



Changing tomorrow

For the Year Ended March 31, 2021  
ANNUAL REPORT

2021



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## Annual Report 2021 Editorial Policy

Astellas publishes its annual report as an integrated report to enable deeper stakeholder understanding of Astellas' efforts to continuously create value for sustainable growth. In order to provide timely information, we publish the Annual Report on the web site.

### Scope of the Report

Period covered: Fiscal year ended March 2021 (April 1, 2020 - March 31, 2021)

- As much as possible, we have included 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 cases individually.

Organizations covered: Astellas Pharma Inc. and its consolidated subsidiaries in Japan and overseas (referred to in this report as “Astellas”)

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 Pharma. These statements are based on the 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.

## On the Publication of Annual Report 2021

Annual Report 2021 covers the results of Corporate Strategic Plan 2018 promoted over the past three years and our Strategic Goals under Corporate Strategic Plan 2021, newly established this year, and Astellas' value creation story for achieving these goals and realizing our VISION.

The Report was prepared with reference to the revisions to the International Integrated Reporting Framework published by the International Integrated Reporting Council (IIRC) in January 2021 and the Revisions of Japan's Corporate Governance

Code and Guidelines for Investor and Company Engagement and was produced with the help of internal divisions with the relevant expertise.

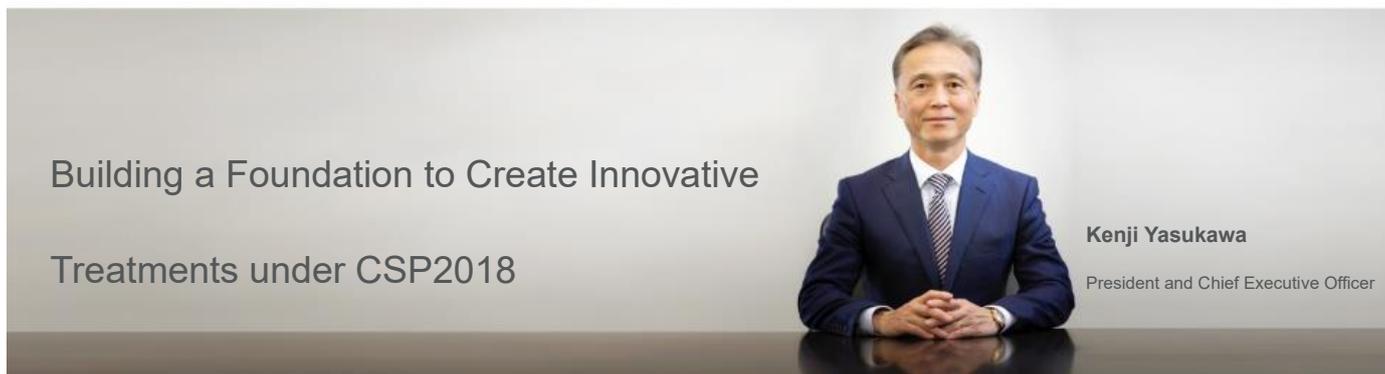
I hereby state that this report was prepared in good faith and that the information contained herein accurately conveys Astellas' achievement to date and its new medium- to long-term strategies.



**Kenji Yasukawa**

President and Chief Executive Officer

# CEO Message



**CSP2021: Evolved Strategy. Ambitious Goals. Transformative Execution.  
Same Deep Commitment to Our VISION.**

The ongoing novel coronavirus disease (COVID-19) pandemic has made people more health-conscious and greater importance has been placed on the role of healthcare providers than ever before. We remain committed to fully utilizing our core capabilities to deliver VALUE to society.

## **On the Forefront of Healthcare Change to Turn Innovative Science into VALUE for Patients**

Astellas' VISION is “to be at the forefront of healthcare change to turn innovative science into VALUE for patients.” With research and development at the heart of everything we do, we will constantly take on challenges to deliver innovative new drugs and medical solutions by leveraging our core capabilities.

In recent years, the external environment has changed at dizzying speeds. We need to achieve sustainable growth in step by flexibly adapting to change. We aim to generate benefits both for society and for us as a company through the formulation of strategies that contribute to the sustainability of society and make Astellas more sustainable as a result. This approach will build trust with stakeholders, and we will live up to stakeholders' expectations through the allocation of generated funds to appropriate therapeutic areas. This is Astellas' value creation process. By implementing this process in a continuous cycle, we will sustainably enhance our corporate value and continue to make innovative medical solutions available to patients.

## **Building a Foundation to Create Innovative Treatments under CSP2018**

In fiscal 2020, which was the final year of Corporate Strategic Plan 2018, or CSP2018, (for fiscal years 2018 through 2020), revenue was in line with the plan if we exclude the impact of foreign exchange rates, albeit falling slightly short of the full-year forecast, and core operating profit also reached the planned level. Sales of major products that drive growth, namely XTANDI® (enzalutamide), XOSPATA® (gilteritinib) and PADCEV® (enfortumab vedotin), expanded and we continue to contribute to many patients.

Looking back on CSP2018 as a whole, we focused on three Strategic Goals and achieved outcomes as planned over the three years. During this period, I believe we succeeded in building a foundation to create innovative treatments, which will be our mainstay products from the mid-2020s onwards. In other words, our six key post-POC projects progressed steadily, and our Primary Focuses identified through our Focus Area Approach grew. Further, with Rx+®, in addition to succeeding in expanding projects, we were able to identify the areas we needed to focus on and clarify the direction for their commercialization.

Over the past three years, our portfolio has changed substantially. We have achieved steady progress on six key post-POC projects and obtained approvals for these products. We have also out-licensed many of our long-listed products, developing a framework that will allow us to focus more effectively on our core businesses. As a result, growing products such as XTANDI® and mirabegron, new products such as XOSPATA® and PADCEV®, and PROGRAF, which is still a core product, are expected to account for a combined share of 80% of revenue in fiscal 2021 compared with just under 60% in fiscal 2018. Negative financial impacts from products such as Vesicare® and Celecox® after the expiration of exclusive license agreements and from the termination of agreements for *sales* of in-licensing products in Japan, such as Symbicort® and Micardis®, have mostly worn off. I believe that the three-year period of CSP2018 was a period in which we overcame this period of transition in our portfolio and prepared for the achievement of sustainable growth. We will use the foundation built in CSP2018 to further enhance the execution of CSP2021, which will continue to evolve and develop each strategy.

## **Pursuing Ambitious Outcomes while Contributing to Social Sustainability**

In May 2021, Astellas announced CSP2021.

In the face of the diverse global challenges in recent years, as members of society, pharmaceutical companies need to be strongly committed to improving social sustainability by actively meeting growing medical needs and sincerely addressing environmental challenges. We included “Deepen our engagement in sustainability” in our four strategic goals under CSP2021. We will continue to achieve ambitious targets as we pay close attention to the external environment and contribute to social sustainability.

Under CSP2021, we have set four Strategic Goals, three Organizational Health Goals as signposts for fostering a culture to reach these goals, and three Performance Goals, which we consider achievable if all the above are accomplished. The Organizational Health Goals, which clearly set out our aspirations as an organization, will further strengthen the organizational health and human resource development programs, which are Astellas’ core capabilities.

### **Strategic Goal 1: Enable patients to achieve better outcomes**

Astellas is committed to maximize patient access to our products and to partner effectively with healthcare stakeholders to secure the realization of VALUE. To achieve this, we strive to accelerate submission of New Drug Applications (NDAs), reducing the time to achieve broad geographic coverage, implementing sophisticated launch plans and prioritizing our efforts across the portfolio towards where the VALUE opportunity is greatest. We will take a patient-oriented approach, adopting new techniques to create and use data and implement solutions that overcome obstructions to patient access or important factors that limit real-world outcomes. It is through pursuing these activities in association with this strategic goal that Astellas will maximize the value of XTANDI® and strategic products that drive medium- to long-term growth.

### **Strategic Goal 2: Translate innovative science into proven VALUE**

Astellas will enhance its pipeline value by giving priority to the investment of management resources into its Primary Focuses. Through acceleration of the demonstration of VALUE, the growth of Primary Focuses, and the effective exploration of cutting-edge biopharmaceutical innovation, we aim to take our efforts under CSP2018 to the next level. Astellas is working on researching and developing life-changing therapies through priority investment in Primary Focuses selected based on an R&D strategy dubbed the Focus Area Approach. We have already established four Primary Focuses: Immuno-Oncology, Blindness & Regeneration, Mitochondria Biology and Genetic Regulation. I believe that therapeutic approaches building on our core technologies in Immuno-Oncology and especially Genetic Regulation could bring about a paradigm shift. They will enable us to move from symptomatic therapy to radical therapy, bringing great hope to patients desperate for new therapies that will treat previously untreatable diseases.

### **Strategic Goal 3: Advance the Rx+® business**

We changed the goal of “Developing Rx+® programs” under CSP2018 to “Advance the Rx+® Business” under CSP2021. The Rx+® business will enter the stage where efforts for business creation will bear fruit in CSP2021. In the period between fiscal 2021 and fiscal 2025, we expect to commercialize at least five projects. By putting even greater effort into the commercialization of Rx+® programs, we will move closer to achieving our vision of realizing “a world where people can live mentally and physically healthy lives and be true to themselves through healthcare solutions based on scientific evidence.”

### **Strategic Goal 4: Deepen our engagement in sustainability**

This is the strategic goal that we have newly added in CSP2021. We conducted a range of activities that have contributed to society under CSR management. In fiscal 2020, we reviewed our activities to date and plan to shift away from CSR-Based Management towards group-wide initiatives based on Astellas’ Sustainability, which will contribute to the sustainability of both society and Astellas, while taking ESG into consideration. In our sustainability initiatives, we are prioritizing and focusing on Access to Health (ATH), which leverages Astellas’ core capabilities, technologies, and expertise, and Environment, in particular Climate Change.

## Organizational Health Goals

We established Organizational Health Goals (OHGs) to implement CSP2021 more effectively. I believe that fostering a corporate culture enabling the creation of greater innovation to reach more ambitious goals is important for the reliable execution of CSP2021, and above all, for the personal growth of individual employees. I hope that a culture which encourages employees to take appropriate risks without fear of failure and to steadily learn from this to create innovation for the future will lead to growth of “Our People, Our Organization” and help us to achieve our goals under CSP2021. We will achieve this whilst at the same time never compromising on patient safety or product integrity or compliance with regulations.”

## Performance Targets

The level of performance we consider achievable through the pursuit of our aspirations and steady implementation of our four strategies is expressed as numerical targets in these performance goals.

- 1. Sales Revenue of XTANDI® and Strategic Products: ≥ ¥1.2 trillion in FY2025**
- 2. Pipeline Value: Focus Area projects expected sales ≥ ¥0.5T in FY2030**
- 3. Core Operating Profit Margin: ≥ 30% in FY2025**

By achieving these three Performance Goals, we aim to become a company with a market capitalization valued at more than 7 trillion yen in fiscal 2025.

## For Growth with Society

Astellas recognizes that its contribution to social sustainability is essential for the company’s business continuity. As a research and development-orientated company, we recognize we have a responsibility to increase social sustainability and are committed to developing the organization and external cooperation framework needed for this and to working as One Astellas to solve sustainability issues. At the same time, widespread recognition for our initiatives will build trust in society and will also make Astellas more sustainable.

Astellas’ Materiality Matrix, which specifies the priority for our initiatives, identifies 31 material issues besides Access to Health and climate change, including proper use of products, diversity & inclusion, health, and the safety & welfare of employees We are tracking various material issues in accordance with our priority.

In addition, Astellas is a signatory to the UN Global Compact in 2011. By incorporating the Ten Principles in the four areas of human rights, labor, environment, and anti-corruption into our daily business activities, we conduct globally responsible business activities for the enhancement of sustainability as a consistent supporter of the UN Global Compact.

An effective governance framework is another of Astellas’ strengths. To maintain governance on a global level, we respect our Charter of Corporate Conduct and the Astellas Group Code of Conduct as a set of core ethics and compliance standards for all our activities throughout the world. Acting in accordance with “high ethical standards” is the core of our value here at Astellas.

I hope that this report will provide a better understanding of the full extent of our policies and initiatives for contributing to a more sustainable society.

## **Build the Foundations of Human Resource and Organizational Management Necessary for a Global Organization with Astellas' Unique Approach**

At Astellas, diverse people bring their ideas together as “One Astellas” to transform the company, and we are striving to foster an organizational culture which enables sustainable enhancement of enterprise value and realization of our VISION. Astellas has established the “HR Vision,” which represents its approach to “Our People, Our Organization,” and the “Astellas Way,” which defines a shared set of values underlying this vision, and we are working as a Group on various activities based on a shared global worldview. Through the global standardization of a grade system and compensation philosophy based on the HR Vision, we are building an HR Management system that allows us to fairly and impartially hire the best talent from human resource markets around the world. In 2020, we actively revised multiple HR Management systems that were unique to Japan in the interests of global standardization. Then, in 2021, the contents and training record of employee training were integrated into a global common system.

Astellas' approach for personnel assignments and career development is to assign the right person in the right position and talent development. Since 2020, we introduced a new global common job posting system, and appoint talent who are considered to be the most qualified for the position, regardless of nationality, gender, or age. All employees who meet the requirements can apply for positions if they are interested in them, providing employees with all kinds of career opportunities around the world.

We will continue striving for work styles that enable each employee to demonstrate high productivity and creativity and achieve self-realization. The Organizational Health Goals we set in CSP2021 will further accelerate these initiatives.

## **Continuing to Advance Strongly Towards the Realization of Our VISION**

Through CSP2018, we succeeded in building a foundation to create the life-changing therapies which will be our mainstay products from the mid-2020s. We are confident that this strategy was correct and believe we are even closer to realizing our VISION. CSP2021 will build on this foundation and the steady translation of strategies into results is considered its biggest challenge. As such, the keyword in CSP2021 is “Execution.”

We will harness transformative execution to reach the ambitious targets of CSP2021 and advance strongly towards the realization of our VISION “to be on the forefront of healthcare change to turn innovative science into VALUE for patients.”

# About Astellas



## Turn Innovative Science into VALUE for Patients

Since Astellas was established in 2005, the company has strived to continue to create innovation and deliver innovative medical solutions that meet the needs of patients. Going forward, we are committed to achieving our vision of tuning innovative science into VALUE for patients.

In the future as well, Astellas aims to stand on the forefront of healthcare change to turn innovative science into VALUE for patients and will continually strive to fulfill the expectations of our stakeholders and society.

## At a Glance

### FY2020 consolidated financial results highlights

Revenue: **¥1,249.5 billion**

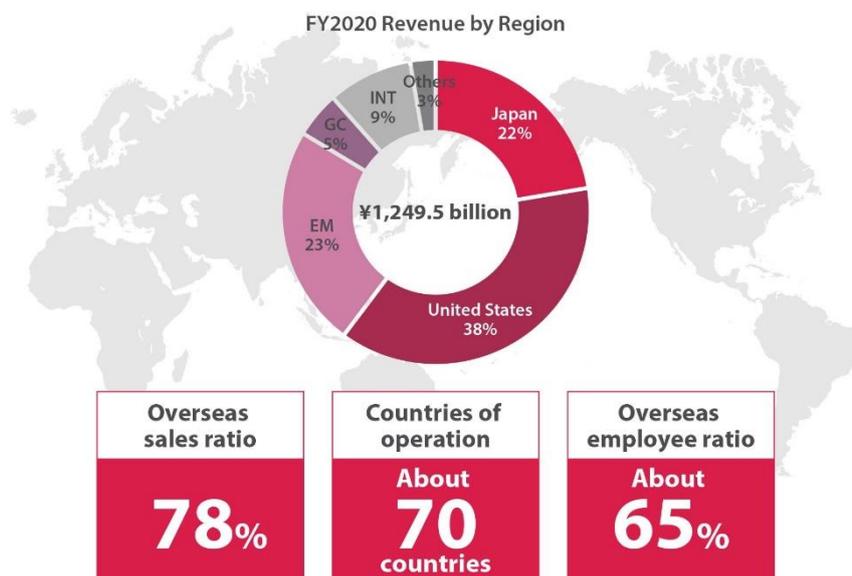
Core operating profit ratio: **20.1%**

ROE (Return on Equity): **9.0%**

R&D expense to sales ratio: **18.0%**

## Global Business Expansion

Astellas' overseas sales ratio is around 80%. We currently sell products in about 70 countries around the world, including developing countries.



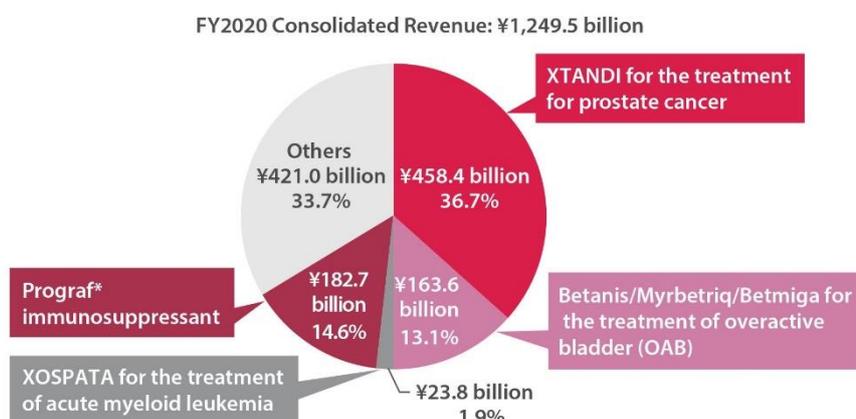
EM (Established markets): Europe, Canada, Australia

GC (Greater China): China, Hong Kong, Taiwan

INT (International Markets): Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

## Sales of Major Products

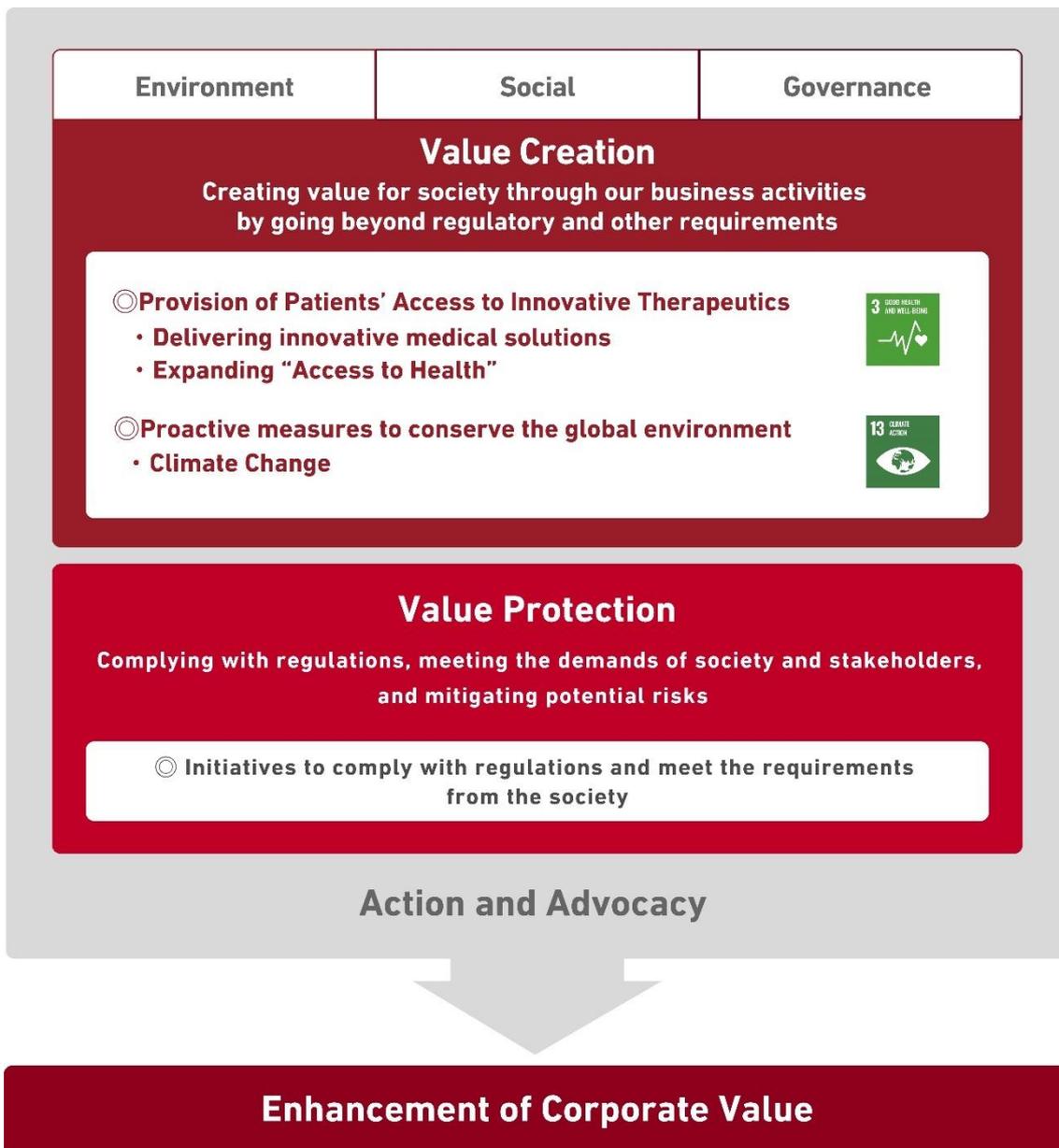
In addition to its main products, XTANDI® for the treatment of prostate cancer and Betanis/Myrbetriq/BETMIGA for the treatment of overactive bladder (OAB), Astellas is working to develop and maximize the value of new products which will drive our growth, such as XOSPATA® for the treatment of acute myeloid leukemia, PADCEV® for the treatment of urothelial cancer, and Evrenzo® for the treatment of anemia associated with chronic kidney disease, launched during the period of Corporate Strategic Plan 2018.



\*Prograf: Includes Advagraf, Graceptor and ASTAGRAF XL

## Sustainability

Astellas recognizes its contribution to environmental and social sustainability is essential for our business continuity. We aim to enhance our corporate value by engaging in Value Creation and Value Protection, while taking environmental, social and governance (ESG) issues into consideration.



## External Evaluation

Astellas' Sustainability initiatives have been receiving positive external evaluations.



FTSE Russell (the trading name of FTSE International Limited and Frank Russell Company) confirms that Astellas has been independently assessed according to the FTSE4Good criteria, and has satisfied the requirements to become a constituent of the FTSE4Good Index Series. Created by the global index provider FTSE Russell, the FTSE4Good Index Series is designed to measure the performance of companies demonstrating strong Environmental, Social and Governance (ESG) practices. The FTSE4Good indices are used by a wide variety of market participants to create and assess responsible investment funds and other products.



FTSE Russell confirms that Astellas has been independently assessed according to the index criteria, and has satisfied the requirements to become a constituent of the FTSE Blossom Japan Index. Created by the global index and data provider FTSE Russell, the FTSE Blossom Japan Index is designed to measure the performance of companies demonstrating strong Environmental, Social and Governance (ESG) practices. The FTSE Blossom Japan Index is used by a wide variety of market participants to create and assess responsible investment funds and other products.

### 2020 CONSTITUENT MSCI JAPAN ESG SELECT LEADERS INDEX

THE INCLUSION OF ASTELLAS IN ANY MSCI INDEX, AND THE USE OF MSCI LOGOS, TRADEMARKS, SERVICE MARKS OR INDEX NAMES HEREIN, DO NOT CONSTITUTE A SPONSORSHIP, ENDORSEMENT OR PROMOTION OF ASTELLAS BY MSCI OR ANY OF ITS AFFILIATES. THE MSCI INDEXES ARE THE EXCLUSIVE PROPERTY OF MSCI. MSCI AND THE MSCI INDEX NAMES AND LOGOS ARE TRADEMARKS OR SERVICE MARKS OF MSCI OR ITS AFFILIATES.

### 2020 CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN)

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## Philosophy



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## VISION



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## History



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## Astellas' Sustainability Governance



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## Materiality



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## SDGs



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## Corporate Information



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## Subsidiaries & Locations



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## Current Share Status



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# Philosophy with Three Elements: Raison D'être, Mission and Beliefs



## Raison D'être

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

- To go beyond all others in exploring and tapping the potential of the life sciences.
- To continue tackling new challenges and creating innovative pharmaceutical products.
- To deliver quality products along with accurate information and retain solid credibility among customers.
- To support healthy living for people around the world.
- To continue shining on the global pharmaceutical field.

## Mission

**Sustainable enhancement of enterprise value**

- Astellas will seek to enhance its enterprise value in a sustainable manner.
- Astellas will seek to be the company of choice among all its stakeholders, including its customers, shareholders, employees, and the global community.
- Astellas will strive to gain the trust of all stakeholders and thereby enhance its enterprise value.

## **Beliefs**

Our “beliefs” provide the code of conduct we prize at all times. Astellas will always be a group of people who act upon these beliefs.

### **High Sense of Ethics**

We will always manage our business with the highest sense of ethics.

### **Customer Focus**

We will always seek to understand customer needs and our focus will always be on achieving customer satisfaction.

### **Creativity**

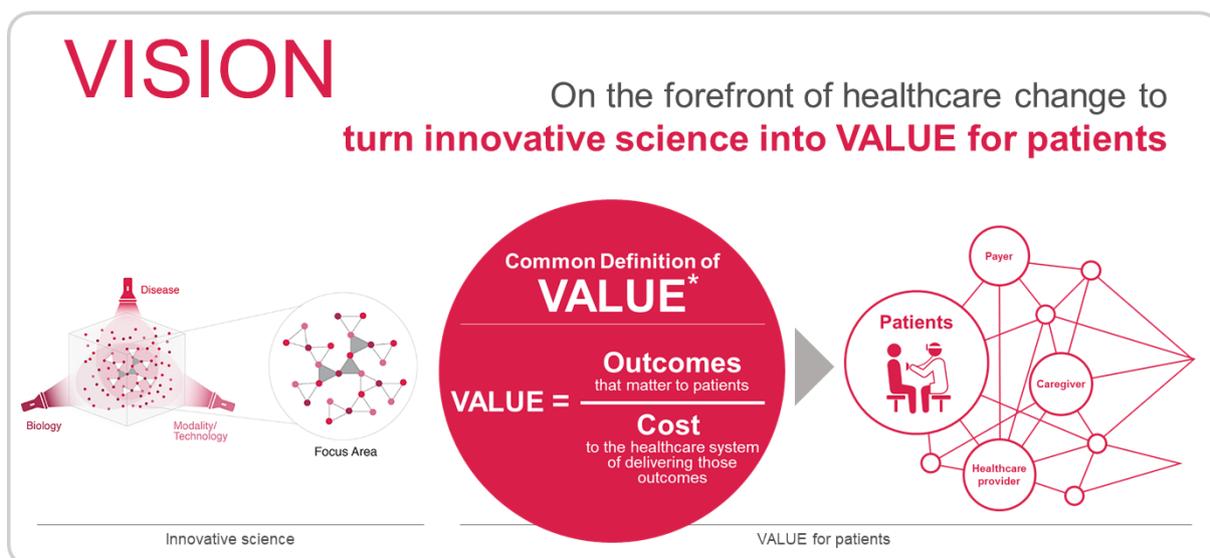
We will not be complacent and will always seek to innovate to create new value.

### **Competitive Focus**

Our eyes will always be directed to the outside world, and we will continue to create better value faster.

Astellas promises to perform its obligations toward all stakeholders by acting ethically and seeking to actively disclose information.

# Deep Commitment to Our VISION



\*Adapted from "What Is Value in HealthCare?" Porter, M.E. (2010). New England Journal of Medicine

In drawing up our VISION in 2015, we made a major shift from the traditional Global Category Leader (GCL) model to a drug discovery approach based on the Focus Area. Corporate Strategic Plan 2018 also designated a common definition for patient "Value.". Astellas defines VALUE as "Outcomes that matter to patients" divided by "Cost to the healthcare system of delivering those outcomes." This common definition has enabled all employees to point in the same direction, and our various efforts, including the Focus Area approach, has since been progressing more vigorously and steadily. Going forward, Astellas will continue standing on the forefront of healthcare change to turn innovative science into VALUE for patients.

## About Astellas / History

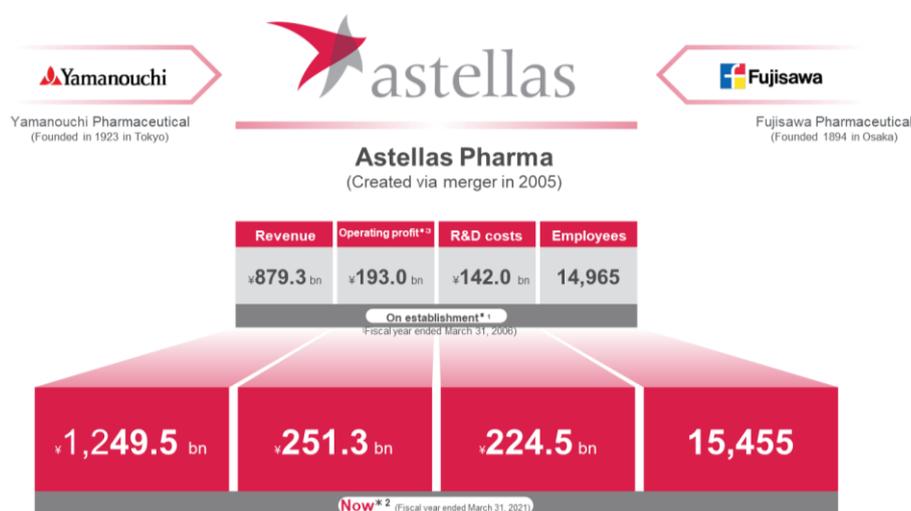
# Astellas' History

– To Contribute Toward Improving the Health of People Around the World Through the Provision of Innovative and Reliable Pharmaceutical Products



## The Birth of Astellas in 2005

Astellas' history began in 2005. Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd., founded in 1923 and 1894, respectively, merged to establish Astellas, which integrate their respective strengths in urology and transplantation / immunology products, synthetic and fermentation technology, and European and North American operations. Astellas' business results (first fiscal year ended March 31, 2006) were revenue of ¥879.3 billion and operating profit of ¥193.0 billion (under Japanese accounting standards). However, Astellas has grown significantly over the past 15 years and, in the fiscal year ended March 31, 2021, we posted revenue of ¥1,249.5 billion and core operating profit of ¥251.3 billion (under international accounting standards), representing revenue growth exceeding 40% and operating profit growth of around 30%. Moving forward, Astellas will continue aiming to realize its VISION: "On the forefront of healthcare change to turn innovative science into VALUE for patients."

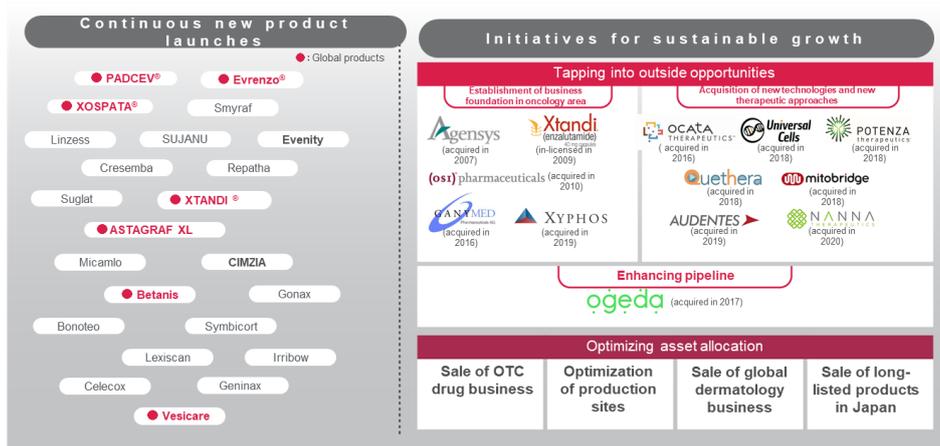


\*<sup>1</sup> Japanese GAAP \*<sup>2</sup> IFRS \*<sup>3</sup> Figure for fiscal year ended March 31, 2021 is core operating profit

## History After the Merger

Astellas continues to make steady progress as a global pharmaceutical company. As for products, we are continuously launching XTANDI®, XOSPATA®, PADCEV® Evrenzo® and many other high value-added products in the global market. We are also pursuing external opportunities and optimizing resource allocation for Astellas' sustainable growth. When it comes to capturing external opportunities, Astellas is actively incorporating cutting-edge external science and technology based on the idea of open innovation. We will continue to actively collaborate with academia / ventures and various companies. To optimize resource allocation, we are proceeding with efforts to pursue efficiency. Leveraging our drug discovery capabilities that turn science into value, we are focusing on the creation of innovative new drugs.

### Drug discovery capabilities turning science into value Focus on creating innovative new drugs for sustainable growth



## Growth Trajectory

### Company management and sustainability



#### Apr. 2005

Astellas Pharma Inc. (Astellas) was established by merging the former [Yamanouchi Pharmaceutical Co., Ltd.](#) and the former [Fujisawa Pharmaceutical Co., Ltd.](#)



#### Apr. 2006

Astellas sold Zephama, operating in the over-the-counter drug business, to Daiichi Sankyo Co., Ltd. in Japan to concentrate Astellas' managerial resources on its ethical drug business.

#### Nov. 2011

Astellas signed United Nations Global Compact.

#### Mar. 2012

Astellas launched a wind turbine power generation station and a woodchip biomass boiler in the Kerry Plant in Ireland.



#### July 2012

Astellas participated in the new public-private partnership to develop a treatment for schistosomiasis-infected preschool children.

#### Apr. 2013

Astellas announced participation in Global Health Innovative Technology Fund (GHIT Fund).

#### Nov. 2018

Science Based Targets Initiative approved Astellas' greenhouse gas reduction plan.

#### Nov. 2018

Astellas launched the Astellas Global Health Foundation to support improving access to health for underserved populations.

#### Dec. 2020

Astellas supported recommendations of Task Force on Climate-related Financial Disclosures (TCFD).

## Main products



### July 2011

Astellas launched Betanis® in Japan for the treatment of overactive bladder (OAB).



### Sep. 2012

Astellas launched XTANDI® in the U.S. for the treatment of metastatic castration-resistant prostate cancer.



### Oct. 2012

Astellas launched MYRBETRIQ® in the U.S. for the treatment of OAB.

### May 2014

Astellas launched XTANDI® in Japan for the treatment of prostate cancer.



### Dec. 2018

Astellas launched XOSPATA® in Japan and the U.S. to provide a therapeutic option for the treatment of Acute Myeloid Leukemia.



### Nov. 2019

Astellas launched Evrenzo® in Japan for the treatment of renal anemia in patients on dialysis.



### Dec. 2019

Astellas launched PADCEV® in the U.S. for the treatment of urothelial cancer.

### Sep. 2020

Astellas launched science-based fitness service, Fit-eNce®.

## Building a foundation to support growth



### Dec. 2007

Astellas acquired Agensys, Inc., a biotechnology company specialized in therapeutic antibody research and development in cancer in the U.S.

### Feb. 2016

Astellas acquired Ocata Therapeutics, Inc., a biotechnology company in the U.S. to enable Astellas to establish a presence in ophthalmology and a leading position in cell therapy.



### Feb. 2018

Astellas acquired Universal Cells, Inc., a bio-venture company which has ability to produce pluripotent stem cells that have lower immunological rejections.



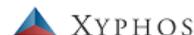
### Aug. 2018

Astellas acquired Quethera, a gene therapy company in the U.K. to further Astellas' commitment to innovation in ophthalmology with addition of novel gene therapy program for glaucoma.



### Dec. 2019

Astellas acquired Xyphos Biosciences, Inc., a biotechnology company in the U.S. to accelerate next-generation cancer immunotherapy.



### Jan. 2020

Astellas acquired Audentes Therapeutics, Inc., a biotechnology company in the U.S. to complement capabilities and resources of Astellas for creating an industry-leading gene therapy company.



### Oct. 2020

Astellas acquired Iota Biosciences, Inc. in the U.S. to explore new biosensing and treatment measures using ultra-small implantable medical devices.



About Astellas / Astellas' Sustainability Governance

# Contributing to a More Sustainable Society is Essential for Business Continuity



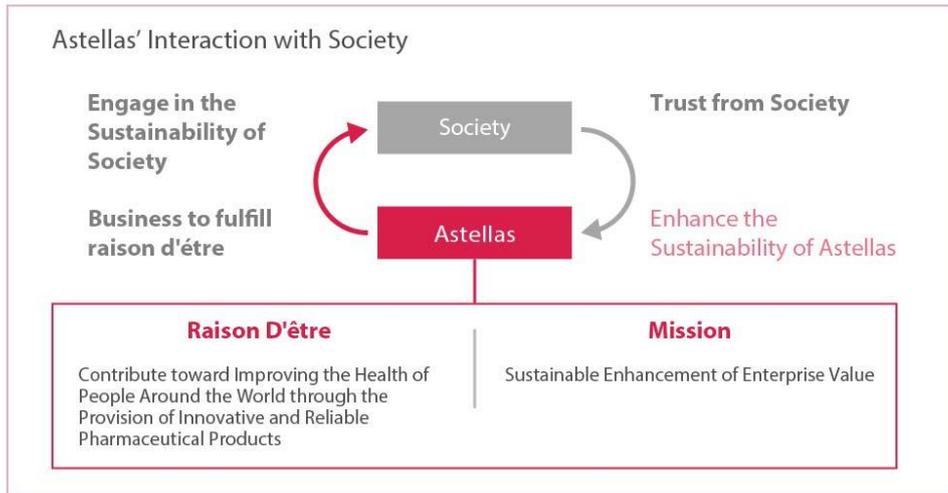
## Realizing Our Mission of Making Astellas Sustainable

Astellas recognizes our contribution to environmental and social sustainability is essential for our business continuity.

Astellas is committed to engaging in the sustainability of society by fulfilling our social responsibilities as a pharmaceutical company, including but not limited to providing our products such as a pharmaceutical products that satisfy unmet medical needs. As a result, we earn trust from society for both the Company and our products, which enhances Astellas' sustainability.

This positive cycle will lead to the realization of our mission, "sustainable enhancement of enterprise value" through fulfillment of our raison d'etre "contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products." In short, for Astellas, contributing to the sustainability of society means the realization of its philosophy.

The activities we have carried out under the aforementioned philosophy continue to be well-received externally. For example, Astellas has been named to the FTSE4Good Index Series, a representative investment index, for 10 consecutive years. Astellas is also included as a constituent in all of the ESG investment indexes adopted by the Government Pension Investment Fund (GPIF) in Japan, which are FTSE Blossom Japan Index, MSCI Japan ESG Select Leaders Index, MSCI Japan Empowering Women Index (WIN) and S&P/JPX Carbon Efficient Index.



## Engaging in Value Creation and Value Protection

Sustainability that Astellas is engaged in 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 rewarding stakeholders.

By reinvesting the profit we gain through business activities, we strengthen our capabilities in research and development. In addition, by winning the trust from government and business partners in each country, we create new business opportunities. That is to say, value for Astellas is created.

### Value Protection

Astellas seeks to reduce its environmental burden, preserve biodiversity, ensure compliance, and takes measures to prevent corruption. In addition to the social value of these activities, these contribute to mitigating reputation risks and enhancing our corporate brand, thereby protecting our enterprise value.

## Value Creation & Protection for Society & Astellas

	Value for Society	Value for Astellas
Value Creation	Supporting Healthy Living for People All Over the World through the Creation of Innovative Drugs Return to Stakeholders	Strengthening R&D Capabilities by Reinvesting Profits Creating New Business Opportunities
Value Protection	Mitigating Impact on Climate Change and Preserving Biodiversity by Reducing Environmental Burden Maintaining Social Order by Ensuring Compliance and Taking Measures to Prevent Corruption	Mitigating Reputation Risk Elevating Corporate Brand

## Framework for Contributing to Sustainability

Astellas has established the Sustainability Advisory Panel, and Environment, Social or Governance Working Group (ESG Working Group) led by Corporate Advocacy and consisting of cross-functional members. These organizations promote activities to contribute to sustainability by all departments from a long-term, strategic and groupwide perspective.

### Sustainability Advisory Panel

The panel's primary focus is on Astellas' sustainability issues that are overarching to Environment, Social and Governance matters.

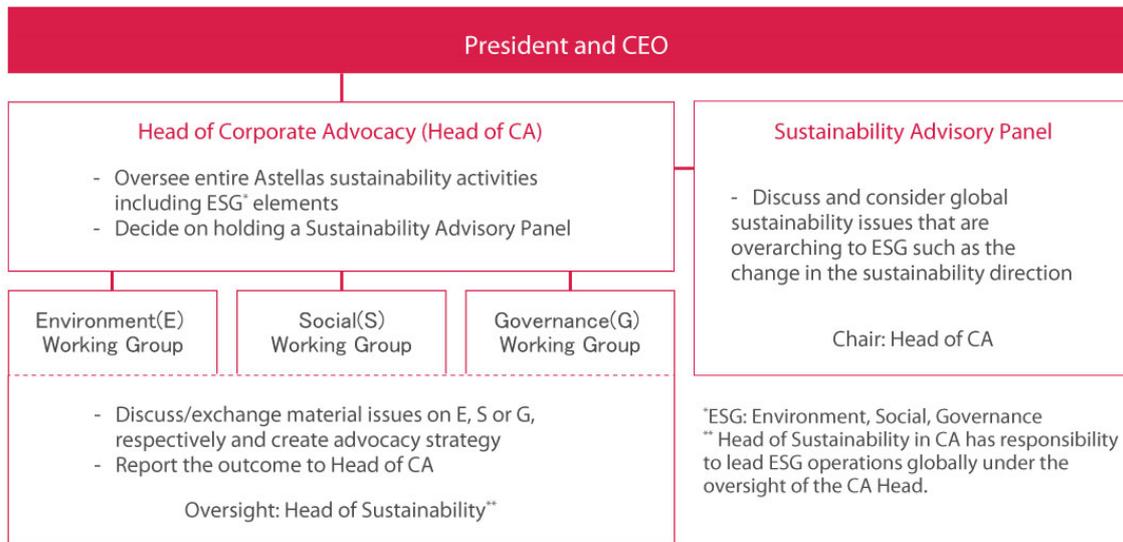
### ESG Working Groups

With reference to the principles, guidelines and the external environment, respective Working Groups identify important ESG matters for the company and consider plans for improvements. They also verify the progress of ESG initiatives and create advocacy strategies.

### Sustainability, Corporate Advocacy

Sustainability, Corporate Advocacy is responsible for working as a secretariat of the Sustainability Advisory Panel and each Working Group and responding to sustainability matters throughout the entire Astellas Group, raising sustainability awareness internally and externally in collaboration with communication functions.

Governance of Astellas' Sustainability



About Astellas / Materiality

# The 31 Material Issues Guiding Our Sustainability Activities



## **Identification and Prioritization of Material Issues**

Astellas' Materiality Matrix guides the company's sustainability activities. Astellas has identified material issues to be addressed based on the issues regarded as prerequisites of business activities. These material issues include global issues related to medical care, health and other broader social issues.

With consideration to the expectations and requests from a broad range of stakeholders, the company classified and prioritized the material issues into three categories by evaluating their societal significance and relevance to our business (Materiality Matrix.) In order to tackle important material issues, we are executing a concrete action plan.

# Three Steps for Determining Materiality

## Step 1

### Identify Issues

Astellas' material issues have been identified with reference to various principles and guidelines (such as ISO 26000, the UN Global Compact's ten principles and the SASB\* Materiality Map), communications with stakeholders and criteria for Socially Responsible Investment (SRI) indices.

\* SASB: Sustainability Accounting Standards Board. A U.S. non-profit organization which sets industry-specific standards for corporate sustainability disclosure. SASB has prepared industry-specific materiality maps by evaluating the materiality of sustainability topics.

## Step 2

### Prioritize

We prioritize Astellas' material issues from the dual perspectives of societal significance and relevance to our business.

## Step 3

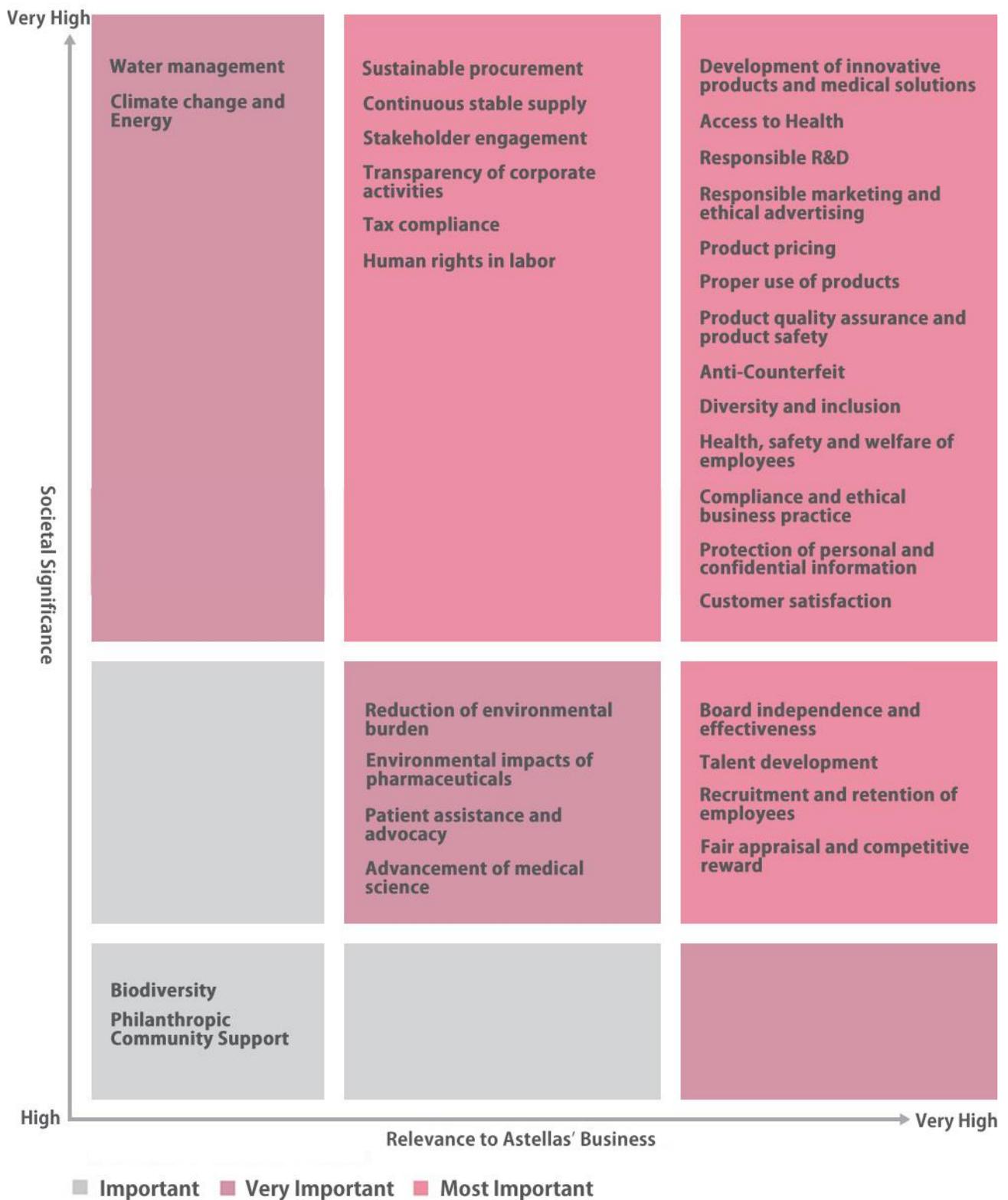
### Review

- Dialogue with stakeholders (investors, patient groups, doctors, employees, consultants, and academics)
- Deliberating on matters during the Sustainability Advisory Panel which is composed of cross-functional Astellas employees
- Deliberating on matters by the Executive Committee\* and obtaining approval by the Board of Directors

\*The Committee discusses material issues concerning business strategies, product strategies, corporate management, and personnel of the Astellas Group companies. The Committee consists of the President and Chief Executive Officer; the Chief Strategy Officer and Chief Financial Officer; the Chief Administrative Officer and Chief Ethics & Compliance Officer; the Chief Medical Officer; the Chief Commercial Officer; the Chief Scientific Officer, the Chief Business Officer; and the General Counsel.

Astellas' material issues are reviewed and verified by the Corporate Advocacy Division once a year. When necessary, the material issues will be modified depending on the level of initiatives implemented and/or any changes regarding the needs of society.

# Materiality Matrix



## Definition and Explanation of Material Issues

Material issue	Definitions / explanation of material issues
Development of innovative products and medical solutions	Creating innovative medicines and medical solutions sustainably in therapeutic areas with a high level of unmet medical needs.
Access to Health	Developing and delivering necessary healthcare to people around the world by accelerating social benefit-driven research and development, enhancing availability, strengthening healthcare system, and improving health literacy
Responsible R&D	Ensuring ethical consideration throughout the entire R&D process, and conducting R&D in compliance with global and/or local guidelines, including ethical considerations in animal testing and clinical trials.
Responsible marketing and ethical advertising	In compliance with laws and guidelines in each country, ensuring equitable and appropriate marketing and advertising activities, raising awareness about diseases and treatments to contribute toward improving health of people.
Product pricing	Striking a sustainable balance between fostering innovation and ensuring access to such innovation by setting prices reflecting the benefits of our products.
Proper use of products	Enhancing the proper use of our products by Healthcare professionals and patients to ensure patient safety and the efficacy and safety of our products. This includes the adoption of user-friendly package design in consideration of convenient universal design.
Product quality assurance and product safety	Ensuring our products are manufactured with appropriate quality assurance standards, and maintaining a functional and robust pharmacovigilance system
Anti-counterfeit	Preventing counterfeit drug problems and improper distribution
Diversity and Inclusion	Ensuring equal opportunity and fair employment regardless of characteristics, including race, nationality, gender, sexual orientation, age or disability
Health, safety, and welfare of employees	Ensuring the mental and physical health of employees, and ensuring a safe workplace. Enriching the welfare of employees and their family
Compliance and ethical business practices	Acting with integrity and making ethical decisions in all aspects, and going beyond compliance with applicable laws, regulations and industry codes. Promoting such behavior through our global compliance structure, the development, implementation, and continuous enhancement of necessary policies and processes, and focusing our activities on Anti-bribery/Anti-corruption compliance, avoiding conflicts of interest, encouraging a "speak-up" culture, and demonstrating our commitment to integrity, ethics, and compliance
Protection of personal and confidential information	Appropriately handling confidential information or our stakeholders' personal information, including data obtained in clinical trials (including post marketing clinical

	trials) by complying with applicable laws, regulations, and Company policies and procedures
Customer satisfaction	Meeting the needs and expectations of customers, such as patients and healthcare professionals, which includes ensuring effective infrastructure and practice to appropriately respond to customers' complaints, inquiries, and consultations
Board independence and effectiveness	The Board of Directors consists of a majority of outside Directors who satisfy the Company's independence standards for outside Directors and the required conditions for independent Directors stipulated by Tokyo Stock Exchange, Inc. The independence and effectiveness of the Board of Directors is ensured by analyzing and evaluating its effectiveness.
Talent development	Providing career development opportunities that respect the ownership, talent, and aptitude of employees
Recruitment and retention of employees	Recruiting and retaining talented people
Fair appraisal and competitive reward	Recognizing the contributions of and appraising and treating employees in a fair manner according to their role and achievement
Sustainable procurement	Selecting suppliers in compliance with selection criteria, including sustainability perspectives, such as compliance with laws and respecting human rights. Guiding less-compliant suppliers and supporting their capacity building for improvement through procurement activities
Continuous stable supply	Ensuring a continuous stable supply of products
Stakeholder engagement	Having mutual dialogues with multiple stakeholders, including patients and shareholders, to understand their expectations and demands from society to reflect their opinions of Astellas' business activities and decision-making process
Transparency of corporate activities	Enhancing the transparency of our corporate activities by disclosing information to all stakeholders in a timely, proper, and fair manner regardless of laws and regulations Examples: <ul style="list-style-type: none"> <li>• Data and information acquired in research and development activities</li> <li>• Board structure</li> <li>• Executive compensation</li> <li>• Risk management system and material risks with mitigation plans</li> </ul>
Tax compliance	Complying with the local tax laws and regulations in each country where we operate and seek to pay the right amount of tax in the right place at the right time
Human rights in labor	Respecting the human rights of employees and business partners, including the elimination of discrimination, the freedom of association and the protection of the rights to organize, and the exclusion of child labor and forced labor

Reduction of environmental burden	Mitigating the environmental burdens caused by business operations to the minimum level, including measures for preventing atmospheric pollution, recycling resources, and the management of chemical substances
Environmental impacts of pharmaceuticals	Identifying and managing the environmental impact of our pharmaceutical products throughout their lifecycle from their manufacture and usage to disposal
Patient assistance and advocacy	Supporting patient organizations for charitable purposes and conducting advocacy activities*, including funding for patient organization activities, sharing knowledge and information such as holding peer support training sessions, promoting disease awareness through disease awareness events, defending patients' rights, and representing the patient's voice  * Advocacy activities: Encouraging the advancement of public policy and society through policy recommendation
Advancement of medical science	Supporting medical and scientific research which contributes to the advancement of medical sciences
Water management	Using water resources efficiently by reducing the volume of withdrawal, reusing, and recycling
Climate change and energy	Reducing greenhouse gas emissions associated with business operations by efficient use of energy
Biodiversity	Mitigating negative impacts on biodiversity and promoting the sustainable use of benefits from biodiversity
Philanthropic community support	Supporting the communities in which we operate. For example, social contribution, such as Disaster Relief, support for employees' volunteering, and nurturing the next generation

## About Astellas / SDGs

# Contributing to the Achievement of Sustainable Development Goals (SDGs)



The Sustainable Development Goals (SDGs) were formally adopted at the United Nations General Assembly in 2015 as universal targets that should be achieved by 2030. Astellas assessed the impact on the SDGs across its entire business activities and identified items for priority action, using the SDG Compass as a reference. In our Corporate Strategic Plan 2021, Astellas has selected “Deepen our engagement in sustainability” as one of its strategic goals and is committed to focusing on the sustainability of society. Key focus areas are provision of patients’ access to innovative therapeutics, and the proactive efforts to improve global environment such as climate change response that are categorized as a value creation activity. These are aligned with “SDGs Goal 3: Good Health and Well-Being” and “SDGs Goal 13: Climate Action”, respectively. We will continue to contribute to the attainment of the SDGs through a variety of business activities.

## Goal 3: Good Health and Wellbeing



Astellas is tackling the SDGs with a focus on Goal 3, which has the strongest affinity to its business philosophy to “contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.” Health is not just a healthcare issue, because losing health could lead to restricting opportunities for education or employment and be the cause of poverty in cases. In light of this, attaining Goal 3 will also contribute to achieving the other SDGs.

### Improving Access to Health in Four Areas

Astellas has adopted “Deepen our Engagement in Sustainability” as one of strategic goals outlined in the Corporate Strategic Plan 2021 and aims to contribute to Goal 3 of the SDGs through the initiatives. 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. We recognize this problem as an Access to Health issue and have identified four areas where we are working to address such issues by making full use of the strengths and technology that we have. The four areas are (1) Creating innovation, (2) Enhancing availability, (3) Strengthening healthcare systems, and (4) Improving health literacy. In doing so, we will make maximum use of our partnerships as defined in Goal 17 (Partnerships for the Goals) of the SDGs.

[Please click here for more detailed information.](#)

## Goal 13: Climate Action



One of the principles of the Astellas Charter of Corporate Conduct is “Recognizing that harmony between the global environment and our business activities is a prerequisite to our corporate existence, we shall take proactive measures to conserve the global environment.” Astellas will need to sensitively grasp changes in the environment and continuously evolve in step with those changes.

Mitigating and adapting to the threat posed by climate change requires active involvement by national governments, local governments, corporations, citizens, and others. Recognizing that climate change will become a constraint on conducting sustained corporate activity, Astellas contributes to SDG Goal 13 “Climate Action” as part of its initiatives to “Deepen our Engagement in Sustainability,” which is one of strategic goals outlined in the Corporate Strategic Plan 2021.

In April 2020, Astellas changed the electricity supply plan in three



Hydroelectric Plant that supplies the electricity generated by renewable energy sources  
(Provided by TEPCO Renewable Power, Inc.)

of its research and production facilities in Japan, to hydroelectric power, which is free of greenhouse gas (GHG) emissions.



Additionally, in December 2020, Astellas expressed its support for the recommendation of the Task Force on Climate-related Financial Disclosures (TCFD), established by the Financial Stability Board (FSB).

Based on the recommendation, Astellas will analyze climate-related risks and opportunities, and proactively disclose information on climate change measures beginning in FY 2021 around the four thematic areas of Governance, Strategy, Risk Management, and Metrics and Targets.

## Initiatives for SDGs

SDGs	Examples of Astellas' initiatives
	<p><u>Creating innovation</u></p> <p><u>Access to Health</u></p>
	<p><u>Human resource development for employees</u></p> <p><u>Provision of training for surgeons through support for the ACTION ON FISTULA™ program, and occupational training for obstetric fistula patients</u></p>
 	<p><u>Diversity and inclusion initiatives</u></p> <p><u>Human rights initiatives</u></p> <p><u>HR Vision</u></p>
     	<p><u>Maintenance/preservation of biodiversity</u></p> <p><u>Reduction of greenhouse gas emissions</u></p> <p><u>Use of renewable energies</u></p> <p><u>Resource recycling initiatives</u></p> <p><u>Prevention of air and water pollution</u></p> <p><u>Disaster relief (COVID-19 response)</u></p>
	<p><u>Promotion of a work-life balance</u></p> <p><u>Occupational health and safety initiatives</u></p> <p><u>Promoting Health Management</u></p>
	<p><u>R&amp;D to create innovative medicines and medical solutions</u></p>

	<p><u>Promotion of R&amp;D for global health through collaboration between the public and private sectors (GHIT fund)</u></p>
	<p><u>Sustainable procurement</u></p> <p><u>Ensure product quality assurance and safety</u></p> <p><u>Reduce the environmental burden of products</u></p>
	<p><u>Compliance and ethical business practices</u></p> <p><u>Established an internal reporting system with a third-party helpline</u></p> <p><u>Anti-bribery and anti-corruption</u></p>
	<p><u>Collaborated with biotechnology startups and academia to create innovative medical solutions</u></p> <p><u>Participated in Access Accelerated</u></p> <p><u>Participated in the GHIT Fund</u></p> <p><u>Signatory to the United Nations Global Compact</u></p> <p><u>Social Contribution</u></p>

## About Astellas

# Corporate Information



### Company Name

Astellas Pharma Inc.

### Headquarters

2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan

Tel. +81-3-3244-3000

[Headquarters Access Map \(Google Maps\)](#)   [Headquarters Annex Access Map \(Google Maps\)](#)

### Foundation

1923

### Capital

103,001 million yen (March 2021)

### Representative Director

Kenji Yasukawa (President and Chief Executive Officer)

### Employees

15,455 (Consolidated basis, March 2021)

### Business Description

Manufacturing, marketing and import/export of pharmaceuticals.

### Organization Chart

As of April 1, 2021

[Organization Chart \(pdf 136KB\)](#)

## About Astellas

# Subsidiaries & Locations



## Office Locations

### Headquarters

2-5-1, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan

Tel.:+81-3-3244-3000

[Access Map \(Google Maps\)](#)

[Headquarters Annex Access Map \(Google Maps\)](#)

### Takahagi Chemistry & Technology Development Center

160-2, Akahama, Takahagi-shi, Ibaraki 318-0001, Japan

### Tsukuba Research Center

21, Miyukigaoka, Tsukuba-shi, Ibaraki 305-8585, Japan

### Tsukuba Biotechnology Research Center

5-2-3, Tokodai, Tsukuba-shi, Ibaraki 300-2698, Japan

### Yaizu Pharmaceutical Research Center

180, Ozumi, Yaizu-shi, Shizuoka 425-0072, Japan

## Major Subsidiaries

### Japan

#### Manufacturing base

Astellas Pharma Tech Co., Ltd.

#### Other

Astellas Green Supply, Inc.

### Americas

The company holds business locations for R&D, manufacturing and sales & marketing in Americas under the name Astellas U.S. Holding.

#### Holding company in North America

Astellas US Holding, Inc.

#### Regional headquarters

Astellas US LLC

#### R&D bases

Astellas Pharma Global Development, Inc.

Astellas Institute for Regenerative Medicine (AIRM)

Astellas Research Institute of America LLC

Astellas Innovation Management LLC

Astellas Venture Management LLC

#### Sales bases

Astellas Pharma US, Inc.

Astellas Pharma Canada, Inc. (Canada)

Astellas Farma Brasil Importação e Distribuição de Medicamentos Ltda. (Brazil)

Astellas Farma Colombia SAS (Colombia)

#### Other

Astellas US Technologies, Inc.

## EMEA

The company holds business locations for R&D, manufacturing and sales & marketing also in EMEA, under the name Astellas B.V.

### **Holding company in EMEA**

Astellas B.V.

### **Regional headquarters (Astellas EMEA operations)**

Astellas Pharma Europe Ltd.

### **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.m.b.H (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 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 ilaç Ticaret ve Sanayi A.Ş. (Turkey)

Astellas Pharma DMCC (United Arab Emirates)

Astellas Pharma Ltd. (United Kingdom)

## Asia/Oceania

The company holds sales & marketing and manufacturing functions in China, and sales offices in Hong Kong, Taiwan, South Korea, the Philippines, Thailand, Indonesia, India, Australia and Singapore.

### **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)

The Representative Office of Astellas Pharma Singapore Pte. Ltd. in Vietnam(Vietnam)

## About Astellas

# Current Share Status



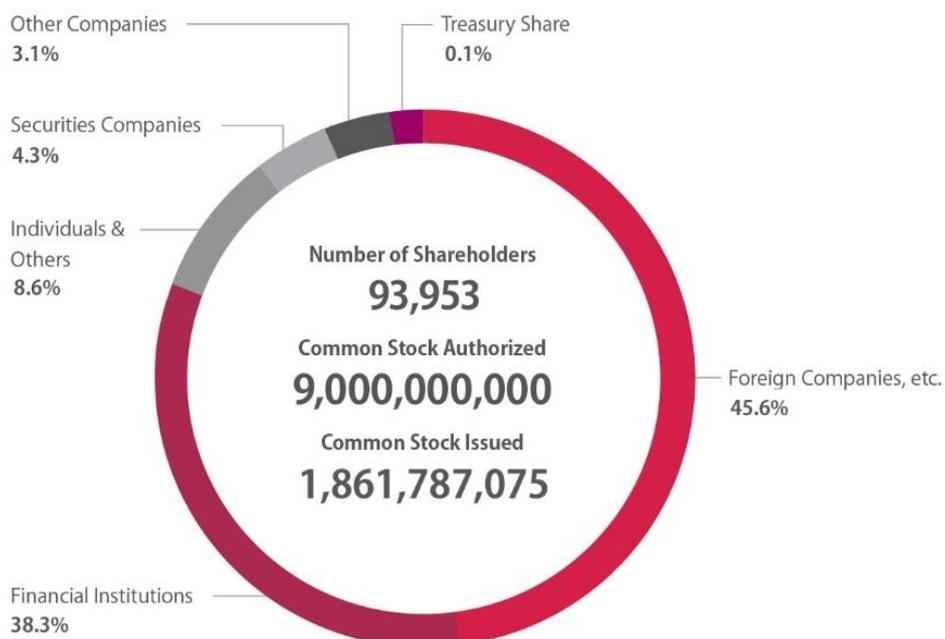
(as of March 31, 2021)

**Number of shareholders: 93,953**

**Common stock Authorized: 9,000,000,000**

**Common stock Issued: 1,861,787,075**

### Breakdown of Shareholders by Type



**Top ten (10) principal shareholders in the register of shareholders:**

	<b>Name of shareholders</b>	<b>Number of shares held (Thousand)</b>	<b>Percentage of shares held (%)</b>
1	The Master Trust Bank of Japan, Ltd. (trust account)	238,582	12.82
2	Custody Bank of Japan, Ltd. (trust account)	128,764	6.92
3	STATE STREET BANK AND TRUST COMPANY 505001	71,274	3.83
4	Nippon Life Insurance Company	64,486	3.46
5	Custody Bank of Japan, Ltd. (trust account 7)	47,934	2.57
6	STATE STREET BANK WEST CLIENT - TREATY 505234	29,094	1.56
7	BNYM AS AGT/CLTS NON TREATY JASDEC	28,863	1.55
8	Custody Bank of Japan, Ltd. (trust account 5)	26,589	1.42
9	GOVERNMENT OF NORWAY	26,537	1.42
10	JP MORGAN CHASE BANK 385781	23,952	1.28

\*Number of shares held are presented by discarding the numbers down to the thousand, and percentage of shares are presented by discarding the numbers down to the third decimal.

# Astellas Value Creation



## **Towards the Realization of Our VISION**

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 "be on the forefront of healthcare change to turn innovative science into value for patients." This is Astellas' VISION.

For the realization of our VISION, we announced Corporate Strategic Plan 2021 ("CSP2021") in May 2021. While inheriting the basic strategy of Corporate Strategic Plan 2018, the company set four strategic goals with the intention of evolving and developing each strategic goal.

To address Strategic Goal 1 "Enable patients to achieve better outcomes," we will seek to maximize the value of strategic products.

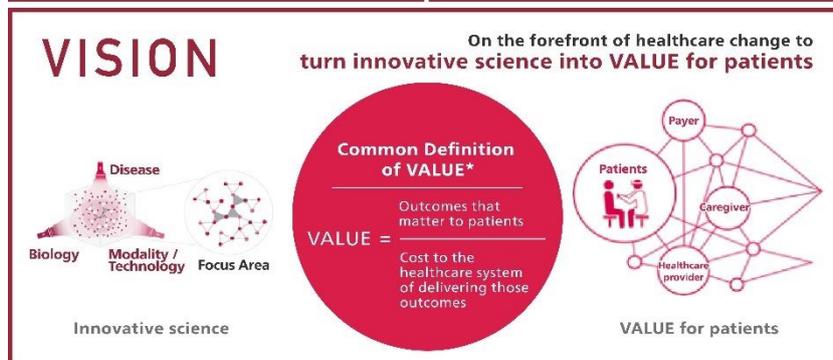
For the achievement of Strategic Goal 2 "Translate innovative science into proven VALUE," Astellas will enhance its pipeline value by giving priority to investing management resources into multiple programs, created from the Focus Area approach.

For Strategic Goal 3 "Advance the Rx+<sup>®</sup> business," Astellas aims to commercialize multiple projects during the CSP2021 period.

In addition, we set "Deepen our engagement to sustainability" as a brand new, fourth Strategic Goal under CSP2021.

By firmly committing to these Strategic Goals, we will make steady progress towards the realization of our VISION.

<b>Raison D'être</b> Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products	<b>Mission</b> Sustainable enhancement of enterprise value
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Philosophy  
[Read more](#)

VISION  
[Read more](#)

### Corporate Strategic Plan 2021

<b>SG1</b> Enable patients to achieve better outcomes	<b>SG2</b> Translate innovative science into proven VALUE	<b>SG3</b> Advance the Rx+® business	<b>SG4</b> Deepen our engagement in sustainability
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### Business Review

Corporate Strategic Plan  
[Read more](#)

Business Review  
[Read more](#)



### Realization of our VISION

\*Adapted from "What Is Value in Health Care?" Porter, M.E. (2010). New England Journal of Medicine

# Corporate Strategic Plan 2021 - Deep Commitment to Realize Our VISION



Over the last three years, empowered by Corporate Strategic Plan 2018 (“CSP2018”), Astellas has continued to offer meaningful VALUE for patients by translating innovative science into life-changing therapies. We are convinced that the steps taken so far are along the right path. Leveraging our accomplishments under CSP2018, we will move forward with renewed ambition as represented by Corporate Strategic Plan 2021 (“CSP2021”). CSP2021 sets three types of goals: Strategic Goals as signposts towards the realization of our VISION; Organizational Health Goals to build a workplace where innovation and exceptional execution are cultivated and sustained; and Performance Goals that represent the subsequent enhancement of Astellas corporate value achieved through all of its activities. By constantly striving towards these three types of goals, designed to guide and maintain an appropriate balance in our efforts, Astellas will make the right judgments to maximize its value to society.

## Overview of Corporate Strategic Plan 2021



\*1 Adapted from “What Is Value in Health Care?” Porter, M.E. (2010). New England Journal of Medicine

\*2 XOSPATA, PADCEV, zolbetuximab, Evrenzo, fezolinetant, AT132

## Four Strategic Goals to Create VALUE and Realize Our VISION

Creating and delivering VALUE through the pursuit of four goals



### SG1: Enable patients to achieve better outcomes

Astellas is committed to maximize patient access to our products and to partner effectively with healthcare stakeholders to secure the realization of VALUE. To achieve this, we strive to accelerate submission of New Drug Applications (NDAs), reducing the time to achieve broad geographic coverage, implementing sophisticated launch plans and prioritizing our efforts across the portfolio towards where the VALUE opportunity is greatest. We will take a patient-oriented approach, adopting new techniques to create and use data and implement solutions that overcome obstructions to patient access or important factors that limit real-world outcomes. It is through pursuing these activities in association with SG1 that Astellas will maximize the value of XTANDI<sup>®</sup> and strategic products that drive medium- to long-term growth.

### SG2: Translate innovative science into proven VALUE

Astellas will apply a Focus Area Approach and create products which deliver high levels of VALUE through combinations of biology, modalities, and diseases. At every stage of the research and development process, we will evaluate the potential for innovation based on VALUE and choose the right way to proceed in order to fully demonstrate that potential. We will accelerate and expand strategies for each Primary Focus and create a framework that will allow us to apply new capabilities across organizational boundaries. Astellas will focus on open innovation to make breakthrough discoveries available to patients. Bearing in mind regions with cutting-edge science, top talent, and the highest potential success rates, we will continue collaborating with world-leading partners. Astellas will make its presence felt at the ever-changing cutting-edge of science and aim to be the partner of choice as a company. We will further advance our Focus Area Approach, while considering the optimal balance between research and development in existing Focus Areas and the exploration of new Focus Area candidates.

### SG3: Advance the Rx+<sup>®</sup> business

The Rx+<sup>®</sup> business will enter the stage where efforts for business creation will bear fruit in CSP2021. Astellas will continue to pursue turning innovative science into VALUE for patients in unprecedented ways. We will focus on Spheres where we are actively developing new businesses, especially “Chronic Disease Progression Prevention” and “Patient Outcome Maximization via Precise Surgery/Diagnosis,” and will work on achieving commercialization of Business Accelerator Programs (BAPs), creating and implementing projects with a high

success rate. During the period of CSP2021, we plan to commercialize multiple projects including BlueStar<sup>®</sup>, digital therapeutics for patients with diabetes in Japan, and ASP5354, an imaging agent being investigated for intraoperative ureter visualization in patients undergoing minimally invasive and open abdominopelvic surgeries.

#### **SG4: Deepen our engagement in sustainability**

Astellas' core business provides meaningful VALUE for patients by translating innovative science into life-changing therapies and delivers VALUE to society. We will further increase our efforts to improve the sustainability of society and Astellas. Leveraging Astellas' strengths, technologies, and expertise, we will strengthen value creation activities which will help improve access to health and address environmental issues, especially climate change. We will also actively advocate our sustainability efforts, including topics related to environmental, social, and governance (ESG) concerns, therefore earning the trust of all stakeholders through maximizing positive societal impact.

### **Establishment of Three Organizational Health Goals**

For the first time in a Corporate Strategic Plan, CSP2021 sets three Organizational Health Goals, designed to overcome organizational and behavioral obstacles to strategy execution. Through this, Astellas aims to create an environment which will translate into a superior performance in the longer term.

The first is "Empowerment to take appropriate risks and support to be 'outcome-driven' and 'innovation-focused'." Fostering a culture in which smart risk taking and smart failures are acceptable will lead to continuous and more valuable innovation faster, whilst at the same time never compromising on patient safety or product integrity or compliance with regulations.

The second is "Purposeful talent management with a consistent leadership style." The deployment of a global human resource management strategy will give all employees more opportunities to use their skills and abilities to contribute to patients and business performance and to advance their careers according to their chosen career path while growing as individuals.

The third is "Effective co-operation with robust and coordinated execution to achieve common goals." A better understanding of Astellas' strategies and the actions expected of us as One Astellas will lead to closer cooperation, helping us learn from each other, trust each other, and continue to create breakthrough innovations.

### **FY2025 Performance Goals**

Realize sustainable growth by steadily implementing the following three goals.

- 1. Revenue: XTANDI and Strategic products\* sales  $\geq$  ¥1.2T in FY2025**
- 2. Pipeline Value: Focus Area projects expected sales  $\geq$  ¥0.5T in FY2030**
- 3. Core Operating Profit Margin:  $\geq$  30% in FY2025**

By achieving these three Performance Goals, we aim to become a company with a market capitalization valued at more than ¥7 trillion in fiscal 2025.

## Plan for Realization of CSP2021

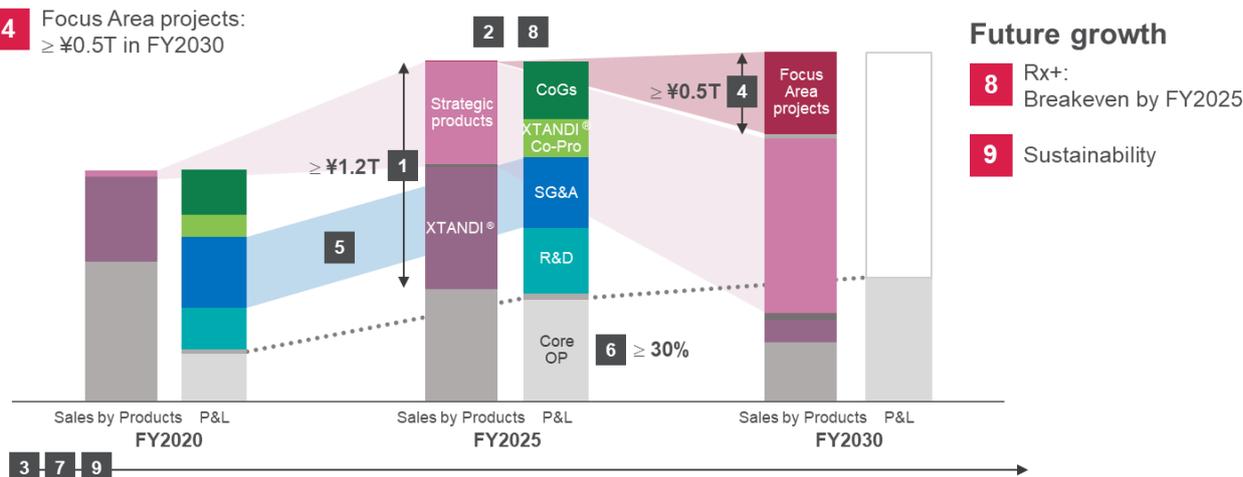
### Revenue, Pipeline Value

- 1 XTANDI® and Strategic products:  $\geq \text{¥}1.2\text{T}$  in FY2025
- 2 Post-PoC projects from Primary Focuses
- 3 Multiple technology platforms
- 4 Focus Area projects:  $\geq \text{¥}0.5\text{T}$  in FY2030

Market Cap  
**¥7T**  
in FY2025

### Core OP

- 5 Flat SG&A in absolute terms
- 6 Sufficient R&D investments  
Core OP margin of  $\geq 30\%$  in FY2025
- 7 Steady increase in dividends



### Future growth

- 8 Rx+: Breakeven by FY2025
- 9 Sustainability

### Expansion of revenue and pipeline value

Astellas aims to achieve sales revenue of XTANDI® and strategic products (XOSPATA®, PADCEV®, zolbetuximab, EVRENZO®, fezolinetant, AT132) of more than  $\text{¥}1.2$  trillion in fiscal 2025. We will maximize the product value of XTANDI®, XOSPATA®, and PADCEV®, which have already been approved for one or more indications, by continuing to implement various strategic initiatives to expand approval to include earlier stage patients. We plan to file initial applications for zolbetuximab, fezolinetant, and AT132 in fiscal 2022. As shown in the table below, our peak sales estimates are  $\text{¥}600\text{-}700$  billion for XTANDI® and around  $\text{¥}1$  trillion in total for the strategic products from fezolinetant through AT132, excluding XTANDI®.

## Potential peak sales XTANDI® and strategic products

Product	Potential Peak Sales (Global, billions of yen)
XTANDI® (enzalutamide)	600 - 700
fezolinetant	300 - 500
PADCEV® (enfortumab vedotin) <sup>1</sup>	300 - 400
XOSPATA® (gilteritinib)	100 - 200
Zolbetuximab	100 - 200
Evrenzo® (roxadustat) <sup>2</sup>	50 - 100
AT132 (resamirigene bilparvovec)	50 - 100

Note) Only indications undergoing pivotal studies are included for projection (as of May 2021)

1. Sales for Americas are calculated based on the sales booked by Seagen

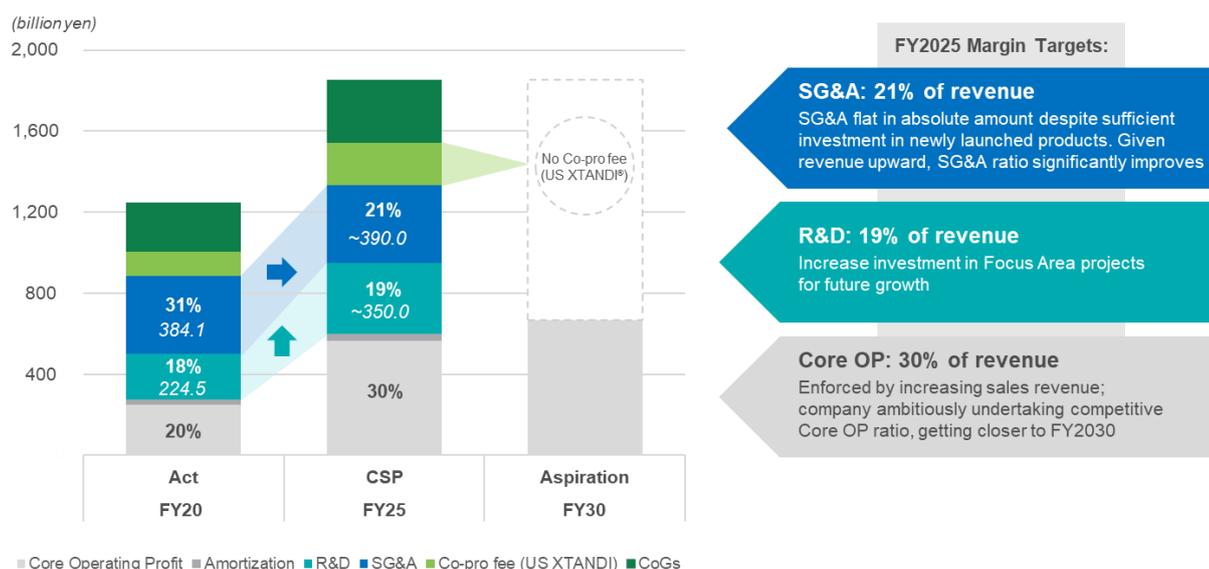
2. Astellas territories only; Japan, Europe, the Commonwealth of Independent States, the Middle East, South Africa, etc.

Based on the unique Focus Area Approach, Astellas has currently defined four Primary Focuses: Immuno-Oncology, Blindness & Regeneration, Mitochondria Biology, and Genetic Regulation. We are prioritizing these areas for the investment of management resources to enhance pipeline value. Currently, there are approximately 30 projects driving towards clinical proof of concept by the end of fiscal 2025 in Primary Focus and Primary Focus Candidates. As a result, the company expects to contribute more than ¥500 billion to sales in fiscal 2030 from these projects.

### Aiming for a core operating margin of more than 30%

Based on estimates of revenue growth and necessary costs during the period of CSP2021, Astellas believes it can aim for a core operating margin of more than 30%. By implementing Strategic Goals 1 and 2, sales revenue is expected to grow at around 8% per year, alongside the company's continued focus on investment in new product launch readiness and digital transformation while taking initiatives to drive efficiency and excellence. As a result, the company will hold SG&A expenses in fiscal 2025 to approximately ¥390 billion, which is the same level as in fiscal 2020, and reduce the ratio of SG&A to revenue to 21% (fiscal 2020: 31%). With this expected strong sales growth, Astellas could achieve its performance goal of core operating profit margin of more than 30% in fiscal 2025 even if the company increases R&D expenses to 19% of sales in fiscal 2025 (fiscal 2020: 18%) and an absolute amount of ¥350 billion.

## Growth Scenario under CSP2021



## Capital Allocation Consistent with Basic Policy

The capital allocation plan is consistent with our previous basic policy, that is, while putting a priority on business investment to assure future growth, we will strive to increase dividend payments stably and continuously based on our medium- to long-term profit growth.

During the five-year period starting from the first fiscal year of CSP2021, we will move towards a full-scale profit growth trend. Throughout the period of CSP2021, we will aim for stable and sustainable improvement in dividends based on medium-term profit growth.

In fiscal 2021, Astellas expects to pay an annual dividend of ¥50, an increase of ¥8 compared with the previous fiscal year's dividend of ¥42. We believe that higher dividends will increase long-term shareholder returns and will also open up ways for achievement of our market cap target. We will also flexibly execute share buybacks utilizing excess cash to increase capital efficiency and shareholder return.

### Basic Policy for Capital Allocation Under CSP2021

- 1 Top priority is investment for business growth
- 2 Raise dividend level aligned with profit / cashflow plan and actual performance throughout CSP2021 period
- 3 Flexibly execute share buyback by excess cash

### Investing in growth while keeping SG&A flat in absolute terms

Astellas will make the necessary investments in growth from a medium- to long-term perspective, allocating resources as appropriate, while at the same time thoroughly implementing groupwide cost-cutting measures. During the period of CSP2021, we plan to launch new priority products and obtain approval of new indications.

We will make investments in priority areas to maximize launch opportunities for new products such as fezolinetant and zolbetuximab, the establishment of a commercial organization framework for cell and gene therapies, and IT and digital investment to evolve our business.

### Transformation of SG&A Cost Structure during CSP2021



# Business Review



## Delivering Proven VALUE for Patients

Our VISION is “Be on the forefront of healthcare change to turn innovative science into VALUE for patients.”

Through our business activities, we will realize our VISION by pursuing cutting-edge science and utilizing our global network to create continuous innovation.

Our Strategic Goals under Corporate Strategic Plan 2021 are to “Enable patients to achieve better outcomes,” “Translate innovative science into proven VALUE,” “Advance the Rx+® business” and “Deepen our engagement in sustainability.” By steadily pursuing these goals, we will achieve medium-to long-term growth and improve the sustainability of Astellas and society.

### Corporate Strategic Plan 2021

#### Our Strategic Goals (SG)



## Main Products



[Read more](#)

## Rx+<sup>®</sup> Business



[Read more](#)

## Pipeline Projects



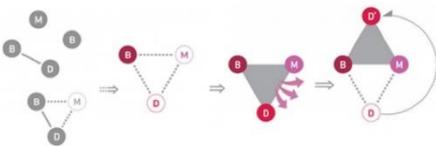
[Read more](#)

## Major Pipeline



[Read more](#)

## Focus Area Approach



[Read more](#)

# Main Products for Maximizing Value



Products listed on this website are the main products that Astellas provides globally. These products may not be available in all countries or regions and may be available under different brand names and trademarks, for different indications and patient populations, in different dosages, and in different strengths. These products generally are available only by prescription through local healthcare professionals. Please visit [our local country or region websites](#) for local product information.

## Prostate Cancer Treatment

### XTANDI®

XTANDI® is an androgen receptor signaling inhibitor indicated for the treatment of different forms of advanced prostate cancer. Since being launched in the United States in 2012, XTANDI® is now available around the world, including in Europe, Japan and China. Since its launch, it has obtained additional indications for the earlier stages of prostate cancer and has contributed to the treatment of many patients.

With a strong presence in the urological field and by leveraging abundant data based on accumulated clinical experience since its launch, Astellas is striving for a further penetration of approved indications.

## **Acute Myeloid Leukemia (AML) Treatment**

### **XOSPATA®**

XOSPATA® is a FLT3 inhibitor for adult patients with FLT3 mutation-positive relapsed/refractory acute myeloid leukemia. In addition to Japan, the United States, and Europe, and a few other countries, it was launched in China in April 2021.

AML is a cancer that affects the blood and bone marrow, and about 30% of the patients are reported to have mutations in the FLT3 protein, a receptor tyrosine kinase involved in the growth of cancer cells. XOSPATA® is believed to inhibit the growth of tumor cells bearing FLT3 mutations by showing inhibitory activity against mutations in both internal tandem duplication mutations (Internal Tandem Duplication: ITDs) and tyrosine kinase domain mutations (Tyrosine Kinase Domain: TKDs), which are activating mutations in FLT3.

Astellas contributes to the treatment of AML by providing XOSPATA® as a new treatment option for FLT3m+ relapsed or refractory AML patients and healthcare professionals.

## **Metastatic Urothelial Cancer Treatment**

### **PADCEV®**

PADCEV® (enfortumab vedotin-ejfv), a treatment for adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1/L1, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting, was launched in the United States in December 2019.

PADCEV® is a first-in-class antibody-drug conjugate (ADC) that is directed against Nectin-4, a protein located on the surface of cells. Nonclinical data suggest that the anticancer activity of PADCEV® is due to the binding of the ADC to Nectin-4-expressing cells followed by internalization of the ADC-Nectin 4-complex and release of MMAE via proteolytic cleavage. Release of MMAE disrupts the microtubule network within the cell, subsequently inducing cell-cycle arrest and apoptotic cell death.

Metastatic urothelial cancer is a serious disease with limited treatment options. Astellas will contribute to the treatment of metastatic urothelial cancer by providing PADCEV® as a treatment option in the United States for adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1/L1, and a platinum-containing chemotherapy in a neoadjuvant/adjuvant, locally advanced or metastatic setting.

## **Renal Anemia Treatment**

### **Evrenzo®**

Evrenzo® is an oral, first-in-class treatment for anemia associated with chronic kidney disease (CKD). In November 2019, it was launched in Japan for the treatment of anemia in adult CKD patients who are dialysis dependent (DD). Additionally, in November 2020, we obtained approval for an additional indication of anemia of chronic kidney disease (CKD) in adult patients not on dialysis based on the results of clinical trials in Japanese

patients. The additional indication has expanded the indication for renal anemia in general.

Evrenzo® is an inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase (PH), which is different from that of erythropoiesis-stimulating agents (ESAs). As a HIF-PH inhibitor, Evrenzo® activates a response that occurs naturally when the body responds to reduced oxygen levels in the blood. This response involves the regulation of multiple, complementary processes to promote erythropoiesis and to increase the blood's oxygen-carrying capacity.

As a new treatment option for adults with CKD anemia, where unmet medical needs still exist, the drug will further contribute to patients with CKD anemia and healthcare professionals involved in its treatment. It is under development in Europe and elsewhere in addition to Japan.

### **Betanis/Myrbetriq/BETMIGA (mirabegron)**

Betanis/Myrbetriq/BETMIGA for the treatment of OAB is a beta-3 adrenergic receptor agonist. Since the first launch in Japan in 2011 under the brand name of Betanis, the product has since been launched as Myrbetriq in the Americas, as BETMIGA in Europe and China, and a few other countries.

The drug improves various symptoms associated with OAB, such as urgency, urinary frequency, and urge urinary incontinence.

Astellas aims to maximize its product VALUE by ensuring that more physicians understand the balance between efficacy and tolerability, the feature of this product.

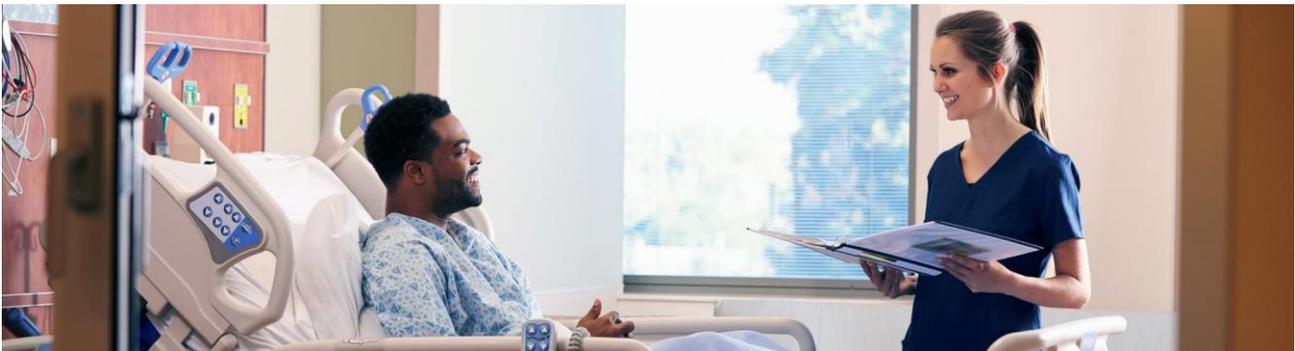
### **Immunosuppressants**

#### **Prograf and Advagraf/Gracaptor/ASTAGRAF**

Prograf and Advagraf/Gracaptor/ASTAGRAF are immunosuppressants used to suppress organ rejection following a transplant. Although the patent for this drug has already expired in major countries, it continues to be used in transplants globally and contributes to the treatment of autoimmune diseases such as rheumatoid arthritis and ulcerative colitis in Japan.

Please refer to the Supplementary Documents (pdf) of the [Business Results](#) in regard to the sales of major products in each region, including the products above.

# Seven Projects Positioned as Strategic Products for Priority Development



## **enzalutamide (brand name: XTANDI®)**

Enzalutamide is marketed worldwide for the treatment of castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Astellas is developing enzalutamide in collaboration with Pfizer Inc. to expand the indications to earlier stages of prostate cancer.

Enzalutamide is an androgen receptor (AR) inhibitor. It targets the AR and exerts its effects on three steps of the AR signaling pathway: inhibiting androgen binding to the receptor; preventing nuclear translocation; and impairing DNA binding of the AR to the DNA.

Prostate cancer is the second most common cancers in men and 1.4 million men annually are newly diagnosed worldwide.\*<sup>1</sup> Astellas is focusing on further development so that enzalutamide can help more patients.

\*<sup>1</sup> World Health Organization Cancer Fact Sheet 2020

## **gilteritinib (brand name: XOSPATA®)**

Gilteritinib is marketed for the treatment of patients with relapsed or refractory FLT3 mutation-positive acute myeloid leukemia (AML) in regions including Japan, the U.S., Europe, and China. Astellas is developing gilteritinib to expand the indications to earlier stages of AML.

Gilteritinib inhibits mutated FLT3, a receptor type tyrosine kinase known to be involved in cancer cell

proliferation. FLT3 mutations are seen in approximately one-third of patients with AML.<sup>\*2</sup> Gilteritinib demonstrates inhibitory activity against major types of mutations that are internal tandem duplications and tyrosine kinase domain mutations.

AML is a life-threatening disease and requires early intervention. Induction and consolidation chemotherapy are the current standard care. However, resistance to current AML treatments and ineligibility of high-intensity induction chemotherapy for elderly patients due to excessive physical burden makes AML treatment challenging. Promising new treatment options targeting specific genetic mutations have been awaited in the AML treatment landscape.

\*2 Patel JP, et al., 2012

## **enfortumab vedotin (brand name: PADCEV®)**

In the United States, enfortumab vedotin is marketed by Seagen Inc. for the treatment of locally advanced or metastatic urothelial cancer previously treated. Further development to expand the regions and the indications to earlier stages of urothelial cancer is ongoing.

Enfortumab vedotin is an antibody-drug conjugate (ADC)<sup>\*3</sup> composed of an anti-Nectin-4 monoclonal antibody attached to a microtubule-disrupting agent, MMAE, using Seagen's proprietary linker technology. Enfortumab vedotin targets Nectin-4, a cell adhesion molecule that is expressed in many solid tumors.

Urothelial cancer is the most common type of bladder cancer (90% of cases). Globally, approximately 570,000 people are diagnosed with bladder cancer annually, and there are approximately 210,000 deaths worldwide.<sup>\*4</sup> It is known that Nectin-4 is highly expressed in urothelial cancer.<sup>\*5</sup>

Enfortumab vedotin is currently also under development for other solid tumors.

\*3 Antibody-drug conjugate (ADC): ADCs are monoclonal antibodies that are designed to selectively deliver cytotoxic agents to cancer cells.

\*4 World Health Organization Cancer Fact Sheet 2020

\*5 Challita-Eid PM, et al., 2016

## **zolbetuximab**

Astellas is developing zolbetuximab as a treatment for gastric and gastroesophageal junction (GEJ) cancer. Zolbetuximab is an antibody that targets Claudin 18.2, a transmembrane protein that forms a tight junction connecting and binding two adjoining cell membranes. In normal cells, Claudin 18.2 is expressed locally in stomach cells, while in cancerous cells, it is expressed in various cancer types including gastrointestinal adenocarcinomas, as well as pancreatic, biliary duct, ovarian, and lung cancers.

Gastric and GEJ cancer is one of the malignancies that has the highest unmet medical needs. Gastric cancer is the fourth leading cause of cancer death worldwide.<sup>\*6</sup> Moreover, the overall five-year survival rate for metastatic gastric and GEJ cancer is under 20%.<sup>\*7</sup> 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 for HER2-negative patients who lack effective targeted therapies.

Zolbetuximab is currently under development also in pancreatic adenocarcinoma. Pancreatic cancer is the seventh leading cause of cancer death worldwide<sup>\*6</sup> and shows a low overall five-year survival rate at 4%.<sup>\*8</sup>

\*6 World Health Organization Cancer Fact Sheet 2020.

\*7 Pennathur A, et al., 2013; Sahin U, et al., 2008

\*8 Ilic M, et al., 2016

## **roxadustat (brand name: EVRENZO®)**

Astellas is developing roxadustat in collaboration with FibroGen, Inc. as a treatment for anemia associated with chronic kidney disease (CKD). Astellas has the development and commercialization rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa. Roxadustat is marketed in Japan for the treatment of renal anemia.

Roxadustat has a new mechanism of action, inhibiting hypoxia-inducible factor (HIF) prolyl hydroxylase (PH). By inhibiting HIF-PH, roxadustat increases HIF involved in the production of red blood cells, thereby enhancing the production of red blood cells and improving anemia.

Anemia is one of the common complications of CKD. It is reported that the progression of anemia in CKD leads to end-stage renal disease and increases its mortality rate.<sup>\*9</sup> Roxadustat can be a new treatment option as the first-in-class and orally administered drug for anemia associated with CKD, a condition with high unmet medical needs.

Roxadustat is currently under development also in chemotherapy-induced anemia.

\*9 Stauffer ME, et al., 2014

## **fezolinetant**

Astellas is developing fezolinetant as a non-hormonal treatment for vasomotor symptoms (VMS) associated with menopause (hot flashes (also called hot flushes) and/or night sweats).

Fezolinetant is an antagonist of the NK3 receptor. Fezolinetant works by blocking neurokinin B (NKB) signaling and normalizing KNDy (kisspeptin/NKB/dynorphin) neuron activity, which modulates the temperature control center and reduces the frequency and severity of MR-VMS.

Hot flashes are the most common symptom for women transitioning through menopause.<sup>\*10</sup> Globally, approximately 57% of women aged 40 to 64 years have reported occurrences of hot flashes and sweating.<sup>\*11</sup> VMS have a significant impact on a woman's quality of life, including sleep. Currently, there are limited non-hormonal options for managing this condition, and new safe and effective non-hormonal therapeutics are awaited.

\*10 Freedman RR, 2014

\*11 Utian WH, 2005

## **resamirigene bilparvovec (AT132)**

Astellas is developing resamirigene bilparvovec (AT132) as a treatment for X-linked myotubular myopathy.

AT132 is an AAV8 vector containing a functional copy of the MTM1 gene and may provide patients with significantly improved outcomes based on the ability of AAV8 to target skeletal muscle and increase myotubularin expression in targeted tissues following a single intravenous administration.

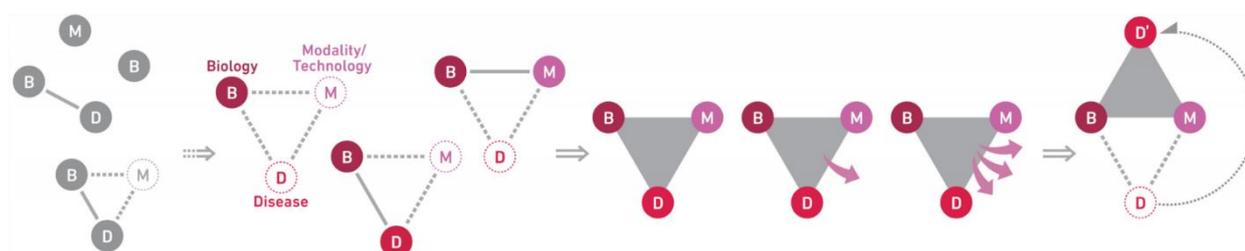
XLMTM is a serious, life-threatening, rare neuromuscular disease that is characterized by extreme muscle weakness, respiratory failure, and early death. XLMTM is caused by mutations in the MTM1 gene that lead to a lack or dysfunction of myotubularin, a protein that is needed for normal development, maturation, and function of skeletal muscle cells. The disease affects approximately 1 in 40,000 to 50,000 newborn males, and mortality rates are estimated to be 50% in the first 18 months of life. More than 80% of patients require ventilator support, and normal developmental motor milestones are delayed in most patients. Currently, only supportive treatment options, such as ventilator use or a feeding tube, are available.

AT132 is expected to be the first gene therapy for XLMTM.

Please see [here](#) for details of target diseases and the status of each project.

## Business Review

# Focus Area Approach



## Our Focus Area Approach

Astellas has established a Focus Area Approach for its research and development strategy. Specifically, our Focus Area Strategy is defined as combinations of three components: (1) biologies with high disease relevance, (2) versatile modalities/technologies, and (3) diseases with high unmet medical needs that are expected to be tackled by the first two components. We view this strategy as a way to build a sustainable, expandable drug discovery approach to develop new platforms, leverage expertise and create innovative products.

The Focus Area is constantly adapting in response to advances in science and changes in disease treatment paradigms.

In the past, we have achieved success by identifying business opportunities from a disease domain perspective, based on the concept of the Global Category Leader (GCL) model. However, given major changes in the healthcare industry environment, we realize that identifying drug discovery opportunities more flexibly and efficiently is becoming crucial to continuously create new drugs and bring VALUE for patients. To this end, we developed our Focus Area Approach. It is designed to identify opportunities for the continuous creation of new drugs by focusing on biology, modalities, and technologies regardless of the disease area.

We will continue to develop new drug candidates for diseases with high unmet medical needs based on our expertise in each biology, modality, and technology that make up the Focus Area. What is particularly noteworthy is that the Focus Area Approach is not fixed, but continuously evolving by adapting its components to reflect the progress of research and development and the latest progress in science and technology. This will

allow Astellas to develop its strengths while flexibly and efficiently identifying and realizing new drug discovery opportunities.

In particular, Primary Focus is a specific focal point within our Focus Area Approach where a lead and follow-on projects show a clear R&D path with expected commercial feasibility. Based on criteria such as higher scientific validity and identification of leads and follow-on programs, we are currently working on four Primary Focus.

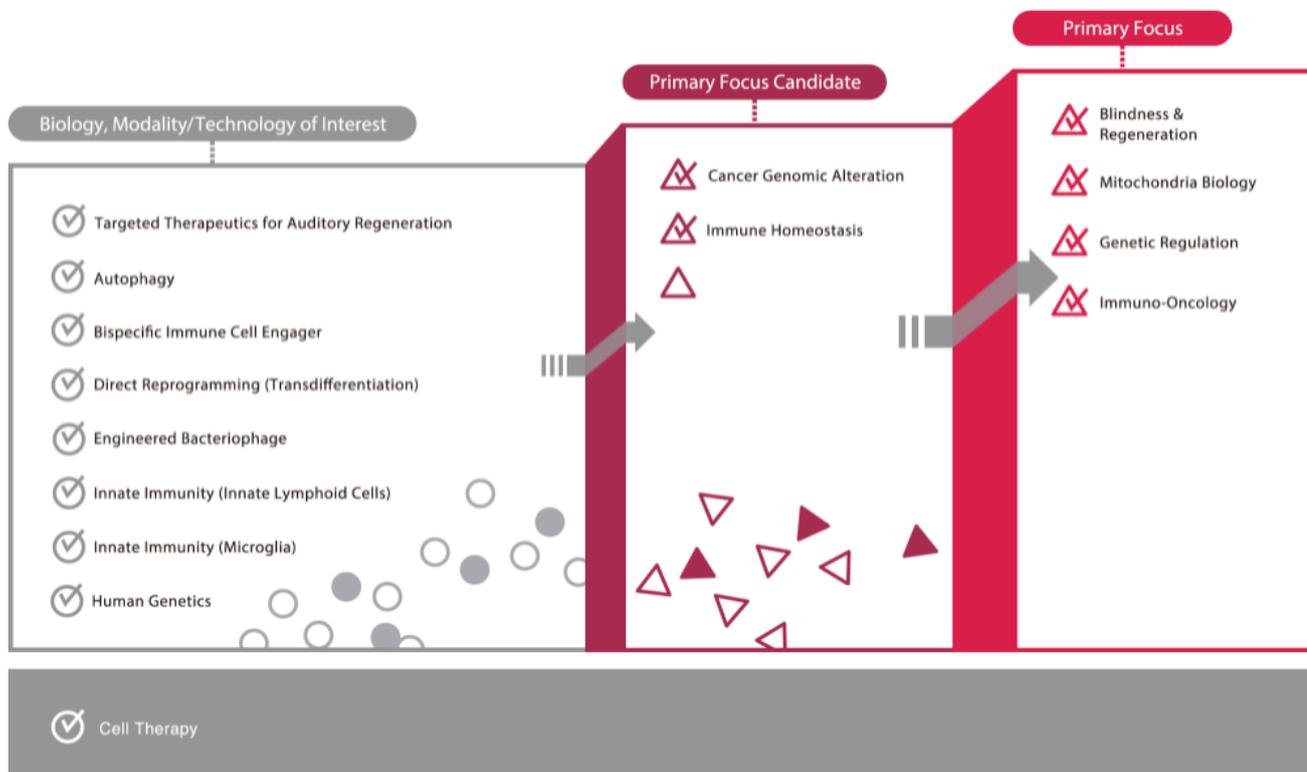
## Systematic Evolution to Identify Primary Focus

Based on a Focus Area Approach, we concentrate our R&D investments on Primary Focus, and work to develop innovative treatments. These include Blindness & Regeneration, which offers new treatment options such as cell therapy for restoring and maintaining vision; Mitochondria Biology, which tackles development of mitochondrial replacement therapy; Genetic Regulation, which works on making progress in gene therapy; and Immuno-Oncology, which works on discovering, developing and delivering the best innovative cancer medicines to patients.

We also identify Biology, Modalities/Technology that may become Primary Focus in the future as Primary Focus Candidates, e.g. Cancer Genomic Alteration, Immune Homeostasis.

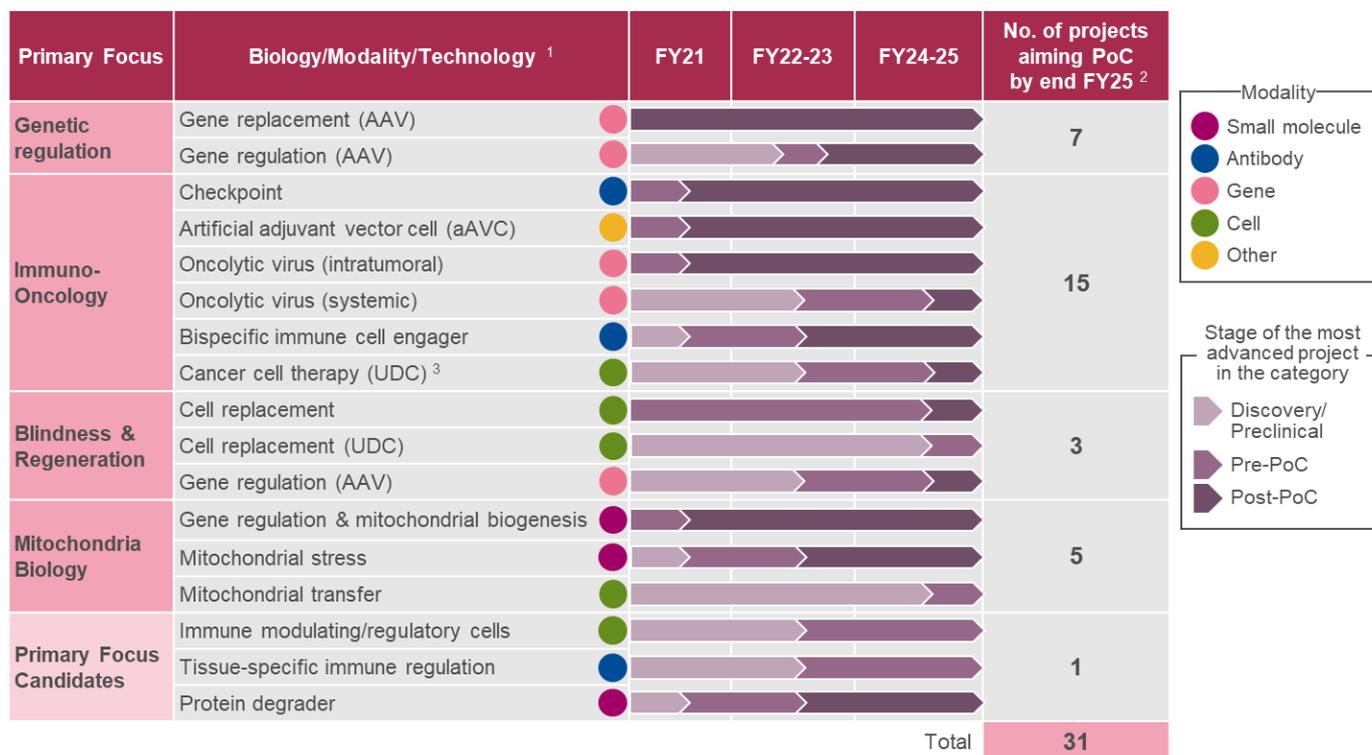
As areas of interest for Astellas, which are much earlier than Primary Focus and Primary Focus Candidates, we are exploring Biology, Modality/Technology, e.g. Targeted Therapeutics for Auditory Regeneration, Autophagy.

The following diagram shows how our research and development areas evolve step by step.



## Clinical Proof and Expansion of Key Platforms

Primary Focuses have a robust pipeline to newly build a Post-PoC portfolio by the end of FY2025.



1. Not exhaustively listed.

2. Estimated based on standard development timelines, assuming 100% probability of success (as of May 2021).

3. The first convertibleCAR program (with autologous cells) IND is planned for late FY2021. PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

### Related Links

[Primary Focus](#)

[Cell Therapy](#)

[Primary Focus Candidates](#)

[Biology, Modality/Technology of Interest](#)

# Primary Focus

## Blindness & Regeneration



Our mission for Primary Focus Blindness & Regeneration is to free patients from the fear of vision loss, and offer the hope of recovery of lost sight. By taking advantage of next-generation modalities such as cell therapy and gene therapy for patients with back of the eye diseases at high risk of blindness, we will provide new treatment options to restore and maintain vision. Cell therapy and gene therapy will enable us to meet unmet medical needs that were difficult to meet with existing therapeutic approaches. It has the promise of delivering safe, effective, and sustainable options for patients who previously have not had any treatment options.

Our capabilities range from research, CMC and development of pluripotent stem cell (PSC)-based cell therapy, Universal donor cell technology, design and CMC of adeno-associated virus (AAV)-based gene therapy, in ophthalmology area. Astellas can be uniquely positioned as an innovative company, armed with both cell-based medicine and virus-based medicine as core strengths.

**Our Primary Focus Blindness & Regeneration has been working on the below leading programs.**

### [Human pluripotent stem cell (PSC) -derived cell therapy programs]

- Retinal pigment epithelial cell (ASP7317, Phase 1)
- Photoreceptor, retinal ganglion cell, corneal endothelial cell (preclinical)
- Universal donor cell-based retinal pigmental epithelial cell (preclinical)

### [Gene therapy programs based on adeno-associated virus (AAV) ]

- Next generation gene therapy targeting retinal diseases (preclinical)

Compound	Modality/Mechanism	Indication	Current phase	Origin/Partner
<b>ASP7317</b>	RPE cell	Geographic atrophy secondary to AMD, Stargardt disease	Phase 1	 OCATA <sup>*</sup> THERAPEUTICS <sup>™</sup> (AIRM)
<b>(Not disclosed)</b>	Gene therapy (AAV)	Glaucoma	Preclinical (IND planned in 2023)	 Quethera <sup>*</sup>
<b>(Not disclosed)</b>	Photoreceptor rescue cell	Retinitis pigmentosa	Discovery	 OCATA <sup>*</sup> THERAPEUTICS <sup>™</sup> (AIRM)
<b>(Not disclosed)</b>	Ganglion rescue cell	Glaucoma, Optic neuropathy	Discovery	 OCATA <sup>*</sup> THERAPEUTICS <sup>™</sup> (AIRM)
<b>(Not disclosed)</b>	Corneal endothelial cell	Corneal dystrophy	Discovery	 OCATA <sup>*</sup> THERAPEUTICS <sup>™</sup> (AIRM)
<b>(Not disclosed)</b>	Universal donor cell (UDC) RPE	Dry AMD, Other macular degeneration	Discovery	 Universal Cells <sup>*</sup>
<b>(Not disclosed)</b>	Gene therapy (AAV)	Dry AMD, Other macular degeneration	Discovery	University of Pittsburgh

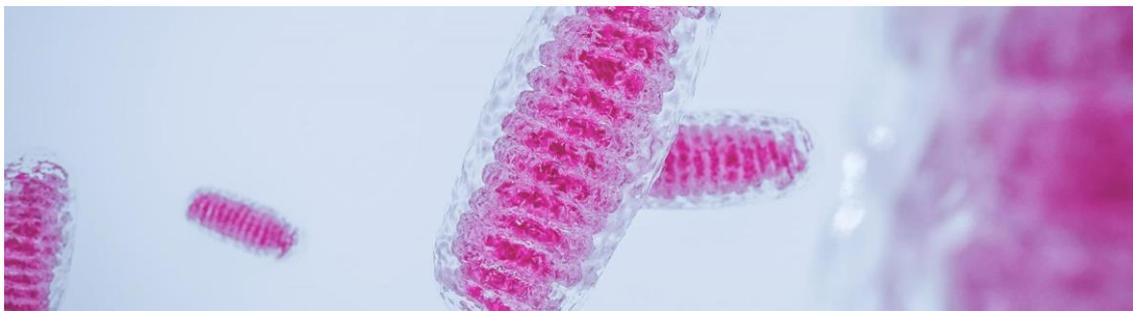
\* Acquired (current programs classified as 'in-house' )

RPE: Retinal pigment epithelial, AIRM: Astellas Institute for Regenerative Medicine, AMD: Aged-related macular degeneration, AAV: Adeno-associated virus, mVChR1: Modified Volvox channelrhodopsin-1, IND: Investigational New Drug application

In addition, Astellas has the following capabilities:

- Creation, manufacturing and development of PSC-derived differentiated cells for therapeutic
- Universal donor cell technology
- Creation of next generation cell products using gene-editing technology
- Design and manufacturing of AAV-based gene therapy product
- Preclinical evaluation of cell and gene therapy candidates

## Mitochondria Biology



Health is Our Passion and Priority. Astellas' VISION is to turn innovative science into VALUE for patients. We are committed to making a difference for our patients today and providing them with additional therapeutic options for a brighter future tomorrow.

Our target, the mitochondrion, is remarkably complex. While it is primarily thought of as an energy supplying organelle, it also has multifaceted functions and is controlled by multiple biological pathways. In fact, mitochondria play an important role in the aging process with many clinical and preclinical evidence, and mitochondrial dysfunction causes and/or aggravates a wide variety of diseases.

Our goal in Primary Focus Mitochondria Biology is to become the global leader in discovering, developing and commercializing mitochondrial biology-based medicine that provides clear VALUE for patients, clinicians and healthcare systems.

To achieve the goal, Astellas acquired Mitobridge in January 2018 and established it as an Astellas Company based in Cambridge, Massachusetts. Building upon the emerging scientific findings linking mitochondrial function with disease pathophysiology, Mitobridge and Astellas are advancing innovative mitochondrial approaches to the treatment of diseases with high unmet medical needs.

### **Astellas continues to prioritize investment in the following fields.**

- ASP0367: This is a highly selective Peroxisome Proliferator-Activated Receptor (PPAR) delta modulator with oral formulation. It stimulates mitochondrial respiration through increased fatty acid oxidation-related genes and mitochondrial biogenesis. Thus, ASP0367 is being investigated as a treatment to improve function for Duchenne Muscular Dystrophy (DMD) and Primary Mitochondrial Myopathy (PMM) patients. Visit [clinicaltrials.gov](https://clinicaltrials.gov) to learn more about ASP0367 clinical trials. Also, visit the United Mitochondrial Disease Foundation's website to learn more [about the clinical trial for the patients with PMM](#).
- ASP1128: This is a highly selective PPAR-delta modulator which is administered as an i.v. formulation. ASP1128 is being evaluated for the treatment of acute kidney injury (AKI) after Coronary Artery Bypass Grafting (CABG) and a POC study started in November 2019. Visit [clinicaltrials.gov](https://clinicaltrials.gov) to learn more about ongoing ASP1128 clinical trials.

Compound	Modality	Mechanism	Target indication	Current phase	Origin
<b>ASP1128</b>	Small molecule (i.v. form)	PPAR $\delta$ modulator	Cardiac surgery associated acute kidney injury	Phase 2 (Phase 2a PoC study FSFT in Nov 2019)	 mitobridge*
<b>ASP0367</b>	Small molecule (oral form)	PPAR $\delta$ modulator	Primary mitochondrial myopathy ----- Duchenne muscular dystrophy	Phase 2 (To start Phase 2/3 study in 1Q 2021)  Phase 1 (To start Phase 1b study in patients in early 2021)	 mitobridge*
<b>(Not disclosed)</b>	Small molecule	(Not disclosed)	(Not disclosed)	Discovery	 mitobridge*
<b>(Not disclosed)</b>	Small molecule	(Not disclosed)	(Not disclosed)	Discovery	 NANNA THERAPEUTICS*

\* Acquired (current programs classified as 'in-house' )

i.v.: Intravenous, PPAR $\delta$ : Peroxisome proliferator-activated receptor delta, PoC: Proof of concept, FSFT: First subject first treatment

Astellas is also evaluating several other modulators of mitochondrial function in preclinical studies for potential use in additional indications.

## Genetic Regulation



Genetic medicines have the potential to be transformative. Mutations or deficiencies in genetic code cause nearly 7,000 human diseases\* and contribute to the pathophysiology of many common diseases. New technologies to replace or regulate genes safely have advanced rapidly and are now a reality. One single treatment intervention has the potential to deliver transformative benefits to patients with few or no alternative treatment options.

Our vision and strategy aim to build capabilities for global leadership in Adeno-Associated Virus (AAV)-based genetic medicines. In January 2020 we completed the acquisition of Audentes Therapeutics, a leader in developing AAV-based genetic medicines with a focus on rare neuromuscular diseases. Audentes will become our Center of Excellence for Genetic Regulation as we aspire to address unmet medical need in patients with rare as well as more common diseases. Audentes plans to further strengthen its manufacturing capacity with a new cutting-edge gene therapy manufacturing facility in North Carolina which will become operational and GMP ready by mid-2022.

\*: Online Mendelian Inheritance in Man® (OMIM®) Gene Map Statistics available at <https://www.omim.org/statistics/geneMap> (Accessed December 9, 2020)

### **Our Primary Focus Genetic Regulation has been working on the below leading programs**

- AT132: A gene replacement therapy being investigated for X-linked Myotubular Myopathy (XLMTM), a rare and fatal disease caused by lack of myotubularin protein in skeletal muscle cells.
- AT845: A gene replacement therapy being investigated for Pompe Disease, a severe progressive neuromuscular condition caused by lack of acid alpha-glucosidase (GAA) enzyme activity leading to accumulation of glycogen in skeletal and cardiac muscle.
- AT702/751/753: A vectorized exon skipping gene regulation therapy being investigated for the treatment of Duchenne Muscular Dystrophy (DMD), a severe progressive neuromuscular disease caused by mutations in the gene coding for dystrophin.

Compound	Mechanism	Target indication	Current phase	Origin/Partner
<b>AT132</b>	MTM1 gene replacement	X-linked myotubular myopathy	Phase 2 - Pivotal	<b>AUDENTES</b>  * <small>An Astellas Company</small>
<b>AT845</b>	GAA gene replacement	Pompe disease	Phase 1	<b>AUDENTES</b>  * <small>An Astellas Company</small>
<b>AT753</b>	Vectorized exon 53 skipping	Duchenne muscular dystrophy	Preclinical (To enter into clinical phase in FY2021)	<b>AUDENTES</b>  * <small>An Astellas Company</small>
<b>AT702</b>	Vectorized exon 2, 1-5 skipping	Duchenne muscular dystroph	Discovery	<b>AUDENTES</b>  * <small>An Astellas Company</small>
<b>AT751</b>	Vectorized exon 51 skipping	Duchenne muscular dystrophy	Discovery	<b>AUDENTES</b>  * <small>An Astellas Company</small>
<b>AT466</b>	Vectorized exon skipping / vectorized RNA knockdown for DMPK	Myotonic dystrophy	Discovery	<b>AUDENTES</b>  * <small>An Astellas Company</small>
<b>GT0001X</b>	ADAR2 gene expression	Sporadic amyotrophic lateral sclerosis	Preclinical	 **
<b>MDL-201</b>	(Not disclosed)	Muscle disease	Preclinical	<b>MODALIS</b>
<b>MDL-202</b>	(Not disclosed)	Muscle disease	Preclinical	<b>MODALIS</b>

\* Acquired (current programs classified as 'in house' ), \*\* Option agreement

R&D: Research and development, MTM: Myotubularin, GAA: Acid alpha-glucosidase, RNA: Ribonucleic acid, DMPK: Myotonic dystrophy protein kinase, ADR2: Adenosine deaminase acting on RNA2

With Audentes as our Center of Excellence we have access to a pipeline of transformative therapies, including AT132 in late stage clinical development, and industry-leading manufacturing capabilities.

## Immuno-Oncology



Our mission is to discover, develop and deliver the best innovative cancer medicines to patients and ultimately, cure cancer. We are activating our best innovative capabilities and building a strong network of collaborations with external partners, in order to complete our mission.

Despite the approval of multiple novel cancer treatments, such as immune checkpoint inhibitors, over the past few years, significant unmet needs still exist. Many cancer patients do not respond to a given treatment (“refractory”) or fail to maintain a response (“relapse”) during the treatment, with as many as 80 percent of patients estimated to be refractory to immune checkpoint inhibitors or to relapse during the treatment.

Our strategy is to target multiple aspects of the immune response to the cancer simultaneously.

### **Our Primary Focus Immuno-Oncology has been working on the below leading programs**

We have established a robust and competitive development, and research stage Immuno-Oncology portfolio through internal efforts and strategic external collaborations. We have built internal discovery, protein engineering, pre-clinical and clinical development, translational sciences and manufacturing capabilities in the US (greater Boston area, Seattle, Washington, South-San Francisco, California, and Northbrook, Illinois) and in Tsukuba, Japan. We have also formed collaborations with leading academic institutions and biotech companies worldwide to develop unique therapeutic approaches in Immuno-Oncology.

- ASP1948: Anti-NRP1 antibody
- ASP1951: GITR agonistic antibody
- ASP9801: Oncolytic virus (Collaboration with Tottori University)
- ASP7517: WT1 loaded artificial adjuvant vector cell (aAVC) (Collaboration with Riken)

MODALITY	COMPOUND	MECHANISM	DISCOVERY	PRE-CLIN	PHASE 1	PARTNER
Checkpoint	ASP1948	NRP1				
	ASP1951	GITR agonist				
Oncolytic virus (OV)	ASP9801	OV IL-7, IL-12				
	VET2-L2	Systemic OV Leptin-IL2 fusion				
aAVC	ASP7517	WT1				
	ASP0739	NY-ESO-1				
Bispecific immune cell engager	(Not disclosed)	Bispecific antibody				
	(Not disclosed)	Probody® T cell engagers				
	(Not disclosed)	Bispecific immune cell engager				
Cell therapy	(Not disclosed)	CD20 convertibleCAR-T				
	(Not disclosed)	Mesothelin HiT TCR-T				
	(Not disclosed)	convertibleCAR-NK				

IO: Immuno-oncology, NRP1: Neuropilin-1, GITR: Glucocorticoid-induced TNFR-related protein, IL: Interleukin, aAVC: Artificial adjuvant vector cell, CAR: Chimeric antigen receptor, TCR: T-cell receptor, HiT: HLA (human leukocyte antigen)-independent TCR, NK: Natural killer

# Cell Therapy



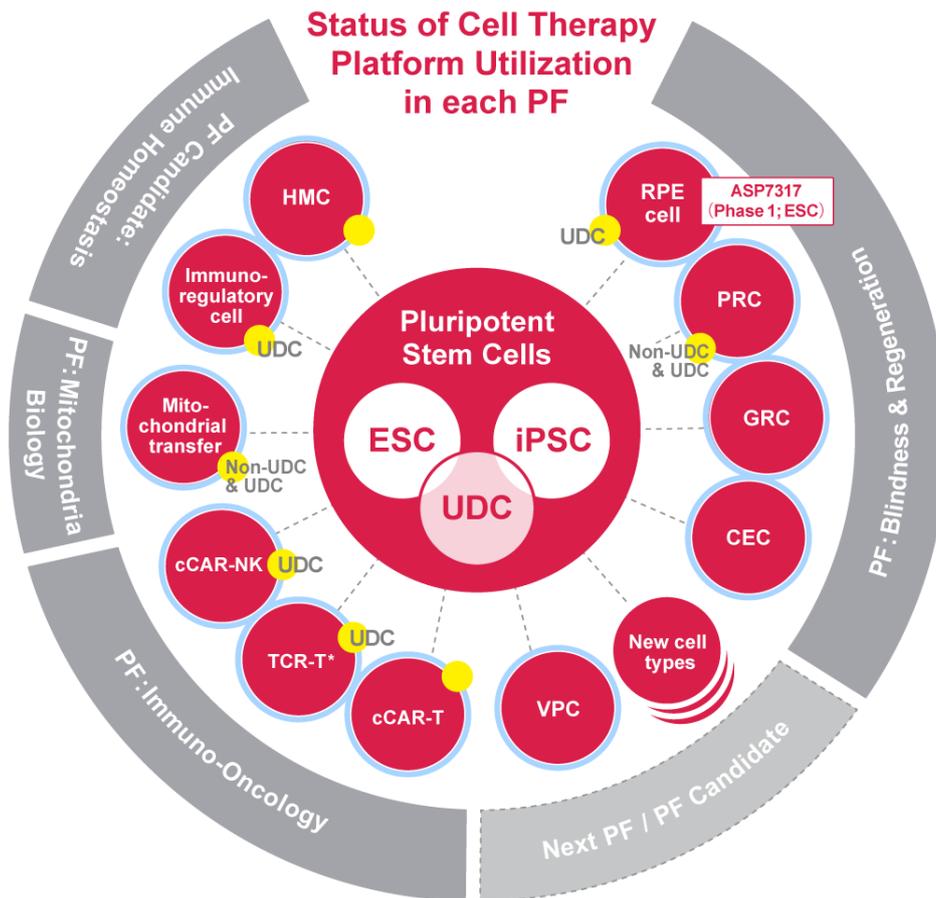
Cell-based therapeutics have tremendous potential to satisfy unmet patient needs across a broad range of disease areas. They are also in their earliest stages of use within healthcare systems around the world, in only a handful of diseases. Those two facts put cell therapy at Astellas' sweet spot, turning innovative science into VALUE for patients. There is still so much to explore in terms of both where the science can go and how it can help patients, particularly those for whom no other treatment exists.

Over the last few years, we have acquired and developed the means to create a broad portfolio of different cell types. We collaborate with leading minds in a variety of therapeutic areas to fully explore the potential of cell therapy for treating diseases with high unmet medical need and unlock the VALUE that it can provide to patients. We also work hard to apply the latest technologies to the development of these therapies which allows us to stay at the forefront of breakthroughs in this fast-paced and emerging new field. Our goal is to develop "off-the-shelf" cell-based therapies that can be used in any patient and so we are working at the intersection of cell science and genetic science to develop the cell-based therapies of the future. The field of cell-based therapies truly excites us because we believe through our scientific expertise, we can make a difference for patients.

## **Our leading programs in Cell Therapy**

Our most clinically-advanced program is looking at the use of retinal pigmented epithelium cells for improving vision in patients with dry age-related macular degeneration. We also have several other ocular cell types in our portfolio, such as Photoreceptor Cells, Corneal Endothelial Cells and Retinal Ganglion Cells. Our lead asset in the non-ocular space is our human hemangioblast-derived mesenchymal stem cell program, which has the potential to be of use in a wide range of conditions and diseases that involve immune response. This is closely followed by our Vascular Progenitor Cell asset with potential to add value in areas such as chronic limb ischemia and pulmonary hypertension.

Astellas has evolved cell therapy, which is our important modality platform, and the organic application of cell therapy platforms is progressing in multiple primary focus strategies.



\*In partnership with Adaptimmune

PF: Primary Focus, ESC: Embryonic stem cell, UDC: Universal donor cell, iPSC: Induced pluripotent stem cell, HMC: Hemangioblast-derived mesenchymal stem cell, RPE: Retinal pigment epithelium, PRC: Photoreceptor rescue cell, GRC: Ganglion rescue cell, CEC: Corneal endothelial cell, VPC: Vascular progenitor cell, CAR: Chimeric antigen receptor, cCAR: convertible CAR, TCR: T-cell receptor, NK: Natural killer, IND: Investigational New Drug Application

- Cell differentiation protocols established as of May 2021
- IND expected by FY2025
- Cells planned to be utilized for next PF / PF Candidate

# Primary Focus Candidates

## Cancer Genomic Alteration

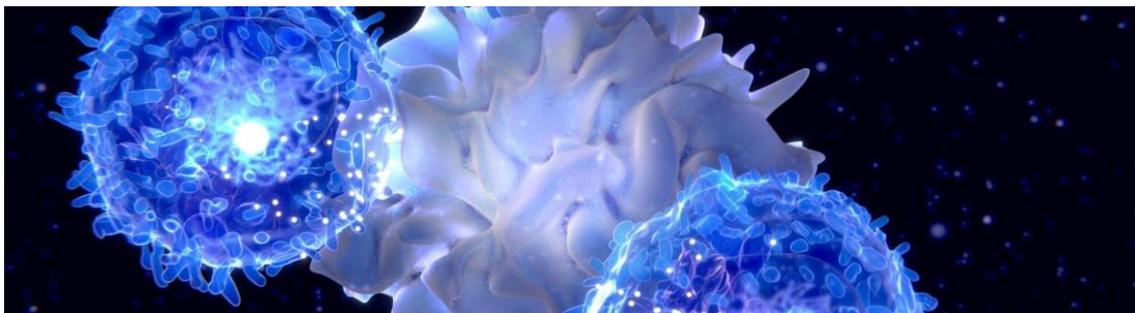


Our aspiration is to deliver disruptive clinical benefit for selected cancer patients by inhibiting pathologic genomic signaling. We will achieve our goal by eliminating critical cancer drivers and providing solution for acquired resistance as well.

Many critical cancer drivers were thought to be “undruggable.” Growing scientific knowledge, and evolution of technology, like PROTAC, shallow pocket and RNA binders enable us to access, eliminate, or reprogram these driver mutations. Increasing number of newly discovered cancer targets expand the potentially addressable cancer types as well. Astellas has established deep R&D and commercial expertise in developing and commercializing targeted medicines to selected patients (erlotinib and gilteritinib).

We are highly focused on building a novel pipeline of targeted medicines as monotherapy, and as combination partners for immune oncology medicines.

## Immune Homeostasis



Our vision for Primary Focus Candidates Immune Homeostasis is to deliver curative therapies for patients suffering from immune-related diseases. Current treatments, such as corticosteroids, are mainly symptomatic treatments that suppress the entire immune response and may cause serious adverse side effects and increased risk of infection. In addition, most autoimmune diseases are chronic and difficult to control and/or cure. Safe and effective treatments that could specifically suppress the pathogenic immune response would represent a significant advancement in the treatment of autoimmune diseases.

Immune homeostasis is the natural mechanism that maintains the balance between immunogenicity to pathogens and immune tolerance to self. Naturally-occurring immunoregulatory cells, such as mesenchymal stem cells, tolerogenic antigen presenting cells and regulatory T cells, play an important role in maintaining immune homeostasis. Our aim is to develop innovative therapeutics to restore immune equilibrium in patients suffering from autoimmune diseases, by leveraging the endogenous homeostatic mechanisms of these immunoregulatory cell types.

Astellas has a long history in research and development of various immunoregulatory drugs in the transplant/immunology field, such as Prograf. Recently, we have acquired and developed capabilities in cell-based therapy as well. We now aim to combine our immunology R&D experience and cell therapy capabilities, to develop novel immunomodulatory cell therapies. In addition, we are exploring innovative technology that can induce endogenous immunoregulatory cells in collaboration with external partners.

# Biology, Modality/Technology of Interest

## Targeted Therapeutics for Auditory Regeneration



Hearing ability serves an important role in the daily communications between families, friends, and colleagues and has a big impact on quality of life. There is the public interest in the threat of hearing loss caused by exposure to unsafe levels of sound from audio device and an aged society. Increasing evidences have shown that hearing loss diminishes a person's mode of communication leading to social isolation and is associated with several diseases in the CNS. However, there is still no curable treatment for hearing loss at this point. Astellas is taking the approach of regaining auditory functions by leveraging its core technology in the area of regenerative medicine. It believes doing so will not only help people regain auditory functions, but will also contribute to the well-being of society.

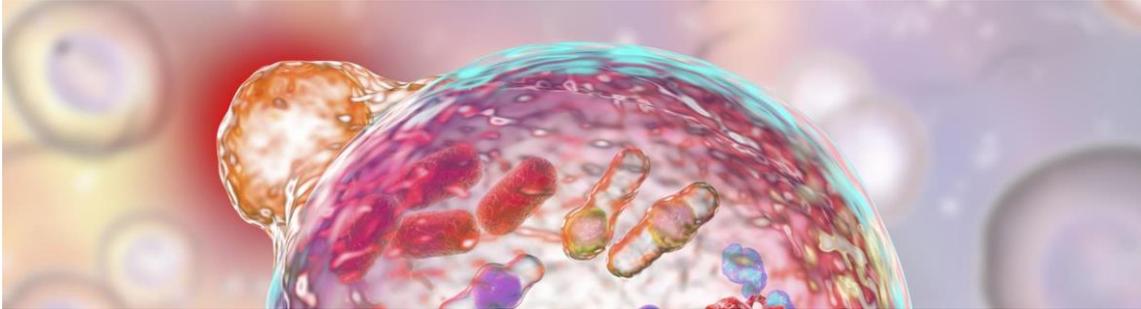
### **Astellas' Auditory Regeneration has been working on the following leading programs.**

- FX-322 (Inner ear progenitor cell activator for sensorineural hearing loss, Phase 2)
- ASP0598 (Recombinant heparin-binding epidermal growth factor-like growth factor (HB-EGF) for regeneration of tympanic membrane, Phase 1)

In addition, Astellas has the following capabilities:

- Unique preclinical programs and optimal animal models for translational research
- Our original local drug delivery system technology in the ear
- Several pipelines in clinical stage and lots of expertise in development.
- Top-notch researchers and clinicians through partnerships

## Autophagy



Many diseases are marked by the accumulation of defective, damaged or no longer required proteins that compromise cellular function.

Autophagy is a key quality control process by which cells eliminate such aberrant proteins.

Potentiating autophagy is a direct way to address the wide range of diseases characterized by defective protein accumulation and is expected as an approach applicable to neurodegeneration, lysosomal storage disorders, renal disease, infectious disease, HIV, cancers, and even some psychiatric disorders.

Astellas utilizes its biochemistry and cell biology expertise in autophagy and aims to provide new safe and effective treatment options to patients who are suffering from various diseases without effective treatments.

## Bispecific Immune Cell Engager



Bispecific immune cell engager is known as an approach that attracts two cells via a bispecific antibody in which two antibodies against an antigen expressed on the surface of each of the two cells of interest are bound. In particular, the bispecific T cell engager is a bispecific antibody that binds an antibody against a target antigen expressed on the surface of cancer cells and an antibody capable of activating T cells, and the T cells are placed near the target cancer cells. It is attracting attention as an approach of effectively removing cancer cells. By utilizing these technologies, high specificity and unique control that cannot be achieved by conventional antibody technologies will be possible, and it is expected that the possibility of drug discovery will be greatly expanded even for diseases other than cancer.

Astellas aims to provide new treatment options for patients with diseases for which there is no effective treatment by combining these approaches of bispecific immune cell engager with the antibody drug discovery technology of Astellas.

## Direct Reprogramming (Transdifferentiation)

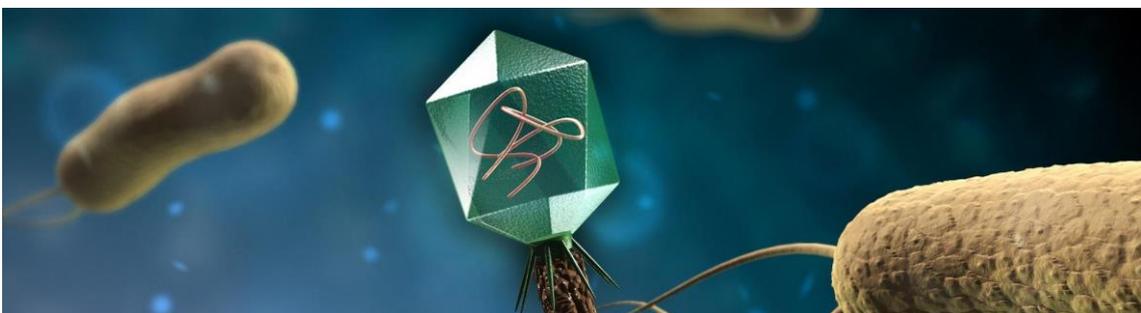


Direct reprogramming is a biology that directly converts the fate of cells without passing through the pluripotent state, and the technology that enables direct reprogramming in vivo has attracted attention as a new regenerative medicine approach. Unlike conventional treatments, direct reprogramming not only removes unnecessary cells or replenishes necessary cells, but also converts unnecessary cells into necessary cells. It is expected to be highly effective against intractable diseases that have been thought to be incurable.

In addition, if agents that generate the desired cells in the body are obtained, it is expected to avoid the risk of immune elimination and tumorigenesis, which are issues in cell therapy.

By utilizing its extensive experience in the gene/cell therapy and regenerative medicine area to provide new treatment options for intractable diseases with high unmet medical needs, Astellas aims to create products in which high efficacy can be expected using the new science of direct reprogramming.

## Engineered Bacteriophage



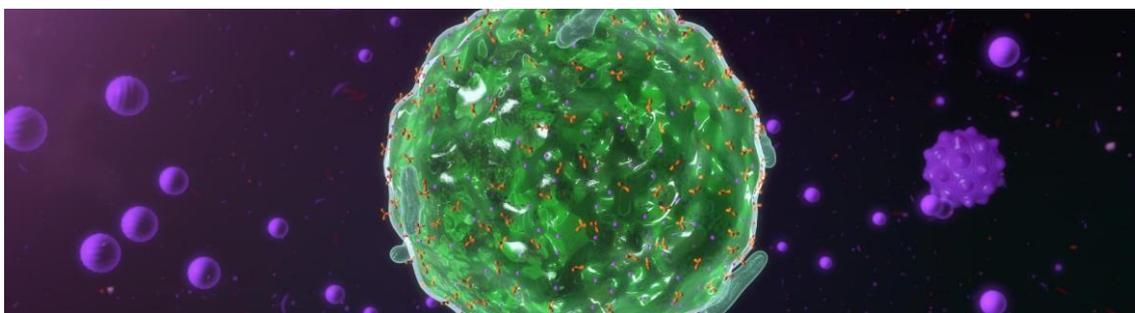
Bacteriophage is a natural virus that specifically infects target bacteria. It is applied to phage therapy that aims to selectively eliminate bacteria from the living body by using bactericidal actions, the primary properties of a virus.

Due to the advancement of genetic engineering technology, progress is being made in recent years in the research of enhancing the usefulness and safety of engineered bacteriophage, and it is attracting attention as the next-generation phage therapy technology.

This technology is expected to be useful not only for the treatment of common bacterial infections, but also as a new treatment for difficult-to-treat bacterial infections and for solving the problem of antimicrobial resistance, a serious global threat to public health.

With the intention of providing new treatment options, Astellas aims to create products in which high efficacy against infectious diseases and microbiome-related diseases—diseases with high unmet medical needs—can be expected by utilizing its expertise in the field of infectious diseases and the new technology of next generation phage therapy.

## Innate Immunity (Innate Lymphoid Cells)

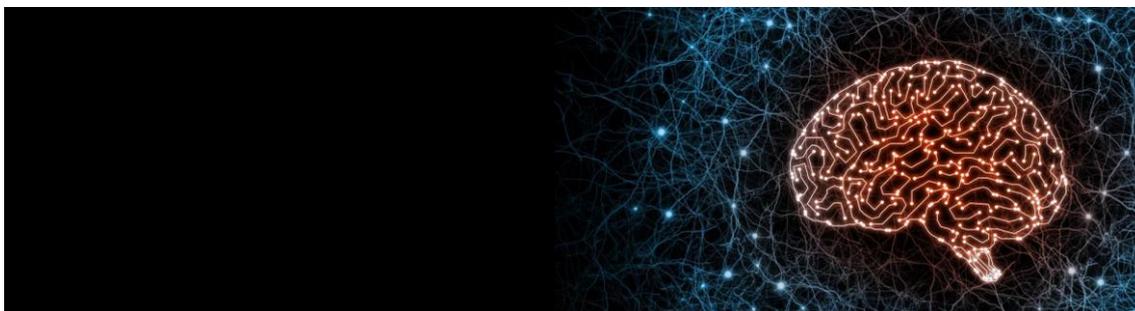


Innate Lymphoid Cells (ILCs) are newly discovered cells of the immune system. Compared to other immune cells, ILCs have superior effector functions and can produce large amounts of cytokines to induce inflammation. On the other hand, they are also known to induce immune tolerance.

If agents that regulate the function of ILCs are found, they are expected to lead to the avoidance of side effects associated with the use of immunosuppressants in addition to the effects that could not be achieved by conventional immunoregulation targeting known immune cells.

With the intention of providing new treatment options, Astellas aims to create products in which high efficacy against autoimmune, allergic diseases, cancer, etc.—diseases with high unmet medical needs—can be expected by utilizing its extensive experience in the field of immunity and the new biology of ILCs.

## Innate Immunity (Microglia)



Microglia are the only immunocompetent cells in the brain and spinal cord that help keep the brain functioning normally by removing dead cells and waste and protecting neural circuits. Excessive activation of microglia by neuropathy, stress, insomnia, infection and aging, etc. induce inflammation in the brain, causing the onset and exacerbation of various neuroimmune diseases such as neurodegenerative diseases, psychiatric disorders, and autoimmune diseases.

In recent years, the role of innate immune cells in central and peripheral nerve functions has attracted attention, and the regulation of microglia function, in particular, is expected to have a new therapeutic effect on a wide range of neuroinflammation-related diseases from neurodegenerative diseases to autoimmune diseases. If agents that control the function of microglia are found, it is expected to avoid the side effects commonly seen with drugs that act directly on the nerves, in addition to the effects that could not be achieved by conventional regulation of nerve function targeting neuron directly.

With the intention of providing new treatment options, Astellas aims to create products in which high efficacy against neurodegenerative diseases, psychiatric diseases, autoimmune diseases, etc.—diseases with high unmet medical needs—can be expected by utilizing its expertise in microglia and its extensive experience in the field of central nervous system and immunoinflammatory areas.

## Human Genetics



The decrease in the probability of drug discovery success and the increase of R & D-related costs have become major issues for the pharmaceutical industry, and appropriate solutions are strongly demanded. In recent years, it has been found that the probability of success can be improved by advancing drug discovery with human genetic evidence, and the importance of human genetics has been reaffirmed. With the tremendous progress of human genome sequence analysis technology represented by next-generation sequencers, the spread of electronic medical records, and innovations in information technology, it is believed that future drug discovery will be changed significantly due to the great improvement of our understanding of human diseases such as the relationship between gene function and human diseases, causes of diseases, and useful factors for prevention. For example, in monogenic diseases, more causal genes have been identified, and new therapeutic approaches such as gene therapy are being actively researched. In addition, in the case of more general diseases, so-called "common diseases," the understanding of the mechanism of disease and identification of drug discovery target molecules are being accelerated. Furthermore, human genetics is expected to contribute not only to the research and development of therapeutics, but also to preventive medicine aimed to suppress the onset of diseases.

Astellas is promoting the identification of causal genes of monogenetic disorders through collaboration with domestic and overseas medical institutions / research institutes that promote cutting-edge human genetics research and it is also conducting research that will lead to the treatment of common diseases by making effective use of collaboration with biobanks in the relative countries. Astellas aims to provide the value of a new treatment option to many patients by integrating these findings and utilizing its extensive experience, know-how, and technology in drug discovery.

## Business Review

# Rx+<sup>®</sup> Business



## Rx+<sup>®</sup> Business

Rx+<sup>®</sup> business is defined as a business that leverages the expertise and knowledge of Astellas, which have been cultivated through its Rx business; integrates innovative medical technology with cutting-edge technology in different fields; contributes to patients through Patient Journey (overall medical care, including diagnostic, preventive, therapeutic, and prognostic care); and creates new revenue streams separate from our core Rx products.

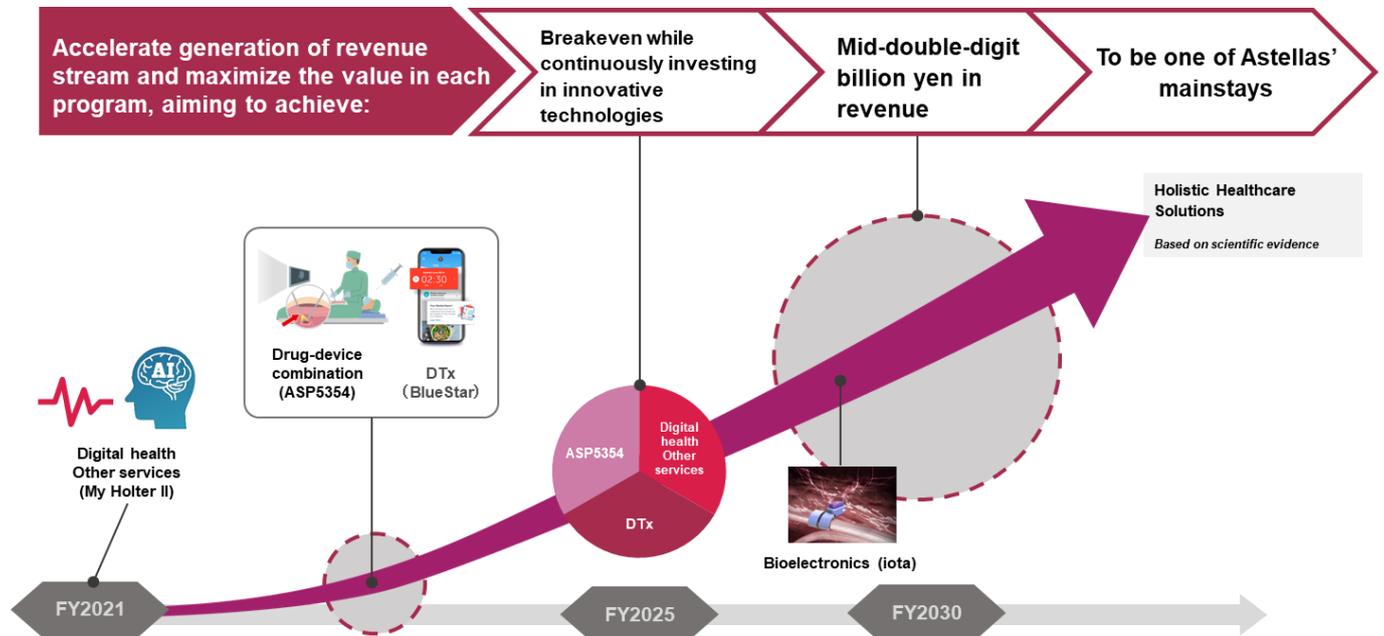
Astellas has mapped out “Rx+ Story<sup>®</sup>” as the strategic direction of Rx+<sup>®</sup> business creation, and aims to realize “a world where people can live mentally and physically healthy lives and be true to themselves through healthcare solutions based on scientific evidence.”

To this end, we are working to create the following three value propositions:

- Prevent disease onset and slow progression by using personal data
- Expand options for people with limited access to current therapeutics
- Support active living by enhancing physical and sensory function

## Potential Growth of Rx+® Business for Realization of the Corporate Strategic Plan

The Rx+® business is expecting to breakeven\*<sup>1</sup> by FY2025 with continuous investment, reach revenue of mid-double digit billion yen by FY2030, and grow toward one of Astellas' mainstay businesses in the 2030s.



\* 1 "Breakeven": a state that the total revenue of Rx+® businesses covers the cost for the entire Rx+-related activities

### Related Links

[We're working on six Spheres.](#)

# We're working on six Spheres.

To make Rx+ Story® a reality, we have established the following six areas, which we call "Spheres." We are actively developing new businesses in these Spheres:

(1) Chronic Disease Progression Prevention; (2) Motor Function Support/Replacement; (3) Digital × Neuroscience; (4) Patient w/o Effective Medicines; (5) Patient Outcome Maximization via Precise Surgery/Diagnosis; and (6) Sensory Function Support/Replacement.

## Chronic Disease Progression Prevention



Amid aging populations, the gap between average life expectancy and healthy life expectancy is not closing, and controlling ever-increasing health care costs is becoming an important social challenge. Pharmaceuticals have made a significant contribution to the treatment of lifestyle-related diseases and other chronic diseases such as diabetes and cardiovascular diseases. For now, the role of pharmaceuticals is not only providing such treatment but also “preventing disease” and “limiting the severity of disease” is becoming much more important.

Solutions for disease management and prevention from disease progression based on scientific evidence utilizing digital technology and medical big data, which have been rapidly developed and widely accepted in recent years, is expected to contribute to further progress in medical care and potential solutions for social problems.

With Sphere "Chronic Disease Progression Prevention," we aim to prevent the onset and severity of chronic diseases such as lifestyle-related diseases by providing solutions for disease management and prevention of severity based on scientific evidence.

In the short and medium term, we aim to develop and provide exercise programs and services that incorporate

gamification (applying game elements to services and systems to improve user motivation and satisfaction) for diabetes and more patient-centric home-healthcare systems or services for preventing cardiovascular diseases progression. Based on the data accumulated through digital devices, we also are working to develop and provide risk prediction and individualized intervention measures through deep learning, which will help lead to disease management and prevention of disease progression according to individual constitution and lifestyle. In the long term, we aim to prevent the onset of symptoms of the diseases and the progression of severity by highly individualized optimization by developing personalized scientific intervention measures from PHR (Personal Health Record)/EMR (Electronic Medical Record).

## Motor Function Support/Replacement



At Sphere "Motor Function Support/Replacement," we are currently working on providing new, drug-free medical care solutions to patients with difficult-to-treat diseases, particularly those who suffer from impaired motor function related to muscles and nerves, and to caregivers who support such patients.

The main diseases we include in this area are physical frailty, limb disorder due to cerebrovascular disease such as stroke, spinal cord injury, limb amputation, and motor function disorder such as Amyotrophic Lateral Sclerosis (ALS), etc. In order to develop new medical methods to assist patients with motor function related disease, we intend to utilize multimodal device technologies, especially bioelectronics (the technologies that complement and replace the aforementioned obstacles with cutting-edge bioelectronics called Neuroprosthesis and Brain-Machine Interfaces (BMI)), based on the following three technologies:

1. Sensing technology that reads motor movements from biological activity information such as brain, nerves and muscles, etc.
2. Modulation technology that activates or bypasses muscles or nerves that are disordered by electrical, magnetic, or ultrasonic stimulation
3. Digital technologies such as sensing and modulation technologies for accurate diagnosis, data utilization for effective and efficient treatment, user interfaces, and applications

In the medium to long term, we aim to provide solutions that utilize individual or multiple technologies among these three technologies for various diseases. Finally, we will work to integrate these three technologies to provide closed-loop medical care solutions that enable autonomous and active diagnosis and treatment throughout the body, thereby creating a suite of products that are able to complement and replace physical exercise functions.

## Digital × Neuroscience



Drug Discovery Research aimed at treating central nervous system (CNS) diseases has led to the discovery of several medicines that are now being used in practice. On the other hand, not all medications can relieve patients from problems associated with their diseases, and CNS disorder is still an area with many unmet medical needs.

Sphere "Digital × Neuroscience" aims to provide medical solutions that utilize digital technology to help patients and caregivers supporting the patients addressing daily problems caused by CNS disorders. In addition, by combining multiple medical solutions, we aim to provide personalized solutions tailored to individual symptoms. In the long term, we aim to prevent the onset of disease and prevent the worsening of symptoms by early detection and to improve detection of various symptoms recognized within CNS disorders through the acquisition of various biometric information.

## Patient w/o Effective Medicines



Sphere "Patient w/o Effective Medicines" aims to provide patients with limited drug options an opportunity to access an alternative solution. We understand that every patient is in a different situation and circumstances. They may be facing a variety of adversities, such as not seeing a doctor because it is difficult to judge for themselves whether their physical condition is good or bad, or they may know it is good to take medicine but they do not want to do so.

To improve the situation for these patients, Astellas started with changing the medical-care environment for women facing various life-stage problems. For example, the general idea is that some degree of discomfort and anxiety cannot be avoided in case of pregnancy, and issues regarding pregnant women had not been taken seriously in the past. Under these circumstances, it is often difficult for these individuals to reveal their physical condition to the people around them, and, therefore, important signs may be overlooked. We may have a room to improve such a situation. This is an issue that we hope to address through Rx+®.

For pregnant women, we are considering providing perinatal management solutions based on prenatal checkup information and various monitoring methods. Monitoring the situation when a pregnant woman is both in or out of the home, not just in the hospital, may reduce her anxiety and make it easier to identify situations that require intervention. We aim to establish a system that can lead to prompt treatment in such a situation.

As Astellas is aware of the difficulty of solving problems of people having limited access to medicine, we look forward to working with external partners.

## Patient Outcome Maximization via Precise Surgery/Diagnosis



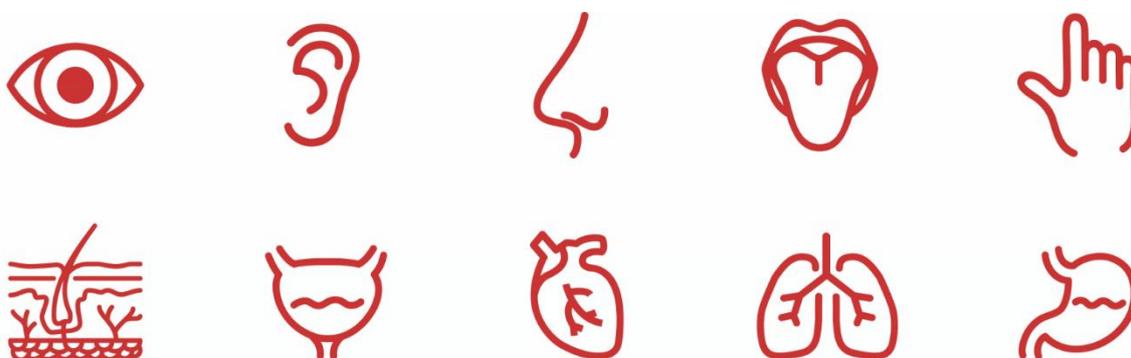
In the evolving medical care environment, hospitals increasingly need to change how they respond to patient needs. In addition to treating patients, hospitals are expected to provide a high quality patient experience (patient experience value) in the future.

Personalizing medical care and enhancing care quality in order to meet changing and diverse patient needs are inevitable. As one of the solutions for such trends, Sphere "Patient Outcome Maximization via Precise Surgery/Diagnosis" aims to optimize patient value with smart hospital services.

Astellas aims to provide various solutions to support realization of personalized smart hospitals. In particular, we are considering the following:

- Surgical navigation utilizing technique-upgrading technology and individual image data
- Minimally invasive medical care as an alternative to surgery
- Enhancing individual patient management, considering proper information provision, suitable treatment and preventing recurrence by adapting to individual circumstances

## Sensory Function Support/Replacement



In our daily lives, we receive, transmit, and process information from the outside world even unconsciously. Much of the information about the outside world is received by the sensory organs (eye, ear, nose, tongue, and skin), and internal organs (i.e., bladder and intestine) and is transmitted to and processed by the brain, where it

is interpreted as light (vision), sound (auditory sense), smell (sense of smell), taste (taste), feel (sense of touch), and sensation that develops in various internal organs.

What happens if these functions are compromised? Needless to say, quality of life (QOL) is greatly affected.

With Sphere "Sensory Function Support/Replacement," we aim to improve QOL of people with impaired sensory functions by incorporating new science and technology, such as engineering, in order to develop a multidisciplinary and superior solution, including the development of sensory function, and a system that supports the patient, surrounding family members, as well as doctors and caregivers. With the elemental technologies to control a sensory function established through these initiatives, we plan to develop new replacement solutions for sensory dysfunction. We are looking at solutions and services that promote, complement, and replace sensory functions, specifically implantable devices, wearable devices, and digital applications.

## Development Status



The list shows the development status in the target diseases for which we aim to obtain approval in Japan, the United States, Europe, and/or China (as of July 2021).

## Key Post-POC Products and Maximization of Their Value

Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase *					Licensor **	
			1	2	3	F	A		
enzalutamide MDV3100 (XTANDI)	Androgen receptor inhibitor	Metastatic castration-sensitive prostate cancer	■	■	■	■	■	Europe Apr 2021 China	Pfizer
		Non-metastatic castration-sensitive prostate cancer	■	■	■				
gilteritinib ASP2215 (XOSPATA)	FLT3 inhibitor	Post-chemotherapy maintenance acute myeloid leukemia	■	■	■				In-house
		Post-hematopoietic stem cell transplant maintenance acute myeloid leukemia	■	■	■				
		Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	■	■	■				
		Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	■	■	■				
		Acute myeloid leukemia in pediatric patients	■	■	■				
enfortumab vedotin ASG-22ME (PADCEV)	Nectin-4 targeted ADC	Metastatic urothelial cancer, PD-1/PD-L1 inhibitor and platinum-containing chemotherapy pretreated	■	■	■	■	■	Europe Mar 2021	In-house [Co-development with Seagen]
		Metastatic urothelial cancer, cisplatin-ineligible and who have previously received one or more therapy	■	■	■	■	■	US Jul 2021	
		Metastatic urothelial cancer, progressed after anti-cancer medication	■	■	■	■	■	Japan Mar 2021	
		Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	■	■	■				
		Muscle-invasive bladder cancer (combo with pembrolizumab)	■	■	■				
		Other solid tumors	■	■					
zolbetuximab IMAB362	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	■	■	■			In-house (Ganymed)	
		Pancreatic adenocarcinoma	■	■					
roxadustat ASP1517/FG-4592	HIF-PH inhibitor	Anemia associated with chronic kidney disease	■	■	■	■	■	Europe Apr 2020	FibroGen
		Chemotherapy-induced anemia	■	■					
fezolinetant ESN364	NK3 receptor antagonist	Vasomotor symptoms associated with menopause	■	■	■			In-house (Ogeda)	
resamirigene bilparvovec AT132	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	■	■				In-house (Audentes Therapeutics)	

\* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region.

The list specifies the area if the compound is developed in limited areas. The details of numbers and alphabets are as follows. 1: P- I, 2: P- II, 3: P- III, F: Filed, A: Approved

\*\* Compounds with "In-house" in this column include ones discovered by collaborative research.

## Projects with Focus Area Approach

Primary Focus	Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase *	Licensor **
				1 2 3 F A	
Immunology-Oncology	ASP1948/PTZ-329	Anti-NRP1 antibody	Cancer		In-house (Potenza Therapeutics)
	ASP1951/PTZ-522	GITR agonistic antibody	Cancer		In-house (Potenza Therapeutics)
	ASP9801	Oncolytic virus carrying IL-7 and IL-12	Cancer		Tottori University [Discovered through collaborative research]
	ASP7517	WT1 loaded artificial adjuvant vector cell	Cancer		RIKEN [Discovered through collaborative research]
	ASP0739	NY-ESO-1 loaded artificial adjuvant vector cell	Cancer		RIKEN [Discovered through collaborative research]
	ASP1570		Cancer		In-house
Blindness and Regeneration	ASP7317	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration, Stargardt disease		In-house (Ocata Therapeutics)
Mitochondria Biology	ASP1128/MA-0217	PPARδ modulator	Acute kidney injury		In-house (Mitobridge)
	ASP0367/MA-0211	PPARδ modulator	Primary mitochondrial myopathies Duchenne muscular dystrophy		In-house (Mitobridge)
Genetic Regulation	resamirigene bilparvovec AT132 ***	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy		In-house (Audentes Therapeutics)
	AT845	GAA gene replacement to express GAA enzyme	Pompe disease		In-house (Audentes Therapeutics)
(Other projects with Focus Area approach)	ASP3772	Pneumococcal vaccine based on a multiple antigen- presenting system (MAPS) platform	Prevention of pneumococcal disease		Affinivax
	FX-322	Inner ear progenitor cell activator (combination of GSK-3 inhibitor and HDAC inhibitor)	Sensorineural hearing loss		Frequency Therapeutics
	ASP0598	Recombinant human heparinbinding epidermal growth factorlike growth factor	Chronic tympanic membrane perforation		Auration Biotech
	ASP2390		House dust mite-induced allergic rhinitis		Immunomic Therapeutics [Discovered through collaborative research]

\* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas. The details of numbers and alphabets are as follows. 1: P- I, 2: P-II, 3: P-III, F: Filed, A: Approved

\*\* Compounds with "In-house" in this column include ones discovered by collaborative research.

\*\*\* AT132 is also listed in "XTANDI and Strategic products".

## Others

Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase *					Licensor **
			1	2	3	F	A	
tacrolimus FK506 (Prograf)	Immunosuppressant	Prevention of rejection after lung transplantation					US Jul 2021	In-house
mirabegron YM178	$\beta_3$ receptor agonist	Neurogenic detrusor overactivity in pediatric patients					Europe	In-house
		Overactive bladder in pediatric patients					Europe	
peficitinib ASP015K	JAK inhibitor	Rheumatoid arthritis					China	In-house
isavuconazole	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients					US	Basilea
ASP8062	GABA <sub>B</sub> receptor positive allosteric modulator	Opioid use disorder						In-house
		Alcohol use disorder						
ASP1617		Systemic lupus erythematosus						In-house

\* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region.

The list specifies the area if the compound is developed in limited areas. "Filed" includes submission of application.

The details of numbers and alphabets are as follows. 1: P- I, 2: P- II, 3: P-III, F: Filed, A: Approved

\*\* Compounds with "In-house" in this column include ones discovered by collaborative research.

## Rx+® Program

Sphere (Business area)	Program	Concept	Status *	Partner
<b>Chronic Disease Progression Prevention</b> 	Game application for exercise support	Smartphone application to support exercise using wearable device for people who needs regular exercise	Under development	BANDAI NAMCO Entertainment
	Fit-eNce	Scientifically evidenced exercise programs and systems which support regular exercise	Launched in limited areas New service model under development	
	BlueStar	Digital therapeutics for adults with diabetes	Under development	Welldoc
<b>Patient Outcome Maximization</b> 	ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy and colorectal surgery etc.	P- II	

\* The list shows the most advanced stage if the stages are different depending on the region.

## Reference Materials

Please click [IR Library: Overview of R&D Pipeline](#) for more detailed information.

# Sustainability



## **Bringing About Worthwhile Changes in Society Based on Our Raison D'être**

Astellas has a shared responsibility and stake in sustainability. We must ensure that the decisions we made today contribute towards a sustainable future for our planet, our society and our business.

Keeping up with advances in science, life sciences companies have created brilliant medical solutions, extending life expectancy in advanced and emerging countries and significantly contributing to improving healthcare in developing countries. However, there are still many areas of unmet medical needs, including diseases with limited treatment options such as cancer and rare diseases. A sustainable scientific approach to overcome such challenges is needed.

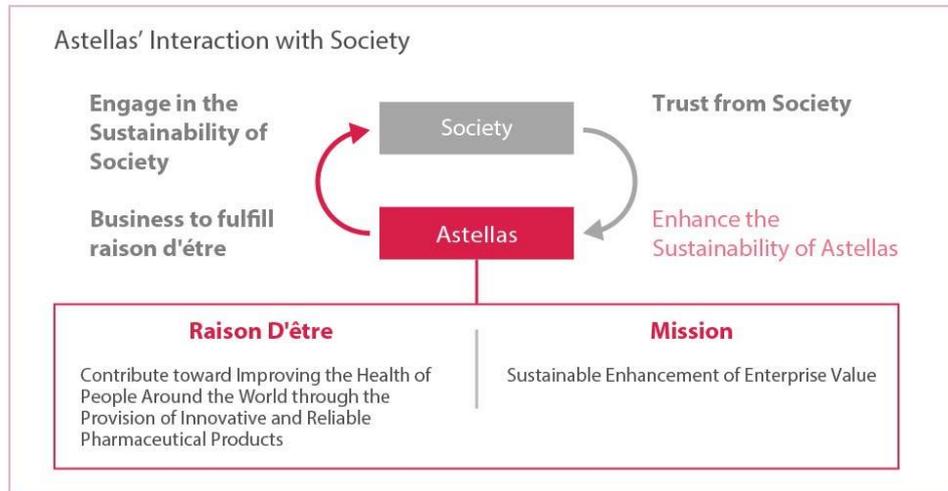
Astellas aims to tackle diseases with high unmet medical needs by creating medical solutions that combine innovative therapeutic approaches such as cell and gene therapy with our own core capabilities and cutting-edge technology in different fields. Through such initiatives, we are committed to engaging in the sustainability of society by fulfilling our social responsibilities as a pharmaceutical company. This will build trust from society, which will, in turn, also make Astellas more sustainable.

This positive cycle will lead to the realization of our mission, “sustainable enhancement of enterprise value” through fulfilment of our raison d'être: “Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.” In short, for Astellas, contributing to the sustainability of society means the realization of its philosophy.

To clearly give priority to our sustainability activities in terms of materiality, we are addressing the broad issues

that are key to our stakeholders and where we can make an impact.

While continuing to conduct close communication with our stakeholders and never forgetting our raison d'être, we will continue to turn innovative science into VALUE for patients.

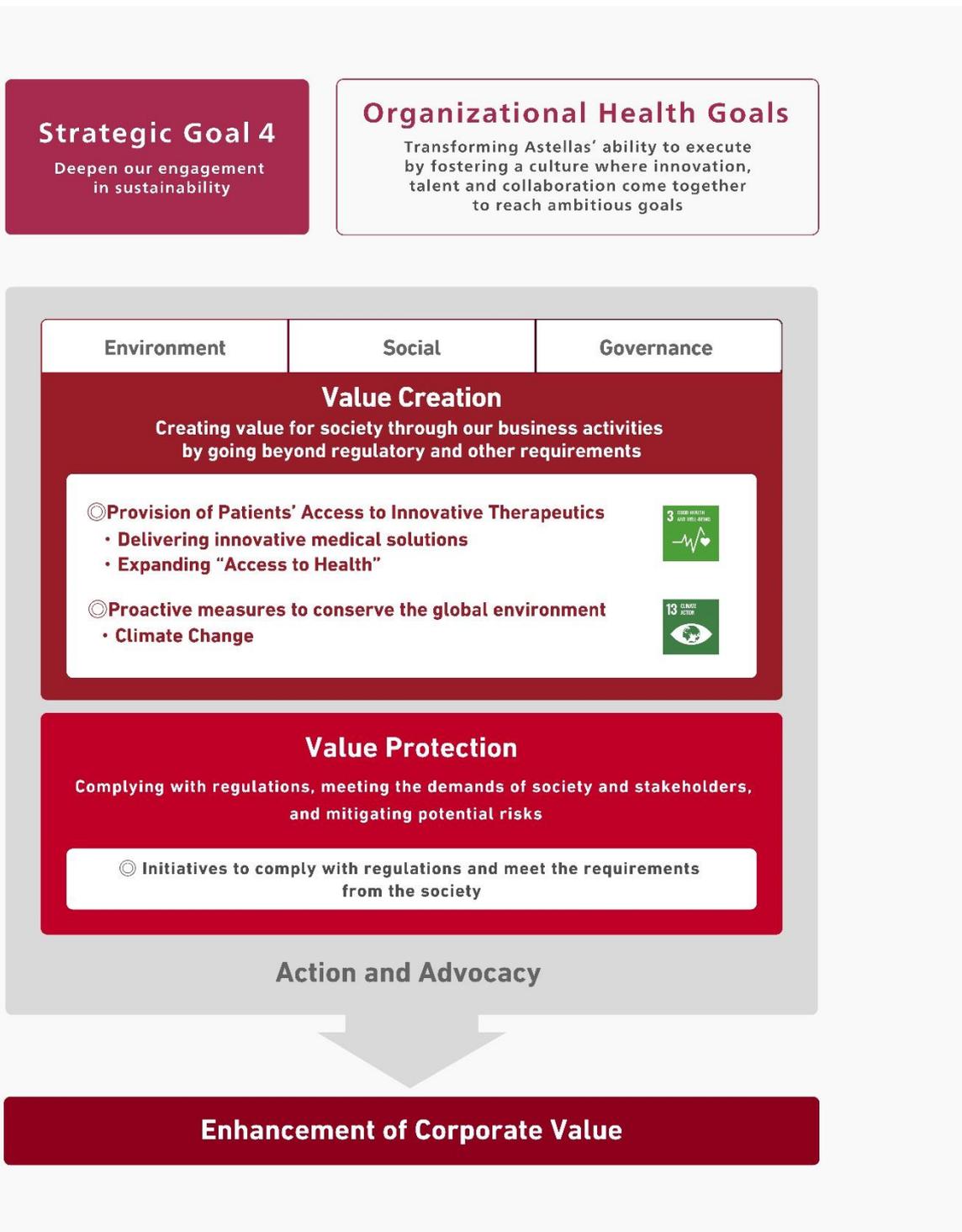


## Contributing to the Sustainability of Society and Astellas

We adopted “Deepen our engagement in sustainability” as one of strategic goals outlined in the Corporate Strategic Plan 2021 (“CSP2021”). We aim to contribute even further to improving the sustainability of society and Astellas by strengthening activities focusing on Access to Health and the Environment (Climate Change), which are considered to provide value to society (value creation).

Under CSP2021, we also set new Organizational Health Goals. Astellas will transform its ability to execute by fostering a culture where innovation, talent and collaboration come together to reach ambitious goals.

# Recognizing the Importance of Our Commitment to Sustainability and Gaining Trust through Our Positive Impact on Society



## Helping Realize a Sustainable Society through Responsible Business Activities

Astellas is engaged in business activities worldwide. To maintain governance on a global level, we respect our [Charter of Corporate Conduct](#) and the [Astellas Group Code of Conduct](#) as a set of core ethics and compliance standards for all of our activities globally.

Astellas is committed to fulfilling our social responsibilities as a pharmaceutical company. We respect human rights in every stage of our business, from research and development to the provision of product information. We also endeavor to ensure compliance with the Pharmaceutical and Medical Device Act and other applicable laws and regulations.

Astellas implements environmental, health and safety initiatives, aiming to create a pleasant working environment for its employees and minimizing the environmental impact of our business activities. We set short- and medium-term targets for climate change, natural resource conservation, biodiversity and waste disposal, and publish these targets in our annual Environmental Action Plan.

Our contribution towards the health of people around the world is not only to supply products through the market. As a responsible corporate citizen, Astellas also strives to understand the expectations of society through continuous dialogue with a broad range of stakeholders and to bring about positive changes in society through active involvement in non-profit activities at a local and a global level.

### Access to Health



[Read more](#)

### EHS; Environment, Health & Safety



[Read more](#)

### Sustainability in Business



[Read more](#)

### Employees



[Read more](#)

### Social Contribution Activities



[Read more](#)

# Contributing to Achievement of the SDGs in Four Areas



## Position on Access to Health

Astellas' vision is to be on the forefront of changing medicine and turning scientific process into value for patients. Astellas is acutely aware of the situation where barriers still remain for many people who have difficulty accessing the healthcare they need due to the lack of available treatments, poverty, healthcare system challenges and insufficient healthcare information. Astellas recognizes this problem as an Access to Health issue. To improve Access to Health, Astellas has identified four areas where we can leverage our strengths and technologies: (1) creating innovation, (2) enhancing availability, (3) strengthening the healthcare system and (4) improving health literacy. We will make full use of our research and development of new drugs based on a Focus Area Approach and our external partnerships to tackle such issues. We believe that undertaking initiatives to create innovation and otherwise improving Access to Health will help enhance the sustainability of society, and developing relationships built on trust with external partners and local governments cultivated through these activities will also make Astellas more sustainable.

## Contributing to the Sustainable Development Goals (SDGs), with a Focus on Goal 3: Good Health and Well-being



Astellas is tackling the sustainable development goals (SDGs) with a focus on Goal 3 “Good Health and Well-being,” which has the strongest affinity to its raison d’être to “contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.” Health is not just a healthcare issue, because losing health can restrict opportunities for education or employment and can sometimes be the cause of poverty. In light of this, attaining Goal 3 will also contribute to achieving the other SDGs.

### Improving Access to Health in Four Areas

Astellas focuses on strengthening initiatives to improve access to health as one of strategic goals outlined in the Corporate Strategic Plan 2021 and aims to contribute to the attainment of Goal 3 of the SDGs through such initiatives.

Many people still have difficulty accessing the healthcare they need due to the lack of available treatment, poverty, healthcare system challenges and insufficient healthcare information. Astellas recognizes this problem as an Access to Health issue. To improve Access to Health, Astellas has identified four areas where it can leverage its strengths and technologies, and is working to solve issues, making full use of external partnerships. These areas are “creating innovation,” “enhancing availability,” “strengthening the healthcare system” and “improving health literacy.” In doing so, Astellas will make maximum use of its partnerships in alignment to Goal 17 of the SDGs.

In the area of (1) *creating innovation*, Astellas conducts research and development based on a Focus Area Approach, combining innovative biology and modalities/technologies to develop therapeutic approaches for diseases where high unmet medical needs exist. Moreover, Astellas has been working with partners on collaborative research to identify lead compounds for tuberculosis, malaria and neglected tropical diseases (Leishmaniasis and Chagas disease), and to develop a pediatric formulation of praziquantel tablets for the treatment of schistosomiasis. Furthermore, in response to the COVID-19 pandemic, Astellas has been cooperating with the development of COVID-19 treatments in cooperation with the bodies concerned to provide drugs in response to requests by the government.

In terms of (2) *enhancing availability*, Astellas has established programs to assist patients who face severe financial constraints with the cost of pharmaceutical products and also supports patients by not filing or enforcing patents in countries facing significant economic challenges. Astellas has also established a cross-departmental project to make its medicines more widely available to patients.

In the areas of (3) *strengthening healthcare systems* and (4) *improving health literacy*, Astellas participates in Access Accelerated, a global initiative which aims to contribute to achieving the SDG of reducing premature

mortality from non-communicable diseases by one-third by 2030. Astellas has supported ACTION ON FISTULA™ helping transform the lives of women in Kenya who have been suffering with obstetric fistula. Furthermore, Astellas has also donated ambulances and wheelchair transport vehicles and moved forward with activities supporting patient associations in Japan. Additionally, the Astellas Global Health Foundation's mission is to improve Access to Health in locations where Astellas does not have a business presence.

## **Related Links**

[Research Activities on Tuberculosis and Malaria](#)

[Research Activities on NTDs](#)

[Development of Pediatric Formulation for Schistosomiasis](#)

[Access Accelerated](#)

# Joint Research on New Treatments for Tuberculosis and Malaria That Afflict People in Developing Countries

## Main Targets



### Creating Innovation

In 2019, 10 million incidences of tuberculosis were observed with 1.4 million deaths (figure includes 0.208 million people infected with HIV), and more than 200 million incidences of malaria were observed with 409,000 deaths. Both tuberculosis and malaria have led to serious social problems and innovative drugs to treat these diseases are eagerly desperately needed.

Astellas is pursuing collaborative research to discover new drugs for the treatment of tuberculosis and malaria, which, together with HIV, form the so-called "Big Three" infectious diseases that have ravaged developing world populations.

The research programs below are funded by the Global Health Innovative Technology Fund ("GHIT Fund"). Program results are published on the [GHIT Fund's website](#).

## Exploring TB Drugs

Astellas conducted joint research ("Screening PJ") for the exploration of new compounds for *Mycobacterium tuberculosis* in collaboration with TB Alliance (Global Alliance for TB Drug Development) from October 2017. The hit compounds discovered in the Screening PJ appear to be unique in their structures compared with TB drugs in use or under development. They also appear not to share the mechanism of action with the existing TB drugs suggesting activity against drug-resistant strains of *Mycobacterium tuberculosis*. Astellas and TB Alliance entered into a new collaborative research agreement on March 31, 2021 to identify lead compounds with improved pharmacological activity pharmacokinetics, as well as safety by utilizing multiple hit compounds obtained from the Screening PJ.

## **Exploration of Antimalarial Drugs**

Astellas entered into a collaborative research agreement with Medicines for Malaria Venture (MMV) for the exploration of an antimalarial drug in October, 2017. Under this agreement, Astellas has provided its original library of tens of thousands of compounds, and MMV has worked to screen the library for compounds that demonstrate the potential to become new antimalarial drugs.

# Contributing to Neglected Tropical Diseases Drug Discovery

## Main Targets



### Creating Innovation

Neglected Tropical Diseases (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.

Astellas is working with external partners on *collaborative research* to discover new drugs for the treatment of NTDs.

## Participation in NTDs Drug Discovery Booster

In March 2018, Astellas participated in the Neglected Tropical Diseases Drug Discovery Booster\*<sup>1</sup>, a consortium established to identify lead compounds\*<sup>2</sup> for leishmaniasis and Chagas disease, both of which are neglected tropical diseases (NTDs). Through this consortium, Astellas will contribute to the discovery of new drugs for patients suffering from leishmaniasis and Chagas disease.

The consortium is supported by funding from the Global Health Innovative Technology Fund (“GHIT Fund”).

\*<sup>1</sup> 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.

\*<sup>2</sup> 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.

## **Involvement in Collaborative Research on New Chagas Disease Drugs**

From October 2018 until March 2020, Astellas was engaged as an advisor to the collaborative research project “Exploratory research aiming to determine target molecules for discovery of new drugs against Chagas disease.” The project has been conducted by the Institute of Tropical Medicine, Nagasaki University (NEKKEN) together with the National Institute of Advanced Industrial Science and Technology (AIST), High Energy Accelerator Research Organization (KEK) and London School of Hygiene and Tropical Medicine (LSHTM).



## Aiming to Make Products Available to Children in Endemic Countries in Africa within the Next Few Years

### Main Targets



#### Creating Innovation

### Schistosomiasis – A Potentially Life-threatening Infection

Schistosomiasis is one of the most prevalent parasitic diseases in developing countries, notably in Africa and South America. The economic and health impacts of schistosomiasis are considerable. If it is left untreated, schistosomiasis causes anaemia, stunted growth, reduced ability to learn, and chronic inflammation of the organs, which can be fatal<sup>\*1</sup>. The disease has a particularly high incidence among children.

The existing “standard of care” treatment for schistosomiasis is praziquantel. However, at present, the group of infected preschool-age children, including infants and toddlers, is left untreated in public health programs due to lack of relevant clinical data and a missing appropriate child-friendly formulation of the drug. Young children cannot swallow the existing tablet because of its large size and bitter taste.

### Pediatric Formulation Developed with Consortium Partners Based on Astellas’ Technology

Within a consortium of partners, involving pharmaceutical companies, research institutions, and international non-profit organizations, Astellas has developed a pediatric formulation of praziquantel.

The pediatric formulation newly developed by Astellas uses proprietary drug formulation technology to create a smaller, orally dispersible tablet of reduced bitterness that can be taken with or without water. The pediatric formulation has also been designed for manufacturing at a reduced cost using simple production technology, yielding tablets that are stable even in hot and humid tropical climates. To facilitate the production of materials

for clinical trials and help develop local pharmaceutical manufacturing capabilities for future supplies, Astellas has transferred to consortium partners in Germany and Brazil the technology and expertise needed to develop the pediatric formulations and produce the tablets.

## Clinical Development of Pediatric Formulation

After successful completion of the Phase II clinical study, the consortium program is currently running the pivotal Phase III clinical trials in Kenya and Ivory Coast to collect data for registration and facilitate access to a novel orally dispersible tablet formulation for young children (below six years of age). In addition, on February 2021, the consortium received additional funding from GHIT and EDCTP to initiate implementation research programs to prepare for large-scale access and delivery of the Consortium's novel pediatric medication in endemic countries. \*2

Astellas is committed to providing the consortium with all necessary technical expertise. As a member of the consortium, Astellas is working with the partners aiming to have the product available for launch in the first endemic country in Africa within a few years.

For more information on the Consortium program and the partners, please refer to the following link:

<https://www.pediatricpraziquantelconsortium.org/>

\*1 <https://www.who.int/en/news-room/fact-sheets/detail/schistosomiasis>

\*2 Consortium activities are currently supported by grants from the Global Health Innovative Technology (GHIT) Fund and the European and Developing Countries Clinical Trials Partnership (EDCTP).

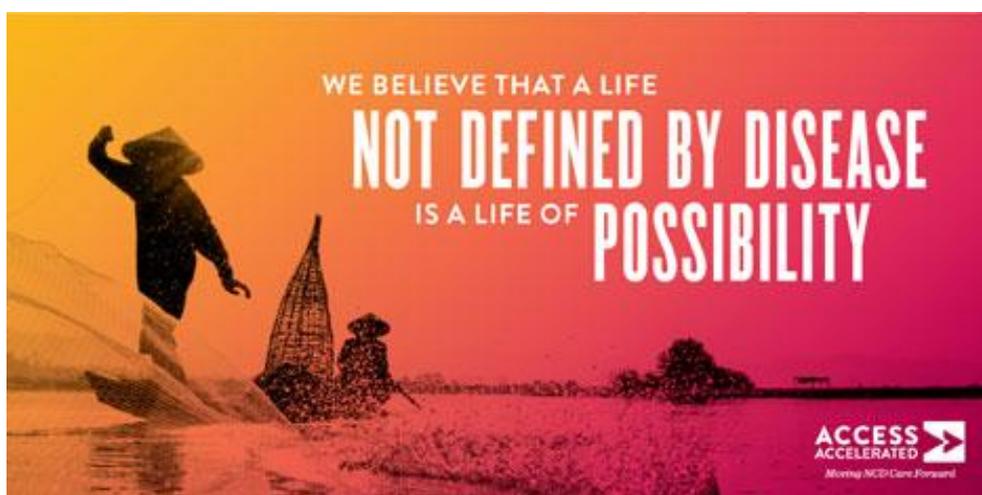


Newly developed pediatric formulation (top) and existing tablet (bottom)



Pediatric Praziquantel Consortium partners and project contributors ©Lygature

# Tackling Non-Communicable Diseases for Patients in Low- and Middle-Income Countries



## Main Targets



**Strengthening Healthcare System /  
Improving Health Literacy**



*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.

Astellas is working with external partners on *improving access to NCDs prevention, diagnosis and treatment* in low- and middle-income countries.

## Supported by Astellas Since Launch in 2017

Access Accelerated\*1 is a global initiative aimed at improving access to non-communicable diseases (NCDs) 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, City Cancer Challenge Foundation, PATH, NCD Alliance and World Heart Federation. Astellas has participated in Access Accelerated since its launch in January 2017.

\*1 For details about Access Accelerated, please visit the following website:

[Access Accelerated Website](#)

[Link to Press Release released by Access Accelerated \(pdf 428KB\)](#)

## Astellas' Efforts under Access Accelerated

Under Access Accelerated, Astellas supports ACTION ON FISTULA™\*2. Since this program began in 2014, 11 doctors who can perform surgery for obstetric fistula were trained, the fistula treatment network was established and a system that provides routine surgery at multiple cooperating hospitals was prepared. As a result of this program, a total of over 6,200\*3 obstetric fistula patients received surgery and their quality of life was improved. Further, 22 support groups were established that take care of patients' mental well-being and provide economic support and employment support so that patients who have received treatment can reintegrate into society. Additionally, in the field of oncology, Astellas launched a new initiative in India structured according to patients' income levels, with the aim of improving their access to its anticancer products since 2017. Moreover, Astellas supported the City Cancer Challenge initiative in Cali city, Colombia. Astellas will continue to push ahead with activities that improve patients' access to the prevention, diagnosis and treatment of NCDs in low- and middle-income countries.

\*2 ACTION ON FISTULA™: A program launched by the Fistula Foundation. Astellas Pharma Europe Ltd., which is a European subsidiary of Astellas, provided funds for the Fistula Foundation, aiming to treat a total of over 4,500 patients by 2020.

\*3 At the end of the program, a total of 6,223 patients accessed fistula treatment.

## Outcomes of Efforts under Access Accelerated

Access Accelerated annual reports introduce outcomes of Access Accelerated. Since its launch on January 18, 2017, over 100 programs have been newly carried out or continued by participating companies. ACTION ON FISTULA™, a program to transform the lives of obstetric fistula patients in Kenya, is also included in this report. Through participation in Access Accelerated, Astellas is working to achieve the United Nations Sustainable Development Goal to reduce premature deaths from NCDs by one-third by 2030 in collaboration with various partners.

[Access Accelerated Year One Report](#)

[Access Accelerated Year Two Report](#)

[Access Accelerated Year 3 Report](#)

[Access Accelerated Year 4 Report](#)

Sustainability / Environment, Health & Safety (EHS)

# Seeking to be Chosen and Trusted by All Stakeholders



## **Working Organizationally and Continuously in Pursuit of EHS Management of Achieving EHS Excellence**

Astellas has embraced the sustainable enhancement of enterprise value as its corporate mission. To fulfill this mission, Astellas seeks to be a chosen and trusted enterprise by all stakeholders, including patients, shareholders, employees, and the global community. The Astellas Charter of Corporate Conduct contains the following principles on Environment, Health and Safety (EHS): "We shall respect employees' human rights, individuality, and differences; promote diversity in the workplace; and provide a safe and rewarding work environment" and "Recognizing that harmony between the global environment and our business activities is a prerequisite to our corporate existence, we shall take proactive measures to conserve the global environment." These principles require employees to conduct themselves based on high ethical standards in EHS fields, among other areas.

Astellas' basic stance toward EHS is outlined in the [Astellas EHS Policy](#). Moreover, Astellas is working organizationally and continuously toward achieving this stance as described in the [Astellas EHS Guidelines](#). In addition, Astellas has set medium-term targets for priority issues in its EHS Action Plan and is working to achieve those targets.

## Environmental Initiatives and Fiscal 2020 Results

### EHS Action Plan

Astellas sets specific numerical targets related to climate change, water resources, waste disposal management and biodiversity as its environmental action plan, and implements initiatives continuously to achieve them.

### Results of fiscal 2020

Item	Goal	Fiscal on 2020 results
Measures to Address Climate Change	Reduce GHG emissions (Scope 1 + Scope 2) by 30% by fiscal 2030 (Base year: fiscal 2015) (Emissions in the base year: 202 kilotons)	Ratio to base year 39% decrease (Emissions: 123 kilotons)
	Reduce GHG emissions (Scope 3) by 20% per unit of revenue by fiscal 2030 (Base year: fiscal 2015)	Ratio to base year 21% decrease
Measures for the Conservation of Natural Resources	Enhance water resource productivity by around 2.5 times the fiscal 2005 result by the end of fiscal 2020 (For research and production sites in Japan and overseas) Indicator: Revenue (¥ billion)/Water resources withdrawn (1,000 m <sup>3</sup> )	Ratio to fiscal 2005 level 3.2 times
Waste management	Improve waste generated per unit of revenue to around 20% of the fiscal 2005 result by the end of fiscal 2020 For research and production sites in Japan and overseas Indicator: Volume of waste generated (tons)/Revenue (¥ billion)	Ratio to fiscal 2005 level 23%
Biodiversity	Triple the biodiversity index by fiscal 2020 from the fiscal 2005 level	Ratio to fiscal 2005 level 3.5 times

### New climate change initiatives

Climate change is positioned as an important strategic goal in Corporate Strategic Plan 2021. Astellas expressed its support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) in

December 2020 and is currently considering information disclosure in line with the TCFD recommendations. For details of our “Position on Climate Change,” please visit the following website:

<https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-change#environment>

For details of other environmental initiatives, please visit the website on the links below:

<https://www.astellas.com/en/sustainability/environmental-action-plan>

<https://www.astellas.com/en/sustainability/measures-to-address-climate-change>

We have received third-party assurance for some of the information published on the website.

## Health & Safety Initiatives and Fiscal 2020 Results

### Occupational Health & Safety Action Plan

Astellas is working to reduce the severity rate of work-related injuries and carry out the risk assessments as part of its occupational health and safety action plan, and implements initiatives continuously to minimize work injuries through prevention of accidents and ensuring maintenance of safe work environments.

Severity Rate of Work-Related Injuries	Prevent the incidence of major occupational accidents while maintaining a severity rate of work-related injuries at or below 0.005 at all business sites
Risk Assessment	Assess all business operations to identify risks in all areas as well as establish self-regulations to reduce such risk

### Incidence of work-related injuries in 2020 (Summary)

From January to December 2020, there were no work-related fatalities, while there were six cases of injuries requiring leaves of absence. The longest number of work days lost was 78 days due to a fall on stairs. The work-related accident severity rate was 0.004, below the target rate of 0.005 or less. Driving sales fleets was limited due to the impact of COVID-19, which resulted in a reduction of work-related accidents accompanying fleet use.

## Global

	2018.1-12	2019.1-12	2020.1-12
Number of work-related injuries (leave of absence)	19	18	6
Frequency rate of work-related injuries* <sup>1</sup>	0.55	0.55	0.18
Severity rate of work-related injuries* <sup>2</sup>	0.009	0.014	0.004

\* Severity rates of work-related injuries for 2018 and 2019 have been revised due to the overreported number of days lost in some occupational accidents in 2018 and 2019, and the settlement of days lost in some occupational accidents in 2019

\*1 Frequency rate of work-related injuries: This rate shows the number of employee deaths or injuries resulting from work-related accidents causing leave of absence per million hours of work. The larger the number, the more frequently work-related injuries occur.

\*2 Severity rate of work-related injuries: This rate shows the number of lost work days due to work-related injuries per thousand hours worked. The higher the number, the more serious the injury.

For details of other health & safety initiatives, please visit the website on the link below:

<https://www.astellas.com/en/sustainability/occupational-health-and-safety>

In order to ensure the transparency and reliability of our data, we have obtained third-party assurance for some of the information published on the website.

## EHS Report

For a printer-friendly version of the EHS Report, please visit the website on the link below:

<https://www.astellas.com/en/sustainability/environmental-report>

## Related Links

[EHS Management](#)

[Environment Initiatives](#)

[Climate Change Measures](#)

Sustainable Biodiversity Initiatives

Initiatives for Resource Recycling

Initiatives for Preventing Pollution

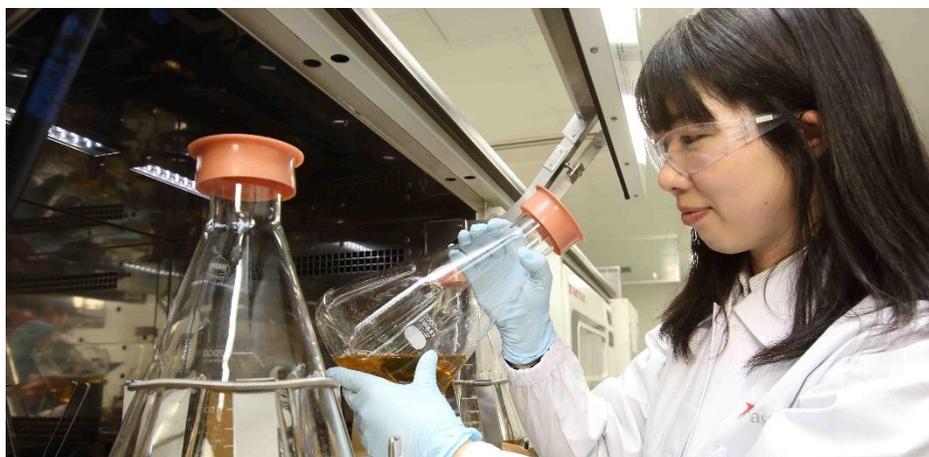
Environmental Impact of Products and Countermeasures

Environmental Accounting

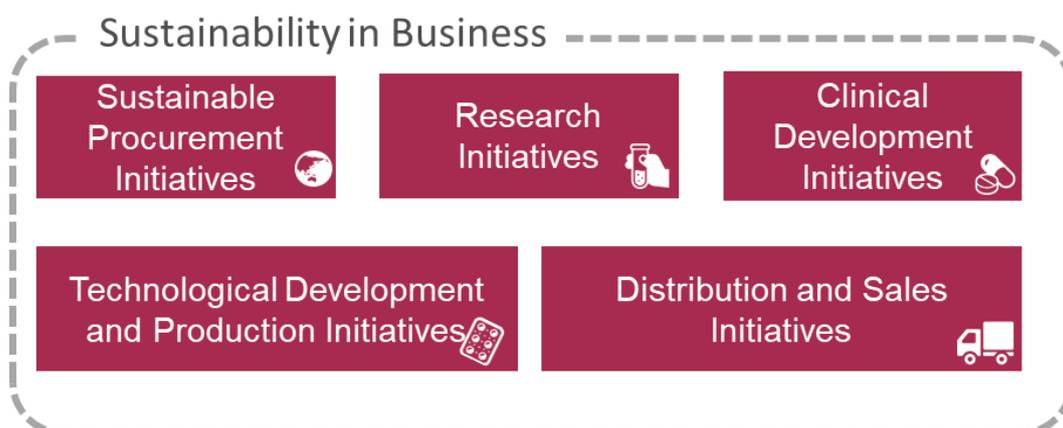
EHS Report

Occupational Health & Safety

# Commitment to Fulfilling Social Responsibilities through Every Business Activity



Astellas is committed to fulfilling its social responsibilities through its business activities as a pharmaceutical company, based on its raison d'être, namely to “Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.” We respect human rights through every business activity from research and development to the provision of product information. We also strive to ensure compliance with the Pharmaceutical and Medical Device Act and other applicable laws and regulations.



## **Related Links**

[Sustainable Procurement Initiatives](#)

[Research Initiatives](#)

[Clinical Development Initiatives](#)

[Technological Development and Production Initiatives](#)

[Distribution and Sales Initiatives](#)

# Sustainable Procurement Initiatives

To fulfill Astellas' social responsibilities across the entire supply chain, it is important for us to conduct our procurement activities with respect for compliance. To achieve this goal, Astellas has formulated the Basic Policy for Procurement Activities and the Astellas Business Partner Code of Conduct. We also undertake measures for sustainable procurement globally to build a sound network for business activities.

## **Risk Assessments for Significant Business Partners**

Astellas conducts a global assessment that includes an evaluation of sustainability risk in the selection process for significant business partners\*, the business partners that have a particularly significant impact on Astellas' business continuity among others. The sustainability risk assessment involves judging a risk level based on a combination of the business partner's response to a questionnaire, external database information, a basic assessment by in-house experts on risks related to sustainability such as human rights, the environment, occupational health and safety and personal information protection, and, if necessary, the results of a local on-site audit carried out by an Astellas employee.

Sustainability risk assessment has started operating in Japan, North America and Europe since February 2019, and has also been deployed in South America and Asian countries.

If Astellas identifies a risk that can be improved during the business partner selection process, it encourages the business partner to make the improvement and monitors its initiatives. Astellas does not engage in business if it identifies a critical risk and it judges the risk is difficult to be improved.

Moreover, business divisions continue monitoring risk status even after business transactions have begun and the supplier's sustainability risk level is assessed once every two years through a questionnaire. If necessary, the assessment takes place even within the two-year period.

\* Business partners that have a significant impact on Astellas' business continuity, such as suppliers of raw materials (regardless of whether they are direct or indirect materials), outsourcing companies, pharmaceutical wholesalers, sales alliance partners and banks.

## **On-Site Audits of Suppliers**

In 2020, there have been movement restrictions due to the impact of COVID-19. We conducted field survey on two companies in Japan regarding the operational status of wastewater treatment facilities, the working environment of employees, and the prevention of chemical substance exposure. In cases where items were pointed out, Astellas indicated an improvement proposal, requested a plan for corrective measures be drawn up and is currently following up on progress of the improvements based on the corrective measures plan.

# Fulfilling Our Ethical Obligations as a Leading Life Sciences Company

Astellas is committed to research activities to create innovative new drugs and medical solutions in compliance with applicable laws and regulations and the highest ethical standards.

## Ethical Considerations in Research on Human Subjects

Astellas conducts research on human subjects and research utilizing specimens and information derived from humans after appropriately obtaining the consent of the subjects in accordance with the Declaration of Helsinki<sup>\*1</sup> as well as the laws, regulations and guidelines of relevant countries.

For example in Japan, Astellas provides training for employees that conduct research, in areas such as bioethics, genome 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 internal/external experts participating in the committee to determine the ethical acceptability and scientific propriety of research plans in a fair and impartial manner. The details of the Astellas Research Ethics Committee have been released on the Ministry of Health, Labour and Welfare's ethics committee reporting system website<sup>\*2</sup>.

<sup>\*1</sup> 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.

<sup>\*2</sup> For details, please visit the following website:

<https://rinri.niph.go.jp/>

## Ethical Considerations in Stem Cells Research and Development

Astellas is advancing research and development activities using stem cells<sup>\*3</sup> in order to supply new treatment methods to address diseases that previously had no known treatment methods.

Astellas recognizes that concerns which need careful consideration could arise when promoting research using human stem cells. In particular, it is necessary to pay full attention to the social and bioethical issues associated with research using human embryonic stem cells (ES cells).

Based on these principles and awareness, Astellas has established its “Policy on Human Stem Cell Research and Development”<sup>\*4</sup>, which sets forth the basic matters it must comply with in the course of conducting human stem cell research and development. Specifically, in all of its research and development activities involving human stem cells, Astellas will comply with the relevant laws, ordinances and regulations of the countries and regions where it undertakes these research and development activities. Moreover, we have set up the committee comprising internal and external experts, from which it will obtain oversight and advice on the ethical aspects and the scientific validity and legitimacy of these research and development activities. All research and development programs will be implemented upon investigation by the committee from an ethical and scientific standpoint. Furthermore, when establishing and using human ES cells, Astellas will take steps to satisfy the ethical standards established by the world’s major scientific authorities, including the guidelines laid out by the National Academy of Sciences of the United States of America.

\*3 Cells that can self-renew and are pluripotent

\*4 For details, please visit the following website:

[https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-development#r\\_and\\_d](https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-development#r_and_d)

## **Ethical Considerations in Human Genome Editing**

As a leading Life Sciences company with a dedicated mission to contribute towards improving the health of people around the world through the provision of innovative and reliable pharmaceutical products, Astellas is at the forefront of advances in human genome editing techniques. In partnership with academic research institutes and biotechnology companies, Astellas employees and partners at sites around the world are developing innovative therapeutic approaches by combining an in-depth understanding of the underlying biology of diseases with innovative platforms and treatment modalities which includes genome editing/genome regulation.

Astellas recognizes and supports the ongoing work of the National Institute of Standards and Technology (NIST) Genome Editing Consortium, European Academies' Science Advisory Council (EASAC), U.S. Pharmacopeia, International Organization for Standardization (ISO), World Health Organization (WHO), and other globally authorized organizations to develop global standards for governance and oversight of human genome editing.

Astellas recognizes and supports the premise that basic and preclinical research using genome editing technologies of somatic cells and germline cells should be carried out in compliance with appropriate legal and ethical rules and oversight in order to contribute to health and welfare for patients. Also at the clinical use stage, Astellas is committed to research and development for appropriate scientific purposes in compliance with all relevant laws and guidelines. Astellas publishes its Position on Human Genome Editing on its website.<sup>\*5</sup>

\*5 For further details, please visit the website on the link below.

[https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-humangenome#r\\_and\\_d](https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-humangenome#r_and_d)

## Animal Welfare in Animal Testing

Astellas conducts animal testing based on its [Policy on Animal Care and Use](#)<sup>\*6</sup>, which was created based on various relevant laws, regulations and guidelines related to animals such as the Act on Welfare and Management of Animals. We have established the Corporate Institutional Animal Care and Use Committee with external experts that verify the 4R Principles<sup>\*7</sup> and determine whether to conduct animal testing. All of Astellas' animal testing facilities have acquired accreditation from AAALAC international<sup>\*8</sup>.

\*6 For details, please visit the following website:

[https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-animal#r\\_and\\_d](https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-animal#r_and_d)

\*7 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).

\*8 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

In compliance with the World Health Organization Laboratory Biosafety Manual<sup>\*9</sup>, the U.S. Centers for Disease Control (CDC) Biosafety Manual<sup>\*10</sup> and the U.S. National Institutes of Health Guidelines<sup>\*11</sup>, as well as the laws of individual countries, Astellas handles experimental materials containing genetically modified organisms and pathogens.

\*9 Laboratory Biosafety Manual 3rd Edition

\*10 Biosafety in Microbiological and Biomedical Laboratories 5th Edition

\*11 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

## Consideration for Biodiversity

As set out in its "[Position on Genetic Resources](#)<sup>\*12</sup>," Astellas is committed to the conservation of biological diversity in accordance with the provisions of the Convention on Biological Diversity<sup>\*13</sup> and, when using new genetic modification techniques, handles genetic resources carefully, mindful about their impact on the environment and people's health. Astellas also follows guidelines on the utilization of genetic resources and distribution of benefits arising out of their utilization set out in the Nagoya Protocol<sup>\*14</sup> and, when accessing the genetic resources of another country, Astellas complies with the relevant laws and regulations of the providing country and ensures the fair and equitable sharing of the benefits arising out of utilization.

\*12 For details, please visit the following website:

[https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-resources#r\\_and\\_d](https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-resources#r_and_d)

\*13 The Convention on Biological Diversity: International convention on the sustainable use and conservation of biological diversity

\*14 Nagoya Protocol: Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization

## 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](#)<sup>\*15</sup>. In addition, Astellas is a signatory to the IP PACT<sup>\*16</sup>, a declaration of 10 key principles affirming our strong commitment to innovation and keeping the needs of patients at the heart of IP practices.

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. Patent information for XTANDI<sup>®</sup>, Lexiscan<sup>(TM)</sup>, Gonax<sup>®</sup>, Suglat<sup>®</sup>, Tarceva<sup>®</sup> and XOSPATA<sup>®</sup> is provided in the Pat-INFORMED database.

Astellas commits to not filing or enforcing patents in Least Developed Countries (LDCs) defined by the United Nations or Low Income Countries (LICs) defined by the World Bank.

Astellas also commits to considering flexibilities in licensing patents in other developing countries on a case-by-case basis, in order to address pressing health challenges, while recognizing these challenges are the shared responsibility of multiple actors, including the pharmaceutical industry<sup>\*17</sup>.

\*15 For details, please visit the following website:

<https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-property#value>

\*16 For details, please visit the following website:

<http://www.interpat.org/wp-content/uploads/IP-PACT.pdf>

\*17 For details, please visit the following website:

[https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-countries#access\\_to\\_health](https://www.astellas.com/en/about/policies-and-position-statements?param=expend-tit-countries#access_to_health)

# 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 applicable 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 regularly implement education and training for employees and staff members involved in clinical trials, and monitor medical institutions that perform clinical trials to ensure full GCP compliance.

In addition, we protect the privacy and confidentiality of the personal information of clinical trial subjects by managing trial data appropriately. 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](#)<sup>\*1</sup> has been published on the Company website to present Astellas' position on this matter.

Astellas registers clinical trials, posts clinical trial information, and discloses clinical trial results. Astellas provides patient-level data that have been anonymized in accordance with applicable laws and regulations through an external website<sup>\*2</sup> to those scientists and healthcare professionals requesting it in the case that review panel consisting of third party experts evaluates and approves the request based on scientific usefulness and scientist eligibility. In addition to disclosing summaries of clinical trial findings from phase 1-4 interventional studies after the approval or discontinuation of the study so that healthcare professionals and the public can confirm them via the clinical trial results website(s), the website(s) also give(s) patients access to plain language summaries of study results prepared for non-experts<sup>\*3</sup>.

\*1 For details, please visit the following website:

[https://www.astellas.com/en/about/policies-and-position-statements?param=expended-tit-data#r\\_and\\_d](https://www.astellas.com/en/about/policies-and-position-statements?param=expended-tit-data#r_and_d)

\*2 Patient-level data are provided through the following website:

<http://www.clinicalstudydatarequest.com>

\*3 Results of the clinical trials are provided through the following website:

[www.clinicaltrials.astellas.com](http://www.clinicaltrials.astellas.com) and/or [www.trialssummaries.com/Home/LandingPage](http://www.trialssummaries.com/Home/LandingPage)

## **Expanded Access to Investigational Medicines**

Astellas has set forth its approach to supplying investigational medicines to patients for purposes other than clinical studies in its [Position on Expanded Access to Investigational Medicines](#)<sup>\*4</sup>.

Astellas recognizes that patients with serious or life-threatening diseases may have exhausted all of their available treatment options, may not qualify for a clinical trial and may seek access to investigational medicines. In these cases, in response to a request for investigational medicines from a primary physician, Astellas fairly, impartially and rapidly evaluates whether or not the patient meets the required conditions to provide early access as appropriate. Furthermore, early access programs may be established in countries where the clinical development of an investigational medicine is progressing and the medicine is targeted for commercial availability. This procedure will be implemented in accordance with the regulations of the country where early access is requested. Information on early access programs can be found on Astellas' corporate website<sup>\*5</sup>.

\*4 For details, please visit the following website:

[https://www.astellas.com/en/about/policies-and-position-statements?param=expended-tit-medicines#access\\_to\\_health](https://www.astellas.com/en/about/policies-and-position-statements?param=expended-tit-medicines#access_to_health)

\*5 For details, please visit the following website:

[https://www.astellas.com/system/files/active\\_expanded\\_access\\_programs\\_en\\_20210823.pdf](https://www.astellas.com/system/files/active_expanded_access_programs_en_20210823.pdf)

## **Patient Centricity in Clinical Drug Development**

The pharmaceutical industry is actively working on patient centricity in clinical drug development and is

discussing it at all points in pharmaceutical development.

We are listening to the opinions of patients, their families and caregivers by working with patient organizations.

For example, to improve our communication and education tools, we obtained feedback from members of patient organizations on our informed consent, pediatric assents, thank you letters to study participants, and the design of our website for patients.

In addition, to understand the patient experience in a clinical trial, one study team is currently obtaining feedback from parents of children in a pediatric trial using a questionnaire.

Through these efforts, we try to make it easier for patients to participate in clinical trials so that we can obtain trial results with scientific significance for patients.

## **Anti-doping Measures**

Doping is an issue closely related to abuse and misuse of medicines in sports. It is a serious priority for the pharmaceutical industry given that it is not only associated with a risk of inducing serious side effects, but it can also become a breeding ground for the unauthorized distribution and counterfeiting of medicines. Astellas is working to identify the compounds under development that have the potential to be used in doping and to prevent the misuse of those compounds.

In October 2016, Astellas made a global agreement with the World Anti-Doping Agency (WADA) to partner on the prevention of misuse and abuse of medicines for doping in sports which aims to contribute to the eradication of doping and improvement of public health.

Doping in sports relies primarily on the misuse and abuse of commercially available medicines, as well as compounds in development that are not as well-known or easily detected. To support WADA in its efforts to address this issue, Astellas identifies compounds solely developed by Astellas or its affiliates with the potential for sport-related doping abuse and cooperates in sharing relevant information to aid WADA in the organization's development of detection methods for these compounds. Additionally, Astellas cooperates with WADA to minimize the risk of misuse of compounds with doping potential during clinical trials to avoid opportunities for abuse.

# Technological Development and Production Initiatives

## Stable Supply and Quality Control

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

Astellas is continuously investing in various manufacturing facilities with the aim of maintaining and strengthening stable supply. In 2020, construction of the Center for Active Ingredient for Biopharmaceuticals was completed at Toyama Technology Center. Bio-drug substances for clinical trials and commercial use are manufactured at the Center and supplied according to global standards. In addition, construction of the Third Fermentation Building has commenced. When the construction is completed, the active pharmaceutical ingredients of immunosuppressant Prograf<sup>®</sup> that suppress rejection after organ transplants will be manufactured at the facility. In Yaizu Technology Center, construction of aseptic drug product manufacturing lines which allow flexibility to manufacture not only antibodies but also new modalities requiring high-level technology in the future was initiated. In the gene therapy domain, Astellas has established plants in *South San Francisco, California* and *Sanford, North Carolina* (GMP manufacturing will commence in 2022), building capability for the in-house manufacture and supply of adeno-associated virus (AAV) drug substances, AAV products, and plasmids which provide self-sufficiency from research to the commercialization of gene therapy programs. Meanwhile, in the cell therapy domain, Astellas has established a new manufacturing base in Westborough, Massachusetts, in April 2020, strengthening our capability to manufacture GMP-compliant, cell-based drug substances and products for use in cell therapy. By constructing such in-house, state-of-the-art manufacturing facilities, we aim to build a more robust manufacturing system capable of supplying high quality products going forward.

## Quality Audits

Astellas has quality systems for auditing both internal sites and external manufacturing and distribution partners.

The risk-based auditing approach determines the sites audit frequency and intensity.

Internal audits are conducted on all Astellas organizations that conduct current Good Manufacturing Practice (cGMP) and/or current Good Distribution Practice (cGDP) activities at all points across the product lifecycle and across the supply chain, in accordance with documented policies and procedures.

Quality audits are conducted for new or established external partners of Astellas. Such audits are performed to evaluate compliance with cGMP, cGDP and applicable Astellas requirements.

In fiscal 2020, Astellas performed a total of 305 audits, including 31 internal audits and 274 quality audits of external partners globally.

## **Supply Chain Management Structure for Stable Supply**

Supply chains are becoming more complicated than ever due to the increase in global products and diversification of modality, along with the increase in partnerships and cooperation with suppliers.

Taking these environmental changes into account, Astellas is strengthening its supply chain management globally by building a framework to centrally manage demand forecasts, inventory data and supply plans for regions all over the world, encompassing the manufacture of drug substances through to finished product supply.

Moreover, in addition to building a global logistics and distribution network to develop the functions and capabilities which flexibly meet the various needs for products, including cold chains, Astellas is advancing logistics and trade compliance, including for imports and exports, to enhance the stable supply management. Furthermore, in the area of commercial supply chain, Astellas has established a function at three locations: Japan, the Netherlands, and the US to continuously develop the supply chain process adapting to the environment changes and strengthened the management framework in global operations.

## **Shared Logistics for Stable Supply**

One of the most important missions for a pharmaceutical company is to continuously improve BCP (Business Continuity Plan) and maintain and continue a stable supply of pharmaceutical products even when natural disasters occur. The Ministry of Health, Labour and Welfare released Japanese GDP (Good Distribution Practice) Guidelines which require greater strictness with respect to ensuring quality in storage and shipment under GDP. Meanwhile, MLIT (Ministry of Land, Infrastructure, Transport and Tourism), METI (Ministry of Economy, Trade and Industry), and MAFF (Ministry of Agriculture, Forestry and Fisheries) are promoting “White Logistics,” an initiative aimed at addressing working style reform, driver shortages, CO<sub>2</sub> reduction among other issues facing logistics. Under this initiative, consignors cooperate with logistics partners to implement activities for improvement and reform, and build sustainable logistics frameworks.

Under the environment changes surrounding logistics, Astellas, Takeda Pharmaceutical Company Limited, Teva Takeda Pharma Ltd., Teva Takeda Yakuhin Ltd. and Nichi-Iko Pharmaceutical Co., Ltd. have co-established a

shared storage and joint distribution platform in Hokkaido, Japan. The platform aims to ensure a diverse and stable supply of pharmaceuticals with adequate contingency, even in the event of a large-scale natural disaster, as well as enhancing efficiency and quality management of product distribution. Astellas will continue initiatives that advance the sharing and standardization of the pharmaceutical logistics within the industry.

The joint distribution platform in Hokkaido has reduced costs. It has not only enabled us to set up a new logistics base but also has reduced the environmental burden through the reduction of carbon emissions. In recognition of these points, Astellas received the Minister of Economy, Trade and Industry Award in 2018 for the Green Logistics Excellent Business Award.

From 2021 onward, a joint distribution center was added in Kyushu, and a system for product inventory and supply management was established at four locations in Japan.

## Measures to Prevent Medical Malpractice and to Improve the Distinguishability of Pharmaceuticals

Astellas strives to supply products from the users' perspective to ensure that healthcare professionals and patients do not mistake one pharmaceutical for another. We are working to prevent medical malpractice in this respect, through measures including printing product names directly on capsules and tablets, as well as printing product names and dosage on packaging sheets (blister sheets) so that the product name and dosage can be easily identified even after the blister sheet is split apart.

To prevent misreading of labeling on blister sheets, Astellas also endeavors to make products easier to identify visually by adopting easily discernible colors and font types for the blister sheets of



certain products. We also adopt blister card packaging\*<sup>1</sup> for pharmaceuticals that require care with dosage frequency from the perspective of preventing medical malpractice. For example, Evrenzo<sup>®</sup> 20 mg / 50 mg / 100 mg tablets newly launched in 2019 are packaged in a set of three tablets in order to prevent taking more or less than the required dosage of three times per week. The size, color and labeling design are also differentiated to reflect the dosage size, to prevent taking the wrong tablet.

In addition, to improve patients' medication compliance and ease of swallowing, Astellas is also reducing the size of the tablet and changing the formulation. For example, the XTANDI<sup>®</sup> 40 mg (10.1 mm dia.) / 80 mg (17.2 mm dia.) tablets launched in 2018 were smaller than the previously released XTANDI<sup>®</sup> 40 mg (21 mm dia.).

Moreover, as the number of tablets per dose is expected to be reduced, it will also reduce patients' burden when taking medications.

\*<sup>1</sup> Blister card packaging: Plastic packaging formed to fit the shape of the product.

## Introducing Universal Design into Product Packaging

We have introduced universal design to certain product packaging. For example, the universal design packaging of Bonoteo<sup>®</sup> 50 mg tablets, which is administered once every 4 weeks, features packaging with good openability. To prevent patients from forgetting to take the drug, there is an area provided on the packaging to write the day when the drug should be taken. A small sticker to be used on a calendar is also attached. In addition, the packaging uses a universal design font type for easy reading.



Universal design packaging of Bonoteo<sup>®</sup> 50mg tablets

## FDA Inspection

Astellas has established its own quality standards in compliance with current Good Manufacturing Practice (cGMP) and applies these standards to Astellas Group manufacturing sites. In fiscal 2020, Astellas underwent two U.S. FDA inspections globally and received no Form 483\*<sup>2</sup>.

\*2 Form 483: An FDA Form 483 is issued to firm management at the conclusion of an inspection when an FDA investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

### U.S. FDA inspection history

FY	The number of FDA Inspections	Warning Letter Issued	Form 483 Issued	Location of Form 483 Issued
2014	5	None	1	Takaoka (Japan)
2015	4	None	2	Norman (US)* Takaoka (Japan)
2016	2	None	1	Toyama (Japan)
2017	2	None	1	Toyama (Japan)
2018	3	None	1	Takaoka (Japan)
2019	2	None	1	Toyama (Japan)
2020	2	None	None	None

\* The Norman plant in the U.S was transferred to Avara Norman Pharmaceutical Services, Inc. in August 2016.

## Quality Manual

Astellas has set forth the quality assurance function and activities in the Quality Manual. The Quality Manual sits on the apex of the document management system hierarchy. Underneath the Quality Manual, policies, standard operating procedures, and guidelines exist defining quality assurance systems, operational management and procedures for a variety of quality assurance-related activities at the global, regional and national levels. Education and training programs are implemented to promote understanding and awareness of these matters.

These documents are revised periodically and as necessary. We respond swiftly to developments in the external environment, such as regulatory changes and amendments through an established Regulatory Intelligence system.

## **Strengthening of Quality Assurance Systems at Affiliates**

Astellas has developed a robust global quality assurance system so that it can ensure patients worldwide a supply of uniformly high quality of pharmaceuticals. This quality management system was developed to be consistent with our quality policy on a global, company-wide basis. The organizational structure of the global quality assurance system incorporates the quality assurance activities of all Astellas affiliates. Our sales affiliates globally receive ongoing support in strengthening our quality culture whilst educating our personnel to the highest standards.

## **Relationship with Local Communities and Consideration for the Environment**

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.

On the premises of the Kerry Plant in Ireland, our nature reserve is a resource made available to the local community and visitors by creating public walkways and information boards, provided by Astellas, detailing the flora and fauna and biodiversity in the nature reserve.

Astellas holds an annual calendar art competition with local schools on the topics of safety, environment and energy. Funds raised from the sale of these calendars are donated to a local charity. Each year, over 1,000 entries are received from 12 local schools.

Astellas helps in promotion of STEM (Science, Technology, Engineering and Math) to local schools through science and engineering talks and tours onsite and online. Astellas communicates with the local community with the publication of the quarterly “Astellas Biodiversity Newsletter.” This newsletter contains biodiversity information relative to the season it is published in. Astellas nurtures good community relationships through integration with and the support of many other local interest groups such as a local nursing home, local Men’s Shed Association, Tidy Towns committee, National Park Education Centre, local bee keepers and local bird and bat conservation groups.

One of industry’s biggest challenges is to develop manufacturing processes that do not unnecessarily burden the environment and to develop sustainably within the local community. The efforts made by Astellas to meet the highest manufacturing standards for our life saving drugs, but also the requirement to do so sustainably limiting our impact on the environment have not gone unrecognized. Since April 2020, the Kerry plant has won SEAI\*<sup>3</sup> award under the category of Energy Team of the Year.

\*3 SEAI: Sustainable Energy Authority of Ireland is an Irish government-affiliated organization supporting the reduction of CO<sub>2</sub> emissions.

# Complying with Laws and Regulations and Upholding High Ethical Standards

## 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 act with high ethical standards and strictly comply with applicable laws and regulations, industry codes and company policies including the Astellas Group Code of Conduct.

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 also act with 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 2020, we responded to approximately 88,000 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 to receive inquiries for information and document medical responses from group companies around the world. This allows us to respond to inquiries in a simple, swift and accurate manner. At the same time, we can analyze

feedback from patients and medical professionals and communicate these insights to support the life cycle management of our products.

We have recently implemented new regional medical information web portals for HCPs to allow for additional and direct access to information regarding our products.

## Anti-counterfeiting Activities

The infiltration of counterfeit/falsified medicines into the legitimate supply chain not only leads to the loss of opportunities for patients to receive effective medical treatment but could also pose severe adverse health consequences. This has become a serious problem worldwide.

Astellas has published a clearly defined [Counterfeit/Falsified Medicines Position Statement](#) on our global website.

As an anti-counterfeit measure, Astellas commissioned a formal Committee comprised of leaders from multiple stakeholder functions (quality assurance, supply chain, etc.), and has also established a product security function to oversee daily activities relevant to product-related security risks. These entities monitor the global market for suspicious activities affecting Astellas products, and implement countermeasures targeting not only counterfeit/falsified medicines, but also diversion, theft and other illicit activities that potentially affect our products and/or present a potential risk to patients. Astellas systematically introduces anti-counterfeit measures, including, but not limited to, product serialization as stipulated by current regulations and pharmaceutical laws. In addition, Astellas regularly engages in various collaborative activities with other members of the pharmaceutical industry to help prevent the spread of counterfeit/falsified medicines. We also proactively support and cooperate with national regulatory and judicial authorities in the prevention of counterfeit/falsified medicines.

## 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 1 product recall in fiscal 2020.

### History of product recall

FY	The number of recall	Severe (Class I)	Moderate (Class II)	Mild (Class III)	Non Classified
2014	3	0	1	1	1
2015	3	0	1	1	1
2016	3	0	2	1	0
2017	3	0	2	0	1

2018	7	0	4	2	1*
2019	2	0	1	0	1
2020	1	0	0	1	0

\* Authority-initiated recall

## Improving the Pharmacovigilance (PV) System

Astellas is continuously improving its pharmacovigilance (PV) system by strengthening collaboration between its PV function and other relevant functions, affiliates and licensing partners. This is to respond to expansion of product strategies and advance the provision of trustworthy product information and proper product use, along with compliance with regulatory requirements.

Astellas has been building a system to collect product safety information from a variety of sources. The Company annually 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 functions other than the PV function, Astellas adds requirements for the collection of product safety information in their contracts as necessary.

Astellas has been maintaining safety databases and procedures used globally to respond to environmental change. In fiscal 2018, it completed a major upgrade of its safety database and procedures to meet regulatory requirement changes. In fiscal 2019 and 2020, it continued to enhance the safety database system to implement electronic submissions of safety reports in accordance with the regulatory requirements of each country.

Astellas is exploring utilizing real-world data such as large healthcare databases for evaluation of its product safety to help minimize risk by enhancing collaboration between PV and other functions. Furthermore, Astellas continues to explore automation technologies and artificial intelligence technologies that can be used for monitoring, intaking, processing and reporting of product safety information, and early identification and analysis of safety signals. We plan to use these technologies to strengthen our PV system.

Sustainability / Employees

# Working at Astellas - Something Special



Developing innovative therapies is one of the most challenging, most essential and personally rewarding fields in science. And there's something special about working at Astellas. It's reflected in our focus on the people we serve, the way we treat each other and the results we achieve as a company.

## Related Links

[HR Vision](#)

[Providing Opportunities for Employees to Succeed Globally](#)

[Diversity Management](#)

[Promoting Health Management](#)

[Respect for Human Rights](#)

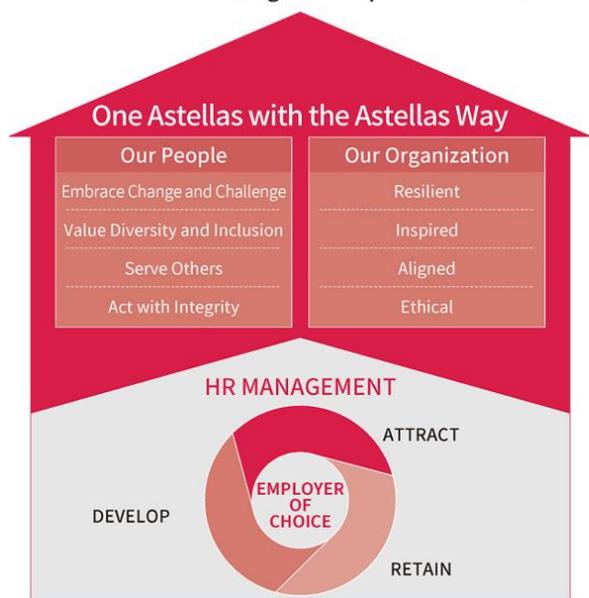
# One Astellas with the Astellas Way

To realize our corporate VISION, employees must work as One Astellas by effectively leveraging all our assets and capabilities. Astellas is an innovative and successful organization because of our diverse and talented people who respect each other and who value the power of long-term relationships. One Astellas with the Astellas Way is fundamental towards achieving our VISION.

Our HR Management approach is based on attracting, developing and retaining the right talent to ensure that human resources services, policies, and systems align with the organization’s strategy and needs.

## Overview of the HR Vision

Towards Realizing the Corporate VISION



### The Astellas Way —Five Messages for One Astellas—

- 
**Patient Focus:**  
 Ask yourself if your decisions and actions contribute to improving patient health.
- 
**Ownership:**  
 Embrace change and always challenge by taking ownership.
- 
**Results:**  
 Commit to results each time you face a challenge, and consider fresh approaches to achieving them.
- 
**Openness:**  
 Maximize your creativity through diversity and open communication.
- 
**Integrity:**  
 Act with integrity by always considering the implications of your actions, and then take responsibility for the outcomes.

**Sustainability / Employees /**

**Providing Opportunities for Employees to Succeed Globally**

# Supporting the Development of Future Leaders

## **Offering Global Development Programs**

Attract, Develop and Retain is at the heart of Astellas' people strategy. At Astellas, we create a lot of opportunities for employees to grow and succeed globally.

To equip our employees with the skills needed in the workplace, we offer digital platforms for employees to self-learn, including programs for managers, aspiring managers and those who perform their duties in a cross-cultural environment. We also provide global development programs targeted to different levels of employees to increase their capabilities and prepare them to be future leaders.

## **Putting the Right Person in the Right Position at the Right Time**

In order to foster a collaborative culture in Astellas, we promote mobility and utilize an internal job posting system globally. Regardless of which location or legal entities our employees join, they can discuss with their managers and develop competencies from our global competency.

In addition to offering employee development programs under HR Vision, we continuously listen to employees' feedback through regular talent reviews and career conversations to build short-, mid- and long-term career development with a standardized, global approach.

With this approach, we believe we will have the right person in the right position at the right time in a sustainable and consistent manner.

# A Diverse Talent Pool Enhances Creativity within Astellas, Attracting Talented People and Improving Competitiveness

## Promoting Diversity in Line with the Regions

Astellas is working to promote diversity so that diverse individuals can play a role, 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 and retain talented people as employees and enhances our competitiveness.

Based on this recognition, Astellas implements measures led by its HR functions in each region to promote diversity in line with the current situation in the relevant 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. We use a two-pronged approach: (1) *change management* alters workplace attitudes and behaviors towards women and (2) *framework reforms* improve business processes and personnel programs. We aim to make Astellas a vibrant and rewarding workplace for women and provide equal job opportunities regardless of gender. We are working to overcome diversity barriers knowing that this will help enhance Astellas' overall competitiveness.

### Employee Ratio per Region and Ratio of Female Managers (The year ended March 2021) \*1

	Established Markets*2	Greater China*3	International Markets*4	Japan	United States	Average
Male	45.4%	38.9%	45.5%	70.8%	44.3%	53.9%
Female	54.6%	61.1%	54.5%	29.2%	55.7%	46.1%
Ratio of female managers	51.1%	58.6%	48.1%	11.6%	53.3%	41.2%

\*1 Expatriate employees seconded within the Astellas corporate group are included in the headcount of their current location. Expatriate employees seconded out of the Astellas corporate group are excluded from the headcount.

\*2 Established Markets: Europe, Canada, Australia

\*3 Greater China: China, Hong Kong, Taiwan

\*4 International Markets: Russia, Latin America, the Middle East, Africa, Southeast Asia, South Asia, Korea

## Promoting Diversity and Inclusion

Furthermore, we are committed to develop individuals, irrespective of nationality, to further accelerate globalization. In Japan, we have employed non-Japanese new graduates since 2014.

The Astellas workplace environment is also well equipped to accommodate employees with disabilities. Aside from establishing the Green Supply Support Office\*<sup>5</sup>, Astellas employs the usage of speech-to-text applications to support employees with hearing impairments. We have also taken part in Accessibility Consortium of Enterprises (ACE)\*<sup>6</sup>

In October 2019, Astellas was awarded “Platinum Kurumin Certification” by the Minister of Health, Labour and Welfare based on the Act on Advancement of Measures to Support Raising Next-Generation Children. The certification recognizes companies that support employees for raising children.

\*<sup>5</sup> Green Supply Support Office: Function established in one of Japanese affiliated companies to support employees with disabilities by offering employment opportunities. Duties including planting, recycling, and cleaning are tailored to promote environmental sustainability.

\*<sup>6</sup> Accessibility Consortium of Enterprises (ACE): Japanese general incorporated association for model innovation of employment services for persons with disabilities

# Supporting Work Style and Employee Health to Improve Overall Organizational Health

## **Fostering Employee Health and a Sound Corporate Culture**

Putting into practice work styles that allow every employee to demonstrate high productivity and creativity and realize their own potential will energize us as an organization and lead to corporate growth as One Astellas. The realization of such work styles is predicated on employee health and the creation of a sound corporate culture. A sound corporate culture requires a psychologically safe environment in which all employees respect each other and can actively communicate with peace of mind.

Astellas is committed to pursuing organizational health through the support of diverse work styles and the promotion of employee health, ensuring all employees enjoy physical and mental wellbeing, thus enabling them to strive for even greater productivity.

## **Priority Initiatives for Health Management (Japan)**

### **Work style reform**

#### **(1) Preventing long working hours**

Astellas strictly complies with the legal working hours laws and prevents long working hours by establishing company standards for “Healthcare Management Hours\*” to manage appropriate working hours.

#### **(2) Encouraging employees to take annual paid leave**

We ensure employees with an annual leave entitlement of 10 days or more to take at least five days of annual

paid leave, and additionally, we encourage them to take at least 70% of their annual paid leave.

\*Healthcare Management Hours: Astellas defines the time to manage employee health as Healthcare Management Hours. Astellas' standards calculate employee daily working hours by using data such as entering and exiting the office and business travel.

## **Creating comfortable workplaces**

### **(1) Open communication**

We value psychological safety of each employee so they can respect each other and communicate openly. We also aim to create a work environment where employees can speak and share without hesitation to prevent and resolve any problems. In fiscal 2020, we held workshops to improve psychological safety on a companywide basis.

### **(2) Improvement of mental health literacy**

We endeavor to educate and raise awareness about mental health. Each year, we conduct a survey of our employees on their current situation and implement measures to resolve issues.

## **Health management**

In cooperation with the health insurance association ("collaboration health"), Astellas is promoting employee health improvement and disease prevention.

### **(1) Promoting health examinations**

We maintain a regular health examination attendance rate of 100% and also work to ensure employees receive secondary health examinations. In cooperation with the health insurance association, we also endeavor to encourage additional health examinations where necessary.

### **(2) Supporting specific health guidance**

We actively provide support for special health guidance which the health insurance association is required to provide to individual employees by law to prevent and improve lifestyle diseases.

### **(3) Measures to tackle health issues**

We conduct employee health surveys, and based on the results, we are implementing measures to improve presenteeism, or sickness presence, from fiscal 2021.

# Groupwide Approach to Emphasize Human Rights

## Clear Commitment to Internationally Recognized Standards

The [Astellas Charter of Corporate Conduct](#) and the [Astellas Group Code of 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 has disclosed its [Position on Human Rights](#) since April 2017. Wherever we operate, Astellas complies with applicable local labor and employment laws and respects internationally recognized basic human rights and labor standards, such as the International Bill of Human Rights, the UN Guiding Principles on Business and Human Rights (UNGPs) and the International Labour Organization's (ILO's) Declaration on Fundamental Principles and Rights at Work.

## Focusing on Five Human Rights Issues

Astellas conducted a human rights impact assessment and has identified five 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, human rights in the workplace and human rights in the community and environment.

## Slavery and Human Trafficking Statement

Moreover, 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.

## System for Swiftly Responding to Issues

We have established a system for swiftly responding to human rights issues that includes the setting up of external and internal hotlines, as well as conducting training sessions for employees. In June and July 2019, Astellas conducted the Global Ethics & Compliance 2019 Employee Survey to better understand the Astellas

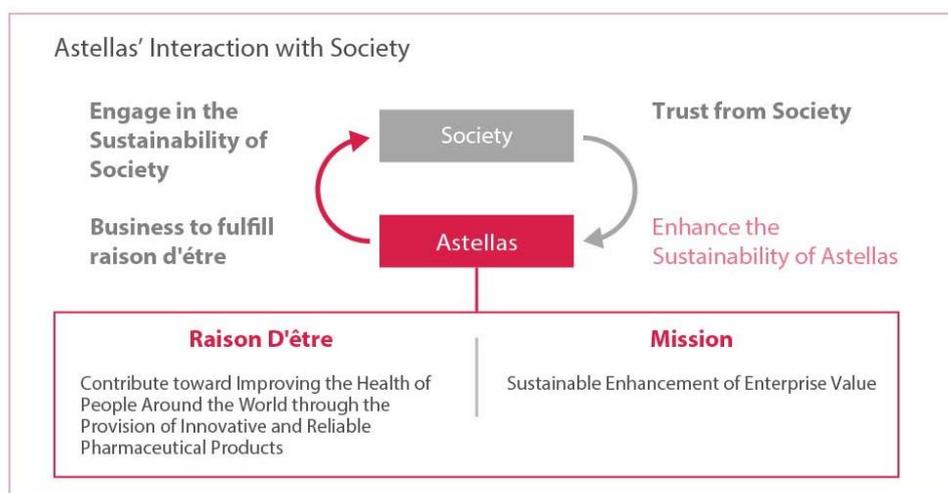
culture and behaviors covering a speak up culture which includes human rights and fair labor matters and identify potential areas for enhancement concerning operational excellence and potential compliance risks. In the year ended March 2021, there were no critical human rights issues or other issues of common, worldwide concern reported in the survey.

# Contributing to the Sustainability of Society through Social Contributions



## Enhancing Our Sustainability by Earning the Trust from Society

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. Our company Charter of Corporate Conduct further states that as good corporate citizens, we shall actively engage in charitable and other activities that benefit society. Astellas believes that we need to enhance our sustainability through earning trust from society for both Astellas and our products.



## Focusing Our Resources on Three Areas

Astellas aims to conduct all of our activities strategically to ensure they create sustainable, long-term benefit for our patients and communities around the world. Astellas will utilize our resources (e.g., people, skills, expertise) to implement our social contributions effectively.

Based on the relevance to Astellas' core business and societal expectation of Astellas, we will focus our resources for social contribution in three areas listed below in order of priority.

**1st priority: Addressing Access to Health issues\***

**2nd priority: Advancement of Medical Sciences**

**3rd priority: Philanthropy/Community Development**

\*Access to Health issues: In the global healthcare environment, there still remain barriers for many people who have difficulty accessing the healthcare they need due to the lack of available treatments, poverty, healthcare system challenges and insufficient healthcare information. Astellas refers to these problems as Access to Health issues.

### The following key activities are conducted in fiscal 2020.

- Research Activities on Tuberculosis and Malaria
- Research Activities on NTDs
- Development of Pediatric Formulation for Schistosomiasis
- Patient Support called Star Light Partner
- Changing Tomorrow Day
- AECEP Overseas Volunteer Program
- Astellas Foundation

### Related Links

[AECEP Overseas Volunteer Program](#)

[Supporting Patients and Their Families](#)

[Astellas Foundation](#)

[Changing Tomorrow Day](#)

# Working with Local Enterprises and NGOs to Address Social Issues in Emerging Countries

## **A Program Drawing on Employees' Expertise, Skills and Experience**

Astellas has run a social contribution program called the Astellas Emerging Countries Empowerment Program (AECEP) since fiscal 2016.

The AECEP is a program that allows Astellas employees to utilize individual specialist expertise, skills and experience to help address societal issues in emerging countries in partnership with local enterprises and non-governmental organizations (NGO). After completing a 1.5-month preparation period, employees volunteering as AECEP participants are assigned for a limited period of 3.5 months to work at a partner enterprise or NGO engaged in projects to develop solutions benefiting society in emerging countries.

Partners are selected from among local enterprises and NGOs involved in addressing medical, health and safety issues or environmental problems. Gaining a valuable learning experience through the cooperation of committed leaders and community members when addressing local social issues, participants can also contribute to building and improving partners' systems by leveraging their personal experience and abilities to help maximize the effectiveness of their activities. The reciprocal and equal nature of this relationship is the key characteristic of the AECEP in terms of contributing to society.

## **Supporting Emerging Countries Even amid the COVID-19 Pandemic**

In the fiscal year ended March 31, 2021, the fifth year of AECEP, we had selected two participants and were preparing to deliver the program. However, the COVID-19 pandemic made it impossible to send employees to emerging countries in person. Astellas considered the support it could provide to emerging countries despite the pandemic and began providing an organization with support remotely, keeping employees in Japan.

The organization we supported rents buffalos from local farmers in Laos to produce and sell dairy products such

as cheese. The organization not only alleviates poverty among the local farmers by paying them rent but also uses the profit generated from sales to employ local staff and improve nutrition in rural villages. However, the COVID19-pandemic caused a dramatic decline in the number of visitors to their farm and dealt a severe blow to sales of dairy products. Given the difficulty of continuing to operate under these circumstances, the organization was developing new sales channels and was considering exporting the buffalo cheese to Japan. The two participants held online meetings with the organization and thought about ways they could support the organization remotely from Japan. They developed sales channels for the buffalo cheese, planned events to raise the organization's profile, and supported the organization's activities.

Conducting AECEP activities remotely, the participants had a lot of discussions with members of various organizations, exploring their potential and gaining valuable experience in actioning the desire to use their skills to contribute to society. Activities like these are also tremendously significant in terms of developing human resources within Astellas.

### **Developing Human Resources Who “Embrace Change and Challenge”**

In its HR Vision, Astellas lists “Embrace Change and Challenge” as a desirable quality in “Our People.” Moving forward, we will continue working with stakeholders to solve social issues around the world.



Astellas' employees (bottom left and top right) working with an organization in Laos on events to raise recognition

# Lighting the Path to “Patient Organization Self-Reliance and Independence” as a Good Partner

## Starlight Partner Activities (Patient Organization Support Activities)

While our raison d'être is to contribute to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products, patient's lives differ and sometimes, there are many problems which cannot be solved through healthcare alone. We believe it is important for us to conduct social contribution activities given that our main purpose is to provide innovative medicines and therapies as a pharmaceutical company, and we engage in patient association assistance (Starlight Partner) to support patients and their families. Harnessing the light of Astellas' flying star\*, we aim to be a good partner to patients and their families, lighting the way to the self-reliance and independent development of patient associations.

\* "Astellas" expresses the idea of "aspired stars" and "advanced stars" based on the Latin "stella," Greek "aster," and English "stellar," which all refer to "stars." This expression also corresponds to the Japanese expression "*Asu wo terasu*" (shine a light on tomorrow). This name conveys our aspiration to bring hope for tomorrow to all people desiring health through the provision of cutting-edge pharmaceutical products and to thrive as a global pharmaceutical company with a commitment to research and development.

## Basic Policy for Starlight Partner Activities

- 1) We promote Starlight Partner activities (patient organization support activities) that align with the «1st priority of access to health: Addressing Access to Health Issues ~ Support for patients and their family members » among the «Priority areas of Astellas' Domestic Social Contribution Activities.»
- 2) We conduct activities that we can commit to as a pharmaceutical company, in principle, and encourage the sustainable development of patient organizations by providing them with support that enables them to demonstrate self-reliance and autonomy.
- 3) We have established an advisory board comprising of experts to advise on the implementation of these activities, ensure fairness and transparency, and make sure activities reflect and anticipate the needs of patient

organizations, and we will regularly review our activities.

4) We make information about these activities internally and publicly available to ensure transparency.

## **Support Provided through Starlight Partner Activities in FY2020**

### **Donations to patient organizations**

Astellas donated 3,260,000 yen to 16 organizations.

### **Briefing sessions and exchange meetings**

The sessions and meetings (held online) were attended by members of patient organizations, including patients/ family members of patients.

### **Patient Expert Program**

Astellas runs “Patient Expert Program” to help patient organizations develop leaders. In FY2020, Astellas paid for members of nine organizations to take part in training provided by an outside organization.

### **Training support for the implementation of online activities**

(Available in FY2020 only as a COVID-19 support measure)

Astellas supported members from seven organizations to take part in seminars on using ZOOM provided by an outside organization.

### **Provision of event materials**

Astellas donated stationary (270 pens, 120 plastic folders, 270 notebooks) for events to five organizations.

# Supporting Activities That Make a Sustainable Impact on the Health of People Around the World

## **Astellas Global Health Foundation**

The Astellas Global Health Foundation (AGHF) is an international philanthropic organization dedicated on supporting three key areas, improving access to health, building resilient communities, and providing disaster preparedness support in underserved global communities in order to make a sustainable impact on the health of people around the world and build toward “One World, A Healthier Tomorrow.

As improving access to health, the AGHF is focused on providing grants to strengthen health infrastructure as well as enhance availability and accessibility of healthcare for mental health, neglected tropical and communicable diseases, and children’s health to help make a positive long-term impact on the world’s most vulnerable populations.

The AGHF primarily funds initiatives to support the most underserved communities in low- and middle-income countries where Astellas does not have a business presence.

For responding to the COVID-19 pandemic, in April 2020, the AGHF opened a request for proposal process, soliciting invited organizations to apply for funding to aid in the fight against COVID-19.

The AGHF has provided a combined \$2 million in new and redirected emergency relief focused on improved healthcare infrastructure, and COVID-19 training and education leading to an improvement of more than 725,000 lives in Kenya, Dominican Republic, South Sudan, Democratic Republic of the Congo (DRC), Ghana, Ethiopia and Nigeria. The funding addresses the urgent needs of partners seeking to prevent the immediate spread and combat the long-term effects of COVID-19 in particularly vulnerable and hard-to-reach communities.

To learn more about the AGHF please visit <https://www.astellasglobalhealthfoundation.org/>

## **Astellas Foundation for Research on Metabolic Disorders**

The Astellas Foundation for Research on Metabolic Disorders (AFRMD), established in 1969, contributes to public health, medical progress, and development of therapeutic drugs.

The AFRMD contributes to medical and life sciences through the awarding of grants for the research initiatives which will open up the next generation, as well as the discovery and nurturing of brilliant young talent and support for researchers by providing training and an opportunity to study abroad.

In fiscal 2020, the Foundation has used it to subsidize COVID-19 related research in the research funding applications for FY2020. Further, the foundation has awarded funding to researchers who have been economically affected by COVID-19 participating in studying abroad program supported by the foundation.

To learn more about the AFRMD, please visit <https://astellas-swift.secure.force.com/byoutai/>

\*The AGHF and the AFRMD are independent organizations from Astellas.

# Contributing to Society Through Groupwide Volunteer Activities

## Changing Tomorrow Day 2020

Astellas encourages group employees around the world to conduct a diverse range of volunteer activities that promote healthcare and maintain the environment as part of Changing Tomorrow Day, thereby contributing to their local communities.

In the year ended March 2021, the world was impacted by COVID-19, but the Company conducted various activities such as virtual volunteer events or innovative activities in each region focusing on taking care of employees' health. More than 3900 Astellas group employees participated in Changing Tomorrow Day 2020.

### Changing Tomorrow Day Data for the year ended March 2021

Region	Participants	Volunteering hours	Number of locations	Number of countries
Established Markets* <sup>1</sup>	421	752	56	12
Greater China* <sup>2</sup>	165	2,081	5	1
International Markets* <sup>3</sup>	270	490	5	4
Japan	1,688	1,244	71	1
United States	1,400	6,000	1	1
<b>Total</b>	<b>3,944</b>	<b>10,567</b>	<b>138</b>	<b>19</b>

\*1 Established Markets: Europe, Canada, Australia.

\*2 Greater China: China, Hong Kong, Taiwan.

\*3 International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea.

## Feedback from Volunteers

“Every activity deeply felt the company’s active investment in CSR. In every event, I am proud of being an employee of Astellas” <Greater China>

“Being part of Astellas and this volunteer activity reminded me of the company’s purpose of caring for people and patients.” <International Markets>

“We might not have been able to be as hands-on as we had planned, but our donations helped make children who have so little feel valued and special. That’s what the Christmas spirit is about.” <Established Markets>

“It was an absolute joy to participate in Changing Tomorrow Day with my family. It was truly an honor to assist our veterans and teach my boys about helping others.” <United States>

“I was pleased that our Christmas cards made them happy and to see their happy faces. I could share each feeling with our colleagues in the sales office.” <Japan>

# Corporate Governance



## Basic View

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 by being chosen and trusted by all stakeholders. 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.

The Company has established the Corporate Governance Guidelines which clarifies the basic views and guidelines of the Company's corporate governance.

[Corporate Governance Guidelines](#)

## Summary of the Corporate Governance Systems

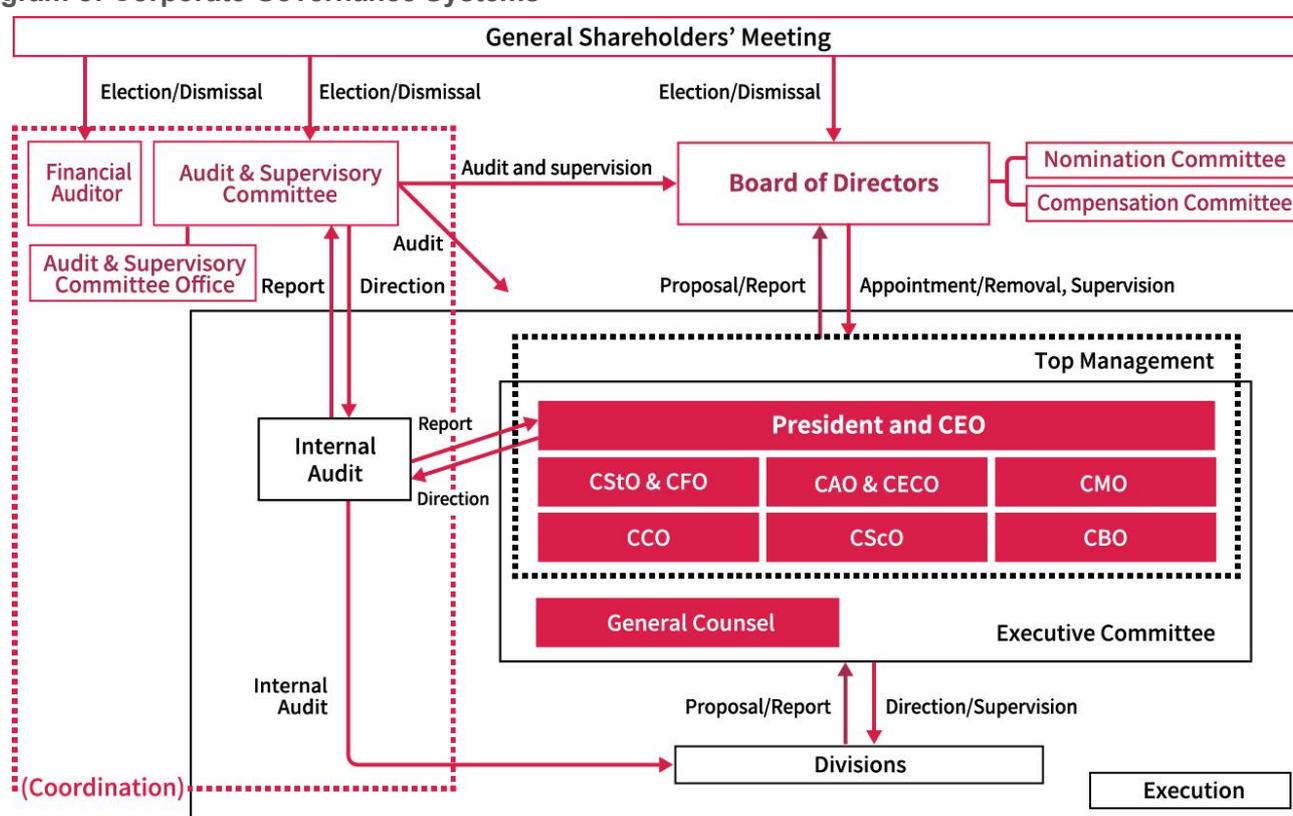
The summary of the corporate governance systems is as follows:

- The Company adopts the organizational structure of "Company with Audit & Supervisory Committee." Outside Directors constitute the majority of the Board of Directors and the Audit & Supervisory Committee, respectively.
- The Board of Directors determines basic policies of management, business strategies and other matters, and serves the oversight function of business execution.
- As an organ for handling execution of business, the Company establishes the Executive Committee for discussing important matters, and also appoints Top Management (the President and Chief Executive

Officer; the Chief Strategy Officer and Chief Financial Officer; the Chief Administrative Officer and Chief Ethics & Compliance Officer; the Chief Medical Officer; the Chief Commercial Officer; the Chief Scientific Officer; and the Chief Business Officer are collectively referred to as “Top Management”), who are responsible for the execution of business. The responsibility and authority for the execution of business by the Executive Committee and Top Management are clearly stipulated in the "Corporate Decision Authority Policy".

- As advisory bodies to the Board of Directors, the Company establishes the Nomination Committee and the Compensation Committee, each of which are composed of a majority of Outside Directors.

### Diagram of Corporate Governance Systems



CEO : Chief Executive Officer, CSto & CFO: Chief Strategy Officer and Chief Financial Officer,  
 CAO & CECO : Chief Administrative Officer and Chief Ethics & Compliance Officer, CMO : Chief Medical Officer,  
 CCO : Chief Commercial Officer, CScO : Chief Scientific Officer, CBO : Chief Business Officer

Please refer to the “Corporate Governance Report” for detail of corporate governance.

[Corporate Governance Report](#)

Related Documents

[Independence Standards for Outside Directors](#)

Please click [here](#) for detail of risk management.

## **Top Management**

[Read more](#)

## **Board of Directors**

[Read more](#)

## **Risk Management**

[Read more](#)

## **Ethics & Compliance**

[Read more](#)

## Corporate Governance

# Top Management

### Executive Committee (as of April 2021)

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

### Standing Members

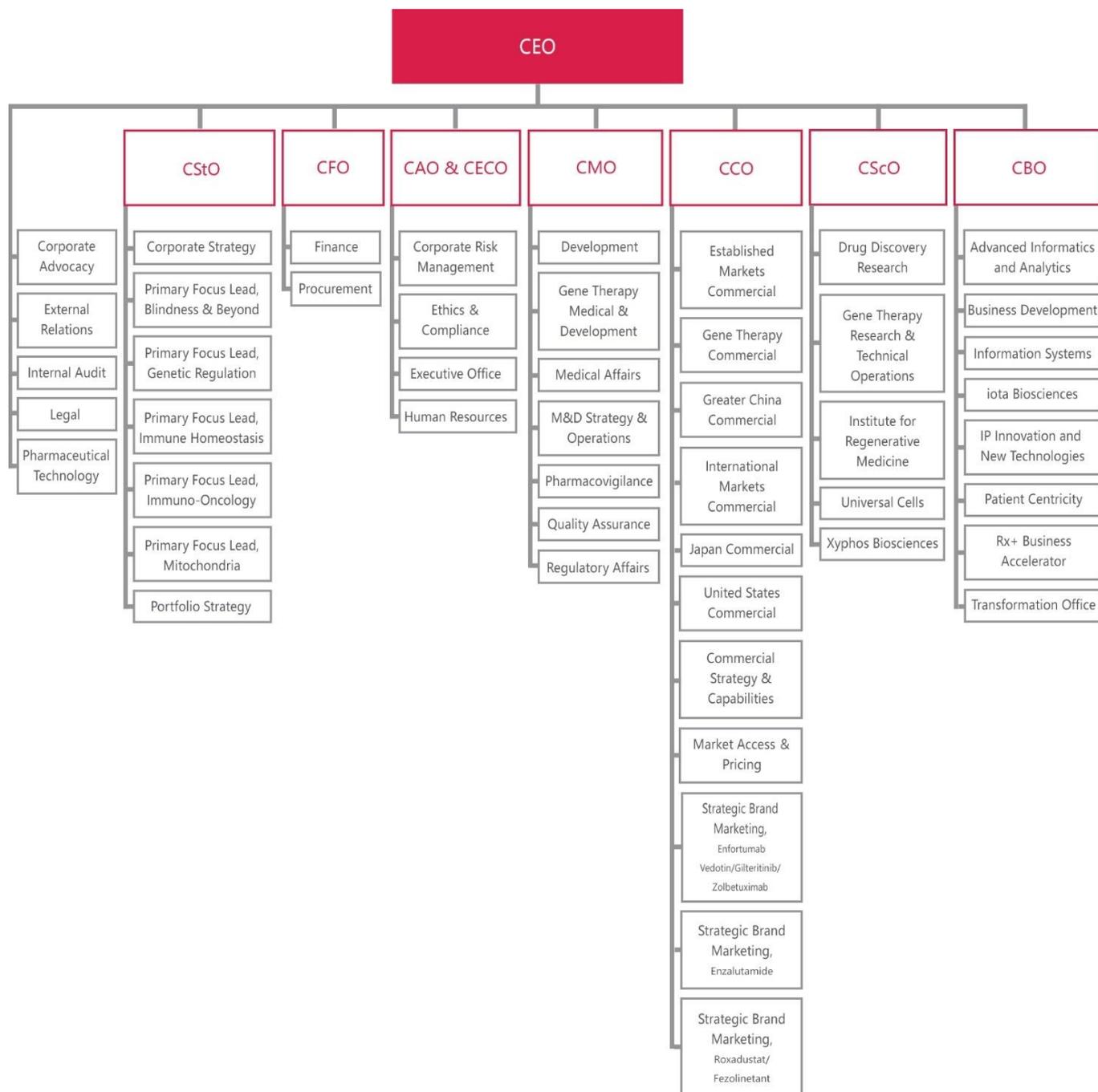
Representative Director, President and Chief Executive Officer (CEO)	Kenji Yasukawa, Ph.D.
Representative Director, Executive Vice President, Chief Strategy Officer (CStO) and Chief Financial Officer (CFO)	Naoki Okamura
Chief Administrative Officer (CAO) and Chief Ethics & Compliance Officer (CECO)	Fumiaki Sakurai
Chief Medical Officer (CMO)	Bernhardt Zeiher, M.D.
Chief Commercial Officer (CCO)	Yukio Matsui
Chief Scientific Officer (CScO)	Yoshitsugu Shitaka, Ph.D.
Chief Business Officer (CBO)	Percival Barretto-Ko
General Counsel (GC)	Catherine Levitt

## Extended Members

President, Drug Discovery Research	Yoshitsugu Shitaka*
President, Pharmaceutical Technology	Hideki Shima
President, Development	Steven Benner
President, Established Markets Commercial	Dirk Kosche
President, Greater China Commercial	Hiroshi Hamaguchi
President, International Markets Commercial	Claus Zieler
President, Japan Commercial	Yasuhiro Tsutsui
President, US Commercial	Mark Reisenauer

\*Yoshitsugu Shitaka, Chief Scientific Officer, concurrently holds the position of President, Drug Discovery Research.

## Group Management Structure (As of April 1, 2021)



## Corporate Governance

# Board of Directors

(Age and resume are as of April 1, 2021)



**Yoshihiko Hatanaka (Age 63)**

**Representative Director, Chairman of the Board**

### **Resume, position and responsibilities at the Company**

April 1980: Joined Fujisawa Pharmaceutical Co., Ltd.

April 2003: Director, Corporate Planning, Fujisawa Pharmaceutical Co., Ltd.

April 2005: Vice President, Corporate Planning, Corporate Strategy Division, the Company

June 2005: Corporate Executive, Vice President, Corporate Planning, Corporate Strategy Division, the Company

April 2006: Corporate Executive of the Company and President & CEO; Astellas US LLC and President & CEO; Astellas Pharma US, Inc.

June 2008: Senior Corporate Executive of the Company and President & CEO; Astellas US LLC and President & CEO; Astellas Pharma US, Inc.

April 2009: Senior Corporate Executive, Chief Strategy Officer and Chief Financial Officer (CSTO & CFO), the Company

June 2011: Representative Director, President and CEO, the Company

April 2018: Representative Director, Chairman of the Board, the Company (present post)

June 2019: Outside Director, Sony Corporation (current Sony Group Corporation) (present post)



**Kenji Yasukawa (Age 60)**

**Representative Director, President and CEO**

**Resume, position and responsibilities at the Company**

April 1986: Joined the Company

April 2005: Vice President, Project Management, Urology, the Company

June 2010: Corporate Executive of the Company and Therapeutic Area Head, Urology, Astellas Pharma Europe B.V.

October 2010: Corporate Executive of the Company and Therapeutic Area Head, Urology, Astellas Pharma Global Development, Inc.

April 2011: Corporate Executive, Vice President, Product & Portfolio Strategy, the Company

April 2012: Corporate Executive, Chief Strategy Officer (CSTO), the Company

June 2012: Senior Corporate Executive, Chief Strategy Officer (CSTO), the Company

April 2017: Senior Corporate Executive, Chief Strategy Officer and Chief Commercial Officer (CSTO & CCO), the Company

June 2017: Representative Director, Executive Vice President, the Company

April 2018: Representative Director, President and CEO, the Company (present post)



**Naoki Okamura (Age 58)**

**Representative Director, Executive Vice President**

**Resume, position and responsibilities at the Company**

April 1986: Joined the Company

October 2010: President & CEO, OSI Pharmaceuticals, Inc.

April 2012: Senior Vice President, Chief Strategy Officer, Astellas Pharma Europe Ltd.

July 2014: Vice President, Licensing & Alliances, the Company

April 2016: Vice President, Corporate Planning, the Company

June 2016: Corporate Executive, Vice President, Corporate Planning, the Company

April 2018: Corporate Executive, Chief Strategy Officer (CSTO), the Company

April 2019: Corporate Executive Vice President, Chief Strategy Officer (CStO), the Company

June 2019: Representative Director, Executive Vice President, Chief Strategy Officer (CStO), the Company

October 2019: Representative Director, Executive Vice President, Chief Strategy Officer and Chief Financial Officer (CStO & CFO), the Company (present post)



**Mamoru Sekiyama (Age 71)**

**Outside Director**

### **Resume, position and responsibilities at the Company**

April 1974: Joined Marubeni Corporation

April 1997: General Manager, Power Project Dept.-I, Marubeni Corporation

April 1998: General Manager, Power Project Dept.-III, Marubeni Corporation

April 1999: Deputy General Manager, Power Project Div.; General Manager, Power Project Dept. I, Marubeni Corporation

April 2001: Senior Operating Officer, Utility Infrastructure Div.; General Manager, Overseas Power Project Dept., Marubeni Corporation

April 2002: Corporate Vice President, Chief Operating Officer, Plant, Power & Infrastructure Div., Marubeni Corporation

April 2005: Corporate Senior Vice President, Chief Operating Officer, Plant, Power & Infrastructure Projects Div., Marubeni Corporation

June 2006: Corporate Senior Vice President, Member of the Board, Marubeni Corporation

April 2007: Corporate Executive Vice President, Member of the Board, Marubeni Corporation

April 2009: Senior Executive Vice President, Member of the Board, Marubeni Corporation

April 2013: Vice Chairman, Marubeni Corporation

April 2015: Corporate Adviser, Marubeni Corporation; Chairman, Marubeni Power Systems Corporation

June 2017: Director, the Company (present post)

April 2020: Outside Director and Audit & Supervisory Committee Member, A.D.Works Group Co., Ltd. (present post)



**Hiroshi Kawabe (Age 68)**

**Outside Director**

### **Resume, position and responsibilities at the Company**

May 1979: Assistant, Department of Internal Medicine, Keio University School of Medicine

April 1990: Assistant Professor, Health Center, Keio University

April 1991: Assistant Professor, Department of Internal Medicine, Keio University School of Medicine  
April 1996: Associate Professor, Health Center, Keio University; Associate Professor, Department of Internal Medicine, Keio University School of Medicine  
April 2002: Professor, Health Center, Keio University; Professor, Department of Internal Medicine, Keio University School of Medicine  
October 2003: Vice President, Health Center, Keio University  
October 2011: President, Health Center, Keio University  
June 2013: Trustee, Japan University Health Association  
March 2017: Trustee, Daiwa Securities Health Foundation (present post)  
March 2018: President, Foundation for Promotion of Medical Training (present post)  
April 2018: Professor Emeritus, Keio University (present post)  
June 2019: Director, the Company (present post)



**Tatsuro Ishizuka (Age 65)**  
**Outside Director**

#### **Resume, position and responsibilities at the Company**

April 1978: Joined Hitachi, Ltd.  
April 2009: Corporate Officer and General Manager, Hitachi Works, Hitachi, Ltd.  
April 2011: Vice President and Executive Officer, and President & CEO, Power Systems Company, Hitachi, Ltd.  
April 2013: Senior Vice President and Executive Officer, Hitachi, Ltd.  
April 2014: Representative Executive Officer, Executive Vice President and Executive Officer, Hitachi, Ltd.  
April 2015: Deputy Chairman, Hitachi Europe Ltd.  
July 2016: Chairman of the Board, Hitachi Research Institute  
April 2017: Representative Executive Officer, Chairman, Hitachi Construction Machinery Co., Ltd.  
June 2017: Representative Executive Officer, Chairman, Executive Officer and Director, Hitachi Construction Machinery Co., Ltd.

April 2019: Director, Hitachi Construction Machinery Co., Ltd.; Advisor, Hitachi, Ltd. (present post)  
June 2019: Director, the Company (present post); President, The Hitachi Global Foundation (present post)  
March 2020: Outside Director, K&O Energy Group Inc. (present post)  
June 2021: Outside Director, Tadano Ltd. (present post)



**Takashi Tanaka (Age 64)**  
**Outside Director**

**Resume, position and responsibilities at the Company**

April 1981: Joined Kokusai Denshin Denwa Co., Ltd. (KDD)  
April 2003: Executive Officer, General Manager, Solution Product Development Division, Solution Business Sector, KDDI CORPORATION  
June 2007: Managing Executive Officer, Executive Director, Solution Business Sector, KDDI CORPORATION  
August 2007: President, Wireless Broadband Planning Inc. (current UQ Communications Inc.)  
April 2009: Managing Executive Officer, Solution Business Sector, KDDI CORPORATION  
April 2010: Managing Executive Officer, Solution Business Sector, Consumer Business Sector, and Product Development Sector, KDDI CORPORATION  
June 2010: Senior Managing Executive Officer, Solution Business Sector, Consumer Business Sector, and Product Development Sector, KDDI CORPORATION; Chairman, UQ Communications Inc.  
December 2010: Representative Director, President, KDDI CORPORATION  
April 2018: Representative Director, Chairman of the Board, KDDI CORPORATION (present post)  
June 2018: Director, Okinawa Cellular Telephone Company (present post)



**Toru Yoshimitsu (Age 58)**

**Director, Audit & Supervisory Committee Member**

**Resume, position and responsibilities at the Company**

April 1987: Joined the Company

April 2013: Senior Vice President, Product & Portfolio Strategy, the Company

June 2015: Corporate Executive, Senior Vice President, Product & Portfolio Strategy, the Company

April 2017: Corporate Executive, Senior Vice President, Corporate Finance & Control, the Company

April 2019: Corporate Executive, Senior Vice President, Corporate Financial Planning & Analysis, the Company

October 2019: Corporate Executive, Senior Vice President, Finance and Corporate Financial Planning & Analysis, the Company

April 2020: Report to CEO, the Company

June 2020: Director (Audit & Supervisory Committee Member), the Company (present post)



**Hiroo Sasaki (Age 65)**

**Outside Director, Audit & Supervisory Committee Member**

### **Resume, position and responsibilities at the Company**

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

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

April 1993: Associate Professor, School of Commerce, Waseda University

April 1996: Professor, School of Commerce, Waseda University

July 1997: Senior Research Officer, Ministry of Finance, Institute of Fiscal and Monetary Policy (current Policy Research Institute); Special Officer for Research, Minister's Secretariat

July 1999: Professor, School of Commerce, Waseda University

April 2005: Professor, School of Commerce, Waseda University; Professor, Graduate School of Accountancy, Waseda University

September 2010: Professor, School of Commerce, Waseda University; Dean, Graduate School of Accountancy, Waseda University

April 2013: Dean, Graduate School of Accountancy, Waseda University

September 2016: Professor, Graduate School of Accountancy, Waseda University

June 2018: Director (Audit & Supervisory Committee Member), the Company (present post)

April 2021: Professor Emeritus, Waseda University (present post)



**Haruko Shibumura (Age 56)**

**Outside Director, Audit & Supervisory Committee Member**

### **Resume, position and responsibilities at the Company**

April 1987: Joined Chiyoda Mutual Life Insurance Company

August 1987: Joined Kyushu University Press

April 1994: Registered as an attorney-at-law (Dai-ni Tokyo Bar Association); Joined Law Offices of Honma & Komatsu (current Homma & Partners)

April 1999: Partner Lawyer, Homma & Partners (present post)

October 2006: Committee member, Compliance Committee, TAMURA Corporation

June 2015: Outside Audit & Supervisory Board Member, NICHIREKI CO., LTD.

April 2016: Committee member, Compliance Special Committee, TAMURA Corporation

June 2018: Outside Director, TAMURA Corporation (present post)

June 2019: Director (Audit & Supervisory Committee Member), the Company (present post); Outside Director, NICHIREKI CO., LTD. (present post)



**Raita Takahashi (Age 58)**

**Outside Director, Audit & Supervisory Committee Member**

#### **Resume, position and responsibilities at the Company**

October 1986: Joined Sanwa Tohmatsu Aoki Audit Corporation (current Deloitte Touche Tohmatsu LLC)

August 1995: Joined Chuo Audit Corporation

May 1997: Established TAKAHASHI Accounting & Tax office (present post)

April 1999: Representative Partner, ChuoAoyama PricewaterhouseCoopers

December 2000: Outside Audit & Supervisory Board Member, Alpha Group Inc. (present post)

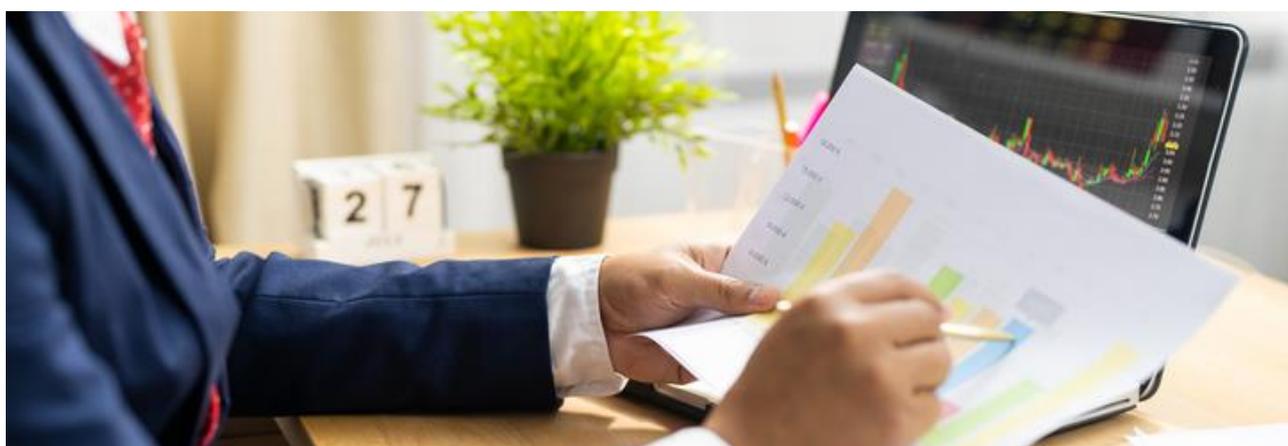
March 2001: Representative Director, Yoshida Management Co. Ltd. (present post)

June 2011: Trustee, Japan Association of Healthcare Management Consultants (present post)

January 2018: Section President, Japanese Institute of Certified Public Accountants, Minami-Kyushu Chapter, Kagoshima Subcommittee

June 2020: Director (Audit & Supervisory Committee Member), the Company (present post)

# Toward Further Development of Risk Management Activities



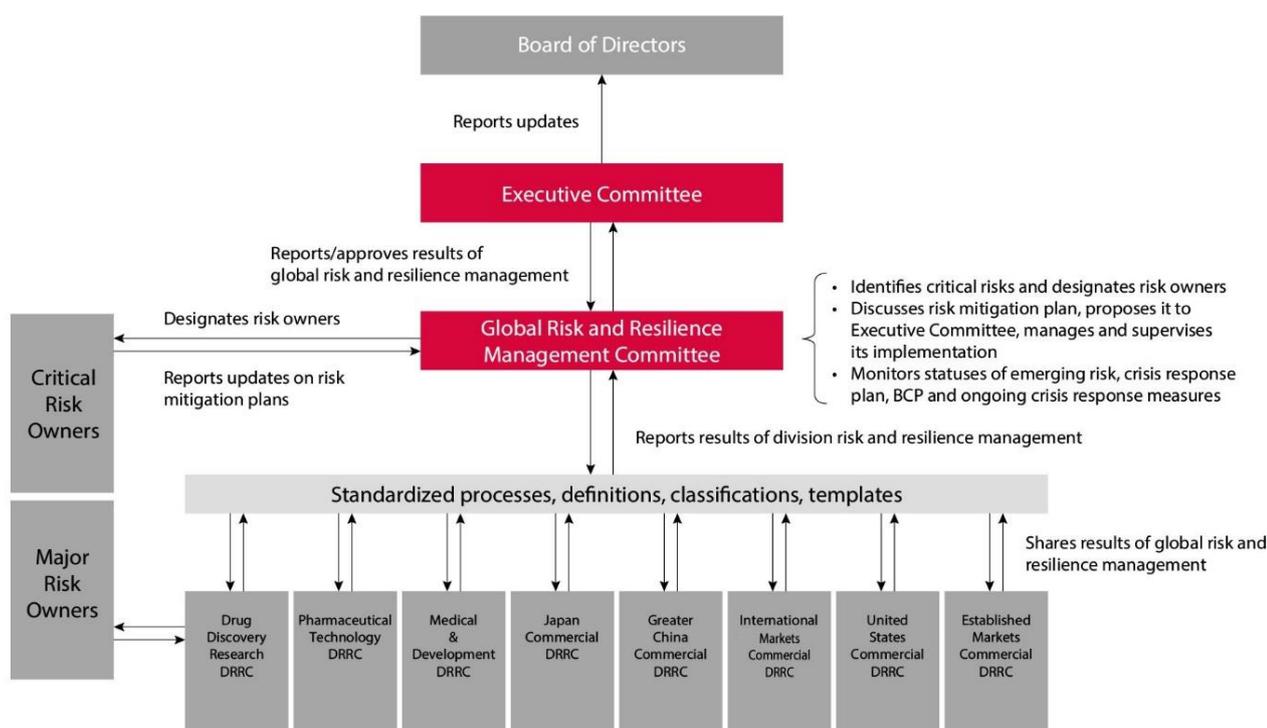
## **(1) Identifying and Mitigating Risks Relating to the Performance of Business Activities**

Pharmaceutical companies that expand their business globally are expected to follow various regulations with a high level of compliance. Accordingly, Astellas must also address various risks that could impact its business results and reputation. In FY2019, Astellas pursued its operation of enterprise risk management with the aim of further developing the risk management activities implemented until now. This involved newly establishing the Corporate Risk Management Division to take control over risk management, and the Global Risk and Resilience Management Committee, chaired by the Chief Administrative Officer and Chief Ethics & Compliance Officer. Under enterprise risk management, risks are identified on the Group-wide level and on the individual division level. Those risks are classified using a uniform evaluation process according to priority and, if deemed necessary, linked to formulation of a universal means for solution. Identified risks are regularly evaluated by the Global Risk and Resilience Management Committee, and solutions and mitigation measures for high priority risks are discussed at the Executive Committee, chaired by the Representative Director, President and CEO.

## (2) Risk Management Framework

Astellas' risk management framework is as follows.

### Risk Management Framework



DRRC : Acronym for Divisional Risk and Resilience Management Committee

## (3) Critical Risks

The risks identified by management as having the potential to have a considerable impact on financial position, business results, and cash flow position of the consolidated companies are mainly set forth below.

Any forward-looking statements are based on judgments as of March 31, 2020.

### 1 Risks related to cybersecurity

In recent years, the technology involved in cyberattacks is advancing at an unprecedented level and the methods of attack are growing more diverse and sophisticated. In light of this environment, Astellas has identified risks related to cybersecurity as one of its critical risks. The Information Systems Division is leading the response to this risk, implementing various countermeasures against cyberattack on a global basis that includes monitoring of networks and facilities, and taking every precaution to manage the risk.

However, despite having such measures in place, in the event that business is substantially interrupted due to a

cyberattack or serious system failure, etc., caused by a cyberattack, or in the event that important data, including information that could identify individuals, is lost, corrupted, or leaked externally, the Astellas Group's business results may be significantly affected.

## **2 Risks related to supply chain management**

In the pharmaceuticals business, the ability to manufacture safe and effective pharmaceuticals reliably and then to provide their stable supply is extremely important. Astellas has identified risks related to supply chain management as one of its critical risks. The Pharmaceutical Technology Division is leading the response to this risk, establishing its own standards compliant with industry standard Good Manufacturing Practice (GMP), including manufacturing and quality controls, and Good Distribution Practice (GDP) as well as rigorously implementing consistent, high-level quality control for not only manufacturing facilities and equipment but inclusive of all operations from ingredient procurement to storage, manufacturing, and delivery. Furthermore, to respond to growing complexities in the supply chain, the Group has introduced on a global basis, management of its Contract Manufacturing Organizations (CMO) and is proceeding with measures including the creation of Business Continuity Plans (BCP) to ensure supply during emergency situations.

However, despite having such measures in place, in the event that interruptions in supply, product shortage, or quality problems arise, or in the event that the reputation of Astellas is damaged as a result of the aforementioned, the Astellas Group's business results may be significantly affected.

## **3 Risk of impact from pharmaceutical regulatory**

The ethical pharmaceutical business is governed by a wide variety of regulations in each country. Astellas has identified changes in pharmaceutical pricing policy by the U.S. government as one of its critical risks and is carefully monitoring trends.

The Astellas Group's business results may be significantly affected by policy for controlling the cost of medical treatment or a tightening of various regulations concerning development, manufacturing, and distribution, particularly in developed countries.

In addition to the above critical risks identified by the Astellas Group, there are many other risks. Some risks are unique to the pharmaceuticals business, which include the uncertain nature of research and development, the risk of being infringed upon or infringing intellectual property rights, the risk of drug side effects or safety issues arising thereof, and the risk of an Astellas Group business's partial dependence on licensing and sales of third-party developed drugs. Other risks include the risk of infringement of related laws and regulations concerning competition with rival products, or environment or health and safety, or of commercial litigation regarding business processes, as well as risks of delays or stoppages in manufacturing due to a natural disaster, etc., or of exchange rate fluctuation. Such risks may affect the Astellas Group's business results and financial position.

Note that the risks stated above do not cover all of the risks relating to the Astellas Group.

## Corporate Governance

# Ethics & Compliance



Astellas is committed to long term, sustainable growth through creating and delivering value to patients and having a positive impact for society. Keeping patients and integrity at the heart of what we do is imperative, and we are passionate about this at Astellas. To create value for patients we do not compromise on patient safety, the quality of our products, or ethics and compliance – we do not compromise on integrity.

We grow and maintain the trust we have earned and continue to earn every day from our patients and other stakeholders through a sound corporate culture which underpins our establishment of an effective global ethics and compliance program.

We act with integrity and make ethical decisions in all aspects of our business, and do what is right, which includes following the letter and the spirit of applicable laws and regulations.

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 everyone who works for Astellas in any location around the world and in any capacity whatsoever as a director, officer, employee, temporary worker, or otherwise, whether full-time or part-time, establishing that they are expected to perform their duties ethically and in compliance with laws and regulations. We also seek to ensure that third parties acting on behalf of Astellas comply with all relevant standards described in the Code.

Astellas' Chief Ethics & Compliance Officer has overall responsibility for overseeing and implementing Astellas' global Ethics & Compliance Program, with the assistance of the Global Compliance Committee. The Chief Ethics & Compliance Officer, in turn, has designated Ethics and Compliance professionals with global and regional responsibilities for Astellas' Ethics & Compliance Program.

## **Related Links**

[Primary Areas of Focus](#)

[Elements of Astellas' Global Ethics & Compliance Program](#)

[Enhancing and Sustaining an Ethical and Compliant Culture at Astellas](#)

# Primary Areas of Focus

## Healthcare Compliance – Interactions with Healthcare Professionals

At Astellas, our fundamental mission is to provide our patients with safe, effective medical products that improve their health and well-being. To achieve that mission, it is essential that we engage with Healthcare Professionals (HCPs), Healthcare Organizations (HCOs), and patient organizations to provide them with accurate information about our products, their approved uses, and if necessary, instruction on the appropriate techniques for using the products. Astellas believes that the medical and scientific exchange between manufacturers and healthcare providers is essential to our provision of innovative and reliable pharmaceuticals and contributes to improving the health of patients around the world.

Astellas also is committed to engaging in appropriate financial relationships with HCPs and HCOs. Astellas enters into consultant agreements, which are a type of fee-for-service agreement, with HCPs and other business experts when there is a documented and reasonable business need for their unique advice, expertise, or services. All such agreements are based on defined eligibility criteria and are never entered into as a reward or incentive for past, present, or future product use or recommendation.

Healthcare Compliance is an important aspect of our Ethics & Compliance function and helps to ensure that all Astellas interactions with HCPs, HCOs and patient organizations are conducted in a legal and ethical manner and always for the ultimate benefit of patients. Our commitment to the highest standard of ethics is at the center of our global business. Compliance with both the letter and the spirit of all applicable laws, regulations, guidelines and company policies is a critical part of that commitment. All Astellas employees are expected to act with the highest ethical standards and in full compliance with applicable laws, regulations, industry guidelines and internal company policy. This helps to protect the independence of medical decision making and to limit even the appearance of improper influence or impropriety, reinforcing trust in Astellas, our brands, and our integrity.

Astellas adheres to all transparency requirements across the globe, disclosing financial relationships (transfers of value) in accordance with local law and code. Such disclosures are not only to stakeholders and legislative bodies, but also to the public, fulfilling our obligations of corporate accountability.

## Data Privacy

At Astellas, we place delivering value for patients at the core of everything we do and that includes safeguarding and ensuring the appropriate use of the personal information that is entrusted to us by individuals within the course of our business. Physicians, patients, employees, suppliers, and other individuals may share their personal information with Astellas, and they trust us to keep that information safe, to use it transparently, and to always handle it with care.

All Astellas employees and third parties working on behalf of Astellas are committed to respecting and protecting the personal information that people share with us. The Astellas Ethics & Compliance (E&C) Privacy Office ensures that Astellas has a robust Privacy Program in place and provides advice and guidance to business to ensure the appropriate collection, processing, sharing, and retention of personal information across Astellas. In particular, Astellas E&C Privacy has established a documented and structured Privacy Management Framework, which covers 21 basic data processing activities and allows the formation of a consistent Global Privacy Strategy. The organizational structure and the privacy tools and process that have been introduced allow the early identification of privacy risks and their effective remediation at a global scale. At the same time, the Astellas E&C Privacy Office works with our affiliate E&C leads at a local level to ensure we adhere to all applicable privacy laws and regulations and monitor Astellas' compliance with them.

Astellas' Global Data Privacy Policy and the privacy processes, controls, and security measures Astellas has put in place, constitute the essential framework to protect our organization, its assets and the personal information we are processing.

## **Anti-Bribery Anti-Corruption**

Astellas takes a strong stance against corruption. Astellas strictly prohibits bribery and corruption in any aspect of its business and is committed to complying with all applicable laws, including anti-corruption laws, consistent with its commitment to conducting its business with ethics and integrity.

This is a core commitment of Astellas embodied in the Astellas Group Code of Conduct and the Astellas Group Policy on Anti-Bribery and Anti-Corruption Compliance. In addition, Astellas is a signatory to the United Nations Global Compact, including its 10th Principle Against Corruption, and the Tokyo Principles for Strengthening Anti-Corruption Practices.

Astellas' ABAC program is designed to provide reasonable assurance of compliance with Astellas' commitment against corruption. The program consists of ABAC policies and procedures, trainings and communications, risk assessments, monitoring and auditing, reporting and investigation activities.

Astellas has ABAC policies and procedures that embody its commitment against corruption. These policies and procedures are consistent with the U.S. Foreign Corrupt Practices Act, the UK Bribery Act, and other applicable local anti-bribery and corruption laws and regulation. Astellas prohibits all forms of bribery and corruption, including facilitation payments.

Astellas is committed to empowering its employees with the knowledge and tools they need to help Astellas fulfill its public commitment against corruption. Astellas requires all employees to complete annual ABAC training. This training is available in 22 languages. Additionally, Astellas provides specialized ABAC training to target audiences based on their functions or roles in the company, as well as where we have identified risks and needs. The Astellas Global ABAC Policy reflects Astellas' commitment to conduct business with integrity and the highest ethical standards and to comply with the letter and spirit of all applicable ABAC laws and regulations. Astellas conducts compliance risk assessments and compliance monitoring, including on aspects of its ABAC compliance program. Astellas Ethics & Compliance also works closely with the Astellas Legal Department to investigate potential incidents of ABAC non-compliance and with the Astellas Internal Audit Department on the audit of Astellas affiliates and third parties covering activities that may involve ABAC risks. Astellas continuously seeks to improve its ABAC program based on these activities to assure the program remains effective and up to

date in addressing changing risk.

Astellas has established an internal control environment designed to comply with J-SOX regulatory requirements to ensure financial reporting integrity as well as fraud prevention and detection. Its financial controls provide complementary assurance of compliance with its anti-corruption commitment.

A core principle of our ABAC compliance program is to prohibit third parties from engaging in activities that we prohibit for our own employees. This principle is embodied in the Astellas Group Policy on Anti-Bribery and Anti-Corruption Compliance and the Astellas Business Partner Code of Conduct. To adhere to this principle and mitigate and manage the risk arising from third parties providing services on our behalf, Astellas has established a process to conduct bribery and corruption compliance due diligence assessments on third parties interacting with healthcare professionals or government officials on our behalf. In addition, Astellas periodically exercises audit rights over third parties, and has risk-based ABAC clauses for contractual arrangements with third parties.

## **Conflicts of Interest**

Another core element of an effective ethics and compliance program is how a company approaches its own conflicts of interest. That is 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 could 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 our 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 maintaining this baseline expectation regarding conflicts of interest contributes to our employees conducting their business with ethics and integrity when engaging with stakeholders outside the Company and where legal risks are involved. Engagement in the disclosure process and global training efforts continue to enhance the ability of internal stakeholders to identify potential conflicts, resulting in increased business ownership of compliance.

## **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. We limit our engagement with competitors and avoid any conversation concerning these topics when engagement is necessary, so that such interactions are not construed to reflect the existence of such an agreement.

# Elements of Astellas' Global Ethics & Compliance Program



\* A Culture of Integrity runs through and is interdependent with an effective Ethics & Compliance Program.

The Astellas Ethics & Compliance Program has at its core a values-based ethical culture of integrity which enables innovation and bold ideas by supporting ethical, compliant and intelligent business risk-based decisions as a core competency for all employees. Our actions and decisions are made to ensure sustainable value is delivered to patients through the provision of risk-balanced, proactive, agile, innovative, expert and practical ethics and compliance guidance.

The Ethics & Compliance Program continues to develop and mature, while standardizing and enhancing the effectiveness of its global program in partnership with the business, through an ongoing cycle of Prevention, Detection, Response and Evaluation.

## Prevention

A values-based ethical culture of integrity begins with Astellas leadership which takes accountability and oversight for creating a psychologically safe environment where employees are empowered to make appropriate ethical and compliant decisions. This is strengthened through the efforts of Astellas' global, regional and local compliance committees and their awareness, knowledge and understanding of ethics and compliance in the context of business operations and activities.

Our comprehensive Ethics & Compliance Program is designed to prevent potential non-compliance or unethical behaviour. Astellas takes steps designed to mitigate risks and to prevent non-compliance through established global policies, processes and systems, tools and controls, and associated training and communications covering ethics and compliance related risk areas.

Compliance risk assessments help identify areas of current and emerging risk which require appropriate mitigation through the design and implementation of standards and controls, appropriate oversight and due diligence of our third-party suppliers and distributors, and targeted and impactful training and communications. The Ethics & Compliance function deploys multiple online and live training programs to continue to foster compliance awareness and understanding among employees. All employees, including new employees, must 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. In addition, global Ethics & Compliance training programs include a survey to determine training effectiveness. The results of these surveys help Astellas in ensuring training programs are meeting the needs of employees and in turn, update the training to make it even more effective.

## Detection

While great efforts are placed on preventing instances of non-compliance, all employees are responsible for ensuring compliance with Astellas policies and the laws, regulations and guidelines that govern our industry. Our goal in Ethics & Compliance is to enable employees and Astellas to make ethical and compliant decisions by providing guidance, clarification and training.

Astellas has partnered with EthicsPoint to provide us with an anonymous and confidential method to hear employees' suggestions, concerns or reports of alleged misconduct. Reporters have the option of using their names or remaining anonymous if allowed by local laws and regulations.

Additionally, proactive monitoring of business activities and processes may provide opportunities for early detection and risk identification allowing us to help the organization avoid non-compliance in the future through lessons learned discussions, communications and training, and process improvement.

## Response

If non-compliance is detected or reports are received alleging non-compliant activities or actions, Astellas will promptly investigate in a fair, robust and objective manner to fully understand the facts and circumstances. If a matter is substantiated, Astellas implements appropriate and proportionate consequences with leadership accountability and support to maintain consistency, objectivity and enforcement of all laws, regulations, policies, SOPs, guidelines and Astellas values.

Reports do not always result in disciplinary action. Many times, we check into the facts and find there is no misconduct, but opportunities for further training and education. We coach individuals on how to provide clear communications or directions to avoid misunderstandings. If there is misconduct, however, we want to address it as soon as possible. Speaking up contributes to making Astellas a better workplace for everyone.

## **Evaluation**

Astellas Ethics & Compliance has processes in place to continuously assess and evaluate maturity and effectiveness of the Ethics & Compliance Program. Evolving established key performance indicators such as training, investigations, disciplinary actions and standardization of programs provide the Astellas Board and Leadership with the awareness and oversight to ensure an adequately and appropriately resourced and empowered Ethics & Compliance Department.

# Enhancing and Sustaining an Ethical and Compliant Culture at Astellas

Astellas promotes an ethical culture where people are expected to act with integrity and put patients first and the long term, sustainable success of the company as their priorities.

Ethics & Compliance's Integrity in Action program reinforces the importance of taking responsibility, acting ethically and leading by example. As part of Astellas' ongoing commitment to this program, our training and communications embed the Astellas Way values and a patient-focused mindset, so employees can understand how being ethical and compliant helps them live the Astellas mission.

Astellas fosters an environment that encourages employees to speak up to report potential or actual violations of the Group Code of Conduct, as well as any unethical behavior or business practices, or receive advice on how to react in the event they discover or suspect misconduct. Reports may be made by employees or third parties and may be made anonymously as permitted by local laws and regulations.

In addition, Astellas strictly prohibits retaliation against anyone who raises a concern or reports a suspected compliance violation in good faith even if the concern or report is not substantiated after investigation. Astellas regularly reinforces the importance of speaking up and the responsibilities that employees have in reporting through Astellas' global Speak Up campaign which includes online resources, posters, communications, and presentations supported by a visual theme.

Having the ability to centrally manage the reports of suspected non-compliance and the corresponding investigations also enhances Astellas' ability to analyze compliance trends globally. Compliance hotline statistics are analyzed and reported to the Global and Regional Compliance Committees on a regular basis.

Astellas leaders and managers are critical to the effective promotion and protection of the Astellas core values of integrity, and ethics and compliance within their teams. Ethics & Compliance works closely with the business to engage in various initiatives designed to continually enhance and sustain an ethical and compliant culture at Astellas. This includes an ethical decision-making initiative with leader and manager workshops dedicated to providing insight into key ethical concepts that impact decision-making and the practical tools leaders and managers can use, as well as help their teams use, to support ethical decision-making in their daily business activities.

Turn the Lights On is an engaging way to build lessons learned discussions around matters brought to our attention for investigation. This enduring platform engages local Compliance Committees and leadership through employee-facing scenario-based panel discussions and encourages dialogue at all levels of the organization to increase compliance maturity and leadership using investigation case studies. Creating a safe speak up environment builds trust among our teams and trust in Astellas.

The Business Ethics Practitioner (BEP) program develops employees and leaders by (1) creating a deeper understanding of the impact of corporate culture on behavior and conduct, (2) embedding an enhanced working knowledge of ethics and compliance in the business, and (3) defining and encouraging the creation of a psychologically safe, ethical environment. These BEPs are then able to lead by example and serve as role models to other employees in responsible and ethical ways of working, identify and address potential ethical and compliance risks, drive successful ethical and compliant decisions, and support employees in speaking up about potential issues.

By putting the patient first and making decisions that support delivering innovation with agility and integrity, we create a long term and sustainable future that will continue to add value to patients and reinforces the trust on which our success is founded.

# Financial Information



## **Financial Highlights**

Find summaries of Consolidated Business Results and Forecasts.

[Read more](#)

## **Financial Data (Annual Data)**

Find annual financial information such as Statement of Income, Statement of Financial Position, Statement of Cash Flows and Per share data.

[Read more](#)

## **Sales of Major Products**

Find information about sales of our Major Products.

[Read more](#)

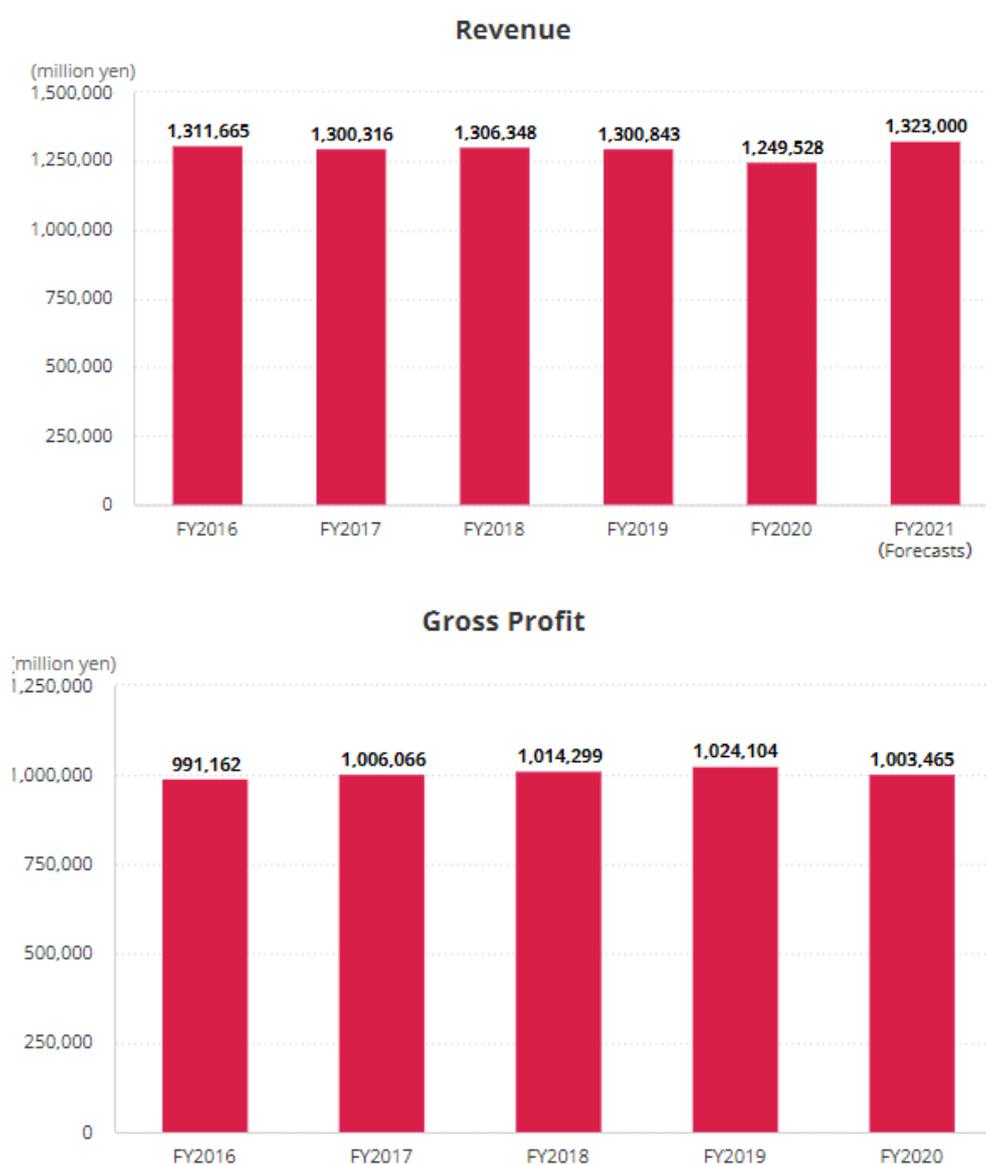
## **Revenue by Region**

Find information about our sales broken out by region.

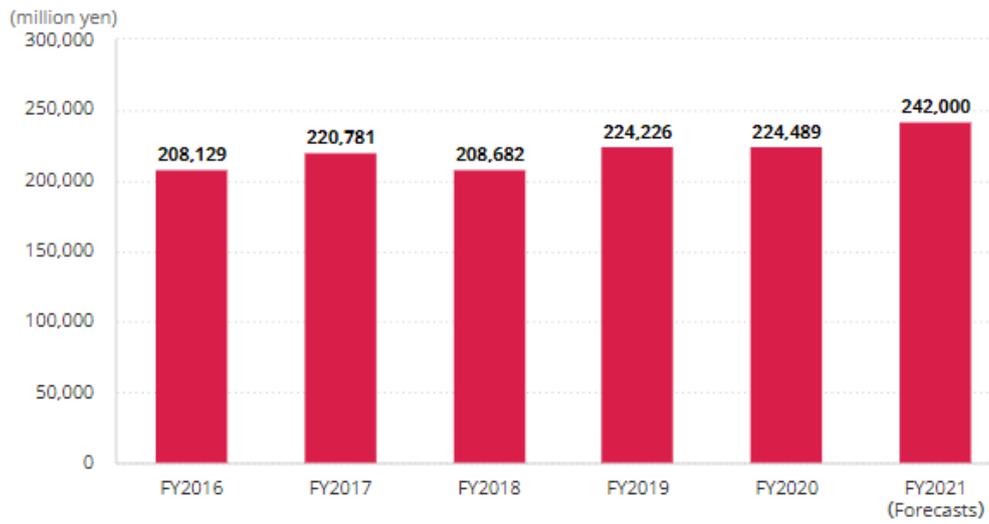
[Read more](#)

# Financial Highlights

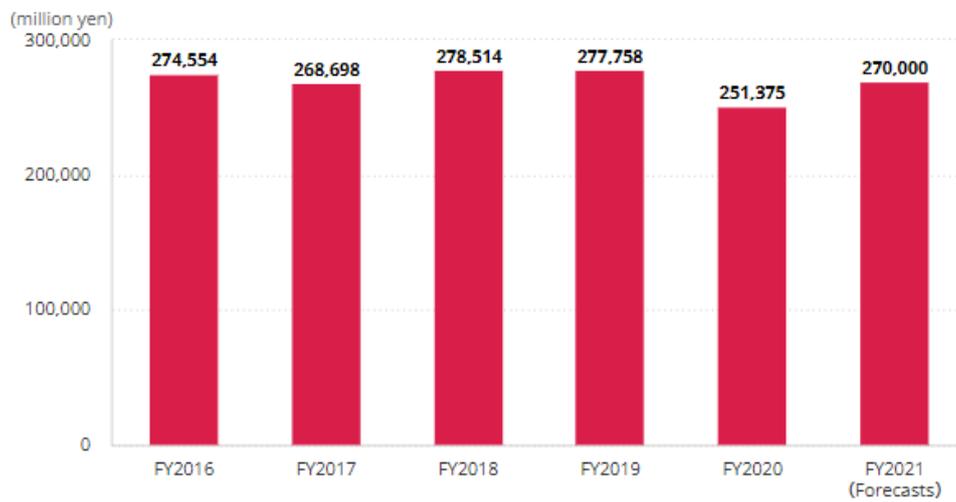
## Graphs of Consolidated Business Results and Forecasts [IFRS]



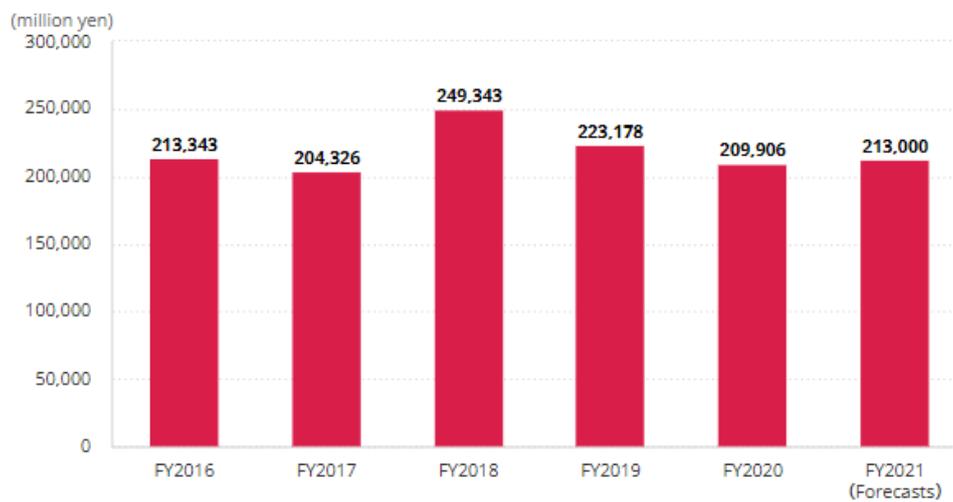
### R and D expenses



### Core operating profit



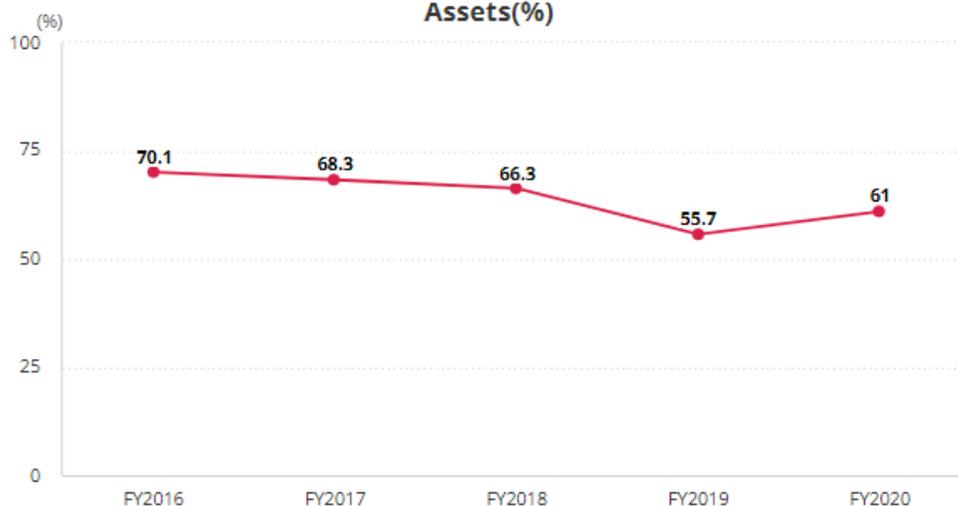
### Core profit



### Total Assets / Total Equity



### Ratio of Equity Attributable to Owners of the Parent to Gross Assets(%)



## Summary of Consolidated Business Results and Forecasts [IFRS]

(million yen)

	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021 (Forecasts)
Revenue	1,311,665	1,300,316	1,306,348	1,300,843	1,249,528	1,323,000
Gross profit	991,162	1,006,066	1,014,299	1,024,104	1,003,465	—
R&D expenses	208,129	220,781	208,682	224,226	224,489	242,000
Core operating profit	274,554	268,698	278,514	277,758	251,375	270,000
Core profit	213,343	204,326	249,343	223,178	209,906	213,000

(million yen)

	FY2016	FY2017	FY2018	FY2019	FY2020
Total assets	1,814,072	1,858,205	1,897,648	2,315,169	2,273,628
Total equity	1,271,810	1,268,289	1,258,396	1,289,168	1,386,115
Ratio of equity attributable to owners of the parent to gross assets(%)	70.1	68.3	66.3	55.7	61.0

(yen)

		FY2016	FY2017	FY2018	FY2019	FY2020	FY2021 (Forecasts)
Exchange rate (Yearly average)	US\$	108	111	111	109	106	110
	Euro	119	130	128	121	124	130

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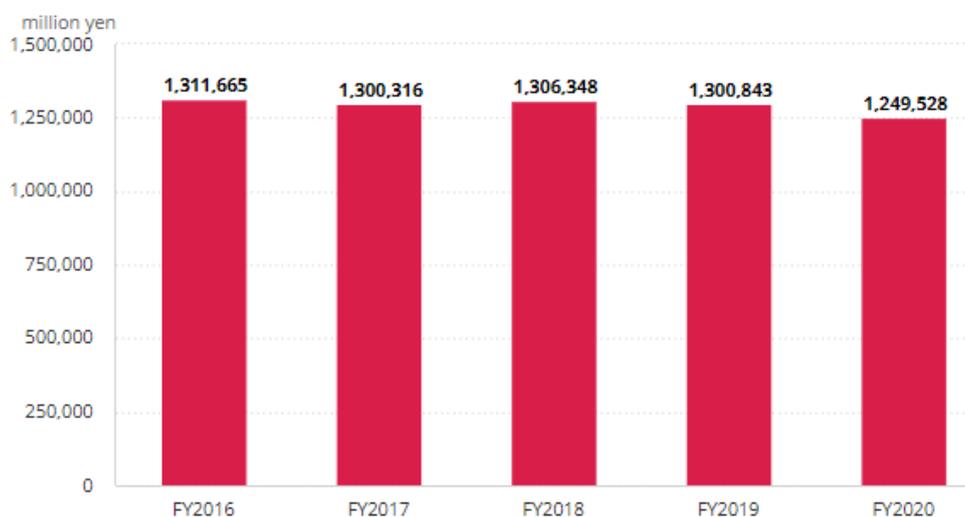
## Financial Information

# Financial Data (Annual Data)

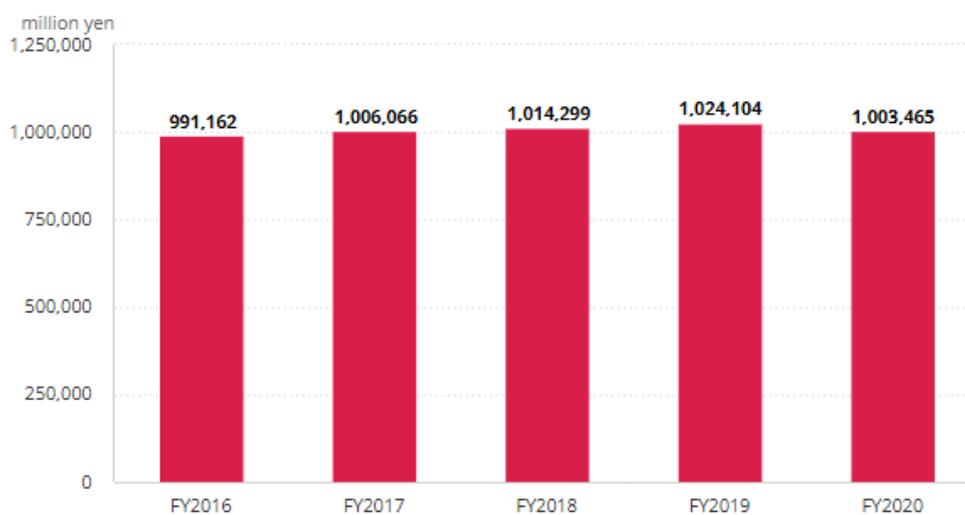
### Statement of Income / IFRS core basis

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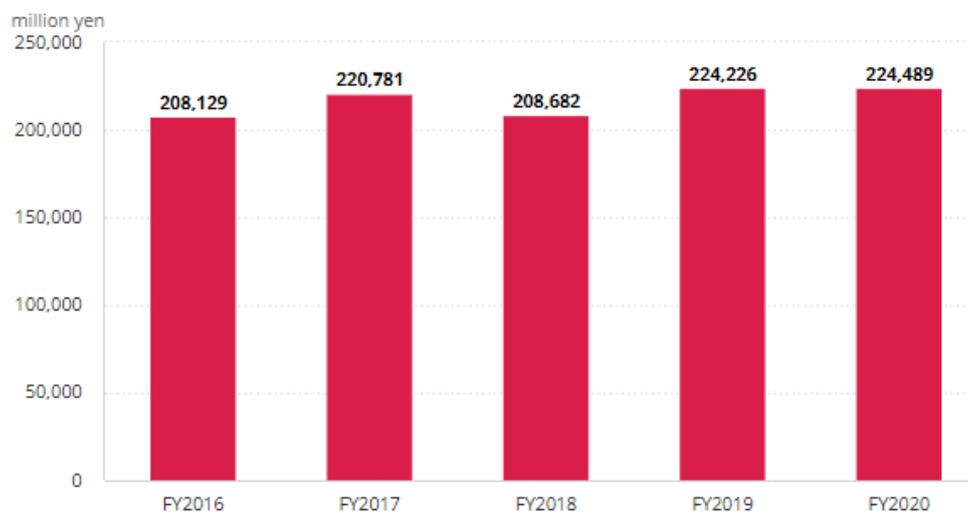
#### Revenue



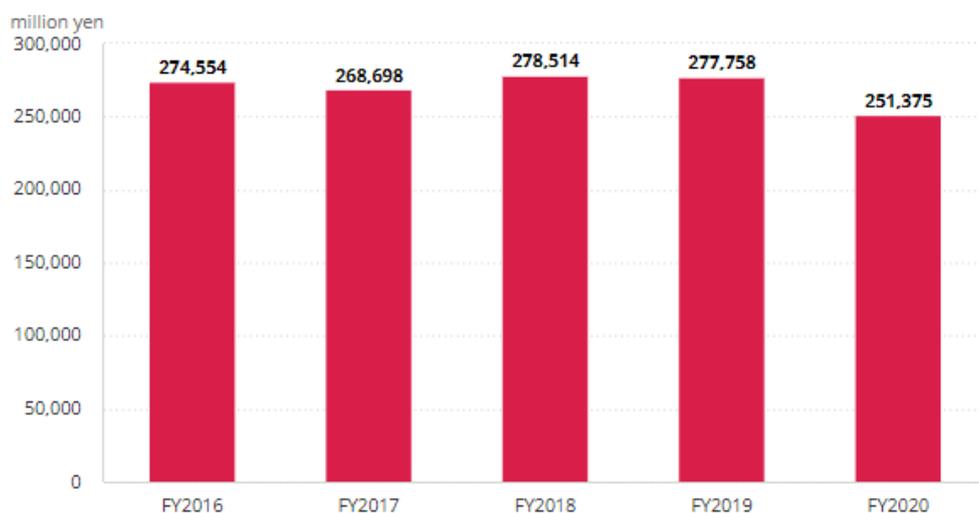
#### Gross Profit



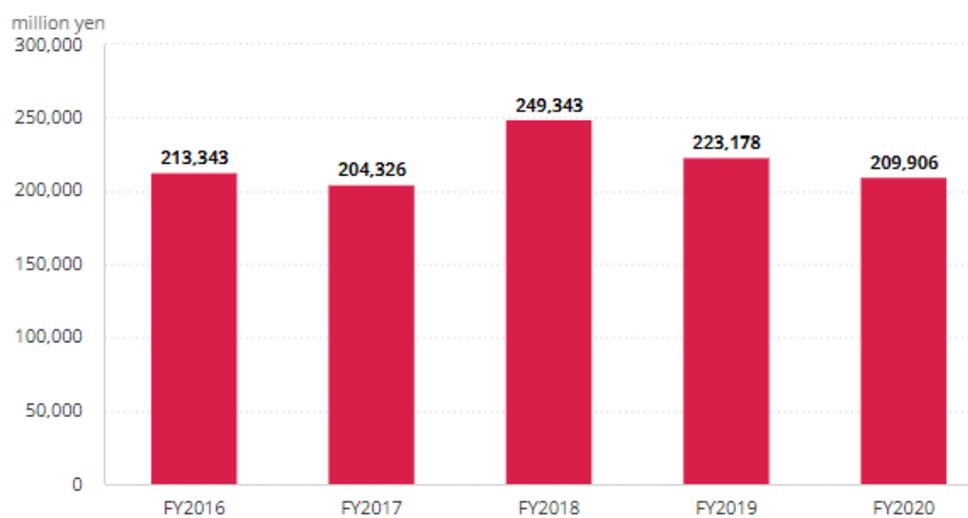
### R and D Expenses



### Core Operating Profit



### Core Profit



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(million yen)

	FY2017	FY2018	FY2019	FY2020
Revenue	1,300,316	1,306,348	1,300,843	1,249,528
Gross profit	1,006,066	1,014,299	1,024,104	1,003,465
R&D expenses	220,781	208,682	224,226	224,489
Core operating profit	268,698	278,514	277,758	251,375
Core profit	204,326	249,343	223,178	209,906

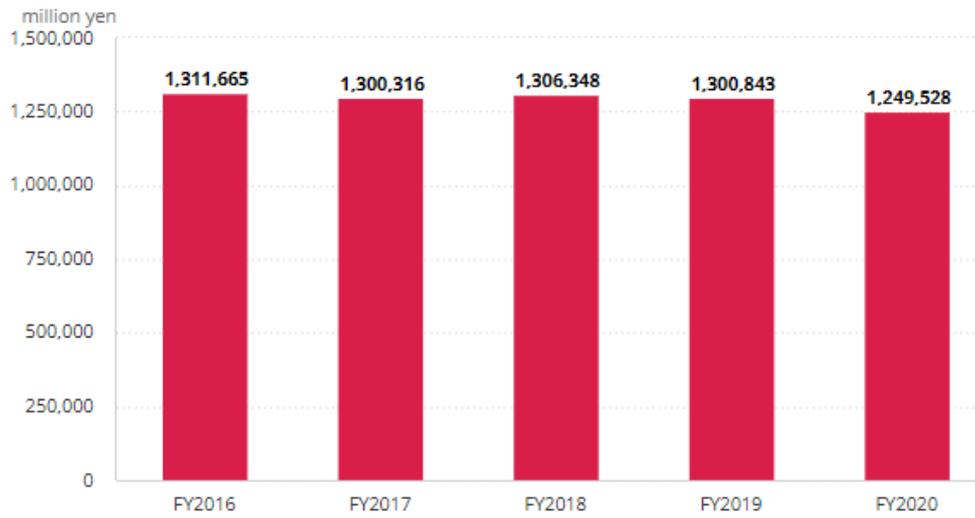
(million yen)

	FY2013	FY2014	FY2015	FY2016
Revenue	1,139,909	1,247,259	1,372,706	1,311,665
Gross profit	809,281	914,062	1,037,110	991,162
R&D expenses	191,460	206,594	225,665	208,129
Core operating profit	186,253	216,500	267,456	274,554
Core profit	132,796	153,244	198,802	213,343

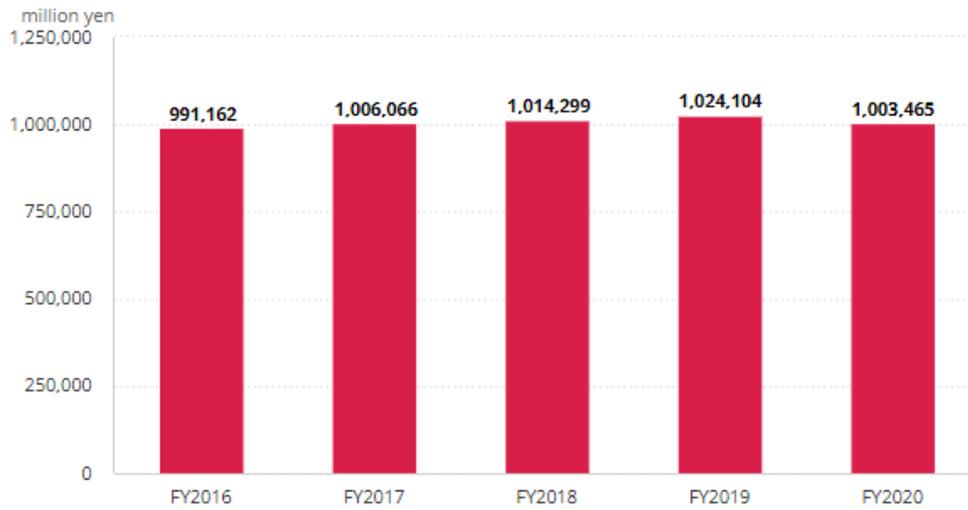
## Statement of Income / IFRS full basis

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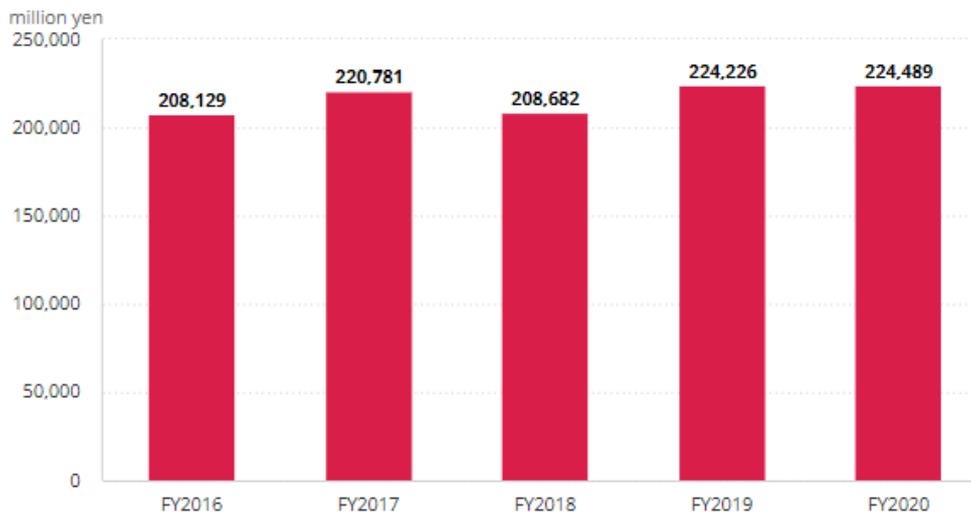
### Revenue



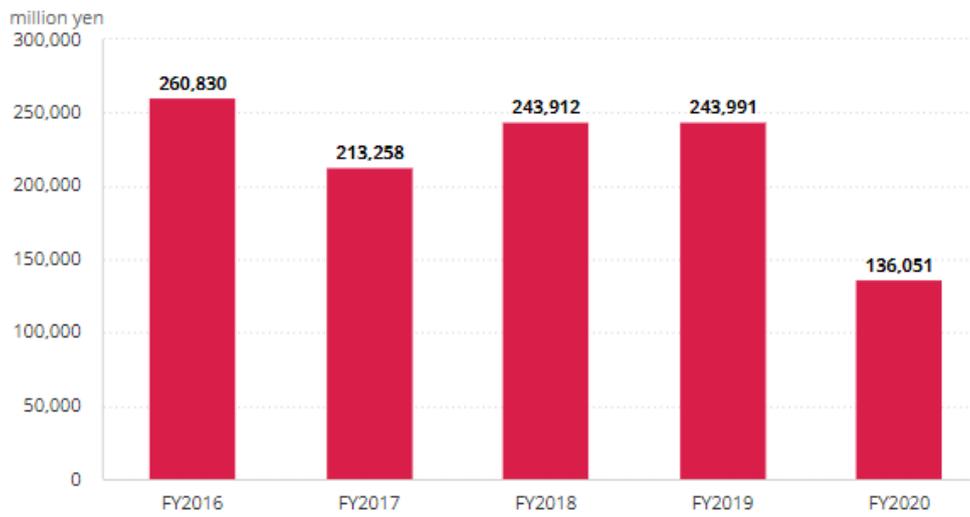
### Gross Profit



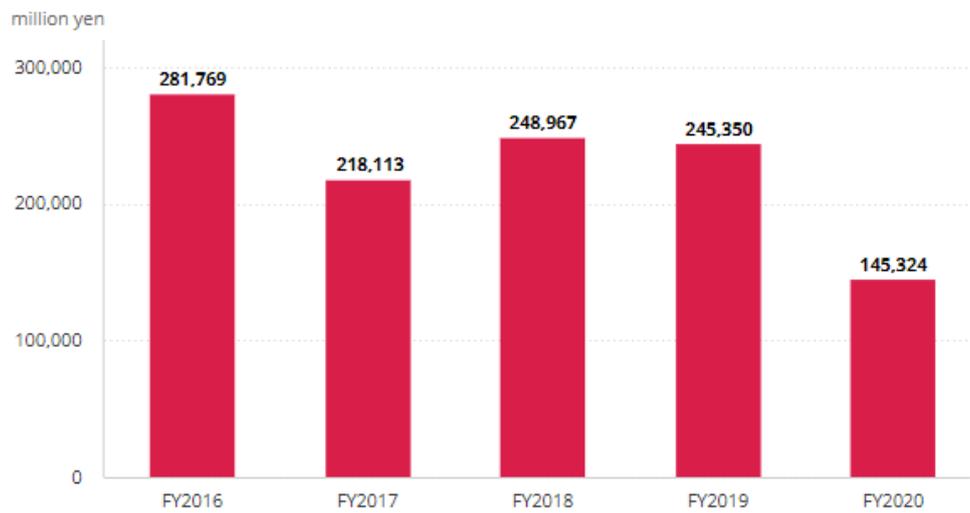
### R and D Expenses



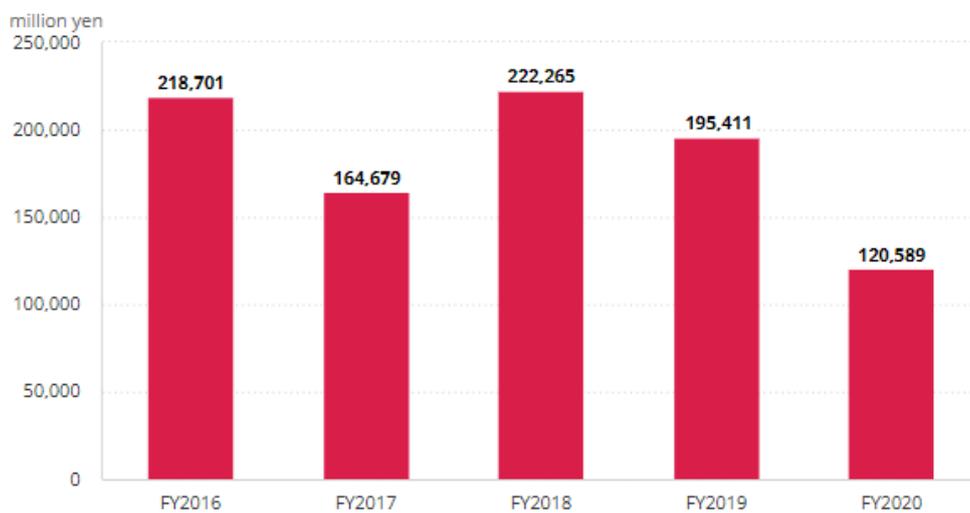
### Operating Profit



### Profit Before Tax



### Profit



(million yen)

	FY2017	FY2018	FY2019	FY2020
Revenue	1,300,316	1,306,348	1,300,843	1,249,528
Gross profit	1,006,066	1,014,299	1,024,104	1,003,465
R&D expenses	220,781	208,682	224,226	224,489
Operating profit	213,258	243,912	243,991	136,051
Profit before tax	218,113	248,967	245,350	145,324
Profit	164,679	222,265	195,411	120,589

(million yen)

	FY2013	FY2014	FY2015	FY2016
Revenue	1,139,909	1,247,259	1,372,706	1,311,665
Gross profit	809,281	914,062	1,037,110	991,162
R&D expenses	191,460	206,594	225,665	208,129
Operating profit	116,806	185,663	248,986	260,830
Profit before tax	121,975	189,683	261,770	281,769
Profit	90,874	135,856	193,687	218,701

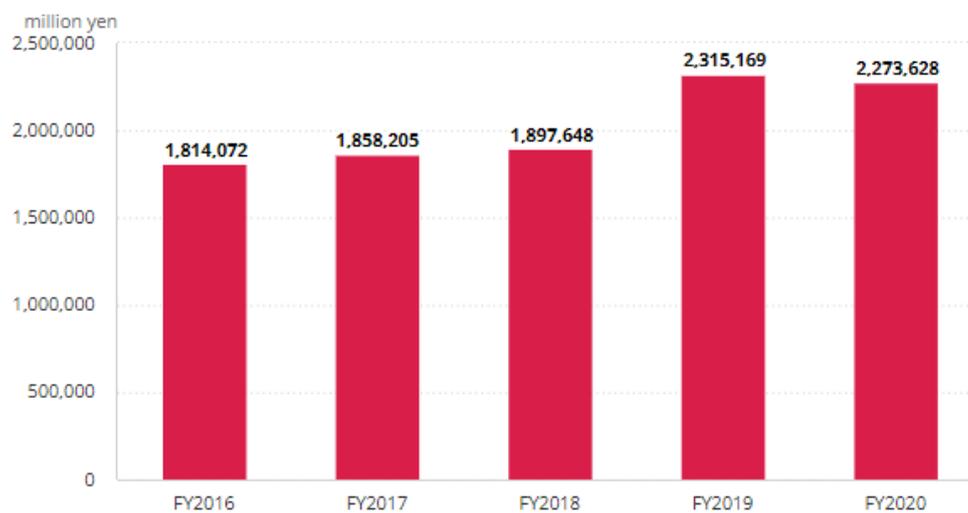
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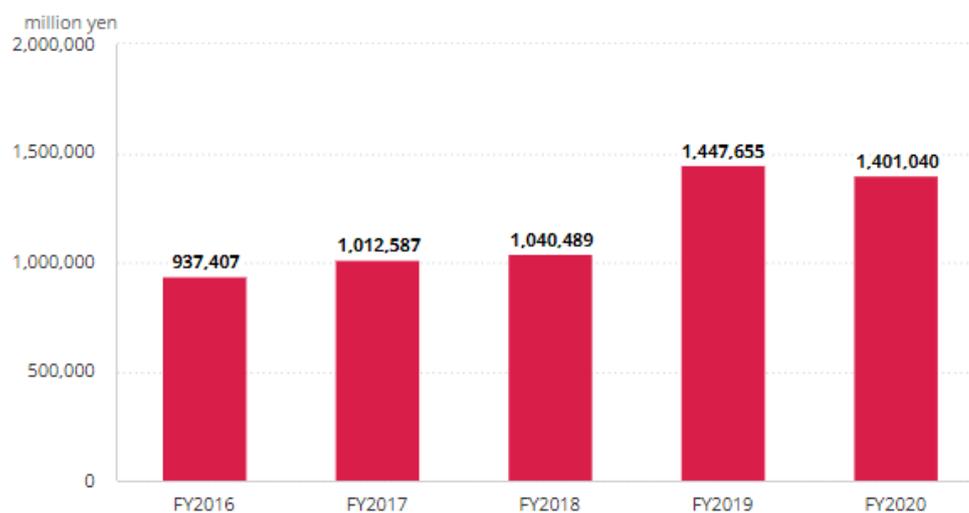
## Statement of Financial Position

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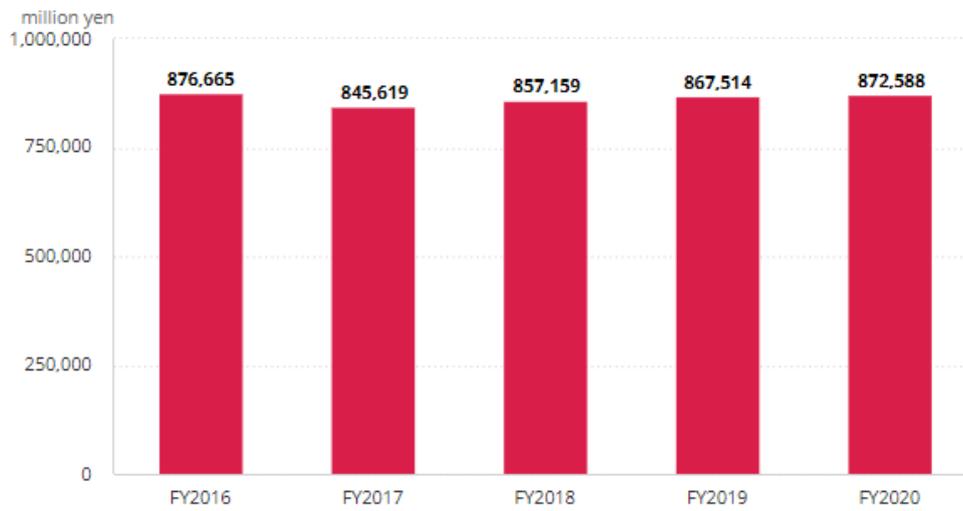
### Total Assets



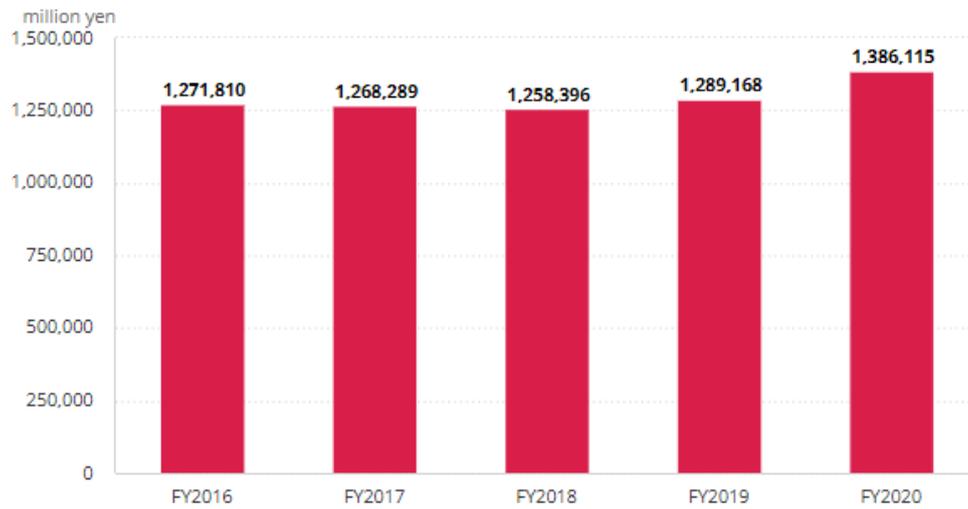
### Total Non-Current Assets



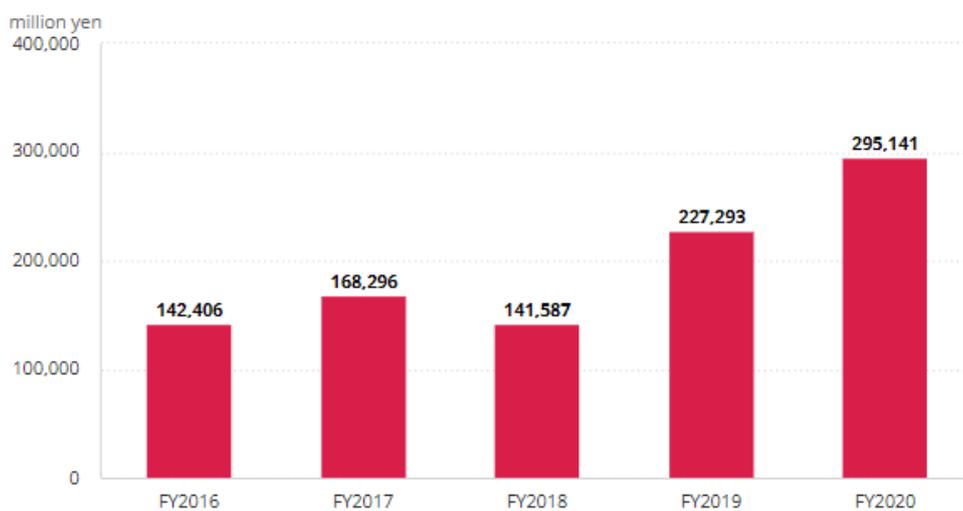
### Total Current Assets



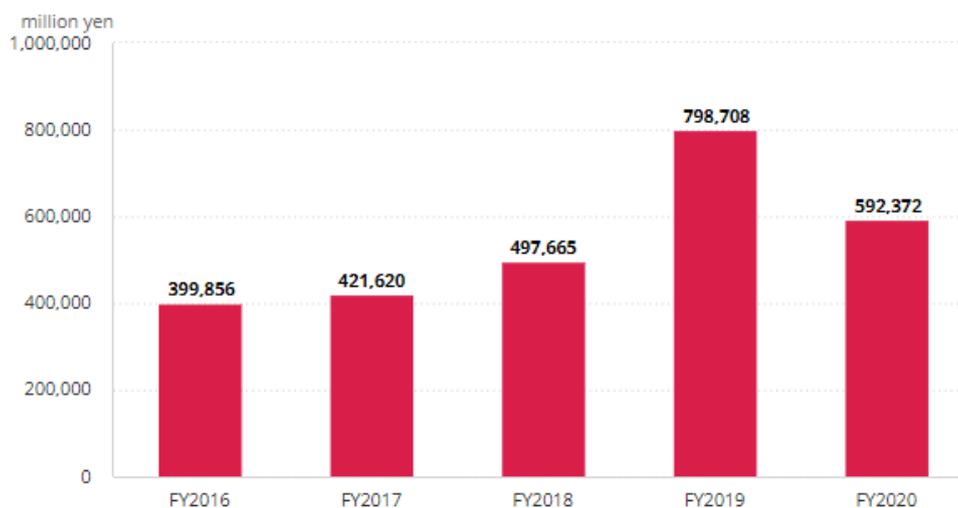
### Total Equity Attributable to Owners of the Parent



### Total Non-Current Liabilities



## Total Current Liabilities



(million yen)

	FY2017	FY2018	FY2019	FY2020
Total assets	1,858,205	1,897,648	2,315,169	2,273,628
Total non-current assets	1,012,587	1,040,489	1,447,655	1,401,040
Total current assets	845,619	857,159	867,514	872,588
Total equity attributable to owners of the parent	1,268,289	1,258,396	1,289,168	1,386,115
Total non-current liabilities	168,296	141,587	227,293	295,141
Total current liabilities	421,620	497,665	798,708	592,372

(million yen)

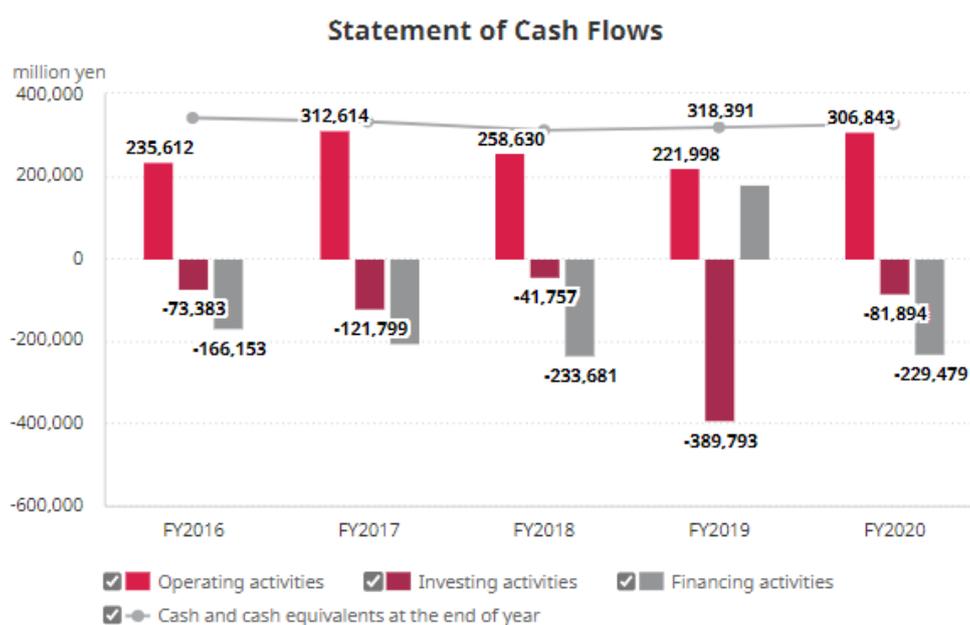
	FY2013	FY2014	FY2015	FY2016
Total assets	1,653,108	1,793,578	1,799,338	1,814,072
Total non-current assets	739,816	827,621	901,801	937,407
Total current assets	913,292	965,958	897,537	876,665
Total equity attributable to owners of the parent	1,268,476	1,317,916	1,259,209	1,271,810
Total non-current liabilities	43,944	54,771	126,769	142,406
Total current liabilities	340,688	420,890	413,359	399,856

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## Statement of Cash Flows

Statement of Cash Flows are available on screen. The Astellas Group has adopted the International Financial Reporting Standards (IFRS), effective from the fiscal year ended March 31, 2014.



(million yen)

	FY2017	FY2018	FY2019	FY2020
Operating activities	312,614	258,630	221,998	306,843
Investing activities	-121,799	-41,757	-389,793	-81,894
Financing activities	-203,429	-233,681	181,055	-229,479
Cash and cash equivalents at the end of year	331,731	311,074	318,391	326,128

(million yen)

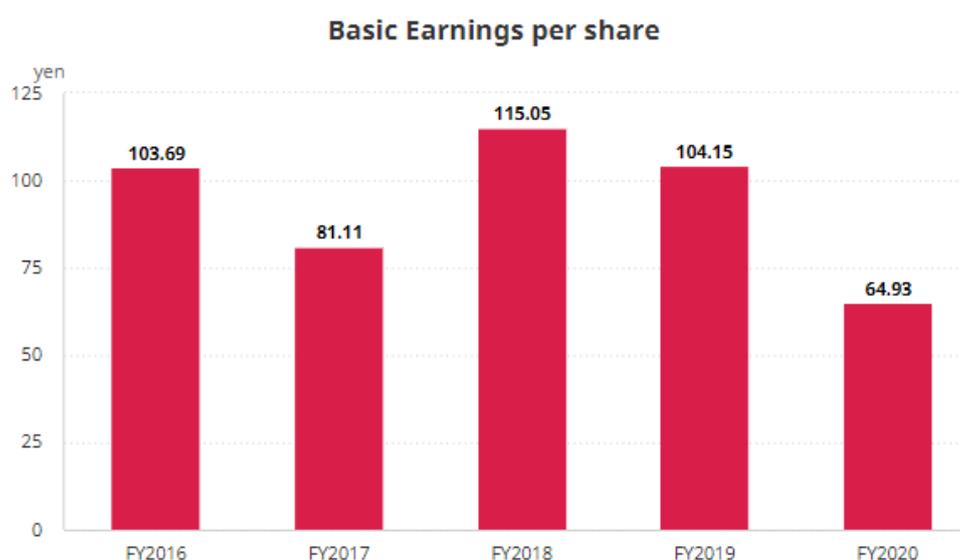
	FY2013	FY2014	FY2015	FY2016
Operating activities	214,257	187,686	313,737	235,612
Investing activities	-26,851	-71,476	-147,050	-73,383
Financing activities	-89,395	-121,118	-193,478	-166,153
Cash and cash equivalents at the end of year	391,374	396,430	360,030	340,923

**Note:**

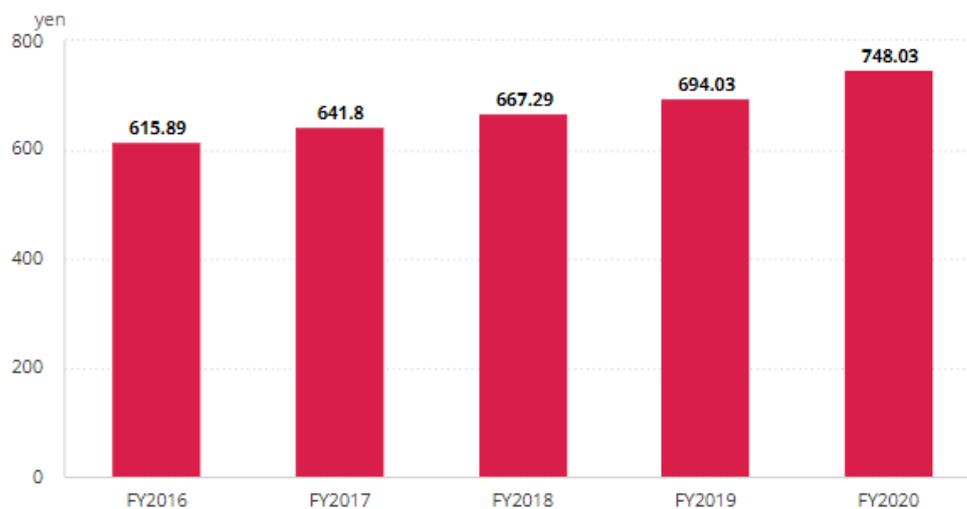
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## Per share data

Per share informations are available on screen. The Astellas Group has adopted the International Financial Reporting Standards (IFRS), effective from the fiscal year ended March 31, 2014.



### Book value per share



### Dividends



(yen)

	FY2017	FY2018	FY2019	FY2020
Basic earnings per share*	81.11	115.05	104.15	64.93
Book value per share*	641.80	667.29	694.03	748.03
Dividends	36	38	40	42

(yen)

	FY2013	FY2014	FY2015	FY2016
Basic earnings per share*	40.45	61.5	89.75	103.69
Book value per share*	568.53	600.93	592.58	615.89

Dividends	135	30	32	34
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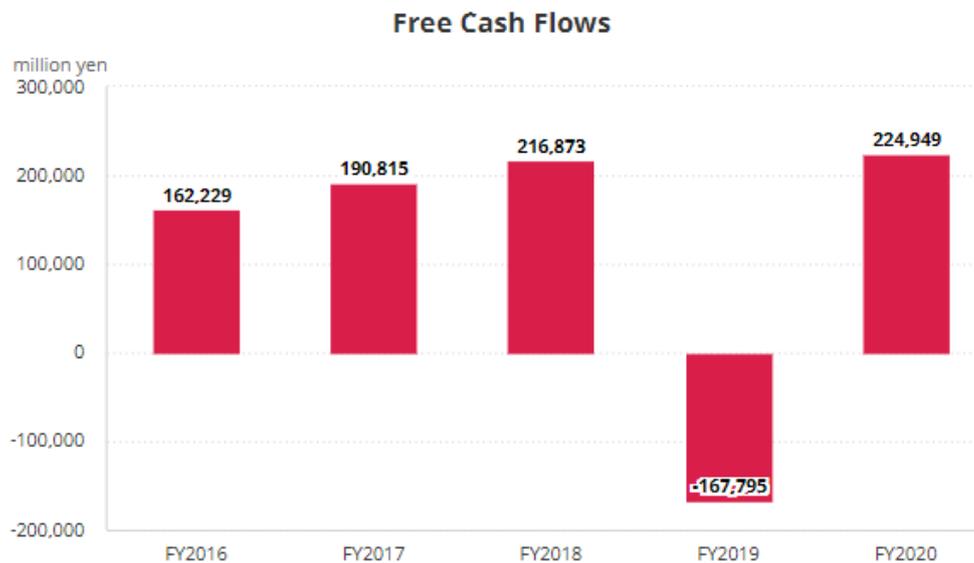
\*The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014. Basic earnings per share and book value per share are calculated based on the number of issued shares after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of FY2013.

**Note:**

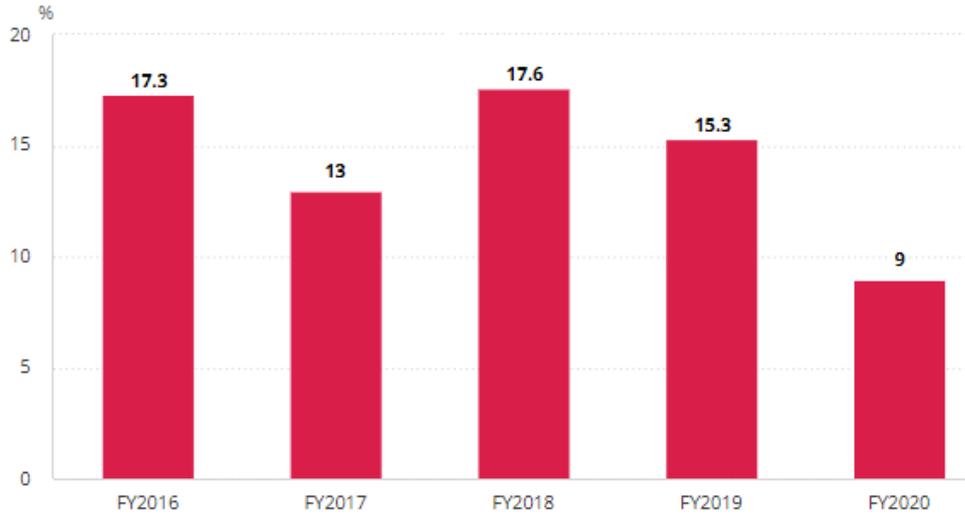
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## Major Indicator

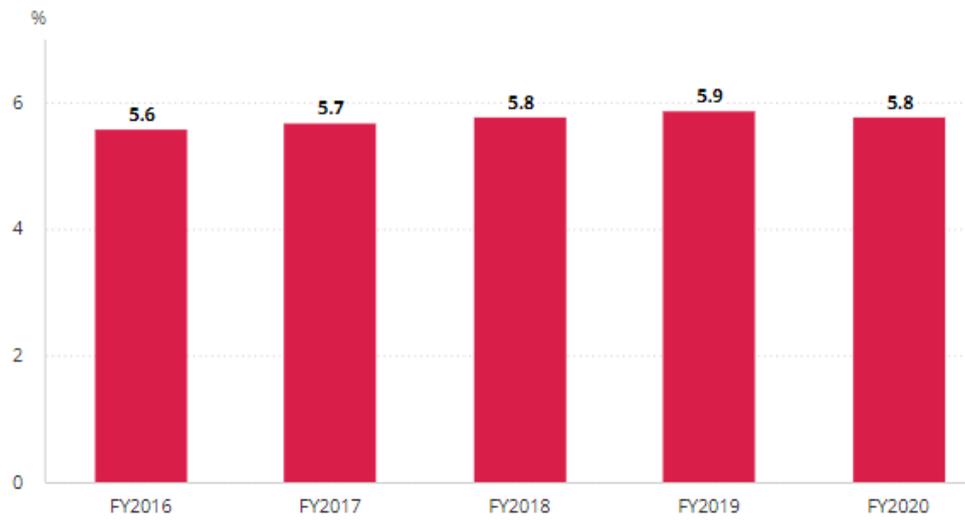
Principal business indexes are available on screen. The Astellas Group has adopted the International Financial Reporting Standards (IFRS), effective from the fiscal year ended March 31, 2014.



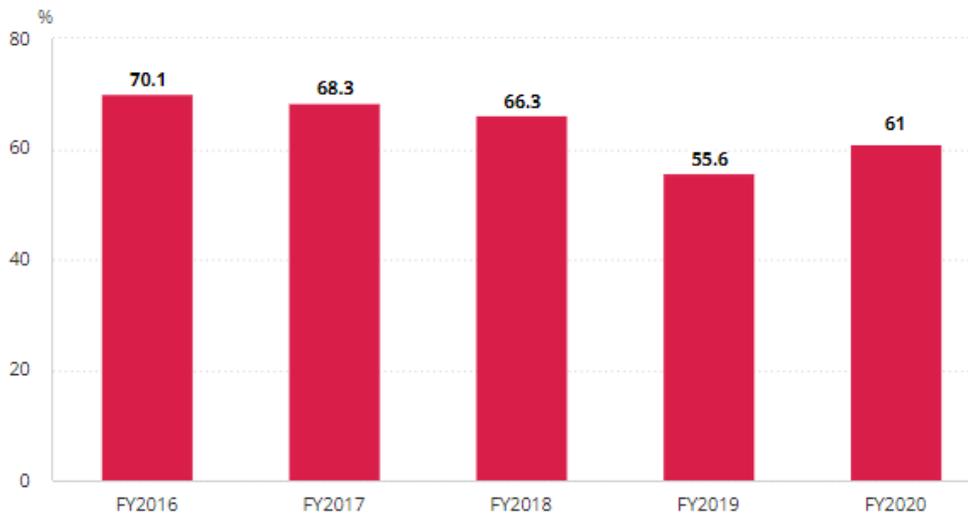
### Return on Equity



### Dividend on Equity



### Ratio of Equity Attributable to Owners of the Parent to Gross Assets



	FY2017	FY2018	FY2019	FY2020
Free cash flows (million yen)	190,815	216,873	-167,795	224,949
Return on equity (%)	13.0	17.6	15.3	9.0
Dividend on equity (%)	5.7	5.8	5.9	5.8
Ratio of equity attributable to owners of the parent to gross assets (%)	68.3	66.3	55.6	61.0

	FY2013	FY2014	FY2015	FY2016
Free cash flows (million yen)	187,406	116,210	166,687	162,229
Return on equity (%)	7.4	10.5	15.0	17.3
Dividend on equity (%)	5.0	5.1	5.1	5.6
Ratio of equity attributable to owners of the parent to gross assets (%)	76.7	73.5	73.5	70.1

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## Financial Information

# Sales of Major Products

## Sales of Major Products

(billion yen)

Sales of products in Japan are shown in a gross sales basis.

		FY2018	FY2019	FY2020
<b>XTANDI</b>		333.1	400.0	<b>458.4</b>
	<b>United States</b>	164.7	203.5	<b>238.6</b>
	<b>ex-United States</b>	168.3	196.5	<b>219.8</b>
	<b>Japan</b>	32.3	35.8	<b>40.2</b>
	<b>Established Markets</b>	119	135.4	<b>149.3</b>
	<b>Greater China</b>	2.2	3.2	<b>4.9</b>
	<b>International Markets</b>	14.8	22.1	<b>25.5</b>
<b>XOSPATA</b>		2.5	14.3	<b>23.8</b>
	<b>Japan</b>	0.6	2.8	<b>3.8</b>
	<b>United States</b>	2	10.5	<b>15.5</b>
	<b>Established Markets</b>	—	0.9	<b>4.4</b>
	<b>Greater China</b>	—	—	<b>0.0</b>
	<b>International Markets</b>	—	—	<b>0.2</b>
<b>PADCEV</b>		—	1.8	<b>12.8</b>
	<b>United States</b>	—	1.8	<b>12.8</b>

<b>Evrenzo</b>		—	0.2	<b>1.1</b>
	<b>Japan</b>	—	0.2	<b>1.1</b>
<b>Betanis/Myrbetriq/BETMIGA</b>		147.2	161.6	<b>163.6</b>
	<b>Japan</b>	32.7	34.3	<b>35.1</b>
	<b>United States</b>	80.8	89.2	<b>88.0</b>
	<b>Established Markets</b>	25.3	28.2	<b>29.9</b>
	<b>Greater China</b>	1.2	1.4	<b>2.2</b>
	<b>International Markets</b>	7.2	8.4	<b>8.5</b>
<b>Vesicare</b>		95	44.7	<b>31.6</b>
	<b>Japan</b>	22.3	20.2	<b>18.5</b>
	<b>United States</b>	36.9	5.4	<b>2.2</b>
	<b>Established Markets</b>	29.4	13.1	<b>6.2</b>
	<b>Greater China</b>	1.9	1.8	<b>1.0</b>
	<b>International Markets</b>	4.6	4.2	<b>3.7</b>
<b>Prograf</b>		195.7	192.9	<b>182.7</b>
	<b>Japan</b>	45.4	44.3	<b>40.7</b>
	<b>United States</b>	14	13.2	<b>11.8</b>
	<b>Established Markets</b>	74.4	71.5	<b>64.2</b>
	<b>Greater China</b>	31.3	32.2	<b>34.2</b>
	<b>International Markets</b>	30.5	31.7	<b>31.7</b>

- Established Markets: Europe, Canada, Australia

- Greater China: China, Hong Kong, Taiwan

- International Markets: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc

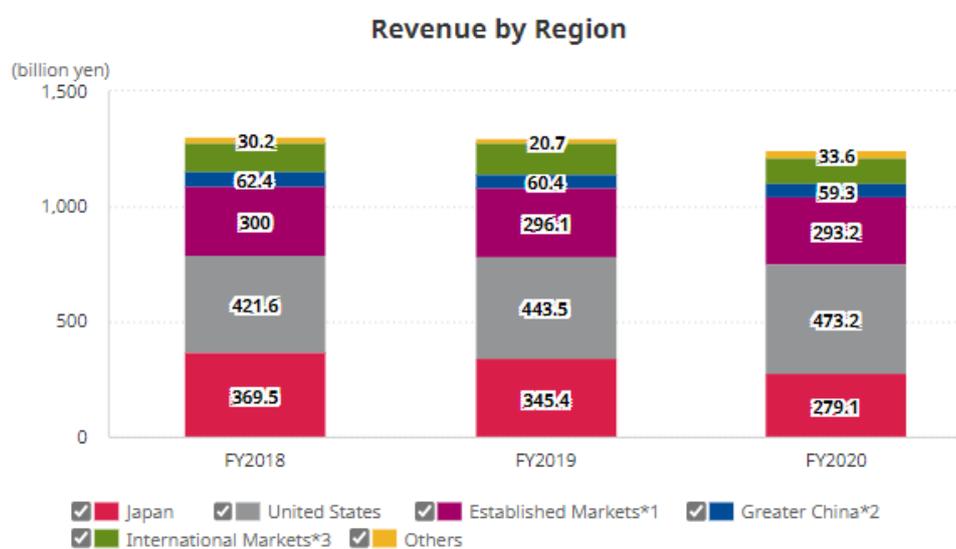
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## Financial Information

# Revenue by Region

## Revenue by Region



(billion yen)

	FY2018	FY2019	FY2020
<b>Japan</b>	369.5	345.4	<b>279.1</b>
<b>United States</b>	421.6	443.5	<b>473.2</b>
<b>Established Markets</b>	300.0	296.1	<b>293.2</b>
<b>Greater China</b>	62.4	60.4	<b>59.3</b>
<b>International Markets</b>	122.7	134.8	<b>111.1</b>
<b>Others</b>	30.2	20.7	<b>33.6</b>

\*1 Established Markets: Europe, Canada, Australia

\*2 Greater China: China, Hong Kong, Taiwan

\*3 International Markets: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

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