Astellas Pharma Inc.

Earnings Call for the Q2 of FY2026

November 4, 2026

Event Summary

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[Participants]	
[Number of Speakers]	5

Naoki Okamura	President and Chief Executive Officer (CEO)
Atsushi Kitamura	Chief Financial Officer (CFO)
Tadaaki Taniguchi	Chief Research and Development Officer (CRDO)
Claus Zieler	Chief Commercial & Medical Affairs Officer (CCMAO)
Nobuko Kato	Chief Communications & IR Officer

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	Seiji Wakao	JPMorgan Securities
	Akinori Ueda	Goldman Sachs
	Atsushi Seki	UBS AG
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Hiroyuki Matsubara	Nomura Securities
	Miki Sogi	Sanford C. Bernstein

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/Taniguchis.

Presentation

Kato: Thank you very much for joining Astellas Pharma Inc.'s FY2026 Q2 year-to-date financial results announcement meeting out of a very busy schedule today. I'm delighted to serve as the emcee today. I'm Kato, Chief Communications and IR Officer. Thank you very much for your time.

Today, after our presentation, we will move on to a Q&A session. Explanation will be made based on the meeting materials posted on our website. Including Q&A, we have simultaneous translation in Japanese and English. We cannot guarantee the accuracy of simultaneous interpretation. Thank you for your understanding. You can choose the language from the menu on the Zoom webinar screen. If you select original, you can listen to the original sound without going through simultaneous interpretation.



This is the precautionary statement.

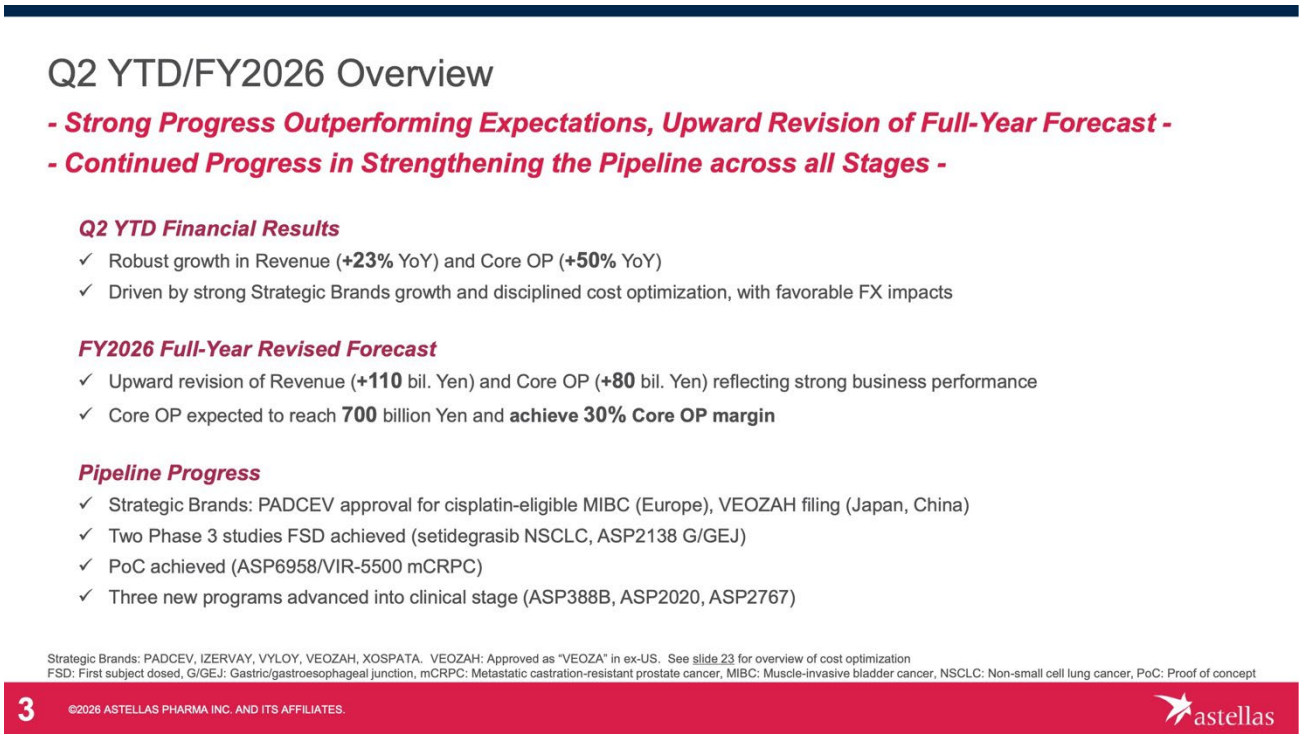
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Let me introduce the participants today. President and CEO, Naoki Okamura; Chief Research and Development Officer, Tadaaki Taniguchi; Chief Commercial and Medical Affairs Officer, Claus Zieler; and Chief Financial Officer, Atsushi Kitamura. We have four members from our company.

We now would like to start the presentation. Okamura-san, please.

Okamura: Hello, everyone. I'm Naoki Okamura from Astellas Pharma. Thank you very much for joining our FY2026 Q2 year-to-date financial results announcement meeting after a very busy schedule today.

This is the cautionary statement regarding forward-looking information. As this was explained by Kato earlier, I'm not going to read this page.



Page three is an overview of FY2026 Q2 year-to-date financial results.

Business performance made a strong progress, outperforming expectations. We have revised our full-year forecast upward. Continued progress was made in strengthening the pipeline across all stages. Revenue increased by 23%, and core operating profit rose by 50% YoY, both made a robust growth. Overall growth was driven by continuous strong strategic brand growth and by ensuring disciplined cost optimization.

Reflecting strong business performance exceeding expectations, we have made an upward revision of revenue by JPY110 billion and core operating profit by JPY80 billion. As a result, we are expecting core operating profit of JPY700 billion, a 30% core operating profit margin to be achieved.

Our pipeline also made a solid progress. Regarding life cycle management of Strategic Brands, PADCEV was approved for cisplatin-eligible MIBC, muscle invasive bladder cancer in Europe. VEOZAH submission was filed in Japan and China. FSD, first subject dosing, was achieved in Phase III studies with setidegrasib for NSCLC, non-small cell lung cancer, and ASP2138 for gastric cancer. What we presented as VIR-5500 is now called ASP6958. In this program, POC was achieved in mCRPC, metastatic castration-resistant prostate cancer. Furthermore, three new programs, ASP388B, ASP2020, and ASP2767, advanced into clinical stage.

Agenda

I **Q2 YTD/FY2026 Consolidated Financial Results**
FY2026 Revised Forecast

II **Pipeline Progress**

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Page four is the agenda for today. From the next page, I will explain these topics.

Q2 YTD/FY2026 Financial Results

Significant growth across Revenue, Core OP and Full OP

(billion yen)	Q2 YTD FY2025	Q2 YTD FY2026	Change	Change (%)	FX impact (YoY)	FY2026 Initial FCST*
Revenue	**1,030.1**	**1,270.9**	**+240.7**	**+23.4%**	+99.3	**2,220.0**
Cost of sales	200.4	247.9	+47.5	+23.7%	+14.1	445.0
SG&A expenses	403.8	430.4	+26.5	+6.6%	+33.8	800.0
US XTANDI co-promote fee	127.2	131.8	+4.7	+3.7%	+11.0	216.0
SG&A excl. the above	276.7	298.5	+21.9	+7.9%	+22.8	584.0
(SG&A ratio**)	26.9%	23.5%	-3.4ppt			26.3%
R&D expenses	143.3	167.7	+24.4	+17.0%	+10.3	355.0
(R&D ratio)	13.9%	13.2%	-0.7ppt			16.0%
Core operating profit	**282.6**	**424.9**	**+142.3**	**+50.3%**	+41.2	**620.0**
(Core OP margin)	27.4%	33.4%	+6.0ppt			27.9%
<Full basis>						
Amortisation of intangible assets	65.5	71.3	+5.8	+8.8%		
Other income	5.2	2.5	-2.7	-52.7%		
Other expenses	25.4	38.2	+12.8	+50.3%		
Operating profit	**199.4**	**316.6**	**+117.2**	+58.8%		**395.0**
Profit before tax	194.6	317.5	+122.8	+63.1%		385.0
Profit	**147.6**	**241.5**	**+93.9**	+63.6%		**300.0**

*Disclosed in Apr 2026, **Excl. US XTANDI co-promote fee
Actual exchange rates of Q2 YTD/FY2026: 159 yen/USD, 184 yen/EUR (Actual exchange rates of Q2 YTD/FY2025: 146 yen/USD, 168 yen/EUR)
Exchange rate assumption of FY2026 initial FCST: 150 yen/USD, 180 yen/EUR

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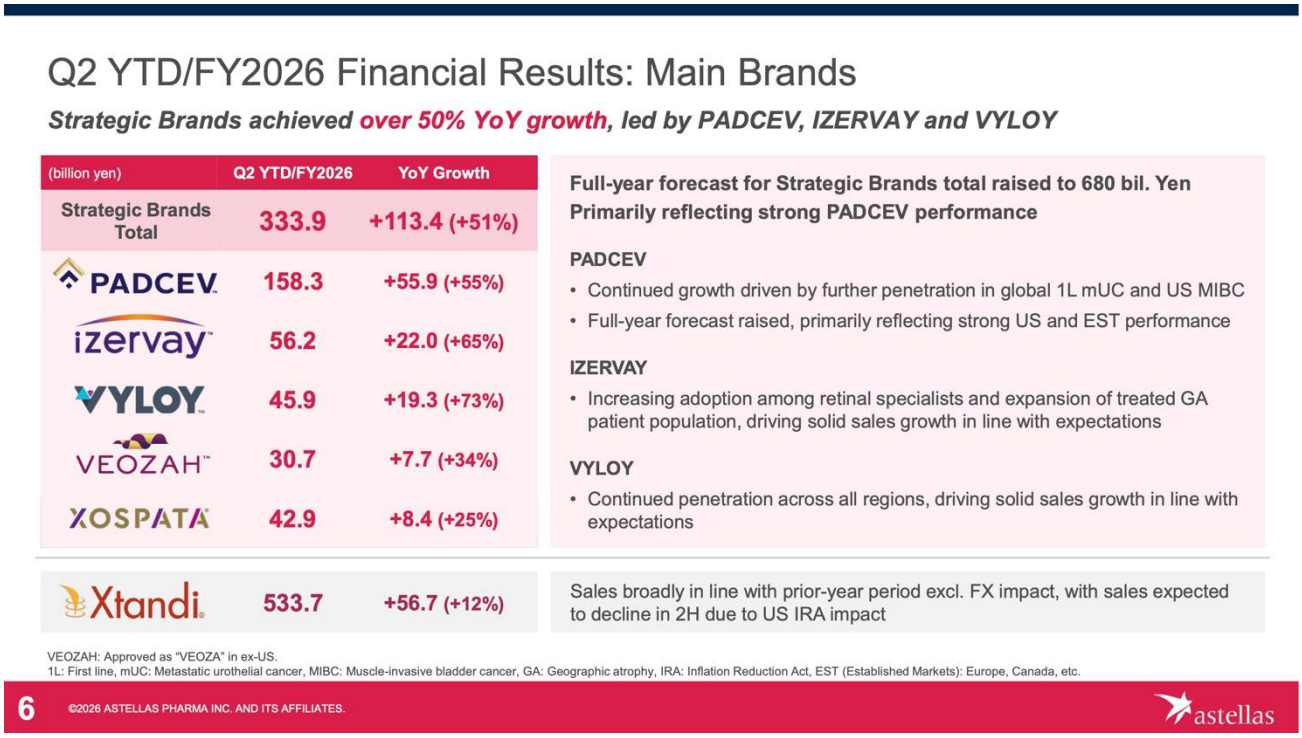
On page five, I will explain FY2026 Q2 year-to-date financial results.

Strong momentum from Q1 continued into Q2 as well. Across revenue, core operating profit and full operating profit, significant growth was seen YoY.

First, let me explain main items. Revenue reached JPY1,270.9 billion, substantially up by 23.4% YoY. Core operating profit increased to JPY424.9 billion, up by 50.3% YoY, realizing high growth rate exceeding revenue.

This strong profit growth was driven by the growth of Strategic Brands continuously. In addition, this was achieved by continuing to steadily make investments necessary for future growth and ensuring disciplined cost management across the Company. We were able to invest for growth and enhance profitability at the same time, which led to top line growth and substantial profit expansion.

Next, I will explain our full basis results shown in the bottom half of this page. Regarding ASP5541 and the development of prostate cancer, based on the clinical trial data obtained so far, we decided to discontinue its development. Accordingly, we booked impairment loss of JPY26.4 billion as other expenses. Including this impact, operating profit was JPY316.6 billion, up by 58.8% YoY, and profit was JPY241.5 billion, up by 63.6% YoY. We achieved a substantial profit increase also on a full basis as well. In H1 of FY2026, based on the growth of Strategic Brands, we were able to show strong progress both in expanding revenue and enhancing profitability.



Page six shows FY2026 Q2 year-to-date results of our main brands.

Strategic brands continue to maintain strong momentum following Q1, driving overall revenue and profit growth for Astellas.

First, sales of five strategic brands, PADCEV, IZERVAY, VYLOY, VEOZAH and XOSPATA exceeded JPY330 billion in total, substantially up by over JPY110 billion or over 50% YoY. All strategic brands achieved robust growth, demonstrating outstanding progress for strategic brands as a whole. PADCEV, in particular, grew at a pace exceeding the expectations at the beginning of the year, driving the growth of Strategic Brands as a whole. Other Strategic Brands are also progressing steadily, in line with the initial expectations.

Based on these results, particularly the growth of PADCEV exceeding expectations, we made an upward revision of our full-year forecast for Strategic Brands as a whole from the initial JPY610 billion to JPY680 billion. According to corporate strategic plan or CSP2026, we are aiming to more than double the sales of Strategic Brands by FY2030 compared to FY2025. Based on the results so far, we are progressing extremely well to achieve that goal according to assessment.

Next, I will explain the status of individual Strategic Brands and XTANDI.

As for PADCEV, sales increased to JPY158.3 billion, up by JPY55.9 billion or 55% YoY. Continued growth is driven by further penetration in global first-line metastatic urothelial cancer. In particular, outside of the United States, mainly in established and international markets, steady progress is seen in reimbursement, which is leading to sales expansion. In the United States, market penetration of MIBC, muscle invasive bladder cancer, is making steady progress, contributing to sales growth. On the other hand, in the United States, market penetration has progressed rapidly. So the growth rate in the United States is expected to be milder gradually over time in the future.

Based on the progress up to Q2, we made an upward revision of our full-year forecast for PADCEV. Furthermore, we believe PADCEV has room for future growth. In the current peak sales forecast, we are not factoring in bladder-sparing MIBC now under development and sales contribution of MIBC in China, which is now under submission. Based on these new growth opportunities, we are reviewing peak sales forecast right now, so we will share that with you at an appropriate timing. We are hoping that we will further expand business opportunities for PADCEV, both in terms of indications and regions. We are expecting further growth of PADCEV as an important product to drive Astellas' growth also in the future.

As for IZERVAY, sales rose to JPY56.2 billion, up by JPY22 billion or 65% YoY, growing solidly in line with our initial expectations. Adoption among retina specialists is making steady progress continuously. Treated GA, geographical atrophy patient population, is also increasing steadily. The expansion of prescribing physicians and an increase in the number of treated patients are leading to continuous sales growth. Also, in the future, we will promote penetration among more retina specialists to achieve further growth by increasing GA treatment rate.

With regards to VYLOY, sales reached JPY45.9 billion, up by JPY19.3 billion or 73% YoY, also growing solidly in line with our initial expectations. In all launched regions, market penetration is making steady progress. Through further penetration of Claudin 18 testing and expansion of new patient share, we're expecting solid growth of its sales into the future as well.

Sales of VEOZAH increased to JPY30.7 billion, up by JPY7.7 billion or 34% YoY. Impact from a competitor product is still within the range of assumptions. We are expecting VEOZAH's steady growth in the future as well.

Regarding XOSPATA, sales reached JPY42.9 billion, up by JPY8.4 billion or 25% YoY. Globally, stable growth is continuing.

Last but not the least, XTANDI. Sales increased to JPY533.7 billion, up by JPY56.7 billion or 12% YoY. On the other hand, this increase is mainly due to ForEx impact. Excluding ForEx impact, sales are at a similar level YoY.

We revised our full-year forecast upward by JPY20 billion, but this is because we are reflecting the change of ForEx assumptions. There is no change in our outlook on a local currency basis. From Q3 onwards, sales are expected to decline due to the pricing impact associated with the IRA, Inflation Reduction Act, in the United States and the impact of the patent expiry in some countries. In H2, we're hoping that further growth of Strategic Brands will strongly drive the performance of Astellas as a whole.

Q2 YTD/FY2026 Financial Results: Cost Items

- ***SG&A expenses* held flat YoY through disciplined management, ratio improved by 3.4ppt YoY***
- ***Cost optimization (SMT): Approx. -22 billion Yen YoY (Total of SG&A expenses, R&D expenses, cost of sales)***

(yen)

Cost Items	YoY change	Ratio to Revenue	
SG&A expenses (excl. US XTANDI co-promote fee)	+7.9% (-0.3% excl. FX impact)	SG&A ratio: 23.5%	Held flat YoY excl. FX impact • Increase in Strategic Brands-related investments for further growth • SMT cost optimization: approx. -10 bil. ✓ Efficiency benefits from Global Capability Center establishment, AI and digital capabilities ✓ Standardization of promotional content and streamlined content development, etc.
R&D expenses	+17.0% (+9.9% excl. FX impact)	R&D ratio: 13.2%	YoY increase excl. FX impact: approx. +14 bil. • Increase in pipeline clinical development costs: approx. +11 bil. ✓ setidegrasib, ASP2138, ASP546C, ASP6958/VIR-5500, etc. • SMT cost optimization: approx. -8 bil. ✓ Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials, etc.

*Excl. US XTANDI co-promote fee and FX impact
SMT: Sustainable Margin Transformation

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Page seven is about cost items.

SG&A expenses, excluding US XTANDI co-promotion fees and ForEx impact, were held flat YoY, while we steadily executed investments necessary for future growth. As a result, the SG&A expense ratio improved by 3.4 percentage points YoY. In addition, our company-wide cost optimization initiative called SMT, Sustainable Margin Transformation, is also achieving the results steadily. In H1, we realized cost optimization of about JPY22 billion YoY for SG&A, R&D expenditure, and cost of sales combined.

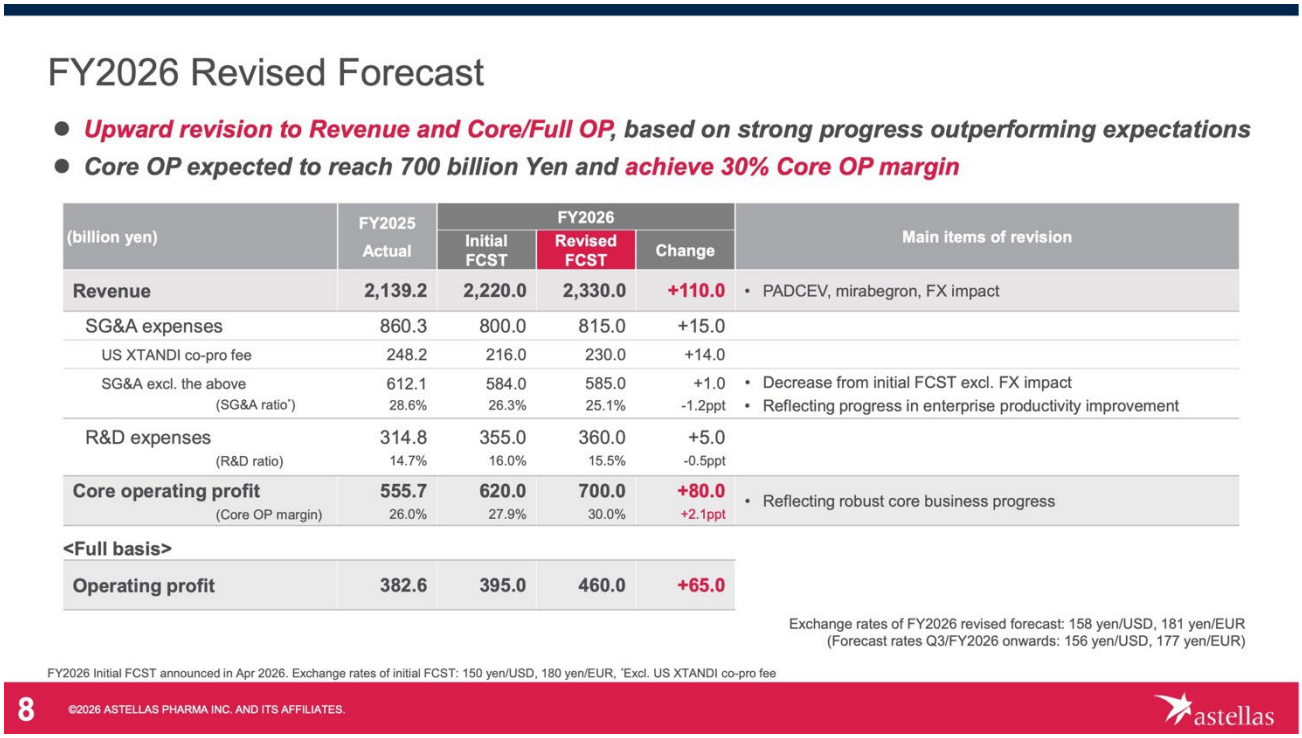
Next, let me explain a specific breakdown of SG&A cost and R&D expenditure. SG&A expenses, excluding ForEx impact, decreased by 0.3% YoY. Our Strategic Brands are growing substantially. While we increased our investments to grow them further, we are able to hold SG&A expenses flat at a level similar to the previous year. We see this as an outcome achieved through our SMT initiatives by now.

Specifically, in addition to efficiency benefits from Global Capability Center establishment, AI and digital capabilities, we actively implemented the standardization of promotional content and streamlined content development process. Through these initiatives, we realized cost optimization of about JPY10 billion. By fully executing growth investments for Strategic Brands, we were able to offset the increase through cost optimization and hold SG&A expenses flat YoY, which we think is a great achievement.

R&D expenditure rose by 9.9% YoY, excluding ForEx impact. This is due to the steady progress in our pipeline development mainly for setidegrasib, ASP2138, ASP546C and ASP6958. Pipeline development costs increased by about JPY11 billion. Also, in R&D expenditure, higher efficiency through SMT is making steady progress. We are continuously making progress in outsourcing cost reduction through in-sourcing development capabilities, including clinical trials, et cetera, and prioritization of research stage programs, which led to cost optimization of about JPY8 billion. We have been able to offset some of the increase in costs through efficiency benefits while we ensure increasing pipeline investment.

In H2, as we will make progress in patient enrollment as clinical trials move forward, we are expecting expansion of further investments. In this way, what we are promoting is not the mere cost reduction. By enhancing enterprise-level productivity, we are realizing high profitability while we make steady investments

in necessary areas such as strategic brands and pipeline. We will continue to secure investments in areas where we should invest. At the same time, we will ensure cost discipline and enhance productivity.



Page eight covers our revised full-year forecast for FY2026.

Based on strong progress outperforming expectations through Q2, we have significantly revised upward our full-year forecast for revenue as well as core and full basis OP. In particular, we expect core OP to reach JPY700 billion, a level that will significantly surpass our previous record high. Furthermore, the core OP margin is projected to reach 30% for the first time in Astellas' history. While we have set a target of 30% by FY2027, this upward revision means we now expect to achieve it within the current fiscal year. In addition to revenue growth driven primarily by our strategic brands, the result of company-wide cost optimization efforts have clearly manifested a significant improvement in profitability, so we believe.

Next, I will explain the details of the full year forecast. First, foreign exchange assumptions. We had initially assumed JPY150 per US dollar and JPY180 per euro. However, we anticipate JPY156 per US dollar and JPY177 per euro starting in Q3. Combined with the actual rate through Q2, JPY159 per US dollar and JPY184 per euro, we have revised to JPY158 per US dollar and JPY181 per euro for full-year forecast.

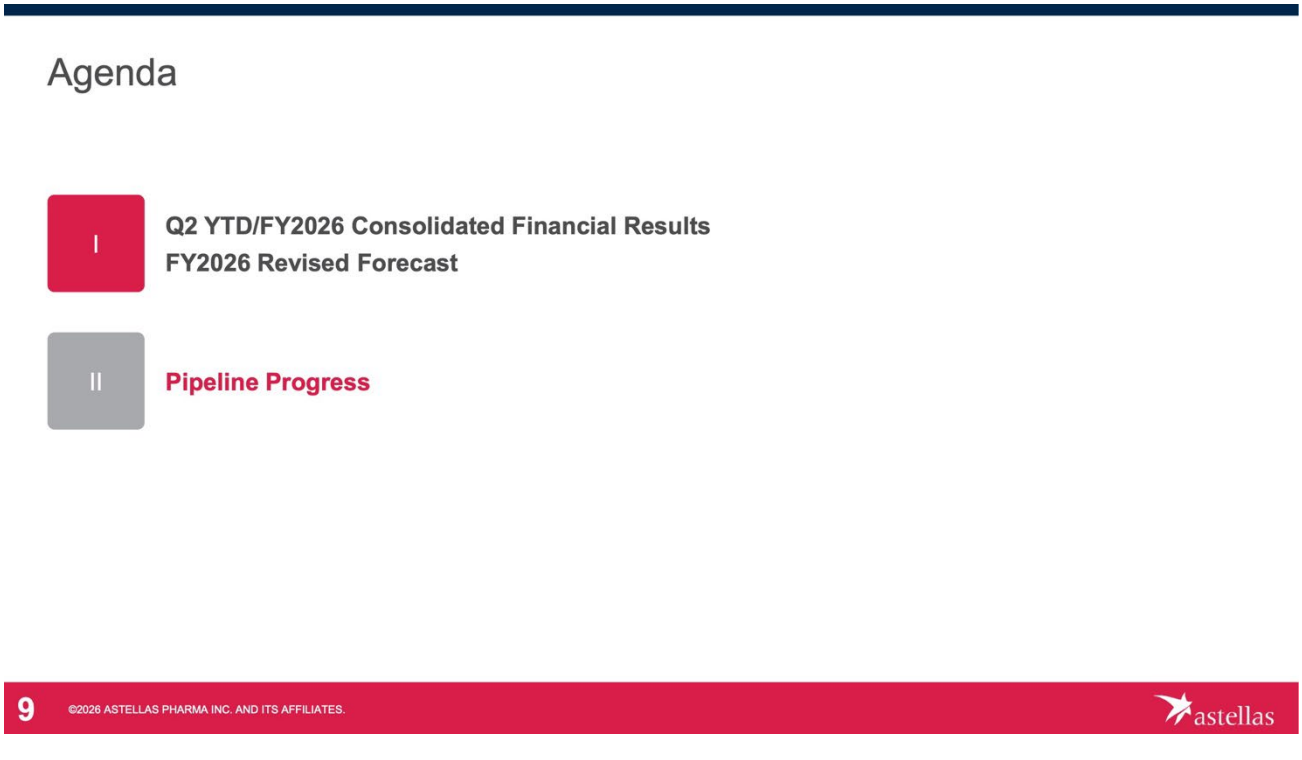
Regarding revenue, in addition to upward revisions to the full-year forecast for PADCEV and mirabegron, we have factored in the impact of the revised ForEx assumptions and revised our revenue forecast upward by JPY110 billion from the initial forecast and now expect it to be JPY2.3 trillion.

Next, regarding expenses. SG&A expenses, excluding co-promotion fee for XTANDI in the US, is projected to be JPY585 billion, reflecting that the enterprise productivity improvements are progressing at a faster-than-expected pace. Excluding the ForEx impact, this level represents a decrease from the initial forecast. R&D expenses are projected to be JPY360 billion, primarily reflecting the impact of changes in the ForEx assumptions as progress is generally in line with the expectations.

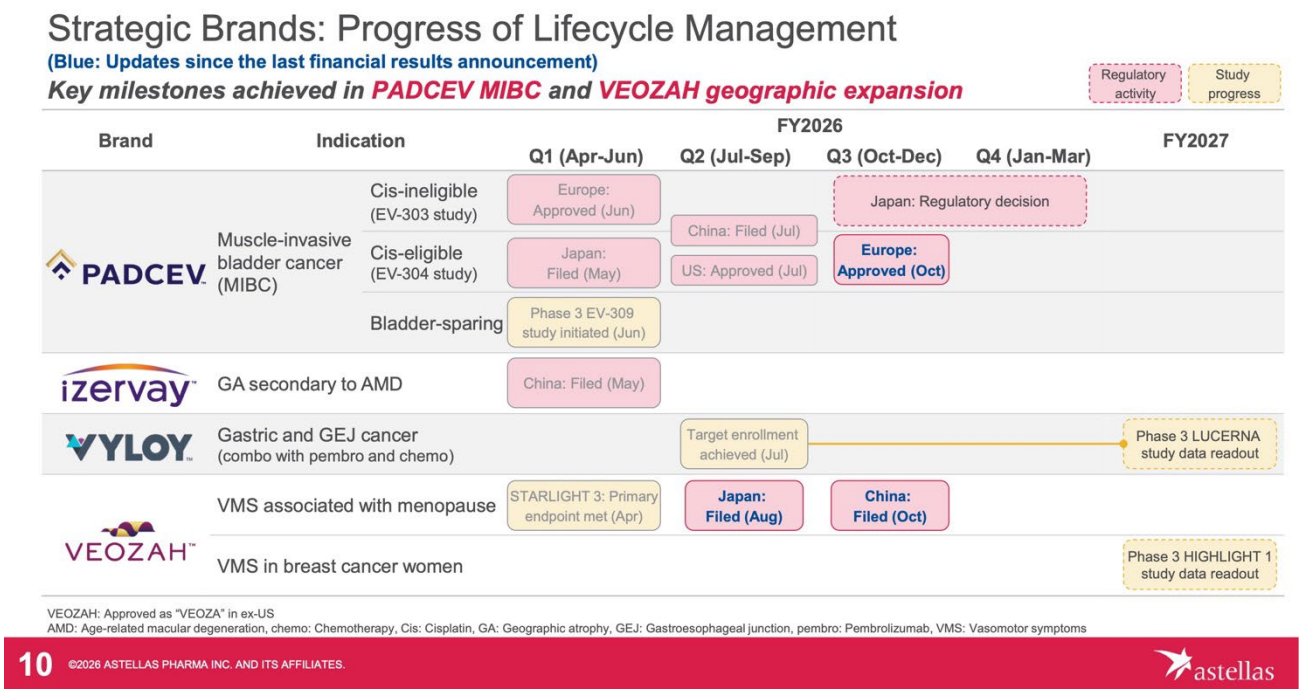
Reflecting the strong performance in our core business, core OP has been revised upward by JPY80 billion from the initial forecast and is now projected to be JPY700 billion. The core OP margin is expected to rise by 2.1 percentage points from the initial forecast, reaching 30%.

Next, full base OP. First, regarding other expenses, the initial focus was approximately JPY80 billion for the full year. Through Q2, we have recorded JPY38.2 billion, including an impairment loss of ASP5541. In this revised forecast, although there are no specific signs of impairment losses at this time, we have factored in additional JPY15 billion for the risk of impairment losses and so on. As a result, we now expect other expenses to total approximately JPY95 billion for the full year.

Reflecting this revision to other expenses, the upward revision to full basis OP amounts to JPY65 billion, bringing the full-year forecast to JPY460 billion. This upward revision demonstrates that we are able to significantly increase revenue while simultaneously substantially improving profitability. We'll continue to steadily build on our results in H2 to achieve our targets of record-high core OP of JPY700 billion and a core OP margin of 30% for the first time in Astellas' history.



Next, I will explain our pipeline progress.

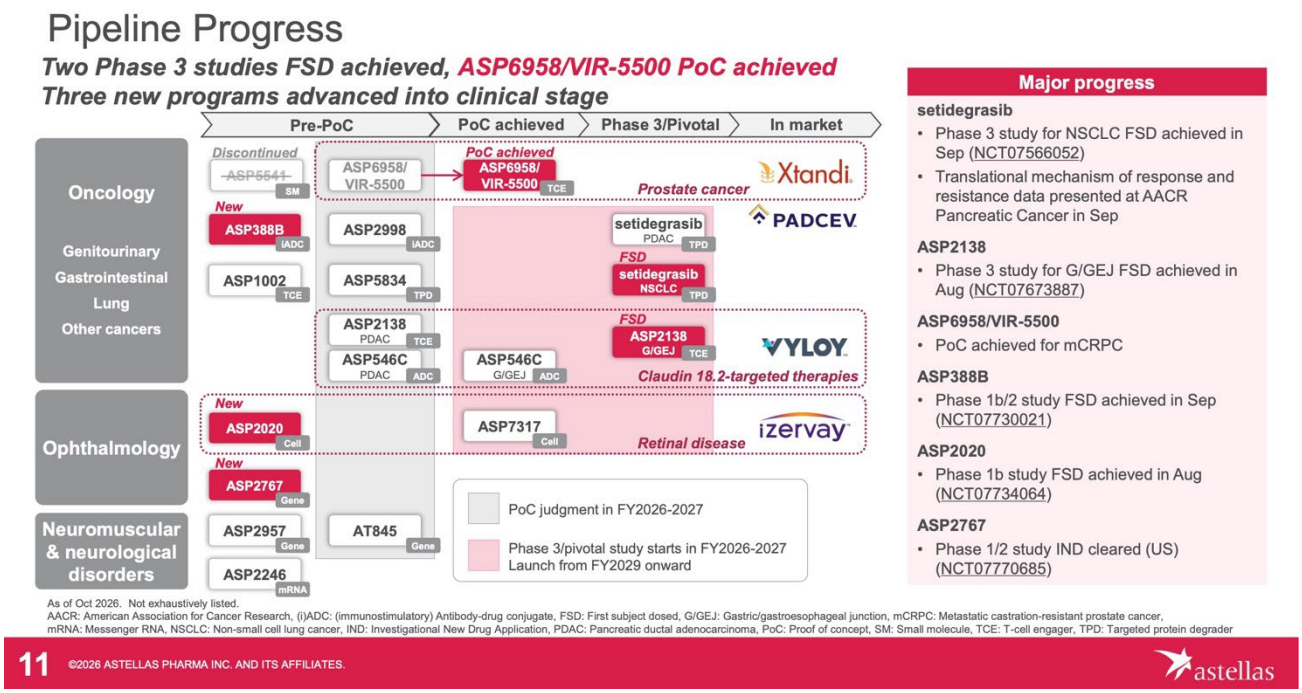


On page 10, I will discuss progress on the life cycle management of our strategic brands.

We have achieved an important milestone of geographic expansion with PADCEV for MIBC and VEOZAH. First is about PADCEV. For cis-eligible MIBC, we obtained an approval in Europe in October based on the results of EV-304 study.

Next is VEOZAH. In Japan, we did the filing in August based on the global clinical trial data in addition to the results of two Phase III STARLIGHT studies conducted in Japanese women. In China, the submission based on data from clinical studies in Europe and the United States as well as bridging study conducted in China was accepted in October.

Regarding IZERVAY, we are planning additional clinical studies to support the European submission. We will provide further details as soon as they are finalized.



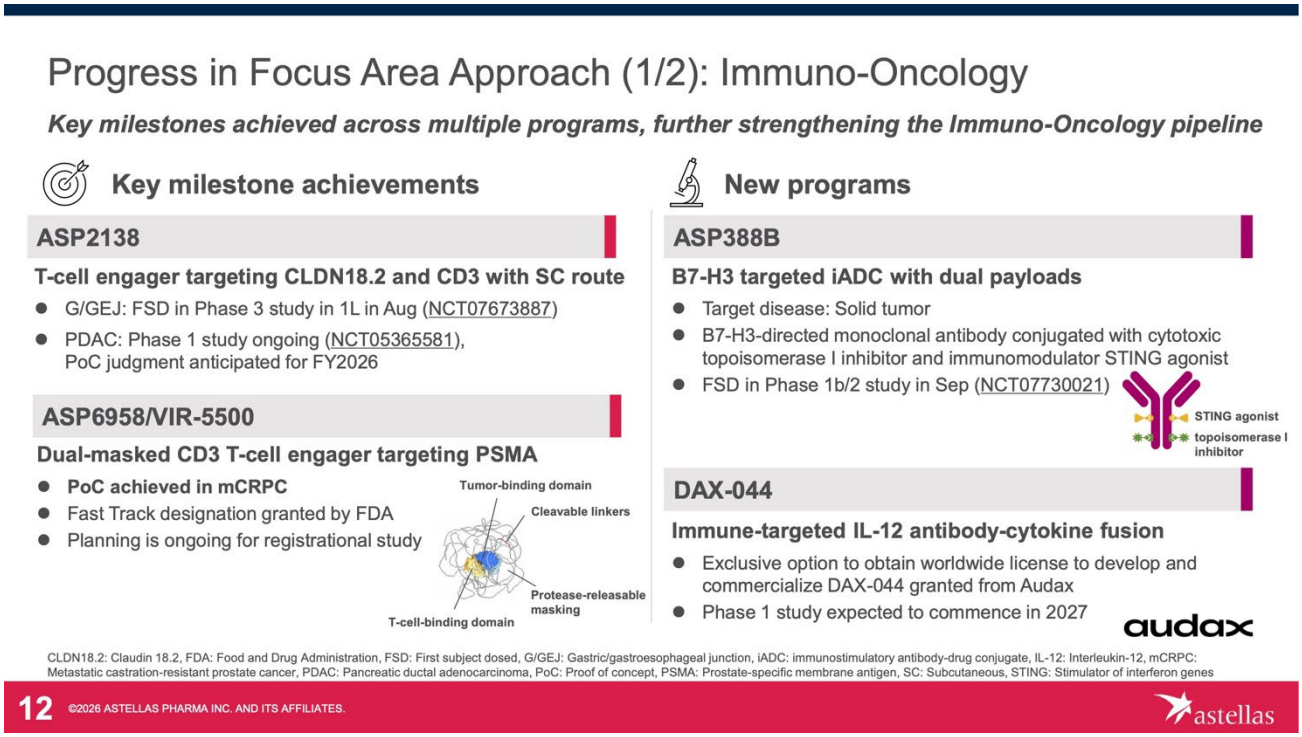
On page 11, I will explain our pipeline progress.

Our pipeline has steadily progressed and expanded ranging from early-stage to late-stage development. We have achieved FSD or first subject dose in two Phase III trials and demonstrated POC for ASP6958. Furthermore, three new programs have entered clinical development. First, we achieved FSD in the Phase III study of setidegrasib for second line or later treatment of NSCLC as well as in the Phase III study of ASP2138 for first-line treatment of gastric cancer. We are making steady progress toward our goal of initiating 10 or more Phase III or pivotal studies by FY2030, which was set as a performance indicator in our CSP2026.

Regarding setidegrasib, we presented data on treatment response and mechanism of resistance at the AACR Pancreatic Cancer meeting held in September. Please refer to page 35 of the appendix for details on the data.

Next, regarding ASP6958, we achieved POC in mCRPC and have begun exploring options for late-stage development. Furthermore, three programs, ASP388B, ASP2020, and ASP2767, have nearly entered the clinical development phase, and we have continued to expand our early-stage pipeline.

In the following slides, I will provide details on the Primary Focus Areas, Immuno-Oncology and Blindness and Regeneration, where we have seen multiple developments.



Page 12, I will update you the progress of Primary Focus area of Immuno-Oncology.

In Immuno-Oncology, we have achieved key milestones in multiple programs, and with the addition of new programs, our pipeline is steadily expanding.

First, ASP2138. In August, we achieved FSD in a Phase III study for ASP2138 as a first-line treatment for gastric and GEJ adenocarcinomas. We expect that the readout of this study will be available in FY2029. For PDAC, Phase I study is underway, and we anticipate a POC judgment during FY2026.

Next is ASP6958. This is a dual-masked CD3 T-cell engager targeting PSMA or prostate-specific membrane antigen. Based on Phase I data obtained to date, we have achieved POC in mCRPC. Fast Track designation was granted by the FDA in August. Based on these results, we are currently planning for a registrational study.

Next, I will explain our new Immuno-Oncology program. ASP388B, developed through our collaboration with Sutro, is our second program following ASP2998 and utilizes a technology platform known as an immunostimulatory antibody drug conjugate or iADC. B7-H3-directed antibody is conjugated with two payloads, a cytotoxic topoisomerase I inhibitor and an immunomodulator STING agonist. In a Phase IB/II trial targeting solid tumors, we achieved FSD in September.

DAX-044 is a program for which we recently secured an exclusive option to obtain a worldwide license to develop and commercialize from Audax. This is a fusion protein that enhances the targeting specificity of interleukin-12. It utilizes Audax's proprietary technology and is designed to specifically exert the immunostimulatory activity of IL-12 within the tumor microenvironment. Audax plans to initiate a Phase I trial in 2027, and we will consider exercising the option based on data obtained in the future.

We will continue to accelerate the development of these programs and focus on further strengthening our immuno-oncology pipeline.

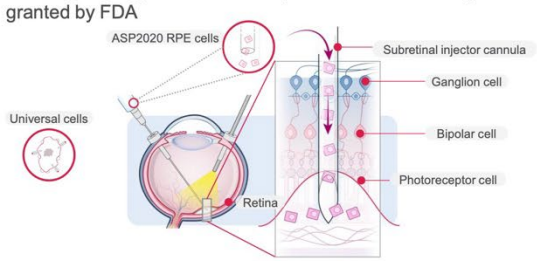
Progress in Focus Area Approach (2/2): Blindness and Regeneration

Next-generation ophthalmology programs advancing into clinical development

ASP2020

iPSC-derived RPE cell therapy with Universal Cell technology

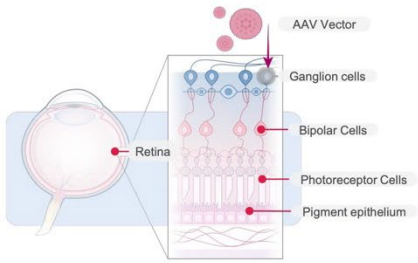
- Target disease: Stargardt-type macular dystrophies
- Aims to complement and/or replace RPE cells and improve vision
- Designed to avoid immune rejection through HLA gene editing (Universal Cell technology)
- Phase 1b study FSD achieved in Aug (NCT07734064)
- Fast Track designation and Rare pediatric disease designation granted by FDA



ASP2767

AAV-based gene therapy delivering dual transgene BDNF and TrkB

- Target disease: Optic neuropathy due to glaucoma
- Delivers dual transgene BDNF and its receptor (TrkB) to protect retinal ganglion cells and help maintain visual function
- Phase 1/2 study IND cleared (US) (NCT07770685)
- Fast Track designation granted by FDA



See slide 42 for Universal Cell technology. AAV: Adeno-associated virus, BDNF: Brain-derived neurotrophic factor, FDA: Food and Drug Administration, FSD: First subject dosed, HLA: Human leukocyte antigen, IND: Investigational New Drug Application, iPSC: Induced pluripotent stem cell, RPE: Retinal pigment epithelium, TrkB: Tropomyosin receptor kinase B

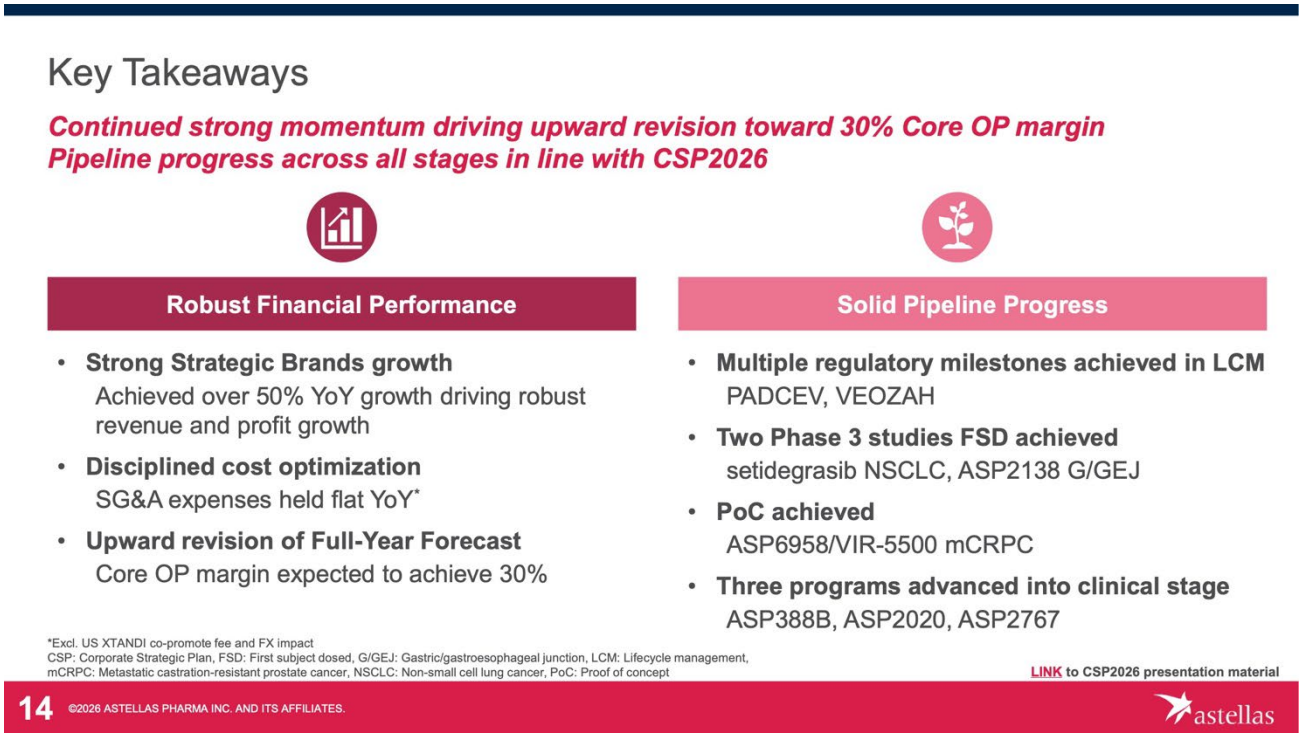
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Page 13 outlines the progress of our Primary Focus area, Blindness and Regeneration.

ASP2020 and ASP2767, our next-generation ophthalmology programs, have recently advanced into clinical development phase. ASP2020 is iPS cell-derived RPE or retinal pigment epithelial cell therapy created using Universal Cell technology. The target disease is Stargardt-type macular dystrophies and aims to complement and/or replace RPE cells and improve vision. It is designed to avoid immune rejection by editing HLA or human leukocyte antigen genes using Universal Cell technology. Please refer to page 42 of appendix for an overview of the technology.

In the Phase Ib study, we achieved FSD in August. Additionally, a Fast Track designation and a rare pediatric disease designation was granted by the FDA. Furthermore, within this program, we're exploring the automation of manufacturing using Maholo, a general-purpose humanoid robot introduced at Cellafa, a joint venture with Yaskawa Electric.

ASP2767 is an AAV-based gene therapy targeting optic neuropathy due to glaucoma. By introducing two genes, BDNF, brain-derived neurotrophic factor, and its receptor, TrkB, into the eye to activate pathways that protect retinal ganglion cells to maintain visual function. In the United States, we have begun enrolling subjects in a Phase I/II clinical study. We also have obtained a Fast Track designation from the FDA. For the Primary Focus, we aim to create treatment options that not only slow disease progression but also lead to the maintenance and restoration of vision by leveraging new modalities, such as cell therapy and gene therapy.



Today's key takeaways.

The primary drivers supporting our robust financial performance were the Strategic Brands, which continued strong growth and drove the expansion of overall revenue and profits. Furthermore, as a result of thoroughly implementing disciplined cost optimization, we managed SG&A expenses to a level of flat YoY. Given the steady progress in both revenue growth and profitability, we have made a significant upward revision of full-year forecast. As a result, we now expect to achieve the 30% core OP margin, a target set for FY2027, within the current fiscal year. To realize the pipeline-driven growth outlined in CSP2026, we are making significant progress toward establishing a profit structure that ensures stable earnings while making sufficient investments for future growth.

Our pipeline has shown solid progress across all strategies from early-stage development to life cycle management. We achieved multiple regulatory milestones in the life cycle management of PADCEV and VEOZAH. We achieved FSD in the Phase III study for setidegrasib in NSCLC and ASP2138 in gastric cancer. ASP6958 achieved POC, and we have begun consideration for late-stage development. Furthermore, ASP388B, ASP2020 and ASP2767 have newly advanced into the development stage, further expanding our pipeline in each primary focus area. To achieve the goals of our CSP2026, we intend to maintain this momentum by focusing on creating and delivering greater value more rapidly.

That concludes my presentation. Thank you for your attention.

Question & Answer

Kato [M]: That's all for our presentation. Next, we'd like to entertain questions from the audience. If you have a question, please press the raise hand button at the bottom of your Zoom screen. If you're joining from your smartphone, please tap details and you can find raise hand so please press it. I'm going to name you one by one. If your name is called, please unmute yourself on your screen and please mention your name and affiliation and then ask questions.

Now, we are going to take your questions. First Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [M]: Yamaguchi from Citigroup Securities. Can you hear me?

Kato [M]: Yes.

Yamaguchi [Q]: Thank you. My first question is about the revision of your full-year forecast. How much was the ForEx impact? Five strategic brands were combined in your disclosure. Mirabegron, XTANDI would be subtracted and JPY20 billion for main brands are shown. But this is mostly PADCEV, including ForEx impact. The revision of your forecast and also the situation by product.

Okamura [A]: For details, Kitamura is going to explain. ForEx impact is taken into account for all products. As a volume, how much was the upward revision? We don't disclose by product, but if you subtract how much for which product, it can be clearer for you.

Kitamura [A]: In principle, ForEx impact and ForEx sensitivity is disclosed. The US dollar is fluctuating and JPY8 billion for revenue and JPY2 billion for profit based on a US dollar fluctuation. Against the initial expectations, yen is depreciating against the US dollar. Simply put, for revenue, JPY110 billion upward revision was made. JPY60 billion to JPY70 billion impact from the US dollar fluctuation. As for the core operating profit, JPY80 billion is the upward revision. There is some ForEx impact here. For yen, the sensitivity is more than JPY2 billion per US dollar. For the core operating profit, we have the sales increase, and we have cost management. That's why our profit is increasing.

Yamaguchi [Q]: Thank you very much. For core operating profit, you cannot say how much clearly.

Kitamura [A]: For core operating profit against the US dollar, JPY2.7 billion per yen in terms of the ForEx sensitivity. A little less than JPY2 billion is from the ForEx impact. We revised the core operating profit forecast by JPY80 billion so ForEx impact is not so big.

Yamaguchi [Q]: Thank you very much. One more question. The initial pipeline including the cell therapies are increasing. ASP6958 is achieving POC. Timing might be too early, but ASP6958, what about its potential? Because of the XTANDI cliff, XTANDI portion is going to be decreased for prostate cancer. How should I explain? Any target or peak timing? What do you think?

Okamura [A]: Thank you for your question. Unfortunately, timing-wise, as an XTANDI successor, legacy created by XTANDI is not going to be taken over as is. Our capabilities will be leveraged. But at the same time, we would create a new market, and that is going to be the positioning. There's no other choice. XTANDI exclusivity will come to an end. There's going to be LOE. When ASP6958 is going to be launched, XTANDI generics will become available in the market so we have to consider the positioning of this product.

PSMA is a target. This is a clear target. But T-cell engagers targeting PSMA were difficult to create, but with Vir's technology, this is becoming feasible. Rather than a novel target, if we do this, this is going to be a target for sure. We are going to take a challenge with the new technology.

Of course, potentially, treatment paradigm, going back to the initial phase of the treatment paradigm and if it is possible to get the approval, it is natural that this will be a very big market. But technology is new, and this is not oral medication. Therefore, based upon the clinical trial results, we need to think where would be the positioning and also the value that we've been seeing. How we can provide that is something we need to consider. We are in such a stage. We are working on the planning of the later phase. If that is created and just like other programs, how big our market would likely be at the time of the peak is possible to communicate to you.

Taniguchi-san, Claus-san, do you have any additional comment you would like to make?

Zieler [A]*: Yes, happy to add, as Naoki said, XTANDI will be generic and other ARPIs will be generic at the time of the launch. But there still is, even after ARPI class treatment, there is significant unmet medical need in prostate cancer. That's where we are targeting this agent. Because in a generic market, you can only create value if you target that patient population where there's still unmet medical need. That would be my answer in addition to what Naoki has already said.

Yamaguchi [M]: If nothing from Taniguchi-san, that would be okay.

Taniguchi [M]: Yes. Okamura covered everything.

Yamaguchi [M]: Thank you.

Kato [M]: Thank you for your question. Next, JPMorgan Securities, Mr. Wakao, please.

Wakao [Q]: Thank you very much. JPMorgan, Wakao is my name. Thank you for this opportunity.

First question is, well, you mentioned the centering around the Strategic Brands. You made a great profit increase, and this result is really significant. Forecast is modified this time and how this change would impact on to the capital allocation. You have profit secured, and I believe that you are going to have sufficient cash flow. You think about the investment for your growth and then return to the shareholders. That's probably what you think. Based upon your thinking of this situation, for the dividend, JPY2 or more of the dividend, that is likely to be possible from this fiscal year or from next fiscal year. Would it be changed? When you announced about the midterm plan, from the perspective of the return to the shareholders, even if the profit will be available, the dividend is going to be more towards H2 of the CSP or midterm plan. What is your current status?

Okamura [A]: Thank you for your question. Capital allocation policy slide is available on the screen, and we haven't really changed this for many years. This is how we prioritize. As Wakao-san mentioned, first, we invest into the business and the growth opportunity. Then, stably, we increase the dividend. Still, if we have the sufficient cash in other ways, we'll think about that return to the shareholders. That is the priority order for us. Up until Q2, our result is really good, and the full year, we've made a revision. But we are not thinking to come up with a completely new policy of the dividend. In the beginning of the fiscal year or at the time of CSP, we are committed for the increase of JPY2 per year for the dividend or continue that for five years. That is what we would like to fulfill.

Depending on the situation and the full-year financial results for FY2026 and we have sufficient cash and we have excessive cash and just keep it on the balance sheet, we are not going to do it that way. We might find out opportunities for the investment for the business or we might return this to our shareholders. But here,

we are still in the midterm. At this moment, we are not thinking to change our policies completely. At the time of the full-year result, considering the situation at the time and also thinking about the needs afterwards, we will consider how to return to our shareholders. That's what we would like to discuss.

Kitamura [A]: I agree with what Okamura said. If I add, this is what we have been repeatedly saying. Regarding the dividend and shareholder return, it's not in the shorter term. It's not going to be changed because of the fluctuations in the results. Our mid- to long-term cash flow and also the funding, we make a decision. During the course of the CSP2026, we are going to increase the dividend by more than JPY2 every year. This is the minimum requirement for us. We will continue to achieve great results to continue those investments and return profit back to the shareholders.

Wakao [Q]: Understood. Based on the current progress, as Okamura-san said, cash flow is in excess and making business investments or make shareholder returns. You may be heading into that direction. Or am I wrong?

Okamura [A]: In the CSP, in the coming four years, we can earn JPY4.3 trillion, and we would make investments into businesses and R&D. We would use the money flexibly. We are developing a plan based on this. Regarding business development opportunities, if it's a deal where we can add value, we may decide to invest. What we have said before, six months results are good right now, it's not going to start anything different compared to what we have said. That's what myself and Kitamura said.

Wakao [Q]: Understood. My second question is about the pipeline. ASP2138 Phase III is starting. ClinicalTrials.gov, FY2029 is the primary completion. Any room for acceleration? That's what I'd like to know. LUCERNA study is being performed. Recruitment was very fast to complete, and it was 20 months earlier than scheduled. Claudin area is where you are a leader, and you have the know-how for enrollment or recruitment. Regarding the Phase III study, you can advance the schedule of recruitment. I think you can expect that perhaps. What do you think?

Okamura [A]: Thank you for your question. This is true for LUCERNA study. From April last year, we are managing the organization. This is the patient access. We have a cross-functional team. Asset Maximization Team is the name we use. We give a lot of authority delegation. Based on the newest data in the field, they can create a larger value more rapidly. One of the achievements is the LUCERNA study very quick enrollment completion. Needless to say, regarding ASP2138 Asset Maximization Team, we will consider how to create greater value faster. They are considering very seriously, and there is room for acceleration there.

Furthermore, SMT, as I said in the context of SMT, up until now, contract research organization was very dependent upon in the conduct of the clinical studies, but we are trying to in-source. Because these are our own products, we would like to proceed faster. The determination of the employees would be resulting in the progress of the program. There is such a momentum and the possibility of acceleration.

Regarding ASP2138, Taniguchi is going to explain.

Taniguchi [A]: Thank you very much. ASP2138, as Okamura presented, is already a Phase III study. Enrollment has started. For the time being, it's progressing well. Needless to say, from now on, competition is very intense. We will do our best to enroll patients and complete the recruitment as soon as possible for this program as well. Regarding the status of enrollment, based on the progress, we are hoping to report to you.

Wakao [Q]: Thank you very much. Primary completion was 2031. LUCERNA, in one year or so, recruitment may be over.

Taniguchi [A]: I shouldn't think about that possibility. It depends on the situation. Competition is intense. In Claudin 18.2 intensifying more. We have to take that into account to select better sites as we proceed. For the time being, it's progressing well, so you can count on us.

Wakao [M]: Thank you very much. That's all.

Kato [M]: Thank you. Next, Goldman Sachs Securities, Ueda-san, please.

Ueda [Q]: Ueda from Goldman Sachs. Thank you very much for this opportunity. First question, you revised the plan this time. Some tentative factor for this fiscal year and also some factors likely to be favorable for the profit next year and afterwards, I would like you to sort them out. Well, this time, you have the matured products factor and also including the strategic basis, you can expect for the next year and afterwards and also cost reduction efficiency. Considering your performance for the next fiscal year, would you please sort out the favorable factors for that?

Okamura [A]: Thank you for your question. Where should I start? Regarding revenue, first of all, XTANDI, as has been mentioned within the presentation, the volume basis or the net growth basis, we've hit the peak already. Because of the FX impact, we had certain positive or the plus. In the case of the United States, in Q4, that is January from the next year based upon the IRA, the price is going to be changed, and that impact is taken into account for this guidance this time.

Skipping Strategic Brand, let me talk about something else first. Mirabegron, as you know, with the generic manufacturers, we came to the agreement, and things are settled. Therefore, we are on an upside at this time, but it's not going to be continued forever. When the mirabegron patent is expired, then this will be replaced with a generic erosion. For the long-term perspective, you need to think in that way.

For Strategic Brands, first of all, PADCEV, there are two different dynamics mixed up, meaning, first of all, the first-line addition is expanding in the regions other than the United States. This is a real sense of underlying growth driver. On top of that, in the United States, MIBC is up taken in a very accelerated manner or speed. That growth of both added. That's why, seemingly, it is a great growth. However, MIBC in the United States is going to hit a plateau at a certain point of time. This growth will be gradual later on, and first-line growth in the regions other than United States is going to grow further. But in the bladder-sparing and the situation of China, the first line are not taken into consideration. Therefore, for the long-term perspective, we still have a lot of potential of the growth. For this, when we come to the certain final perspective of the forecast, then we can let you know.

VYLOY, IZERVAY, VEOZAH, we have planned trajectory of the growth, and I think that is followed currently. Of course, the situation of the competitors or IZERVAY in Europe for example, what we should do is under the consideration. For the long-term perspective, further, the growth trajectory and its direction could be changed. However, so far, our growth is just in line with our forecasted trajectory.

Now, about the expenses, with this explosive growth of Strategic Brands, will be settled at a certain point of time. Then the cost or expenses necessary to grow the Strategic Brands will be reduced or declined. But in FY2029 to FY2030, that is the next phase where those derived originally from the Focus Area pipeline will come into the market. There, we have to think about the investment for the preparation of the commercial launch rather than the development. We have the disciplined cost management based upon SMT, which is considered to be continued further. Then the settled down Strategic Brands costs are going to be replaced with the preparation of the next phase generation products launch. When we have more products, the more cost we will face. No, we would like to avoid that.

As for SMT, in four years, JPY150 billion was the commitment. But in CSP2026, on top of FY2026 and FY2027, we would add three more years to achieve JPY200 billion cost reductions. As a commitment, we are making

steady progress against this goal and commitment. In initiatives like this, if we track, it may seem like a reduction, but it doesn't hit the P&L goals. We have a structure not to have such a situation. Regarding the savings, we will have profits on P&L. That is going to be desirable.

Sorry for a long explanation, but in CSP2026, in our external announcement, we showed the following. XTANDI, LOE slope will occur. If you look at the revenue as a whole, it's in the declining phase, but we will increase the cashflow we can use. With disciplines, we would use the cash for growth investments. At the same time, we are hoping to generate profit. We are now on track, and we are already on track. We are beginning to be on track according to assessment.

Kitamura [A]: As Okamura said, I agree with him. Regarding the cost and the operations, the profit-making capabilities are being established. Using the cash, how to link this to the next growth is important. R&D will become more active, and we will make investments. For that, we have SMT to create more room for investments to grow the Strategic Brands. For the past two, three years, we have done so. This is going to be the same story. We have the profit-making capabilities at the basis. We'd like to use this to accelerate our growth. This time, in CSP2026, rather than a single-year basis, we are talking about the five years. Transformation requires such a time to change the portfolio. During this period, we'd like to build. That's how we are proceeding. This is in the first six months. As a CFO, I think these are the strong results.

Ueda [Q]: Understood. Thank you very much for the meticulous explanation. My second question is about your agreement with the US government for the improvement of access in the United States. What about the impact on the business results? There is no disclosure, so it might be difficult to comment. Any additional investments to be required? Risk factors are easier to control, and they are becoming more manageable. Anything qualitative is going to be fine. Any potential impact on your business performance? Any comments from you?

Okamura [A]: Thank you for your question. The details can be added by Claus. But first, from me, geopolitically, many things are happening right now. In the United States, US administration is ironing out various measures. That's one such movement. If it's beyond our control, we shouldn't make a fuss. Where we can control, we'd like to do business solidly. But at the same time, we have to monitor the trends, performing a scenario analysis. That's what we are doing right now. Without any failure, we would like to be flexible and easy to change. If there's a negative impact, we'd like to recover somewhere else. That's the stance we'd like to create for the Company. Specifically, according to my view and perspective, various impacts are being expected by various companies. But for us, for the time being, no negative impact. We don't have to assume, but still, it's going to be fine for us. That's how we are doing business right now.

Claus, anything to add?

Zieler [A]*: Yeah. I think in the generous agreement that we signed with the US administration, we were able to satisfy the expectations of the US government and maintain our access to the Medicaid population in the US with, as Naoki already said, a non-material impact to our business.

Ueda [M]: Understood. Thank you very much. That's all from me.

Kato [M]: Thank you. Next, UBS, Seki-san, please.

Seki [Q]: UBS, Seki is my name. Thank you very much for your explanation. I have two questions.

First, cost, how to think about SG&A expenses. In H1, with the sales revenue, 14-15% increase excluding FX impact and SG&A is almost flat. This means that for the commercial model, you don't need to invest for that because this is unlikely in other companies. For example, if this is true, then other companies are spending

too much money. Incremental SG&A return or other companies may be spending too much. What do you think about it?

Okamura [A]: Thank you for your question. I'd rather refrain myself from comparing with other companies. But what I can say here is that XTANDI, that is JPY950 billion sales per year. That kind of product that we have, in that case, the discipline for the cost is going to be eased and relaxed. As a company, as a historical record, we had eased discipline for the cost management. We try to make it more tight. That's why the cost is not really increasing. That's my interpretation. Other companies are spending too much or Astellas found a very good method to deal with it, we don't interpret it that way.

Compared to our past, we are now more disciplined for cost management. With a small investment, we can bear the bigger return. That method, that is not really magic. We just made a very appropriate prioritization, and the new plan is leading to the execution. I think our approach is making success. That's what I understand.

Seki [Q]: Thank you very much. I think a consultant will make certain drawings. I'm looking forward to it.

Kitamura [A]: Kitamura speaking. Let me make additional comment. SG&A expenses, excluding ForEx impact, is flat, 0.3% reduction. Sales-wise, it's a 14% increase, excluding FX. Our management is working well. Looking in a mesh manner, we are increasing SG&A in some areas. For example, Strategic Brands like PADCEV. In other countries as well, we are doing line extension. For example, VEOZAH in Japan, we've done the submission, and same is applied for China. For that, we've done a lot of preparation. We spend money for the areas where we need to spend money, but there are other areas not needed to do so. We have to take a good balance. We reduced the spending, but no impact on the sales. With increasing the operational efficiency, then with increasing the productivity, we can reduce the expenses. We're doing such management. So SG&A-wise, it's flat YoY. It's not the one way of cost cutting. In that sense, we can say that our approach is working quite well.

Of course, we invest in the area where we need to invest. There are four pillars in SMT and one of them is increasing ROI and commercial marketing. For their commercial-related expenses, market access-related expenses, based upon the analysis of ROI, we make them or ship them to the higher level. We have to be smart for the investment and cost management. We have two approaches, and they are working quite well.

Seki [Q]: Thank you very much. The second question is about PADCEV. Peak revenue forecast is revisited. That is bladder-sparing, China excluded. VOLGA announced in ESMO, how do you see the impact of VOLGA? VOLGA is with Imfinzi when KEYTRUDA is used and used in neoadjuvant but not used for adjuvant. In terms of the PADCEV, could you explain the dynamics of plus and minus?

Zieler [A]*: Yeah. The VOLGA trial, that as you referenced was presented at ESMO was a long-awaited result from our end, and it actually strengthens the positioning of PADCEV in the perioperative space because we now have evidence in the cis-ineligible population that PADCEV not only works in combination with KEYTRUDA, but also with Imfinzi. This is a very important data point for doctors who may want to combine PADCEV in the future once VOLGA is approved and in the label with a different IO agent than KEYTRUDA. Of course, we don't have data yet in the cis-eligible population. The combination that we have in our label with KEYTRUDA covers the entire MIBC combination. That's a very strong data set, and that's why we are standard of care in that combination, both in the label and in our guidelines across the world. We don't expect VOLGA to materially impact the positioning of PADCEV, if anything, even strengthen the positioning of PADCEV in that space.

Seki [M]: Okay. Understood. Thank you.

Kato [M]: Thank you very much. Next, Morgan Stanley MUFJ Securities, Mr. Muraoka, please.

Muraoka [Q]: Thank you very much. Muraoka from Morgan Stanley.

Regarding the future concept of business results, I'd like to ask you a question. This may be a nearsighted view, but on a quarterly basis, how should we look at your core operating profits? As was explained, January - March period, XTANDI price will decline. Nothing we can do about it. But I've heard about Q3. Some people may refrain from purchasing. Core operating profit in Q3 and Q4, the level of Q1 may be difficult to be exceeded if you look at the quarterly basis. That's how I feel.

Next year, in August, the patent is going to expire in the United States. April - June, July - September, quarterly operating profit will decline on a quarterly basis. Should I think that way? Or because of the growth of the five strategic brands, it can be offset? Sorry for a vague question. I know that. Any advice you can give to me?

Okamura [A]: I'd like to analyze through an analysis or by disintegrating this. The quarterly XTANDI sales in the United States, as you said, because of the repricing, some may decide not to purchase. They may want to purchase after the price decrease. Such US dynamics, I'd like to hear the view from Claus.

Zieler [A]*: I think that Naoki, you've hit the nail on the head, right? The transition from Q3 into Q4, with what will the urologist in the US purchase and how much inventory will they hold just before the price decrease from the IRA impact and after, is a little bit difficult to model. What we do know is that we have a strong momentum in the market going into Q3. That will continue. Then we will hit that wobble between Q3 and Q4. Then things are expected to stabilize after the IRA price impact then becomes clearer.

As you correctly mentioned, the next inflection point then is in August of 2027, in FY2027, when XTANDI loses its exclusivity in the United States. Let me just remind you that at that point, we will not only start seeing generics enter and thereby erode the revenue of XTANDI in the US, but that will also then start affecting our profit share agreement with Pfizer. Remember, in the US specifically, we have a 50/50 profit split with Pfizer due to our co-promotion agreement in that market. Not all of the revenue that is lost will be on our account. It will be shared on a profit basis with Pfizer. That does introduce an element that dampens the impact of the US erosion for our bottom line.

Okamura [A]: Thank you, Claus. US XTANDI behavior is taken into account. Based on that, on a QoQ basis, what is going to happen to the core operating profit? This is not something to be disclosed on a quarterly basis, but Kitamura may want to say something. Kitamura, please.

Kitamura [A]: Thank you. Muraoka-san, I would like you to have a bit longer perspective. Probably, there are about four major dynamics. First of all, Strategic Brands. There's PADCEV and how these brands are going to be grown. Growth curve is one thing. XTANDI, IRA, with a longer perspective, we have IRA and LOE and the transitions of them. The third dynamic is what we want to do in a good manner. That is R&D acceleration. We will make the sufficient investment for them. As has been pointed out a little while ago, acceleration of the enrollment of the patients. In a word, acceleration for the growth investment and also the cost optimization or SMT and the speed of cost optimization. These four are intertwining each other to come up with a forecast.

For this, in a short-term perspective, which one is going to be which strength and what level of the speed? Well, that is the important point. Those are all important things. But within this CSP2026, we would like to double Strategic Brands and the cost is optimized and investment is accelerated so that we can increase the size of the sales of the pipeline for the future. That is in our mind for our business management. It would be really great if you could have a bit longer-term perspective.

Muraoka [Q]: I'm sorry about that. I have another question. This might be also shortsighted. But today, we had the interim election in the United States, and the democratic parties took the majority now. I haven't done, I believe, simulation yet. But based upon this result or in the industry as a whole or your company-wise, whichever we find, because of this result, you would see this type of opportunities increased or risk will be increased. If you could share with us something with that regard, that will be really helpful.

Okamura [A]: Thank you very much for your question. Even Muraoka-san, you cannot do the analysis, right? That's why it's very difficult for us to mention something. However, under the Trump administration, affordability and also innovation-free right is now acceptable. That position, well, regardless, the administration or who takes the administration, which part is going to be the majority, in a long-term perspective, I think that part wouldn't be changed probably. However, as specific measures, where will be the forecast to introduce the measures with that point, that is probably in the case of Democrats, democratic parties. Probably they would go more toward the affordability with a wider scope, so they will introduce the measures accordingly. Then relationship with our pipelines and our product mix, that's the matter.

What I want to say is what type of speculation wouldn't be done in ourselves so we wouldn't prepare for that. We do analysis of the scenario so that we can be quick and resilient enough at the time when something happened. Yes, that's always what we think about. But at this moment, Democratic Party is majority so it's likely to be this. That's why we have to prepare this. I'm not thinking about doing something like that. In the United States and the government affairs, we have teams that specialize in analysis on that. I'm sure that they are going to do the analysis and they're looking at that result. The management will think about what is to be done based upon the pros and cons and execute them and make them as the measures. Counting the vote has been progressing, but it's not been ended. It might take long to settle down. I'm not thinking we'll do something right after this from the next day.

Muraoka [M]: Thank you very much. It was very good information for me. Thank you.

Kato [M]: Thank you. Next, Nomura Securities, Matsubara-san, please.

Matsubara [M]: Matsubara speaking. Can you hear me?

Kato [M]: Yes, we can hear you.

Matsubara [Q]: Thank you very much. Thank you for the presentation. Operating profit, 30% to be achieved. Congratulations on the good results. I would like to ask you a question about the market in China. In FY2025, you changed the sales strategy in China, and there was variability among quarters. There are profits in Q3 and not much in Q2. But this time, PADCEV, VYLOY profits are booked for Q2 as well. Any change in the trend or dynamics?

Zieler [A]: No, no change in the dynamics. What you're probably seeing is the fact that on the new launched products, specifically VYLOY and PADCEV, we book our sales in China when we import into the country. That's a different model that we have for the time being versus the older products where we book as is normal. We would book when we sell to a wholesaler. That introduces, of course, volatility in the numbers we report for China for the newly launched products because we ship in batches into the country. But when you look at data that is our sales to wholesalers, so the local sales, that's very much a smooth trend and very much on track with our expectations in China. There's a difference between the numbers that you see and the numbers that we see internally simply because we have a different model in the newly launched products in terms of how we book and how we report our sales.

Matsubara [Q]: Thank you very much. My second question is about DAX-044. You exercised the exclusive option. Some time has passed. You're changing from cold tumor to hot tumor. I think this can be an interesting program. When you exercise the option right, tumor-specific action is seen, like cytokine storm is not going to occur so much according to the description. That round of the MOA and also your non-clinical data, what about the synergy and how you can apply this technology?

Okamura [M]: Before I respond, DAX-044 is the topic of your question, right?

Matsubara [M]: Yes, DAX-044.

Okamura [A]: I'd like to make a correction. We just got the option right. Exercising the option right is going to happen in the future, perhaps. Audax is going to conduct clinical studies in Australia mainly. We will see the results to decide whether to exercise the option right or not for licensing. Is that clear? We have not exercised the option right yet.

Matsubara [M]: Okay. Understood.

Okamura [M]: Based on this assumption, regarding the scientific question, Taniguchi is going to explain.

Taniguchi [A]: Regarding DAX-044 by Audax, IL-12 antibody, as you know, there is an effect of immune activation for the future. Cold tumor may be effective. This may be effective in cold tumor. But if this is administered systemically, cytokine syndrome and other various side effects may occur as we can tell. It was difficult to put this to practice. Audax has new technologies which we want to use to have a protein or antibody to be bound to cytokines in the blood to prevent the adverse events or adverse reaction. When it reaches the area around the tumor, IL-12 effect can be seen by this technology.

The target is cold tumor first. PD-1 and other checkpoint inhibitors were difficult to demonstrate effectiveness in these tumors, and we can expect how much effect we can see with this product based on our pipeline. Needless to say, T-cell engagers are what we have. Combination with T-cell engagers can be promising for the future. Needless to say, PD-1 products, PD-L1 products and antibodies as well, there are many of them in the market. Combination with them can be a possibility into the future. First of all, as Okamura explained, Audax Phase I study results is something we'd like to see. In what kind of patients and what is going to be the target tumor and what is going to be the combination it would work best, we'd like to consider those points. We will decide whether to exercise our option right or not. We would like to make a comprehensive decision.

Matsubara [M]: Thank you for your explanation. That's all from me. Thank you.

Kato [M]: Thank you very much. Next, Sanford C. Bernstein, Sogi-san, please.

Sogi [Q]: Thank you very much. My first question is about PADCEV and the bladder-sparing MIBC trial currently under development. Could you explain what kind of patients will be targeted in this trial? Are these Stage II patients? Also, approximately what percentage of MIBC patients would be eligible for this treatment?

Taniguchi [M]: Thank you. Taniguchi will explain.

Taniguchi [A]: The indication for bladder-sparing targets MIBC patients, and we have just started the study. For MIBC, we have the PADCEV and pembrolizumab combination, followed by cystectomy and adjuvant treatment with PADCEV and pembrolizumab. We expect these types of treatment to be increasingly adopted.

One of the greatest challenges for patients with bladder cancer is the significant impact on quality of life associated with cystectomy. That is why we started this study to explore whether the bladder can be preserved.As I mentioned, the target population is patients with MIBC. In this trial, we are initially targeting patients who are not eligible for cystectomy or who decline cystectomy. We have now started enrolling these patients.

Sogi [Q]: If that is the case, among MIBC patients, approximately what percentage would be ineligible for cystectomy or decline cystectomy?

Taniguchi [M]: Claus will provide some additional explanation regarding the specific patient population.

Zieler [A]*: Yes. Thank you for the question, Sogi-san. The way to think about it is, as Tadaaki explained, if we can obtain a label for PADCEV in a bladder-sparing setting, it would extend the duration of PADCEV treatment in the MIBC setting, particularly in the perioperative setting before cystectomy. We expect this to result in a significant extension of treatment duration. That would be very attractive, of course, both for patients who want to preserve their bladder and from the perspective of PADCEV use.

Now, you have to remember that MIBC represents a minority of PADCEV use. We have always been very transparent that we see MIBC as an opportunity to add approximately 20% to the PADCEV business. The main opportunity remains first-line PADCEV in metastatic urothelial cancer. Within the MIBC setting, commercially speaking, we expect the bladder-sparing approach to significantly extend the duration of treatment.

Sogi [Q]: Thank you. My next question is about Claudin 18.2. You are developing both an ADC and a T-cell engager targeting Claudin 18.2, while other companies have also reported favorable results with Claudin 18.2 ADCs. How are you thinking about the different development approaches for the T-cell engager and the ADC?

Okamura [A]: Thank you for your question. I'll start, and if any additional explanation is needed, our specialists can add to it.

The target population for VYLOY is patients with high Claudin 18.2 expression, specifically those with expression of 75% or higher. With ASP2138, our T-cell engager, we see the greatest value in potentially bringing Claudin 18.2-targeted therapy to patients with relatively lower expression levels, including those with low to medium expression.

In addition, by administering ASP2138 subcutaneously, we hope to provide greater convenience for patients and healthcare professionals. At the same time, one of the key challenges with T-cell engagers is excessive T-cell activation. Our working hypothesis is that subcutaneous administration may help mitigate such excessive activation. That is one of the key ways we see differentiation between VYLOY and ASP2138.

When it comes to ADCs, we should not speculate before seeing the actual clinical data. However, based on the clinical and preclinical data we have obtained for ASP546C, what we would ideally like to achieve is a treatment that does not require combination with chemotherapy. If Claudin 18.2-targeted ADC therapy alone could treat the disease, we believe that would be a significant benefit for patients. We are designing our clinical studies with that potential differentiation in mind.

So, as shown on the slide, VYLOY and ASP2138 could expand the patient population we can address, and then, if ASP546C could enable a chemo-free regimen, we believe that would be an ideal outcome for patients.

Anything to add?

Taniguchi [A]: Naoki Okamura has covered most of the points, but I think there is something somewhat unique about ASP2138 as a T-cell engager.

With an ADC, the targeted antibody is conjugated with a payload such as a topoisomerase inhibitor, which then acts on the targeted tumor. In the case of a T-cell engager, the CD3 component activates T cells, potentially enhancing the immuno-oncology effect and, in our view, offering the possibility of extending OS.

Of course, we still need to see the actual data. But in the Phase Ib study that formed the basis for the LUCERNA study, the combination of VYLOY and a PD-1 inhibitor showed improvements in PFS and OS. Looking ahead, one area of particular interest is how much the combination of the CD3 component of a T-cell engager with a PD-1 checkpoint inhibitor could contribute to extending survival.

Over the longer term, as Naoki Okamura explained, we would like to advance ASP546C, our Claudin 18.2-targeted ADC, into earlier lines of treatment and potentially establish a chemo-free regimen. This is still in Phase I, so as the data become available, we will evaluate whether that is feasible. Ultimately, we hope to enable the most appropriate treatment for gastric cancer to be selected for each individual patient.

Sogi [Q]: Thank you. Just one follow-up question. With VYLOY and ASP2138, the target patient populations appear to be relatively clearly differentiated based on the level of Claudin 18.2 expression. ASP546C is still in the early stages of development, but is it broadly correct to think that its target population could overlap with the populations targeted by both VYLOY and ASP2138?

Zieler [A]*: Let me put it this way. The VYLOY target population represents approximately 35% to 40% of gastric cancer patients and includes patients with Claudin 18.2 expression of 75% or higher. At present, we are only able to treat approximately 35% to 40% of the Claudin 18.2-positive population.

ASP2138 could open up an additional approximately 35% of patients, namely those with low to medium Claudin 18.2 expression. ASP546C could potentially address a broader patient population with a chemo-free regimen. That's how you should think about the target populations.

Sogi [M]: Thank you very much.

Kato [M]: Thank you very much. Many people are still raising their hands, but the time has come. With this, we'd like to close today's explanatory meeting here.

Thank you very much for the many questions and thank you for your attendance as well.

[END]

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