

# **Astellas Pharma Inc.**

The 18th Term Annual Shareholders Meeting

June 22, 2023

## **Event Summary**

[Company Name] Astellas Pharma Inc.

[Company ID] 4503-QCODE

[Event Language] JPN

[Event Type] Shareholders' Meeting

[Event Name] The 18th Term Annual Shareholders Meeting

[Fiscal Period] FY2023 Annual

[Date] June 22, 2023

[Time] 10:00 – 11:54

[Venue] "Banquet Room Fuyo" Hotel New Otani Tokyo

[Number of Speakers] 17 (including 10 Directors)

Kenji Yasukawa Representative Director, Chairman of the

**Board** 

Naoki Okamura Representative Director, President and CEO

Mamoru Sekiyama Outside Director
Hiroshi Kawabe Outside Director
Takashi Tanaka Outside Director
Eriko Sakurai Outside Director

Toru Yoshimitsu Director, Audit & Supervisory Committee

Member

Haruko Shibumura Outside Director, Audit & Supervisory

Committee Member

Raita Takahashi Outside Director, Audit & Supervisory

Committee Member

Mika Nakayama Outside Director, Audit & Supervisory

Committee Member

Yoshitsugu Shitaka Chief Scientific Officer Tadaaki Taniguchi Chief Medical Officer

Hideki Shima Chief Manufacturing Officer
Claus Zieler Chief Commercial Officer
Adam Pearson Chief Strategy Officer

Katsuyoshi Sugita Chief People Officer and Chief Ethics

&Compliance Officer

Catherine Levitt General Counsel

## Opening- The reports - The explanations for the proposals

**Okamura:** Good morning. I am Naoki Okamura, President of Astellas Pharma Inc. Thank you very much for attending this Annual Shareholders Meeting of Astellas today despite your busy schedule. Today, I will be serving as the Chairman of the shareholders' meeting.

Now we will commence the 18th Term Annual Shareholders Meeting of Astellas Pharma. As we've already announced, this Annual Shareholders Meeting will be held both for the shareholders gathered here at this venue and those attending virtually through the Internet.

We will strive to conduct the proceedings smoothly, and we ask for your cooperation.

Furthermore, starting with this Annual Shareholders Meeting, we are electronically providing the materials for the shareholders' meeting, including the Notice of Convocation of the 18th Term Annual Shareholders Meeting, in accordance with laws and our Articles of Incorporation, by posting them on our website and the Tokyo Stock Exchange website. For shareholders who have not specifically requested paper delivery, we have sent a written extract of the Notice of Convocation. To shareholders who have requested paper delivery, we have sent the full Notice of Convocation posted on Astellas website and the Tokyo Stock Exchange website, which is not the extract version. Also, at the reception desk today, we are distributing the full version of the Notice of Convocation, not the extract version.

In this meeting, when referring to page numbers in the Notice of Convocation, we will be referring to the full version, not the extract version. Please keep this in mind.

Today's agenda, as stated on page 7 of the Notice of Convocation, includes the matters to be reported and the matters to be resolved, which are Proposal No. 1 and Proposal No. 2. I also report here that we have already met the necessary quorum for all proposals to be resolved in this meeting.

Regarding today's proceedings, I would like to proceed in the order shown on the slide now. We will start with the reports and explanations for the proposals to be resolved.

After that, we will answer questions from shareholders in three parts. First, we will answer questions that shareholders have submitted in advance using the method outlined in the Notice of Convocation. We will then accept all comments from shareholders in attendance at the venue, including questions, opinions, and motions, regarding the reports and proposals to be resolved. Finally, we will respond to questions and comments from shareholders attending online.

For the method of asking questions from online shareholders, please refer to page 13 of the Notice of Convocation. We will be accepting questions and comments from online shareholders from the opening of this meeting until the completion of responses to questions submitted in advance. We expect the question acceptance period to last approximately 45 minutes.

Once we have finished responding to the three types of questions I just stated, we will move on to the voting on the proposals. At that time, I will announce the voting time for the proposals, and we ask you to vote within that time frame.

As stated on page 12 of the Notice of Convocation, we will only accept motions submitted by shareholders in attendance at the venue, including those related to the procedures of the shareholders meeting and proposals. We will not accept submissions from online shareholders. We ask for your understanding.

Also, among the executives present today, there are those who are not Japanese. When they provide answers, it will be done through an interpreter.

Now before we proceed with the deliberations on the reports and proposals, we will have an audit report from the Audit & Supervisory Committee. This report will also include the audit report from the Financial Auditor on the consolidated financial statements, all presented by the Audit & Supervisory Committee.

Now, Mr. Yoshimitsu, please go ahead.

**Yoshimitsu:** I am Yoshimitsu, a full-time Audit & Supervisory Committee member. On behalf of the Audit & Supervisory Committee, I will report the results of our deliberations.

The results of our audit of the execution of duties by the directors for the 18th term of Astellas Pharma are as stated in the audit report of the Audit & Supervisory Committee on page 75 of the Notice of Convocation.

We confirm that both the business report and its accompanying details correctly represent the Company's status in accordance with laws and the Articles of Incorporation. We confirm that no misconduct or a material fact constituting a violation of any laws or regulations, or the Articles of Incorporation was found with respect to the Directors in the performance of their duties. We confirm that the resolution of the Board of Directors relating to the internal control system is reasonable.

In addition, there are no matters to be pointed out regarding the details of the Business Report and Directors' performance of their duties on the internal control system. Next is the audit of the consolidated financial statements and their accompanying details. We have received reports and explanations from the Financial Auditor, Ernst & Young ShinNihon LLC, as stated in the audit report on pages 71 to 74 of the Notice of Convocation.

After considering the independence of the Financial Auditor, the audit methods, and quality control system, we confirm that the method and results of the Financial Auditor's audit of the consolidated financial statements, financial statements, and their accompanying details are appropriate.

That concludes my report on the results of our audit of the execution of duties by the directors for the 18th term of Astellas Pharma.

**Okamura:** Next, we will move on to the business report, consolidated financial statements, and financial statements. Please note that the business report for this fiscal year is posted on pages 24 to 63 of the Notice of Convocation and on Astellas website as well as the Tokyo Stock Exchange's website.

In addition, the consolidated and nonconsolidated financial statements are as posted on pages 67 to 70 of the Notice of Convocation and on Astellas website as well as the Tokyo Stock Exchange's website.

Now I would like to report on the overview of our consolidated performance for the 18th term and review the second year of our midterm management plan, Corporate Strategic Plan 2021, which began in FY2021.

Please note the following cautionary statement. The information we are about to share includes forward-looking statements, and actual results may differ from these projections.

Let's start with the overview of our consolidated results for FY2022.

Our core performance is a measure that's adjusted from our full performance by excluding temporary special factors, providing a reflection of the Company's underlying performance.

Our consolidated performance for this term has increased compared to the previous fiscal year, both in terms of revenue and core operating profit. This term saw a rapid depreciation of the yen, which had a positive impact on our performance, but even excluding the impact of currency fluctuations, it was a term of increased revenue and profit.

Our revenue was JPY1,518.6 billion, an increase of 17.2% compared to the previous term, with expanded sales of XTANDI and our Strategic products, PADCEV and XOSPATA. This is the second consecutive term where we've achieved increased revenue.

Selling, general, and administrative, SG&A, expenses were JPY630.3 billion, an increase of 14.8% compared to the previous term. We made progress in reducing SG&A expenses through optimization of sales personnel and cutting promotional costs for mature products. On the other hand, we actively invested where necessary, such as in launching PADCEV and preparing for the release of new products, such as VEOZAH.

As a result, we successfully managed cost reductions as anticipated, and while we actively carried out necessary investments, we were also able to control SG&A expenses as initially planned, excluding the influence of exchange rates.

Research and development expenses were JPY276.1 billion, an increase of 12.2% compared to the previous term. Just like SG&A expenses, these expenses were in line with our full year forecast.

Consequently, our core operating profit was JPY286.9 billion, an increase of 17.2% compared to the previous term.

Next, let's look at our consolidated performance on a full basis.

While revenue increased, operating profit, profit before tax, and profit for the year decreased. The full basis performance includes revenues and expenses that were excluded as non-recurring items when adjusting for core basis performance.

As a result of the decision to apply for approval, which led to an increase in the fair value of the contingent consideration for zolbetuximab and the impairment loss due to the revision of future sales forecasts for Evrenzo, other expenses for the term were JPY157.5 billion.

Due to these factors, operating profit was JPY133.0 billion, a decrease of 14.6% compared to the previous term. Profit for the year was JPY98.7 billion, a decrease of 20.4% compared to the previous term.

Next, I would like to explain our activities and achievements for the second year of the Corporate Strategic Plan 2021.

We have formulated and are executing the Corporate Strategic Plan 2021 as our midterm management plan for the five years starting from FY2021. Today, I will report on our achievements in FY2022 according to the four Strategic Goals of the Corporate Strategic Plan 2021.

Strategic Goal 1 is to enable patients to achieve better outcomes. I will discuss the current term's sales of XTANDI and our Strategic products, where we have focused our management resources to drive mid- to long-term growth.

Sales of XTANDI, a prostate cancer treatment, increased by 23.7% compared to the previous term to JPY661.1 billion. Sales expanded in all regions. The market environment in the US is tough, with impacts from programs to provide free treatments to low-income patients and the emergence of competitive generics, but we maintain a leading position in all indications.

Next, sales of PADCEV, a urothelial cancer treatment, increased by 104.4% compared to the previous term to JPY44.4 billion. We saw significant growth, particularly in Europe and Japan. In Europe, the number of countries selling the drug expanded to 21, and we achieved insurance reimbursement in 7 countries. In Japan, new prescriptions exceeded our expectations and contributed to sales expansion.

Next, sales of XOSPATA, a treatment for acute myeloid leukemia, increased by 36.7% compared to the previous term to JPY46.6 billion. We achieved a high market share and expanded sales in the US, Europe, and Japan.

Next, sales of Evrenzo, a treatment for renal anemia, increased by 23% compared to the previous term to JPY3.2 billion. Sales fell below expectations due to intensified competition in Japan and our inability to differentiate ourselves from existing standard treatments in Europe.

Next, I will explain the main progress in the development of XTANDI and our Strategic products.

For XTANDI, we obtained good results in two Phase III clinical trials aimed at additional indications.

In addition to obtaining approval in Europe, PADCEV had its approval application accepted in China. We also obtained accelerated approval in the US for an additional indication as a first-line treatment.

Fezolinetant was approved in the US last month, and sales have begun under the product name, VEOZAH. We have also applied for approval in Europe.

Zolbetuximab obtained good results in Phase III clinical trials, and we applied for approval in Japan this month.

Next, I will present our sales forecasts at the potential peak time for XTANDI and our Strategic products that will drive our mid- to long-term growth.

XTANDI continues to grow in sales, and we have previously guided that our peak sales forecast was JPY600 billion to JPY700 billion, but we have now revised it upwards to over JPY700 billion.

Whether we can make up for the sales of XTANDI after the expiration of its exclusivity period depends on the success of the products we consider as our strategic priorities, including VEOZAH and PADCEV. We expect

VEOZAH's peak sales to be between JPY300 billion and JPY500 billion, indicating our expectation for it to become a major product.

We aim to expand sales early by increasing the awareness of controlled substances among both doctors and patients, in compliance with regulations in each country and region.

The peak sales forecasts for PADCEV and XOSPATA, which are already on the market, are JPY300 billion to JPY400 billion, and JPY100 billion to JPY200 billion, respectively, and they are products that we expect to grow further in the future.

Zolbetuximab is an antibody drug currently under development for conditions such as gastric adenocarcinoma. As reported earlier, we obtained good results in Phase III clinical trials, and preparations for global approval applications are steadily progressing, following Japan. We expect peak sales to be between JPY100 billion and JPY200 billion.

The newly approved product in the US, VEOZAH, with the generic name, fezolinetant, is a product we expect to become a significant one as it offers a new option for an unmet medical need, vasomotor symptoms associated with menopause, commonly known as VMS.

VMS is a common symptom of menopause characterized by hot flashes, such as facial flushing and sleep sweats. In the US, about 60% to 80% of menopausal women experience these symptoms.

Previously, hormone replacement therapy was widely used as a treatment. However, the number of patients receiving hormone replacement therapy has significantly decreased following the publication of studies indicating an association with an increased risk of cancer and cardiovascular disease.

VEOZAH is the first non-hormonal treatment for VMS. We expect it to become our flagship product, following XTANDI.

Strategic Goal 2 is to translate innovative science into proven VALUE. I will report on the main progress of our Focus Area approach during this period.

In FY2022, in addition to our existing four Primary Focus areas, we recognized Targeted Protein Degradation as a new Primary Focus.

Targeted Protein Degradation is a new technology that utilizes mechanisms inherently present in organisms. It consists of three parts, the target protein, the E3 ligase, and the linker that connects the two. By bringing the enzyme E3 ligase adjacent to the target protein, a marker is added to the target protein, which is then degraded by the proteasome.

By using this technology, so-called "undruggable" proteins, which were difficult to target with traditional technologies, can be made "druggable," that is they can be made into drug targets. Protein degradation inducers can target various proteins that cause diseases by appropriately combining the three parts.

The recognition of Targeted Protein Degradation as a Primary Focus is also a result of our research organization's renewal. In FY2021, we transformed our research organization into a purpose-oriented agile

model, creating relatively small, autonomous organizations for each research area and delegating authority to them to enable swift decision-making on the ground.

This refresh of the research organization has borne fruit, and in our lead program for this Primary Focus, ASP3082, we have achieved the selection of a new drug candidate compound to the submission of a test permission application, typically a process requiring two years, in a record short period of just one year. This is the world's first clinical trial entry for a compound targeting KRAS G12D.

Moving forward, we have decided to allocate more management resources to continuously generate programs from this platform and accelerate development further and therefore have recognized it as a Primary Focus.

Strategic Goal 3 is to advance the Rx+ business. We have made two main advancements in this period.

First, we started the pilot sale of the disposable Holter electrocardiogram, EG Holter, in June of last year, in collaboration with Nitto Denko and M. Heart for the electrocardiogram examination service we are working on together. After verifying the business model through this pilot sale, we will consider full-scale deployment.

Second, regarding the diabetes treatment support program, BlueStar, we have entered into a partnership contract with Roche DC Japan. By combining the blood glucose data tracking of diabetes patients using Roche DC Japan's self-monitoring blood glucose meter and BlueStar, we aim to provide a new solution that supports disease management.

Strategic Goal 4 is to deepen our engagement in sustainability.

As awareness of the importance of sustainability as a key business issue is increasing among a wide range of stakeholders year by year, we will revise our executive remuneration system from FY2023 to strengthen governance for improving sustainability, adding sustainability performance indicators into bonus calculations.

We will set performance targets related to sustainability efforts for each fiscal year, and the achievement rate of performance targets will be reflected in the bonus payment rate within a plus or minus 10% range.

We plan to set targets and make improvements for the following four items, efforts toward access to health, efforts for human resources and organizations, efforts to ensure a stable supply of products, and efforts toward the environment.

In our Corporate Strategic Plan 2021, we have set Performance Goals. These are embodied in three numerical targets which we anticipate meeting once all four Strategic Goals I've previously discussed are accomplished. By realizing these three Performance Goals, we are setting our sights on becoming a company that, by FY2025, can secure a market capitalization of JPY7 trillion, as evaluated by the stock market.

This slide explains the acquisition of IVERIC bio, which we announced in May.

IVERIC bio is a biopharmaceutical company based in New Jersey, US, focusing on the research and development of ophthalmology treatments for conditions with high unmet medical needs and no existing treatments. The acquisition's scale is approximately USD5.9 billion in total.

There are two strategic implications of this acquisition. The first is the acquisition of the lead program, Avacincaptad Pegol, hereafter referred to as ACP. Age-related macular degeneration is a severe condition with a high risk of blindness. Geographic atrophy associated with age-related macular degeneration has extremely high medical needs and represents a large market due to the lack of a current treatment. ACP holds the potential to become a standard therapy in this field.

We expect ACP to become a new pillar of revenue generation, making the achievement of the sales targets set out in our Corporate Strategic Plan 2021 more certain, as well as offsetting the decline in sales after the expiration of XTANDI's exclusivity period.

The second strategic significance of this acquisition is the establishment of a foundation in the ophthalmology field, which links to the development of our Primary Focus area, regeneration and vision restoration. By integrating the strengths of IVERIC bio in sales and research and development in the ophthalmology field, we expect to further accelerate our own research and development programs.

Note that the completion of this acquisition requires fulfilling certain conditions, such as approval from IVERIC bio shareholders and antitrust authorities in the US.

This slide explains our policy on shareholder returns.

We prioritize business investments to achieve future growth, and based on medium- to long-term profit growth, we aim to increase dividends steadily and sustainably. There is no change to this traditional policy. During the term of the Corporate Strategic Plan 2021, we aim for higher dividends based on robust profit growth expectations. For FY2023, we forecast a dividend increase of JPY10 to JPY70 per share.

FY2023 is the midpoint of our Corporate Strategic Plan 2021, and we will continue to be strongly committed to achieving our goals. We position FY2023 as a turning point to ensure growth in and beyond FY2024.

We will focus on four key items in FY2023. First, for VEOZAH, which we expect to be a blockbuster, we will raise the priority and aggressively invest to achieve rapid market penetration and sales expansion after launch.

We expect PADCEV's 1<sup>st</sup> Line treatment for metastatic urothelial cancer to become a significant growth driver and anticipate the progression of sales expansion in the US and development for global applications.

For zolbetuximab, we will steadily prepare for global application approval and concurrently invest for market penetration post-launch.

While expanding sales with new products and indications, we will also actively push forward with investments for future cost structure optimization, aiming to improve operating profit margin from FY2024 onwards. As a result, we expect the core operating profit margin for FY2023 to be at the same level as the previous year.

We believe that if these investments and initiatives bear fruit, a core operating profit margin of about 25% can be realized in FY2024 and the 30% that we have set in Corporate Strategic Plan 2021 can be achieved in FY2025.

Note that the impact of the IVERIC bio acquisition on our performance is not included in this slide as the acquisition is not yet complete and is currently under review. We will promptly inform you if there are any developments that need to be reported.

Our company is committed to standing at the forefront of evolving healthcare and continuously striving to transform the advancement of science into VALUE for patients. We would appreciate your continued support in the future.

That concludes my report.

Next, I will explain each resolution item in order.

The first proposal on the agenda is the election of seven Directors who are not Audit & Supervisory Committee members. The terms of all six current Directors who are not Audit & Supervisory Committee members will expire at the conclusion of this Annual Shareholders Meeting. Therefore, we would like to request the election of seven Directors who are not Audit & Supervisory Committee members.

The candidates are Kenji Yasukawa, Naoki Okamura, Katsuyoshi Sugita, Takashi Tanaka, Eriko Sakurai, Masahiro Miyazaki, and Yoichi Ohno. Among the candidates, Takashi Tanaka, Eriko Sakurai, Masahiro Miyazaki, and Yoichi Ohno are candidates for outside Directors. Therefore, if this proposal is approved, there will be seven Directors who are not Audit & Supervisory Committee members, four of whom will be outside Directors. Note that at the conclusion of this Annual Shareholders Meeting, Mamoru Sekiyama and Hiroshi Kawabe, who are currently Directors not serving as Audit & Supervisory Committee members, will retire.

The biographies of each candidate are as stated on pages 16 to 20 of the Notice of Convocation.

Next, the second proposal on the agenda is the election of one Director who is an Audit & Supervisory Committee member. At the conclusion of this Annual Shareholders Meeting, the term of Haruko Shibumura, who is currently a Director serving as an Audit & Supervisory Committee member, will expire. Therefore, we would like to request the election of one Director who is an Audit & Supervisory Committee member.

The candidate is Rie Akiyama. Rie Akiyama is a candidate for outside Director. Toru Yoshimitsu, Raita Takahashi, and Mika Nakayama will continue to serve as Directors who are Audit & Supervisory Committee members. Therefore, if this proposal is approved, there will be four Directors who are Audit & Supervisory Committee members, three of whom will be outside Directors.

Note that we have obtained the consent of the Audit & Supervisory Committee for this proposal. The biography of the candidate is as stated on page 21 of the Notice of Convocation.

That concludes the explanation of the proposals for this Annual Shareholders Meeting.

#### **Question & Answer**

**Okamura** [M]: We would like to continue by answering four of the questions we received from shareholders in advance.

First,

**Pre-submitted Question :** I believe that Targeted Protein Degradation will greatly accelerate drug discovery research for a wide variety of target proteins once the ubiquitin ligase binding site and linker technology is established. I was wondering what impression your research department has of Targeted Protein Degradation.

Okamura [M]: Dr. Shitaka will take this question.

Shitaka [A]: Shitaka here. Thank you.

As explained in the Company President's presentation, the targeted protein degradation inducer consists of a binding site to the target protein, a binding site for E3 ligase, and a linker connecting the two. By converting the parts that bind to the target protein according to the target molecule, it is possible to efficiently conduct drug discovery research on a wide variety of targets.

Steps will obviously be needed to optimize the molecule as a whole, but we hope that drug discovery research will be accelerated.

Targeted protein degradation inducers exhibit different forms of medicinal effects than conventional small-molecule drugs, in other words, lysis. Therefore, we expect to be able to target proteins that have been difficult to target with conventional small-molecule drugs for drug discovery.

It has been said that only about 20% of disease-related proteins are suitable targets for conventional small-molecule compounds. We are very hopeful that targeted protein degradation inducers will be able to target the remaining 80%. Therefore, the research division intends to increase its investment in the future. Thank you.

**Pre-submitted Question:** Secondly, the market for conventional small-molecule drugs is also increasing slightly, although the development of new modalities is currently very active. What is the future position of small-molecule drug development in your company? You asked about research strategy, do you consider small-molecule drugs to be the most important modality to focus on?

Okamura [M]: Another question for Dr. Shitaka.

**Shitaka** [A]: Shitaka here. Thank you.

In recent years, many modalities or means of treatment have been developed. Each has its own characteristics. We believe that in drug discovery, it is important to select the most appropriate modality to achieve the desired efficacy.

Synthetic pharmaceuticals, including small-molecule drugs, are currently one of the Company's priority modalities, along with antibodies, cell therapy, and gene therapy. As I mentioned earlier, targeted protein degradation is a technology that we are excited about and that we have designated as our primary focus. If synthetic drugs, including targeted protein degradation, are to be defined as smallmolecule drugs in the broad sense of the term, then this will be a modality in which we will focus our investments in the future. Thank you.

Next question.

Pre-submitted Question: Is the investment in research and development sufficient?

**Okamura [A]:** I will answer this one. First of all, as for actual results, JPY276.1 billion was spent on R&D in FY2022. That amounts to 18.2% of our revenue for the period.

According to the data book of the Japan Pharmaceutical Manufacturers Association, the ratio of R&D expenses to revenue in FY2021 is 3% on average for all industries and 10% on average for the pharmaceutical manufacturing industry. Our figure is obviously much higher. The average figure in FY2021 for major pharmaceutical companies was approximately 18%. We are investing in R&D at a similar or higher level.

Under the Corporate Strategic Plan 2021, we are prioritizing investments in our Primary Focus and other areas. We plan to continue to invest in research and development to achieve sustainable growth. Thank you.

This is the last advance question.

**Pre-submitted Question** I do not see any proposals regarding executive compensation. Please give an explanation of the method of calculation of compensation for directors.

**Okamura** [M]: This will be answered by Mr. Sugita, Chief People Officer.

**Sugita [A]:** I am Sugita, in charge of human resources and compliance. I will take your question.

Remunerations for Directors who are not Audit & Supervisory Committee Members (excluding outside Directors) are composed of a fixed amount basic remuneration as well as bonuses and stock compensation that are performance-linked remunerations. Remunerations for outside Directors and Directors who are Audit & Supervisory Committee Members are composed of a fixed amount basic remuneration only.

At the past Annual Shareholders Meetings of the Company, the ceiling amount of each of basic remuneration, bonuses and stock compensation for Directors was resolved.

Remunerations for each Director who is not an Audit & Supervisory Committee Member are determined by resolutions of the Board of Directors within such ceiling amount. Also, remunerations for each Director who is an Audit & Supervisory Committee Member are determined by the deliberations of the Audit & Supervisory Committee Members within such ceiling amount.

Through the deliberations at the Compensation Committee prior to the resolution of the Board of Directors, the Company ensures greater transparency and objectivity of the deliberation process for remunerations for Directors who are not Audit & Supervisory Committee Members.

There were no revisions to the ceiling amounts of remunerations for Directors or revisions to the remuneration system that would require a resolution at this Annual Shareholders Meeting, so there were no proposals regarding remuneration for Directors.

Please refer to pages 70 to 73 of the Notice of Convocation for the amounts by type of remuneration paid or recorded as expenses for the business year under review for each Director category, as well as targets, actual results, etc. of bonuses and stock compensation that are performance-linked remuneration. The policies and procedures for determining remunerations for Directors are described on pages 74 to 86 of the Notice of Convocation.

Please also see the remuneration levels and the specific remuneration structure for Representative Director, Chairman of the Board; Representative Director, President and CEO; and Representative Director, Executive Vice President for the business year under review and the next business year, that are also described in the Notice of Convocation.

Thank you.

**Okamura [M]:** These are the answers to your advance questions. Thank you very much to the shareholders who sent in their questions.

Since we have finished answering the advance questions, we will now conclude the section on questions and comments from shareholders in online attendance.

We will now take questions and comments from the shareholders present at the meeting regarding the items to be reported and the items to be resolved. The Company will then respond to questions and comments from shareholders in online attendance regarding the items reported and items to be resolved.

After that, we will take a vote on each agenda item.

(Shareholders applauded)

Thank you very much. We will now proceed in this manner.

Shareholders who wish to speak at the meeting are requested to raise their hands. I will nominate you. If you have been nominated, a staff member will hand you a microphone. Please speak after mentioning the number on your attendance sheet. You do not have to tell us your name. After speaking, please return the microphone to the attendant and take your seats.

As mentioned at the outset, the current event is being streamed live for shareholders in online attendance. Those who ask questions should be aware that shareholders who are not in the audience are watching the event. One question per person.

Shareholders who wish to speak, please raise your hand. You there, please go ahead.

[Summary of Question]: Question regarding Astellas employee being held captive in China.

**Okamura [A]:** Thank you for your question. This incident has caused us all a great deal of concern. Our top priority is the safety of the employee, and we are working to gather information and understand the current situation through the Ministry of Foreign Affairs.

But so far, we do not have any information beyond what has been reported in the media. Thank you.

Shareholders with other questions, please raise your hands. Go ahead.

[Summary of Question]: Question regarding the reasons for the appointment of candidates Yasukawa and Okamura.

**Okamura [A]:** The reasons for the appointment of candidates Yasukawa and Okamura are as stated on page 17 of the Notice of Convocation.

[Summary of Question]: The target for market capitalization in FY2025 is more than JPY7 trillion, but the current market capitalization is JPY3.99 trillion. Please explain how you intend to get to the target.

**Okamura** [A]: Thank you for your question. I will now give my response.

The market capitalization is generally calculated by multiplying the current share price by the number of shares outstanding. We also recognize the importance of the trust of shareholders when considering the value of a company.

In Corporate Strategic Plan 2021, sales of XTANDI and Strategic products are forecast to total JPY1.2 trillion in FY2025. We also forecast a total value of compounds in the pipeline still under development at that point. This is difficult for people outside the Company to grasp, so we are disclosing our sales target for FY2030.

In addition, we will raise the core operating margin to 30%, which means that the multiplication of net sales and core operating margin, which I mentioned at the beginning, will mean current profits, and the value of the pipeline that we have built up will mean future growth. If we can achieve these goals, we believe that the stock market will recognize us as a company with a total value of about JPY7 trillion.

These figures are not based on the assumption that we will merge with another company, for example, but rather on the hope that if we continue to carry out our corporate activities as we have in the past, we will be evaluated as a company that has good prospects for future growth. I hope that we will be evaluated as such a company. Thank you.

Shareholders with other questions, please raise your hands. Go ahead.

[Summary of Question]:. Will your company work to increase sales in Japan or optimize the workforce in Japan?

**Okamura [A]:** Thank you for your question. Your question is about how sales in Japan are small relative to the number of employees here. I understood your question to be about how we intend to address the Japanese market in the future.

The Japanese prescription drug market is the second largest in the world at over JPY 10 trillion, so of course, we cannot ignore this very large market. Astellas is listed on the Tokyo Stock Exchange and is a Japanese company, so we would like to contribute to the Japanese market as much as possible.

On the other hand, there are some factors that are not favorable to the Japanese market compared to overseas markets, such as the screening and approval procedures for new drugs in Japan and the way NHI prices are set.

As I mentioned earlier, we have filed an application for approval of zolbetuximab in Japan, and we are planning to launch a number of key strategic products in the Japanese market. Thank you.

Other shareholders, if you have any questions, please raise your hand. Please go ahead.

[Summary of Question]:. As the new president, how will you approach management in the future? I would like to hear your current thoughts, such as your image of growth.

**Okamura** [A]: Thank you for your question. I understood your question to be about how I, as the new president, will approach the future management of the Company.

I am proud to say that I have been at the heart of strategy formulation and implementation at Astellas for the past seven years since I was appointed Vice President of Corporate Planning in 2016. I am very honored to have been asked to put the finishing touches on this project as President and CEO.

Basically, we would like to properly execute Corporate Strategic Plan 2021, which I have just mentioned, and strive to achieve our goals. However, the pharmaceutical business involves a certain amount of risk, so we will invest our management resources appropriately while considering changes in circumstances.

As clearly stated in our vision and in Corporate Strategic Plan 2021, we have declared that Astellas will be a Cutting-Edge, VALUE-driven life science innovator. To this end, continuous innovation is our lifeline.

As such, the Company as a whole must learn from its mistakes while taking smart risks. Each employee should take a leadership role. Furthermore, we will aim for a higher level as One Astellas, without being too siloed by each function. I believe that it is imperative to foster this kind of corporate culture, and I would like to devote my efforts to this.

Astellas is not striving to create cellular medicines or gene therapies that would just improve symptoms. We want to radically address the causes of these diseases. That is at the core of our drug discovery.

Naturally, there are risks involved, but we would like to proceed with this project with an appropriate sense of urgency. Please continue to support us in the future. Thank you very much. Thank you.

Shareholders with questions, please raise your hands. Please go ahead.

[Summary of Question]: How do you assess, for example, the ratio of sales between regions, or the exchange rate risk going forward, in order to achieve the performance targets of Corporate Strategic Plan 2021?

**Okamura [A]:** Thank you for your question. I understood your question to be about the ratio of sales between regions, for example, and how we are assessing risks, including exchange rate risk, in order to achieve the performance targets of Corporate Strategic Plan 2021.

Corporate Strategic Plan 2021 was released in FY2021. It was prepared during FY2020.

Naturally, we have a breakdown of figures for forecast sales and profit margin targets. The exchange rate and the situation in each country will change in various ways, and we are moving forward while evaluating whether we can truly achieve the goals of the Corporate Strategic Plan 2021 by reviewing the plan from time to time.

In the Chinese market as well, the first question is whether or not we can establish a medical care delivery system for our cutting-edge medical services that will be accepted by the Chinese market. Will development practices proceed in the same way as in other developed countries? How will they be assessed? A little more importantly, it depends on how IP will be handled, I think.

After all, China is the most populous country in the world. If the conditions I just mentioned are met, we are ready to develop our business in China.

If you look at the regional breakdown of sales in FY2022, the US accounts for more than 40% of the total. Of course, due to the weak yen, sales in dollars may appear to be inflated when converted to yen, but considering the new product, VEOZAH, that I reported today, for example, sales in the US will inevitably grow in the future. I think we can say to some extent that the regional breakdown will not significantly change.

That said, there will naturally be pressure to reduce the size of the overall drug market in the US through various measures. We will move forward while examining whether our strategy is truly feasible once such measures are clarified.

I apologize for not being able to provide specific figures at this time. Thank you.

Any other questions? Please go ahead.

[Summary of Question]: How are Astellas' R&D, commercialization, manufacturing, and other functions being deployed globally?

**Okamura** [A]: Thank you for your question. I understood your question to be about how our R&D, commercialization, and manufacturing operations are developing globally. Thank you very much.

Astellas has been a global organization for some time now, with most of its functions operating at a global scale, so the best way to see it may be to put aside the question of location and consider that most of our activities are global in nature.

First of all, as far as research is concerned, of course, the research institute in Tsukuba has the largest number of researchers. On the other hand, as a result of the acquisition of cell therapy company, Ocata, for example, cell therapy research is based in Massachusetts. Later, we acquired Universal Cells, a company based in Seattle, Washington. This company has technology to convert cells into a form that is not attacked by the immune system. We have a laboratory there.

Later, we also acquired a San Francisco-based company called, Xyphos, which develops cell therapy for cancer. The research base for mitochondria, one of the Primary Focus areas, is in Massachusetts, with an additional subsidiary laboratory in the UK.

Dr. Shitaka, who answered an earlier question, is organizing the research on a global basis. This is the state of affairs.

As you mentioned, the majority of our development team is based in the US, but of course, we have the capability to conduct development in Japan as well. We also have the capacity to conduct clinical trials in China.

We have three factories in Japan, two in Ireland, and one in the Netherlands. Our supply chain is not entirely self-manufactured. We do not manufacture all of our products by ourselves, but rather, we use a variety of

other companies to help us in the manufacturing process of one of our products. We have a global supply chain.

As for the organization of commercialization, there are, of course, now five regions. We manage our business in five regions. The established markets commercial area covers the US, Japan, Greater China, and Western Europe, and the international markets commercial area covers the rest of the world. We have various organizations in place to meet the needs of each product portfolio and market characteristics.

Although you may naturally assume that the head office is located in Nihonbashi, there are actually people in charge of head office functions in the US, UK, and other countries. It is not necessarily the case that head office functions are established only in Japan. We have a very complex organizational structure across borders. Thank you.

[An Additional Question]: Do you manufacture antibodies in-house?

Okamura [A]: We do. This includes production in Japan.

There are still some shareholders who wish to speak, but since we have received questions from the online shareholders, we will take one more question from the audience here. That will be the last question from the shareholders at the venue.

Please go ahead.

[Summary of Question]: I read in a newspaper report that you are planning to acquire a company called IVERIC bio for 800 billion yen. do you have any specific products that could be a large product to supplement the sales after XTANDI's patent expires?

**Okamura [A]:** Thank you for your question. I understand that your question is about what kind of products will provide sales after the expiration of exclusivity for XTANDI.

We hope to overcome the expiration of XTANDI's exclusivity period by having several Strategic products, such as VEOZAH, PADCEV, and zolbetuximab, which has just been submitted for approval in Japan.

Regarding the acquisition of IVERIC bio, our flagship compound, ACP, is already in the approval review stage in the US, and a decision from the authorities is expected in August of this year. We have strong expectations that ACP, along with VEOZAH and PADCEV, will be products that will support our future.

However, as I mentioned earlier in my report, we have not yet completed the acquisition, so I will refrain from commenting on individual product sales forecasts at this time. Thank you.

I will now move on to answer questions from shareholders in online attendance. We have received several questions and comments from shareholders in online attendance today, and we will give priority to answering questions related to the purpose of this meeting and that we believe are of interest to a wide range of shareholders.

The moderator will now read the questions and comments from the shareholders in online attendance and then respond to them.

**Moderator** [M]: I will now turn to questions from the online shareholders. Shareholders can attend this meeting via the Internet, and the meeting is being live-streamed from the venue. As of this time, we have confirmed that 224 shareholders are attending the meeting online. Thank you for joining us.

Let me now introduce the first question.

[Summary of Question]: Can you give us more details of global engagement survey? What do you think of Astellas' current situation compared to other companies?

Moderator [M]: Mr. Okamura, please go ahead.

**Okamura [M]:** Thank you for your question. I understand that your question is about our perception of the results of our internal global engagement survey. Mr. Sugita of the human resources department will reply to you regarding this matter.

Sugita [A]: I am Sugita, in charge of human resources. I would like to respond to your question.

First of all, what we call a global engagement survey is what other companies call, for example, a job satisfaction survey or an employee satisfaction survey. Therefore, we conduct what we call the global engagement survey to measure employee motivation and whether or not the members of the Company are oriented in a direction that is consistent with the Company's goals.

In layman's terms, we are trying to understand motivation.

First of all, you asked about comparisons with other companies, but the survey items we conduct are different from those of other companies, and the situation of our company is also different from theirs. I will refrain from mentioning other companies at this time.

I would like to comment on our current situation. The purpose of the survey is to gain a timely understanding of the status and trends of engagement, job satisfaction, and motivation, as I mentioned earlier, for the entire global workforce, as well as for each division and region.

The most important thing is not only to understand the results, but also to take concrete actions to improve them.

By properly implementing such a cycle, we hope to improve employee engagement and job satisfaction. We hope to do business in a way that aligns the direction of the Company and the direction of individual employees. That is how we are proceeding. That is the purpose of this global engagement survey.

It was implemented last year and is being carried out again this year. The response rate is also a very important point. A low response rate indicates that employees are not interested in the Company's priorities, priorities or the direction in which the Company is heading.

The response rate is extremely high, and although I said at the beginning that I would not compare it with other companies, the response rate is extremely high even compared to the response rates of other general surveys.

In terms of engagement, motivation, and job satisfaction scores, we are also seeing improvement and an upward trend in our figures. We believe this is another good point.

We have looked at the individual response items in detail, and we have found that 75% of the items have increased in score. One particularly good point is that employees have a very high level of trust in the integrity of the Company. The high scores indicate that this is one of our strengths. Therefore, I believe that we have been able to foster an appropriate corporate culture.

We will continue to conduct this survey in the future, and as we conducted the survey, we wondered whether the various measures we had implemented, not only in the area of personnel matters, were really reaching the target audience correctly. We would like to implement various measures, such as personnel policies, while periodically and properly checking whether they are working. By implementing this, we hope to create a highly engaged organizational culture. Thank you.

[Summary of Question]: Since the company will be borrowing to acquire IVERIC bio, does this mean that it will not be repurchasing Astellas shares in the near term?

Okamura [A]: Thank you for your question. I would like to respond to this.

As you mentioned, we will be borrowing for the IVERIC bio acquisition. This financing will naturally be repaid in a planned manner.

However, there is no change in our shareholder return policy as a result of this acquisition or borrowing. As I explained earlier, our first priority is to invest in growth. We will increase dividends in a continuous and stable manner while taking into account long-term profit trends. If cash remains on hand, it will be returned to shareholders in a flexible manner through share buybacks. This is our basic policy, which remains unchanged.

Although we say that we will actually repay our loans in a planned manner, if cash flows exceed the assumptions of the repayment plan, we may make a decision, taking into account trends in interest rates and foreign exchange rates, as to whether to use the cash for early repayment of loans or for shareholder returns, such as share buybacks. Thank you.

[Summary of Question]: I would be happy if Mr. Okamura and Mr. Sugita would share their thoughts on how they would like Astellas to become a company in the future from a longer-term perspective.

**Okamura** [M]: Thank you for your question. I have just answered a similar question from a shareholder in the audience, so I will let Mr. Sugita answer this time.

**Sugita [A]:** Sugita, human resources and compliance. Thank you. You asked me what I would like the Company to look like in the long term, and I would like to share my thoughts.

As Mr. Okamura mentioned earlier, we are currently putting a great deal of effort into the organizational climate and human resources. In this area, it is unlikely that our actions will have any immediate effect. It will take time to see results.

Therefore, I believe that a long-term perspective is essential. Although we are taking various actions now, they may not necessarily lead to significant results next year or the year after that.

However, what I am aiming for is that, for example, when we look back in five or ten years, I think that the actions we will have taken in 2023 will mark an inflection point. I think in five or ten years, we will be bearing the fruit of the actions we take now. That is what we hope to achieve.

Actually, let me be a little more specific. What we are aiming for is innovation. Mr. Okamura mentioned this in a different way earlier, but we aim to be a company that is capable of risk-taking.

Innovation is not only in R&D, but also in commercial, head office, and all other departments. Innovation can help us build a company that keeps improving. These effects are cumulative over time. We would like to create an environment where all employees aspire to such a goal.

Of course, talent is also a factor. In terms of leadership, employees are very hopeful about their own development and future, and they want to take on more challenges within the Company and grow. We want to foster this kind of virtuous cycle in our company.

Finally, as for "One Astellas" or "One Team," I believe that today's era is not one in which one genius or one great leader is enough to produce great results. It is about how much you can involve those around you. To achieve big things, it is important to get involved and work well with others around you. I would like to make teams that can and will do those things.

I would like to emphasize innovation, risk-taking, talent, and leadership. That is our vision of One Astellas and One Team. The Company has taken such measures to drive this approach and has done wonderfully well on these three points.

Our image of Astellas five or ten years from now is of a very innovative company, and it is a company that works very much as one team. Leadership, or talent, is something that all leaders and all managers take seriously. I would like to make the Company into such a company, and by doing so, I hope to lead to further success and growth of the Company. Thank you.

[Summary of Question]: For projects in the clinical development stage, what is your launch or regulatory filing schedule?

Okamura [M]: Thank you for your question. Dr. Taniguchi, our CMO, will take this question.

Taniguchi [A]: Taniguchi here. Thank you.

In April this year, PADCEV was approved in the US for the 1<sup>st</sup> Line treatment of urothelial carcinoma, for which cisplatin is not eligible. In addition, a Phase III study of EV-302 for PADCEV is currently underway. Based on the results of this study, we are planning to file an additional global application for PADCEV. This is an event-driven project, and we are planning to apply in Q4 of FY2023. However, the timing will vary somewhat depending on how many events the results show.

Also, a few words on fezolinetant, or VEOZAH. In the US, we received approval in May. We are in the process of making applications and responding to authorities in the Established market, including Europe, on an ongoing basis. We expect to obtain approval for this product in Q4 of this year or later.

Then there is zolbetuximab. Recently, we submitted an application for approval in Japan for the indication of gastric cancer and gastroesophageal junction cancer. We plan to prepare and proceed with global applications in the US, Europe, China, and so on. Those applications will be sequentially prepared and proceeded with in H1 of FY2023.

We have also had the XTANDI-EMBARK trial. This is for non-metastatic castration-sensitive prostate cancer. Results have been obtained for this indication. We have already presented data on these results at the

Urological Congress in the US. We are now working on additional indications in the US and Europe. As of now, we are planning to apply in the June to August period in the US and H2 of FY2023 in Europe.

I hope that answers your question. Thank you.

[Summary of Question]: Please explain in more detail how sustainability indicators are reflected in executive compensation.

**Okamura** [A]: Thank you for your question. I explained this earlier in the business report. I would like to answer in more detail here.

Starting in FY2023, we will revise the system to add or subtract within a range of plus or minus 10% depending on the degree of achievement of sustainability performance targets from the evaluation coefficient calculated by the conventional performance evaluation index. However, the overall evaluation coefficient and bonus payment rate will be linked to performance in the range of 0% to 200%. This range will not be exceeded.

As I mentioned on the slide, the evaluation item is what we call access to health. There are also those related to human resources and organizational initiatives, as Mr. Sugita explained earlier. There are also the four initiatives for ensuring a stable supply of products and the environmental initiatives that are often mentioned when talking about sustainability in general.

The evaluation items were selected based on our sustainability efforts in response to important social issues, which we believe are not adequately reflected in our evaluation using existing performance indicators. The evaluation will reflect a wide range of key initiatives that affect as wide a range of stakeholders as possible, especially patients, shareholders, investors, employees, suppliers, or society as a whole. Thank you.

[Summary of Question]: When do you expect fezolinetant to be launched in Europe? Is it expected to take some time for the approval process as it did in the U.S.?

**Okamura** [M]: Thank you for your question. Dr. Taniguchi will answer this question.

Taniguchi [A]: Taniguchi here. Thank you.

As I explained earlier, we are in the process of reviewing fezolinetant with the European Medicines Agency. We are communicating with them on a daily basis.

As for the current schedule for the review process, we expect that the EMA will give its answer between November of this year and January 2024. We are doing our utmost to secure approval in Europe as soon as possible. Thank you.

Okamura [M]: I will now answer just one more question from the shareholders in online attendance.

[Summary of Question]: Could you be more specific as to your thoughts on distributions to shareholders?

**Okamura** [A]: Thank you for your question. I would like to respond.

I will answer about our capital allocation policy.

The Company is and will be actively engaged in returning profits to shareholders as well as striving to sustainably increase corporate value. While prioritizing business investment to achieve growth, we will strive for stable and sustainable improvement in dividends based on medium- to long-term profit growth on a consolidated basis.

In addition to this, if cash remains on hand, we intend to continue to improve capital efficiency and the level of returns by flexibly implementing share repurchases as necessary. Thank you.

This concludes the questions from shareholders in online attendance.

The questions asked in advance and the questions received from shareholders today and the answers to them will be posted on the Company's website at a later date, except in cases where the questions are considered inappropriate to disclose such as personal information or trade secrets, etc.

As the chairperson, I believe that sufficient deliberation has been done and would like to conclude the deliberation and proceed to the vote on the proposals. Is that okay?

(Shareholders applauded)

Thank you very much.

## **Voting - Closing**

**Okamura:** We will now proceed to voting on the proposals.

Now please take two minutes to vote on the two proposals I have just explained. Proposal 1, election of seven Directors who are not Audit & Supervisory Committee Members. Proposal 2, election of one Director as a member of the Audit & Supervisory Committee.

Okay, it has been two minutes, so I will close the voting. Shareholders at the venue, please cut out your ballot from the attendance sheet and hand it in as a staff member will now come to collect your ballot. Please take a few moments to collect your ballots, and then we will inform you of the results of the vote. Please remain seated and wait for a while.

During the confirmation, please watch the video about our company.

[Video]

**Okamura:** Thank you for your patience. I would like to notify the results of the vote.

The first proposal, election of seven Directors who are not Audit & Supervisory Committee Members, has been approved as originally proposed by an affirmative vote of a majority of voting rights of shareholders, including shareholders who exercised voting rights beforehand in writing and via the Internet. Thank you very much.

The second proposal, the election of one Director who is the Audit & Supervisory Committee Member, has been approved as originally proposed by an affirmative vote of a majority of voting rights of shareholders, including shareholders who exercised voting rights beforehand in writing and via the Internet. Thank you very much.

Finally, we would like to present the preliminary results of the exercise of voting rights. Here is the approval rate of the proposals 1 and 2, respectively.. Since the approval rate is a preliminary figure, the final tally will be reported in our Extraordinary Report to be disclosed at a later date. Thank you very much for your vote.

With the above, all items of the 18th Term Annual Shareholders Meeting has been concluded. With this, the meeting is adjourned.

I would now like to introduce the elected Directors who are not Audit & Supervisory Committee Members in the first proposal. Kenji Yasukawa. Naoki Okamura. Katsuyoshi Sugita. Takashi Tanaka. Eriko Sakurai. Masahiro Miyazaki. Yoichi Ohno.

Next, we would like to introduce the elected Directors who is the Audit & Supervisory Committee Member in the second proposal, Rie Akiyama.

These are the officers elected today.

That concludes the meeting for today. Thank you very much for your time.

[END]

#### **Document Notes**

- 1. Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.
- 2. This document has been translated by SCRIPTS Asia.

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