss) before tax of the acquiree since the acquisition date included in the consolidated statement of income for the year ended 31 March 2018:

Dislosure is omitted due to immateriality.

(ii) Profit (loss) before tax of the combined entity for the year ended 31 March 2018 assuming the acquisition date had been at the beginning of the fiscal year (unaudited):

Dislosure is omitted due to immateriality.

## 38. Contingent Liabilities Legal Proceedings

The Group is involved in various claims and legal proceedings of a nature considered common to the pharmaceutical industry.

These proceedings are generally related to product liability claims, competition and antitrust law, intellectual property matters, employment claims, and government investigations.

In general, since litigation and other legal proceedings contain many uncertainties and complex factors, it is often not possible to make reliable judgment regarding the possibility of losses nor to estimate expected financial effect if these matters are decided in a manner that is adverse to the Group.

In these cases, disclosures would be made as appropriate, but no provision would be made by the Group.

# Patient Assistance Foundation Government Investigation

In March 2016 and August 2017, Astellas Pharma US, Inc. (APUS), one of the Company's indirect US subsidiaries, received subpoenas from the U.S. Department of Justice, represented by the U.S. Attorney's Office in Boston, Massachusetts, requesting documents and other information concerning APUS's patient assistance programs including its donations to Patient Assistance Foundations in the U.S. APUS is in the process of responding to the subpoena, and APUS is cooperating fully with the investigation. We cannot predict or determine the timing or outcome of this investigation or its impact on our financial condition or results of operations at this time.

### 39. Events after the Reporting Period

### **Acquisition of Own Shares**

A resolution was adopted to acquire the Company's own shares under Article 156 which is applicable in accordance with Article 165, Paragraph 3 of the Companies Act of Japan at the meeting of the Board of Directors held on 31 May 2018. The particulars are as follows:

(1) Reasons for the acquisition of own shares Shareholder return and improvement of capital efficiency

- (2) Outline of acquisition
- (i) Class of shares to be acquired

Common stock of the Company

(ii) Total number of shares to be acquired

Up to 60 million shares

(The percentage compared to the total number of shares outstanding: 3.04 %)

(iii) Aggregate amount of acquisition cost Up to ¥100 billion

(iv) Period of acquisition

From 1 June, 2018 to 20 September, 2018



Ernst & Young ShinNihon LLC Hibiya Kokusai Bidg 2-2-3 Uchisalwai-cho, Chiyoda-ku Tokyo 100-0011, Japan

Tel: +81 3 3503 1100 Fax: +81 3 3503 1197

### Independent Auditor's Report

The Board of Directors Astellas Pharma Inc.

We have audited the accompanying consolidated financial statements of Astellas Pharma Inc. and Subsidiaries, which comprise the consolidated statement of financial position as at 31 March 2018, and the consolidated statements of income, comprehensive income, changes in equity, and cash flows for the year then ended and a summary of significant accounting policies and other explanatory information, all expressed in

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards, and for designing and operating such internal control as management determines is necessary to enable the preparation and fair presentation of the consolidated financial statements that are free from material misstatement, whether due to fraud or error.

### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due the assessment of the risks of material instance of the consolidated financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Astellas Pharma Inc. and Subsidiaries as at 31 March 2018, and their consolidated financial performance and cash flows for the year then ended in conformity with International Financial Reporting Standards.

Emphasis of Matter

We draw attention to Note 39 to the consolidated financial statements, which describes that Astellas Pharma Inc. resolved to acquire its own shares at the meeting of the Board of Directors held on 31 May 2018. Our opinion is not qualified in respect of this matter.

### Convenience Translation

We have reviewed the translation of these consolidated financial statements into U.S. dollars, presented for the convenience of readers, and, in our opinion, the accompanying consolidated financial statements have been properly translated on the basis described in Note 2.

Ernst & Young Shin Mikon LLC

15 June 2018 Tokyo, Japan

A member firm of Ernst & Young Global Limited

### **Investor Information**

Common Stock (as of March 31, 2018)

Authorized: 9,000,000,000 Issued: 2,068,823,175

(including 91,373,232 treasury shares)

Number of shareholders: 112,028

### Transfer Agent for Common Stock in Japan

Sumitomo Mitsui Trust Bank, Limited

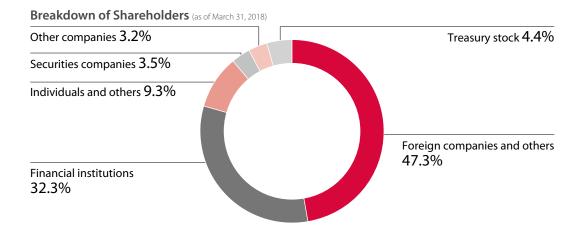
1-4-1, Marunouchi, Chiyoda-ku, Tokyo 100-8233, Japan

### Major Shareholders (as of March 31, 2018)

	Shares owned (Thousand shares)	Percentage of total common shares outstanding (excluding treasury shares)
The Master Trust Bank of Japan, Ltd. (trust account)	175,020	8.85
Japan Trustee Services Bank, Ltd. (trust account)	118,200	5.97
Nippon Life Insurance Company	64,486	3.26
JP Morgan Chase Bank 385632	48,939	2.47
State Street Bank West Client - Treaty 505234	43,534	2.20
Japan Trustee Services Bank, Ltd. (trust account 5)	39,273	1.98
Japan Trustee Services Bank, Ltd. (trust account 7)	38,925	1.96
State Street Bank and Trust Company	37,620	1.90
JP Morgan Chase Bank 385147	32,201	1.62
Japan Trustee Services Bank, Ltd. (trust account 1)	29,175	1.47

Notes: Shares owned are rounded down to the nearest thousand shares, while the percentage of total common shares outstanding (excluding treasury shares) is rounded down to two decimal places.

Astellas holds 91,373 thousand treasury shares, but it is not included in the above list of major shareholders.



### **Corporate Data**

### Company Name

Astellas Pharma Inc.

### Head Office

2-5-1, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan TEL: +81-3-3244-3000 https://www.astellas.com/en/

### Capital (as of March 31, 2018)

¥103,001 million

### Representative

Kenji Yasukawa Representative Director, President and CEO

### Founded

### Professional Institution Affiliation

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Japan Pharmaceutical Manufacturers Association (JPMA), Pharmaceutical Research and Manufacturers of America (PhRMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), etc.

### Stock Exchange Listing

Tokyo (Securities Code: 4503)

### Independent Auditors

Ernst & Young ShinNihon LLC

## **Principal Subsidiaries and Affiliates**

(as of March 31, 2018)

Astellas is a group of companies engaged solely in the pharmaceutical business. The Group consists of 92 companies, which include Astellas Pharma Inc., 83 consolidated subsidiaries and 8 affiliates accounted for by the equity method. Major Group companies are listed as follows:

### Japan

### **Manufacturing Base**

- Astellas Pharma Tech Co., Ltd.

### **R&D Bases**

- Astellas Research Technologies Co., Ltd.\*1
- Astellas Analytical Science Laboratories, Inc.\*2

- Astellas Learning Institute Co., Ltd.
- Astellas Marketing and Sales Support Co., Ltd.\*1
- Amgen Astellas BioPharma K.K.
- \*1 Plan to discontinue all activities in Astellas Marketing and Sales Support Co., Ltd and Astellas Research Technologies Co., Ltd. by the end of the fiscal year ending
- \*2 Plan to divest Astellas Analytical Science Laboratories, Inc. to Eurofins Pharma Services LUX Holding Sarl during the fiscal year ending March 31, 2019.

### Americas

### **Holding Company in North America**

- · Astellas US Holding, Inc.
- 1 Astellas Way, Northbrook, IL 60062-6111, U.S.A.

### **Regional Headquarters**

- Astellas US LLC
- 1 Astellas Way, Northbrook, IL 60062-6111, U.S.A.

#### **R&D Bases**

- Astellas Pharma Global Development, Inc.
- Astellas Research Institute of America LLC
- Astellas Institute for Regenerative Medicine

#### **Sales Bases**

- · Astellas Pharma US, Inc.
- · Astellas Pharma Canada, Inc. (Canada)
- Astellas Farma Brasil Importação e Distribuição de Medicamentos Ltda. (Brazil)
- Astellas Farma Colombia S.A.S (Colombia)

#### Other

- Astellas US Technologies, Inc.
- Astellas Venture Management LLC
- Astellas Innovation Management LLC

Note: All subsidiaries for which no country has been indicated are located in the U.S.

### EMEA

### **Holding Company in EMEA**

Astellas B.V.

Sylviusweg 62, 2333, BE Leiden, The Netherlands

### Regional Headquarters (Astellas EMEA Operations)

• Astellas Pharma Europe Ltd. 2000 Hillswood Drive, Chertsey, Surrey, KT16 ORS, U.K.

### **R&D** and Manufacturing Bases

- Astellas Pharma Europe B.V. (R&D and manufacturing, Netherlands)
- · Astellas Ireland Co., Limited (Development and manufacturing, Ireland)

#### Sales Bases

- Astellas Pharma Ges. mbH (Austria)
- Astellas Pharma B.V. (Belgium)
- Astellas Pharma s.r.o (Czech Republic)
- Astellas Pharma A/S (Denmark)
- Astellas Pharma S.A.S (France)
- Astellas Pharma GmbH (Germany)
- Astellas Pharmaceuticals AEBE (Greece)
- Astellas Pharma Kft. (Hungary)
- Astellas Pharma Co., Limited (Ireland)
- · Astellas Pharma S.p.A. (Italy)
- Astellas Pharma B.V. (Netherlands)
- Astellas Pharma International B.V. (Netherlands)
- · Astellas Pharma Sp.zo.o. (Poland)
- Astellas Farma Limitada (Portugal)
- JSC Astellas Pharma (Russia)
- · Astellas Pharma d.o.o (Slovenia)
- Astellas Pharma (Proprietary) Ltd (South Africa)
- Astellas Pharma S.A. (Spain)
- · Astellas Pharma A.G. (Switzerland)
- Astellas Pharma ilac Ticaret ve Sanayi A.S. (Turkey)
- Astellas Pharma DMCC (United Arab Emirates)
- · Astellas Pharma Ltd. (United Kingdom)

### Asia & Oceania

### Sales and Other Bases

- Astellas Pharma China, Inc. (Sales and manufacturing, China)
- Astellas Pharma Hong Kong Co., Ltd. (Hong Kong)
- Astellas Pharma Taiwan, Inc. (Taiwan)
- · Astellas Pharma Korea, Inc. (Korea)
- Astellas Pharma Philippines, Inc. (Philippines)
- Astellas Pharma (Thailand) Co., Ltd. (Thailand)
- P.T. Astellas Pharma Indonesia (Indonesia)
- Astellas Pharma India Private Limited (India)
- Astellas Pharma Australia Pty Ltd. (Australia)
- Astellas Pharma Singapore Pte. Ltd. (Singapore)
- Astellas Pharma Malaysia Sdn.Bhd. (Malaysia)

Business Review

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### **Inclusion in SRI Indexes**



FTSE4Good

Astellas is a member of the FTSE4Good Index, an equity index series that is  $\,$ designed to facilitate investment in companies that meet globally recognized corporate responsibility standards.



FTSE Blossom Japan

Astellas is a member of the FTSE Blossom Japan Index. Created by the global index provider FTSE Russell, the FTSE Blossom Japan Index is designed to measure the performance of Japanese companies demonstrating strong Environmental, Social and Governance (ESG) practices.



2018 Constituent MSCI Japan ESG Select Leaders Index

Astellas is a member of the MSCI Japan ESG Select Leaders Index, an equity index developed by MSCI Inc. that provides exposure to Japanese companies with high Environmental, Social and Governance (ESG) performance relative to their sector peers.



2018 Constituent MSCI Japan Empowering Women Index (WIN)

Astellas is a member of the MSCI Japan Empowering Women Index (WIN), an equity index developed by MSCI Inc. that comprises leading Japanese companies that promote gender diversity.



### Astellas Pharma Inc.

2-5-1, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan https://www.astellas.com/en/

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