Astellas Pharma Inc.

Financial Results for FY2023

April 25, 2024

Event Summary

[Company Name]	Astellas Pharma Inc.
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[Venue]	Webcast
[Number of Speakers]	6

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Tadaaki Taniguchi	Chief Medical Officer (CMO)
Atsushi Kitamura	Chief Financial Officer (CFO)
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Presentation

Ikeda: Thank you very much for joining our FY2023 analyst call despite your busy schedule. I'm Chief Communications and IR Officer, Ikeda. I would like to serve as the moderator for today.

Today, we'll make a presentation that is followed by a Q&A session. The material is available on our website. In line with that, we are going to give you the presentation including the Q&A. The simultaneous translation of Japanese to English is provided. The accuracy of the translation is not going to be guaranteed by us. As for the language from the Zoom webinar screen, on the menu, you can find the language. When you select the original language in that case, you can listen to it without using the translation service.

The material or presentation and answers and statements by representatives for the Company in the Q&A include forward-looking statements based on assumptions and beliefs in light of the information currently available to manage and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors. They contain information on pharmaceuticals, including compounds under development, but this information is not intended to make any presentations or advertisement regarding the effectiveness of these preparations.

The participants here today are Representative Director, President and CEO, Naoki Okamura; CScO, Chief Scientific Officer, Yoshitsugu Shitaka; Chief Medical Officer, CMO, Tadaaki Taniguchi; Chief Commercial Officer, CCO, CEO, Claus Zieler; Chief Financial Officer, CFO, Atsushi Kitamura. We have five here as representatives of the Company.

Now, Okamura-san, please start your presentation.

Okamura: Hello, everyone. I'm Naoki Okamura from Astellas Pharma Inc. Thank you very much for joining our FY2023 financial results announcement meeting out of your very busy schedule today.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.

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

AGENDA

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I FY2023 Consolidated Financial Results

II Initiatives for Sustainable Growth

III FY2024 Forecast
CSP2021 Outlook

CSP: Corporate Strategic Plan

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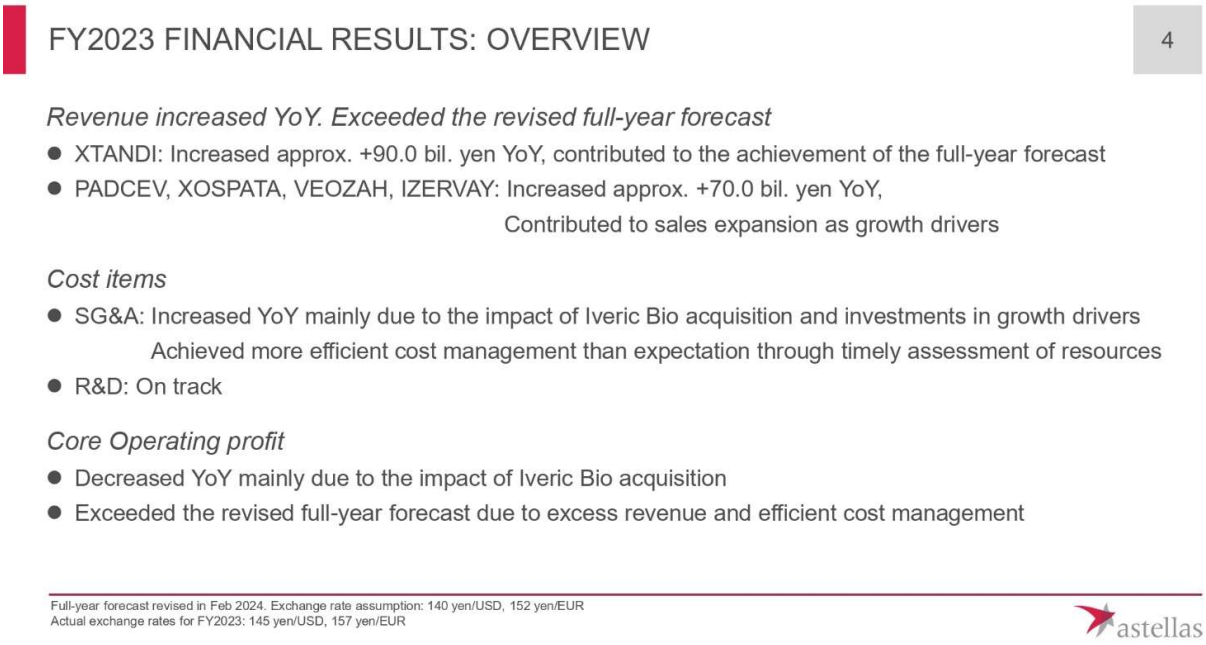
Page three is the agenda for today. Starting from the next page, I will explain these topics in this order.



On page four, I will give you an overview of FY2023 financial results.

Revenue increased YoY and exceeded our full-year forecast revised in Q3. XTANDI sales increased by about JPY90 billion YoY, contributing to the achievement of a full-year forecast. Sales of PADCEV, XOSPATA, VEOZAH, and IZERVAY combined increased by about JPY70 billion YoY, contributing greatly to sales expansion as growth drivers.

SG&A costs increased YoY, mainly due to the impact of the Iveric Bio acquisition and investments in growth drivers. We achieved efficient cost management through timely assessment of resources. R&D expenditure was on track.

Operating profit decreased YoY, mainly due to the impact of the Iveric Bio acquisition. On the other hand, core operating profit exceeded the full-year forecast revised in Q3.

FY2023 FINANCIAL RESULTS

(billion yen)	FY2022	FY2023	Change	Change (%)	FY23 FCST	Achievement	FX impact (YoY)
Revenue	**1,518.6**	**1,603.7**	**+85.1**	**+5.6%**	**1,562.0**	**102.7%**	+96.3
Cost of sales	288.4	292.5	+4.1	+1.4%			+15.8
% of revenue	19.0%	18.2%	-0.7 ppt				
SG&A expenses	630.3	740.1	+109.8	+17.4%	731.0	101.2%	+44.3
US XTANDI co-pro fee	175.5	194.9	+19.4	+11.0%	187.0	104.3%	+12.2
SG&A excl. the above	454.8	545.2	+90.5	+19.9%	544.0	100.2%	+32.0
R&D expenses	276.1	294.2	+18.1	+6.5%	286.0	102.9%	+12.5
Amortisation of intangible assets	38.4	98.8	+60.4	+157.1%			Note) Amortisation of IZERVAY's intangible assets started from Q2
Gain on divestiture of intangible assets	0.2	9.7	+9.5	-			
Core operating profit	**286.9**	**184.6**	**-102.3**	**-35.6%**	**164.0**	**112.6%**	+19.1
<Full basis>							Other expenses (booked in Q4)
Other income	3.6	8.7	+5.0	+138.7%			• Impairment loss for intangible assets : 56.3 (AT808: 39.9, EVRENZO: 16.4)
Other expenses	157.5	167.8	+10.3	+6.5%			• Fair value increase of contingent consideration (zolbetuximab)*: 8.0
Operating profit	**133.0**	**25.5**	**-107.5**	**-80.8%**	**13.0**	**196.3%**	
Profit before tax	132.4	25.0	-107.4	-81.1%	12.0	208.1%	
Profit	**98.7**	**17.0**	**-81.7**	**-82.7%**	**3.0**	**568.2%**	

Full-year forecast revised in Feb 2024, full basis forecast revised on 12th Apr 2024. The Exchange rate assumption: 140 yen/USD, 152 yen/EUR
Actual exchange rates for FY2023: 145 yen/USD, 157 yen/EUR
*Booked due to updates to the clinical development plan for pancreatic cancer and FX impact

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On page five, I will explain the FY2023 financial results.

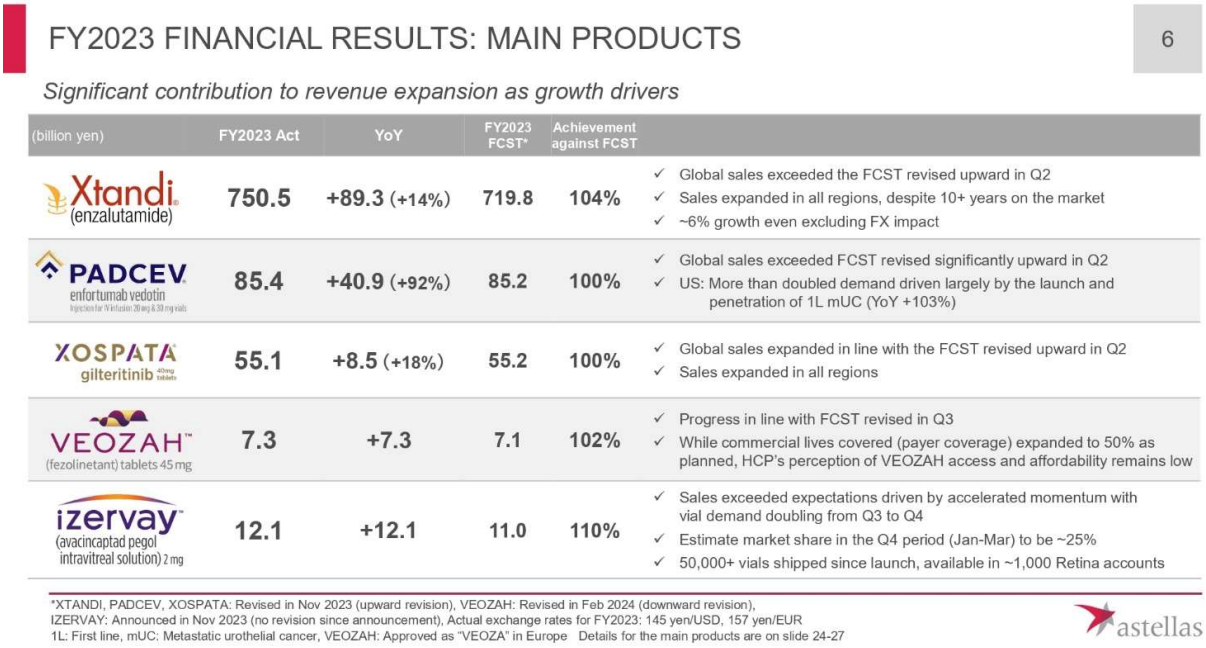
Revenue increased to JPY1,603.7 billion, up 5.6% YoY. We achieved 102.7% of our full-year forecast.

Core operating profit was JPY184.6 billion, down by 35.6% YoY. We achieved 112.6% of our full-year forecast.

You can see the forex impact on the right-hand side of the table. There was a positive impact on revenue by JPY96.3 billion and on core operating profit by JPY19.1 billion.

The bottom half of this page shows the full basis results. In the right bottom of the table, we included other expenses booked in Q4. We booked JPY56.3 billion impairment loss for intangible assets of AT808 and EVRENZO. In addition, we booked JPY8 billion due to fair value increase of contingent consideration for zolbetuximab.

As a result, operating profit was JPY25.5 billion, down by 80.8% YoY. Profit decreased to JPY17 billion, down 82.7% YoY.



On page six, I will explain the FY2023 financial results of our main products.

First, about XTANDI. Sales expanded in all regions despite more than 10 years on the market. Global sales increased to JPY750.5 billion, up by about JPY90 billion or 14% YoY. Even excluding forex impact, XTANDI achieved about 6% growth YoY.

In the United States, which is the biggest market, based on EMBARK study results, M0 CSPC additional indication was approved in November last year. We have been able to confirm the penetration of this additional indication and the ripple effect on other indications as well. Volume, excluding the so-called PAP, patient assistance program, grew steadily by 4% YoY.

PADCEV's global sales increased to JPY85.4 billion, up by 92% YoY, realizing nearly two-fold growth. Performance was in line with our full-year forecast, which was revised significantly upward by nearly JPY20 billion in Q2.

In the United States, the market penetration of the first-line indication was a major driver. Demand more than doubled YoY. Also, NCCN Guidelines, which many physicians are referring to when they decide prescription, were updated last month. The level of recommendation for PADCEV as a first-line treatment of mUC was upgraded from Category 2 to the highest recommendation level, Category 1. Globally, as a whole, the number of launched countries is increasing steadily. In FY2023, PADCEV was launched in additional 14 countries. The number of launched countries had expanded to 36 in total by now.

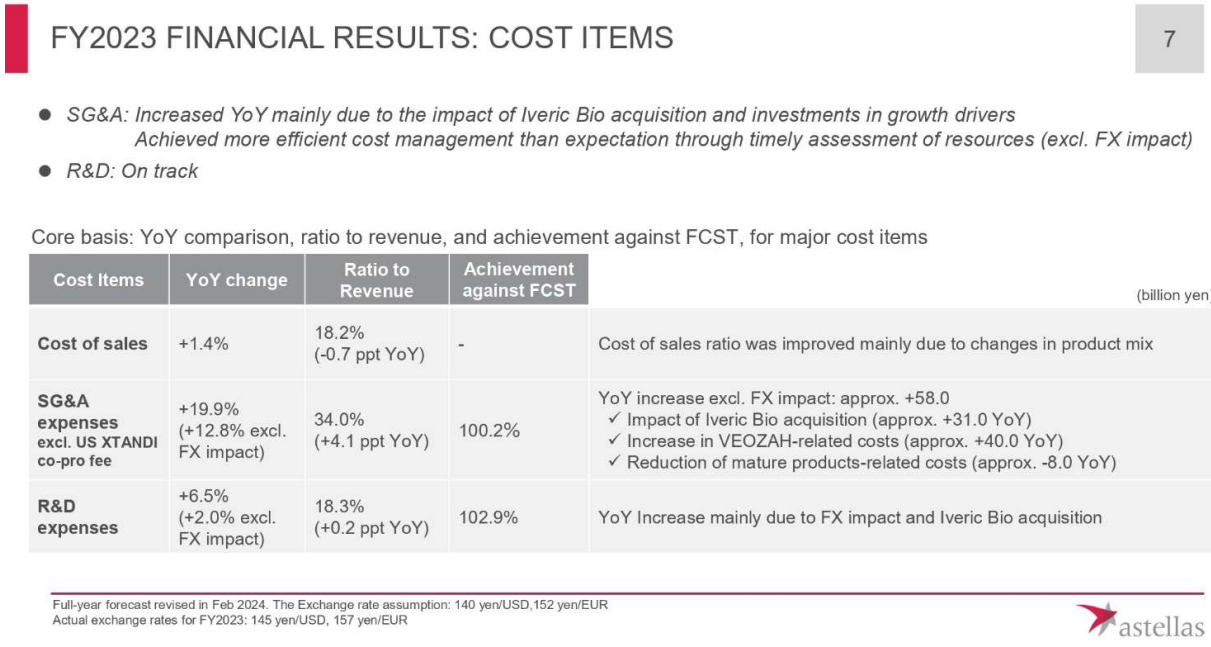
Regarding XOSPATA, global sales increased to JPY55.1 billion, up 18% YoY. Sales expanded in all regions, in line with the full-year forecast revised upward in Q2.

Sales of VEOZAH reached JPY7.3 billion, progressing in line with the forecast revised in Q3. Commercial lives covered, payer coverage, an important KPI for market access, expanded to 50% as planned as of the end of March. On the other hand, HCP's perception of VEOZAH's access and affordability remains low, which is a barrier to prescription. I will talk about our future initiatives and outlook when I explain the FY2024 forecast.

IZERVAY is growing at a speed faster than our expectations. Sales reached JPY12.1 billion, exceeding the full-year forecast we announced after the launch in September last year. Accelerated momentum continues and vial demand doubled from Q3 to Q4. We estimate market share in the Q4 period to be about 25%, calculated based on the reported shipment volume data as well as multiple market research.

Given the fact that our competitive product was launched about six months earlier, we think this is a great achievement. More than 50,000 vials have been shipped since launched, and IZERVAY is now available in about 1,000 Retina accounts. Post-marketing safety profile is reported to be consistent with the results of the clinical study so far. The number of physicians highly evaluating the safety profile of IZERVAY is increasing steadily.

Sales of PADCEV, XOSPATA, VEOZAH, and IZERVAY, as mid- to long-term growth drivers, increased by about JPY70 billion in total YoY. We're expecting further growth into the future as well.



FY2023 FINANCIAL RESULTS: COST ITEMS

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- *SG&A: Increased YoY mainly due to the impact of Iveric Bio acquisition and investments in growth drivers*
  Achieved more efficient cost management than expectation through timely assessment of resources (excl. FX impact)
- *R&D: On track*

Core basis: YoY comparison, ratio to revenue, and achievement against FCST, for major cost items

(billion yen)

Cost Items	YoY change	Ratio to Revenue	Achievement against FCST	
Cost of sales	+1.4%	18.2% (-0.7 ppt YoY)	-	Cost of sales ratio was improved mainly due to changes in product mix
SG&A expenses excl. US XTANDI co-pro fee	+19.9% (+12.8% excl. FX impact)	34.0% (+4.1 ppt YoY)	100.2%	YoY increase excl. FX impact: approx. +58.0 ✓ Impact of Iveric Bio acquisition (approx. +31.0 YoY) ✓ Increase in VEOZAH-related costs (approx. +40.0 YoY) ✓ Reduction of mature products-related costs (approx. -8.0 YoY)
R&D expenses	+6.5% (+2.0% excl. FX impact)	18.3% (+0.2 ppt YoY)	102.9%	YoY Increase mainly due to FX impact and Iveric Bio acquisition

Full-year forecast revised in Feb 2024. The Exchange rate assumption: 140 yen/USD,152 yen/EUR
Actual exchange rates for FY2023: 145 yen/USD, 157 yen/EUR

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On page seven, I will explain cost items.

Cost of sales ratio was 18.2%, improving by 0.7 percentage points YoY, mainly due to changes in product mix. It was on track.

SG&A cost, excluding US XTANDI co-promotion fees, increased by 19.9% YoY. When forex impact was excluded, the YoY increase was 12.8% to about JPY58 billion. As many factors behind, SG&A costs increased by about JPY31 billion YoY. Due to the impact of Iveric Bio acquisition, VEOZAH-related sales promotion costs rose by about JPY40 billion YoY. On the other hand, sales promotion costs related to mature products, such as mirabegron, decreased by about JPY8 billion YoY. We achieved efficient cost management through a timely assessment of resources.

R&D expenditure increased by 6.5% YoY, mainly due to forex impact and Iveric Bio acquisition. We were on track in our spending.

From here on, I will explain our initiatives for sustainable growth.

INITIATIVES FOR SUSTAINABLE GROWTH: OVERVIEW OF QUARTERLY UPDATES

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XTANDI and Strategic products

- enzalutamide / XTANDI : Approval for M0 CSPC* indication (Europe)
- enfortumab vedotin / PADCEV : Acceptance of application for 1L mUC (China)
- zolbetuximab / VYLOY : Approval (Japan)
- fezolinetant / VEOZAH : Phase 3 studies initiated (Japan), Phase 3 study for additional indication under preparation
- avacincaptad pegol / IZERVAY : Acceptance of application for label update (US)

Focus Area approach

- Phase 1 entry : ASP2016 (Genetic Regulation), ASP2802 (Immuno-Oncology), ASP4396 (Targeted Protein Degradation)
- Progress of clinical study : ASP2138 dose expansion cohort in Phase 1 study initiated
- Project termination : ASP2074 (Immuno-Oncology), ASP0367 (Mitochondria)
- Dissolution of Primary Focus Mitochondria

Rx+ program

- BlueStar (Digital therapeutics for diabetes): Pivotal clinical study initiated (Japan)

VEOZAH: Approved as "VEOZA" in Europe
*with biochemical recurrence at high risk for metastasis.
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, 1L: First line, mUC: Metastatic urothelial cancer

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On page nine, you can find an overview of major quarterly updates related to R&D.

I will explain the details of XTANDI, strategic products, and focus area approach in the following slides.

In the Rx+ program, we initiated a pivotal study for regulatory submission in Japan for BlueStar: digital therapeutics for diabetes.

XTANDI AND STRATEGIC PRODUCTS: FY2023 KEY EVENTS

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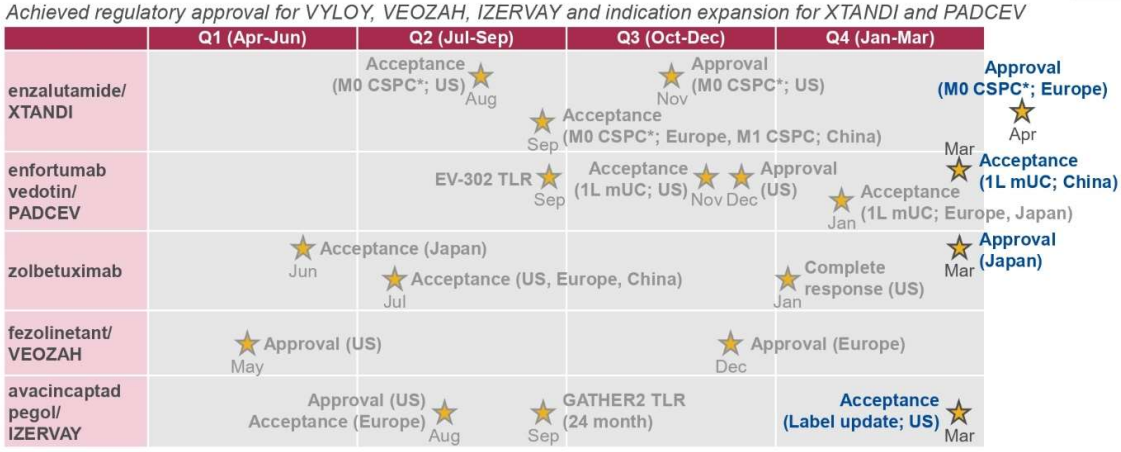
Achieved regulatory approval for VYLOY, VEOZAH, IZERVAY and indication expansion for XTANDI and PADCEV



<Other updates>

- fezolinetant / VEOZAH: FSFT in Phase 3 studies in Japan (STARLIGHT 2 / STARLIGHT 3) in Q4
  Phase 3 study for induced VMS in breast cancer patients on adjuvant endocrine therapy to start in Q2/FY2024

As of Apr 2024, VEOZAH: Approved as "VEOZA" in Europe
*with biochemical recurrence at high risk for metastasis. M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, M1: Metastatic, TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer, FSFT: First subject first treatment, VMS: Vasomotor symptoms

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On page 10, I will explain key events achieved in FY2023 for XTANDI and strategic products.

As an achievement in April, XTANDI was approved in Europe for the additional indication of M0 CSPC with biochemical recurrence at high risk of metastases based on the EMBARK study.

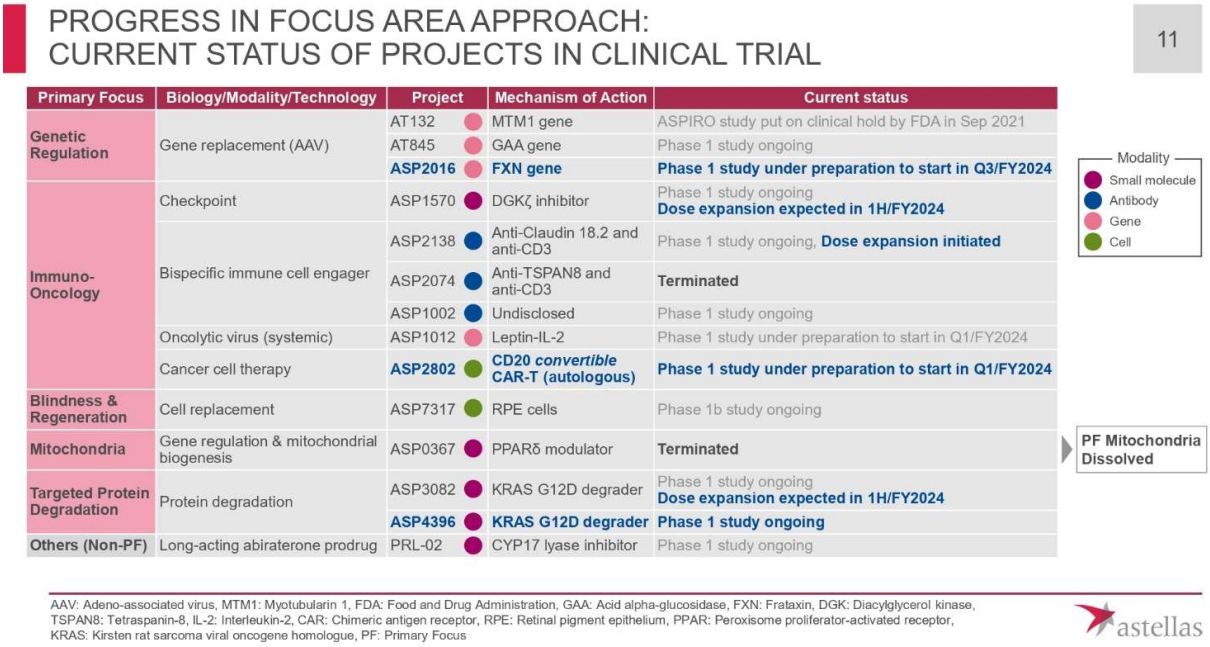
As for PADCEV, our submission in China was accepted in March for the additional indication of first-line locally advanced or metastatic urothelial cancer based on EV-302 study.

VYLOY was approved in Japan in March for CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer.

As for IZERVAY, our submission for label update was accepted in the United States based on a 24-month data from the GATHER2 study.

As for other updates, we achieved first subject first treatment in Phase III studies of VEOZAH, STARLIGHT 2 pivotal study for JNDA in Japan, and STARLIGHT 3 long-term safety study in Q4. Also, towards a new additional indication, we decided to perform a Phase III study for induced VMS in breast cancer patients on adjuvant endocrine therapy. We will give you an update after the specifics of the study are decided.

In FY2023, we achieved many important milestones, such as approval of VYLOY, VEOZAH, and IZERVAY, as well as approval of additional indications for XTANDI based on EMBARK study and PADCEV based on EV-302 study. We have made a lot of progress towards growth in FY2024 onwards.



PROGRESS IN FOCUS AREA APPROACH:
CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

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Primary Focus	Biology/Modality/Technology	Project	Mechanism of Action	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	GAA gene	Phase 1 study ongoing
		ASP2016	**FXN gene**	**Phase 1 study under preparation to start in Q3/FY2024**
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing **Dose expansion expected in 1H/FY2024**
	Bispecific immune cell engager	ASP2138	Anti-Claudin 18.2 and anti-CD3	Phase 1 study ongoing, **Dose expansion initiated**
		ASP2074	Anti-TSPAN8 and anti-CD3	**Terminated**
		ASP1002	Undisclosed	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	Phase 1 study under preparation to start in Q1/FY2024
	Cancer cell therapy	**ASP2802**	**CD20 *convertible* CAR-T (autologous)**	**Phase 1 study under preparation to start in Q1/FY2024**
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells	Phase 1b study ongoing
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	PPARδ modulator	**Terminated**
Targeted Protein Degradation	Protein degradation	ASP3082	KRAS G12D degrader	Phase 1 study ongoing **Dose expansion expected in 1H/FY2024**
		ASP4396	**KRAS G12D degrader**	**Phase 1 study ongoing**
Others (Non-PF)	Long-acting abiraterone prodrug	PRL-02	CYP17 lyase inhibitor	Phase 1 study ongoing

Modality: Small molecule, Antibody, Gene, Cell

PF Mitochondria Dissolved

AAV: Adeno-associated virus, MTM1: Myotubularin 1, FDA: Food and Drug Administration, GAA: Acid alpha-glucosidase, FXN: Frataxin, DGK: Diacylglycerol kinase, TSPAN8: Tetraspanin-8, IL-2: Interleukin-2, CAR: Chimeric antigen receptor, RPE: Retinal pigment epithelium, PPAR: Peroxisome proliferator-activated receptor, KRAS: Kirsten rat sarcoma viral oncogene homologue, PF: Primary Focus

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On page 11, I will explain the update for the past three months with regards to the progress of focus area approach projects in clinical trial. Primary focus projects, ASP2016 in genetic regulation, ASP2802 in immuno-oncology, and ASP4396 in targeted protein degradation, newly entered the clinical trial stage. I will explain the details of these projects on the following page.

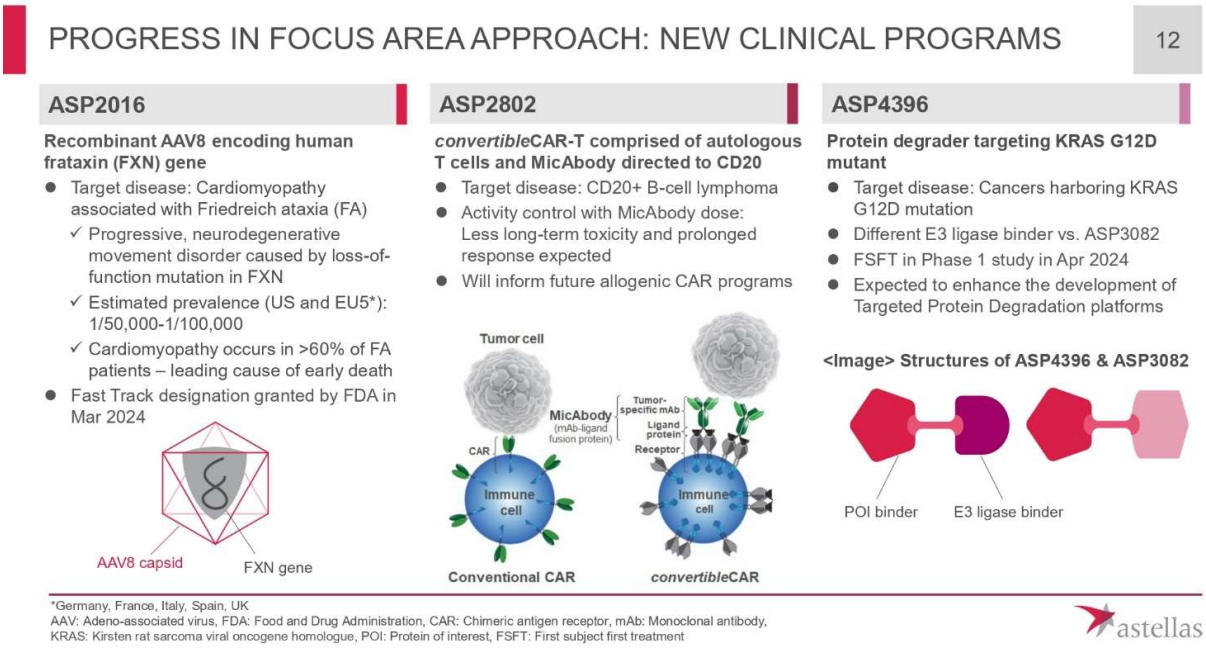
As for ASP1570, the first project described here for primary focus immuno-oncology and ASP3082 in targeted protein degradation, Phase I dose escalation monotherapy cohort is ongoing. For both, no major issues including safety have been observed by now. The study of recommended dose is ongoing. The initiation of dose expansion cohort as the next step is expected in H1 of FY2024.

As for ASP2138, the second from the top in immuno-oncology, dose expansion cohort has been initiated based on the data obtained from the Phase I dose escalation monotherapy cohort. We have not made any decision about data presentation plan at Congress and other forms for any of these yet. Once we make a decision, we will share that with you.

As for ASP2074, the third from the top in immuno-oncology, we decided to terminate the project based on the clinical study data obtained by now.

Regarding ASP0367 in primary focus mitochondria, we decided to terminate this program based on the clinical study data obtained by now. In this primary focus, multiple programs have been generated, but unfortunately, in any of these programs, we have not been able to demonstrate benefit in clinical study results.

Based on these circumstances, we decided to dissolve primary focus mitochondria. So far, we have obtained knowledge and experiences through drug discovery in mitochondria-related areas and new drug development for rare diseases. We will leverage this as important learnings and insights for evaluating disease areas where we will perform R&D in the future.



On page 12, I will explain new clinical programs.

ASP2016 is a recombinant AAV8 encoding human frataxin gene. This drug was created for cardiomyopathy as a target disease within AT808 gene therapy, R&D program for various symptoms of Friedreich ataxia patients. Friedreich ataxia is a hereditary disease caused by frataxin gene mutation. Currently, there is no curative treatment. More than 50% of the patients developed cardiomyopathy, which is a leading cause of death.

ASP2016 was granted Fast Track designation by US FDA in March 2024. We are hoping that a single dose will result in the long-term expression of frataxin in the heart to improve the disease conditions.

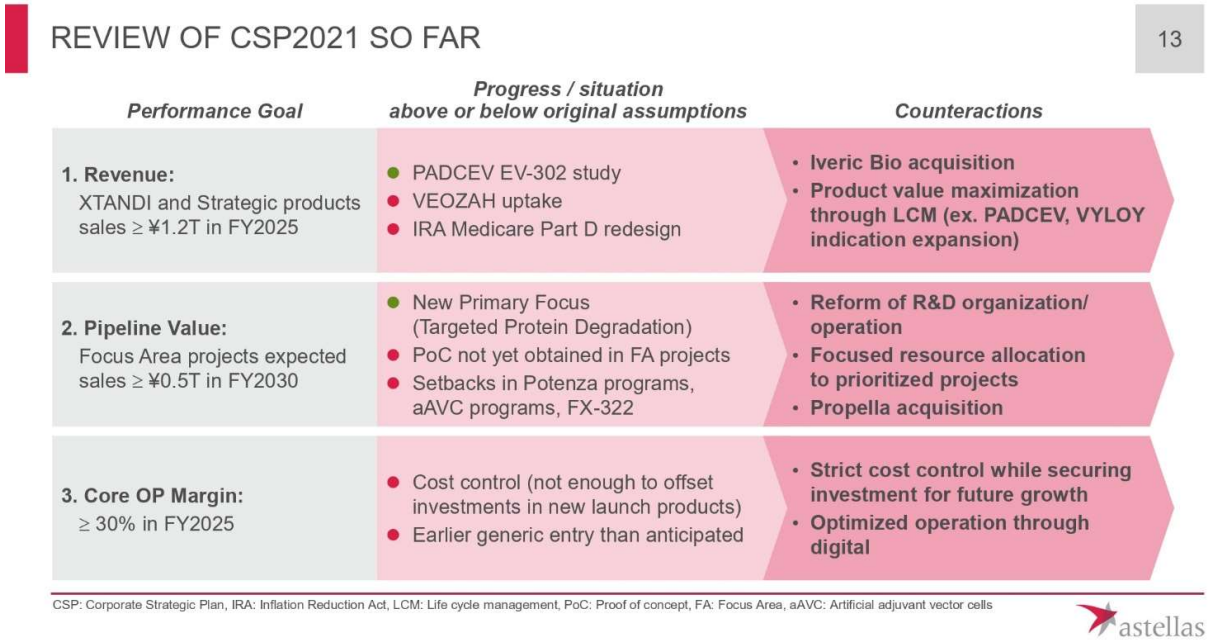
ASP2802 was created with Xyphos technology. This convertibleCAR-T therapy has entered the clinical trial stage for the first time. It is comprised of autologous T cells and MicAbody directed to CD20. MicAbody is a fusion protein which uses a tumor antigen recognizing antibody and an immune cell-binding ligand protein.

According to the convertibleCAR system, activity can be controlled with a MicAbody dose, so benefits such as less long-term toxicity and prolonged response are expected.

ASP2802, the first convertibleCAR program, uses autologous cells harvested from patients. We are hoping that these clinical studies will also inform the development of future allogenic off-the-shelf programs.

ASP4396 is a protein degrader targeting KRAS G12D mutant-like ASP3082. The target protein is the same with ASP3082 but the E3 ligase binder is different. With ASP4396, we achieved first subject first treatment in Phase I study in April 2024, just 50 days after the acceptance of IND by FDA. Generally speaking, it takes about three months so we achieved a much earlier timeline.

By proceeding with the clinical study and accumulating data in parallel with ASP3082, we are hoping that the development of targeted protein degradation platform will be enhanced.



On page 13, I'd like to review the progress of the corporate strategic plan, CSP2021, so far in line with the three performance goals.

As for performance one, we achieved extremely promising results in EV-302 study for PADCEV above our expectations, and we feel more confident about the significant growth in the first-line settings. On the other hand, VEOZAH uptake is below our original assumptions. In addition, as an external environment factor, Medicare Part D redesign will start from January 2025 as one of the measures by the so-called IRA, Inflation Reduction Act, in the United States, which was not included in our original assumptions. This is expected to impact XTANDI sales in the United States in the future.

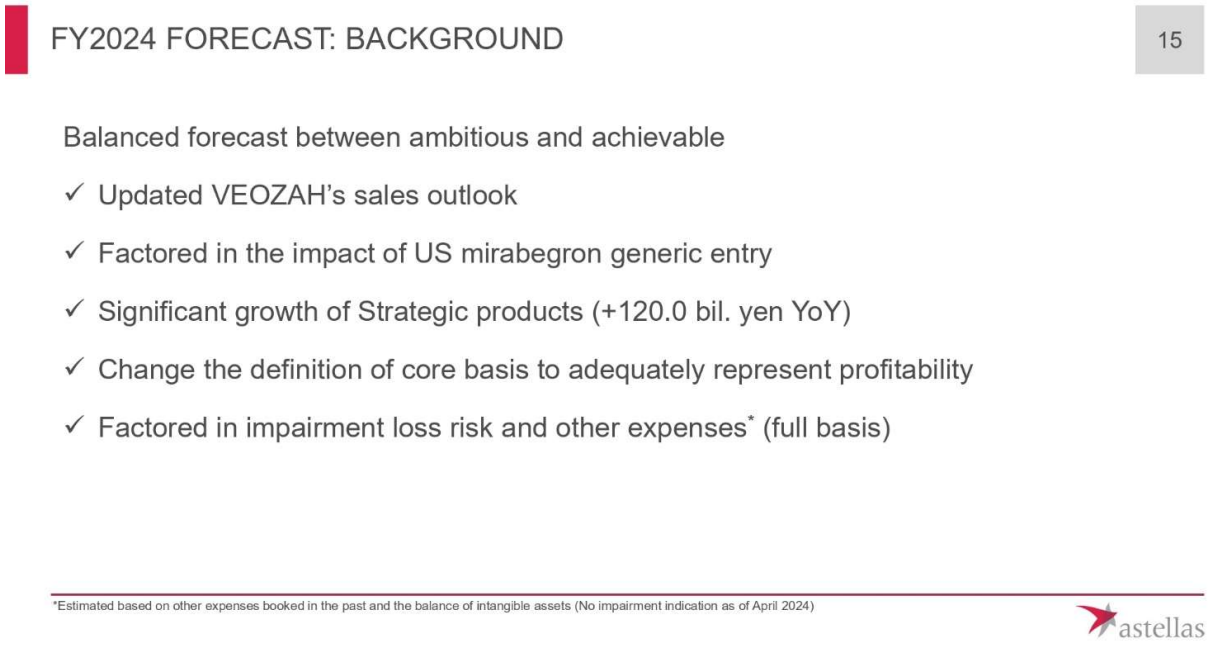
As a measure to secure revenue, we acquired Iveric Bio and our new growth driver, IZERVAY, which is growing at a speed higher than our expectations. Also, we are working on product value maximization through active life cycle management with indication expansion, including MIBC, muscle invasive bladder cancer, for PADCEV and pancreatic adenocarcinoma for VYLOY.

Regarding performance goal two, pipeline value, we started targeting protein degradation as a new primary focus, and multiple promising projects have been generated. On the other hand, PoC has not been obtained yet in focus area projects so far. We are hoping that programs such as Potenza, aAVC, and FX-322 would be launched early and contribute to revenue in 2030 as they were relatively as fast projects as of 2021, but we decided to terminate these programs as we could not obtain clinical study results showing benefit.

In R&D, we are implementing a major reform of the organizational structure and operation, further strengthening the focused resource allocation to prioritize projects and working on the acceleration of PoC judgment. Also, through the acquisition of Propella Therapeutics, we added to our pipeline, PRL-02, a next-generation androgen biosynthesis inhibitor, in order to be able to make up for the termination on the delay of early-stage development projects.

As for performance goal three, core operating profit margin, we were able to control cost to a certain extent, but we recognize it was not enough to offset investments in newly launched products. Lexiscan generics have been launched earlier than expected, and we cannot rule out the possibility of mirabegron generic launches at risk. This is resulting in a major impact on our core operating profit.

From now on, we will review the allocation of our management resources in a timely fashion and implement more stringent cost control while securing investment for future growth. We will focus on optimized operations through digital as well.



From here, I would like to explain about FY2024 forecast and CSP2021 outlook.

Slide 15. Before the FY2024 forecast, I will explain the background of making the plan.

Looking back at FY2023, because of the entry of Lexiscan generic, the increase of expenses due to the acquisition of Iveric Bio, the lower-than-expected progress of VEOZAH, as well as the booking of impairment losses and others, we have made multiple downward revisions on both the core and full basis, and the management takes very seriously the fact that we were unable to meet the expectations of the investors as

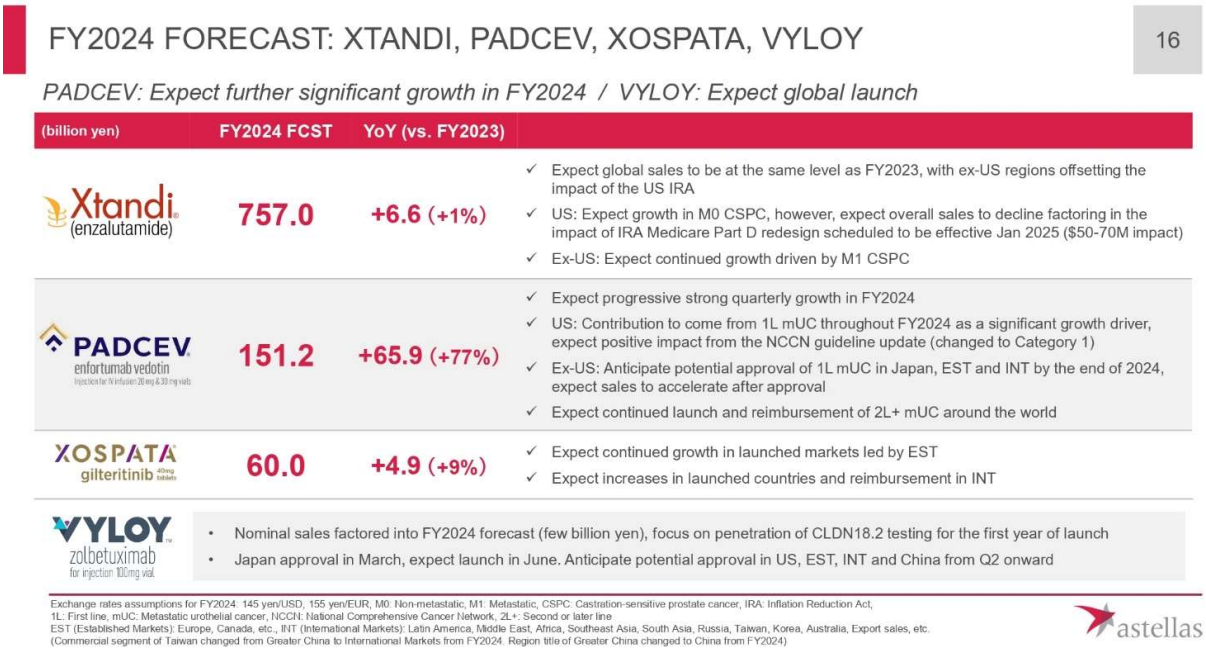
a result. Therefore, we have analyzed the various scenarios for our FY2024 forecast and formulated a more balanced plan that is both ambitious and achievable, taking into account risks and opportunities.

For the FY2024 forecast, we've done a lot of different scenario analysis. Taking into account risks and opportunities, we formulated a more balanced plan that is both ambitious and achievable. First, we updated our sales outlook for VEOZAH. As a result, we have been revising our peak sales forecast.

Next, we factored in the impact of generic entry of mirabegron in the US as we were aware that generic companies were already moving toward a market launch. We believe that the formulation patent for mirabegron is still valid and we will continue to focus on the dispute. On the other hand, we expect the impact of the entry of generic mirabegron in the US revenue to be offset by the full-fledged growth of strategic products.

In addition, we announced in the press release today that the definition of core basis has been changed to more adequately reflect the profitability from core business.

On a full basis, we factored in other expenses such as impairment loss in our initial forecast to reduce the impact of unexpected downward revisions during the period. There are no specific indications of impairment at this time, and the estimate is based on the other expenses recorded in the past and the balance of intangible assets. I will explain the details in the following slides.



Page 16, I will explain our outlook for oncology products in FY2024.

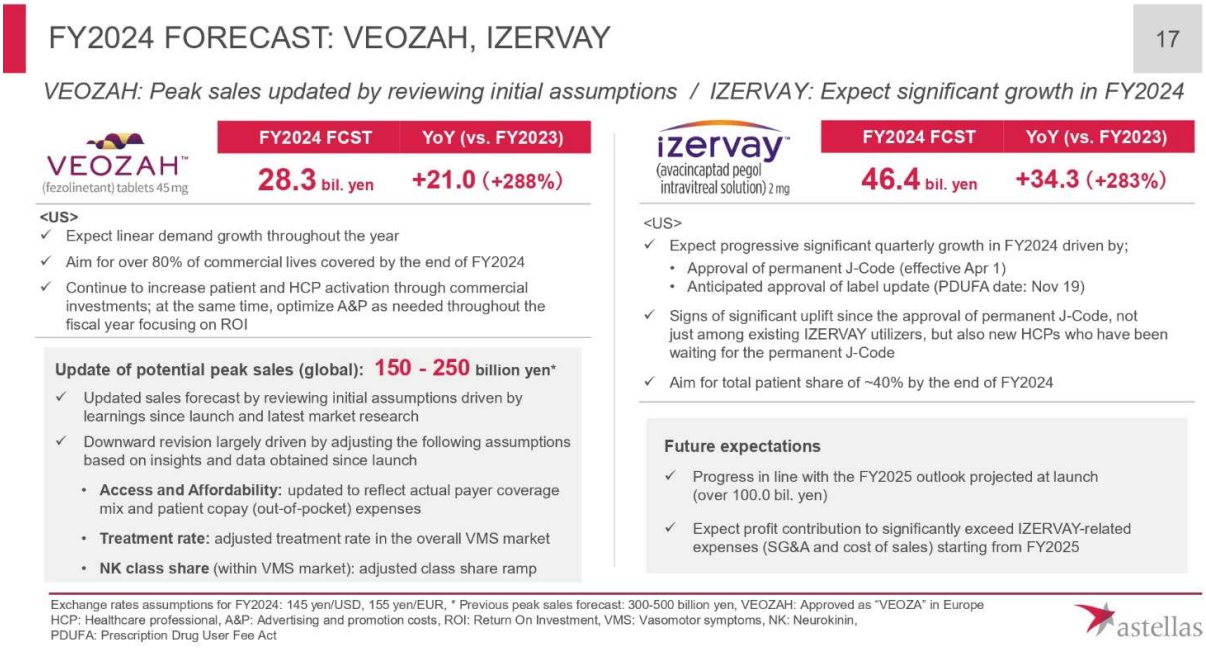
First of all, XTANDI. We expect XTANDI sales for FY2024 to be JPY757 billion, an increase of JPY6.6 billion YoY. Global sales are expected to be at the same level as FY2023, with ex-US offsetting the impact of the US IRA. While we expect growth in M0 CSPC prescriptions in the US, we anticipate a decline in the sales due to the three-month negative impact of IRA Medicare Part D redesign scheduled to be effective in January 2025. That is around USD50 million to USD70 million impact. Outside the US, we expect sales to continue to grow mainly due to the growth of M1 CSPC, metastatic castration-sensitive prostate cancer.

PADCEV for FY2024 is projected to be JPY151.2 billion, a significant increase of JPY65.9 billion YoY. We expect progressive strong quarterly growth throughout the fiscal year. In the US, we expect that first-line indications will make a full contribution from the beginning to the end of the fiscal year. We also expect logistic effects from the NCCN Guidelines updated in March, as I mentioned earlier, and aim to position it as a new standard of care in first-line treatment. Outside of the US, we anticipate the potential approval of an additional indication for first-line therapy based on the EV-302 trial in Japan, the established markets, and international markets by the end of the year, and sales are expected to accelerate in each region once approved. Continued launch and reimbursement of second line, and afterwards, around the world, is also expected.

XOSPATA's focus for FY2024 is JPY60 billion, an increase of JPY4.9 billion YoY. We expect continued growth in existing markets centered on growth in the established markets. In the international market, we expect an increase in launched countries and reimbursement, which we expect will contribute to sales.

VYLOY, which was approved in Japan last month, is factored in as a few billion yen in FY2024 forecast. In the first year of the launch, we will focus on the penetration of the CLDN18.2 testing, a new biomarker, so we expect a full-scale contribution to sales from FY2025 onwards. In Japan, we expect to launch in June. In the US established markets, international markets in China, the approvals are assumed to be in Q2 and onward, and we expect a contribution to global sales.

In addition, pages 24 through 27 of the appendix provide a summary of the FY2023 results and FY2024 forecast for each major product so you can easily compare them.



Slide 17 is our focus for VEOZAH and IZERVAY for FY2024 and beyond.

We expect the linear demand growth of VEOZAH throughout the year, with a forecast of JPY28.3 billion in FY2024, an increase of JPY21 billion YoY. We aim for over 80% of commercial lives as key KPI by the end of FY2024. Physician perception of market access is related to both the quantity and quality of access. And once negative perceptions are formed, it takes time to improve. While progress on access has steadily improved since Q3 of 2023, perceptions have yet to improve and it remains a barrier to prescribe VEOZAH.

Market research analysis indicates that a significant increase in coverage will improve perception so we will continue to make maximum efforts to expand coverage throughout the fiscal year. We'll also work to improve patient and HCP activation through necessary investments, including DTC. On the other hand, we will continue to optimize SG&A as needed while keeping ROI in mind.

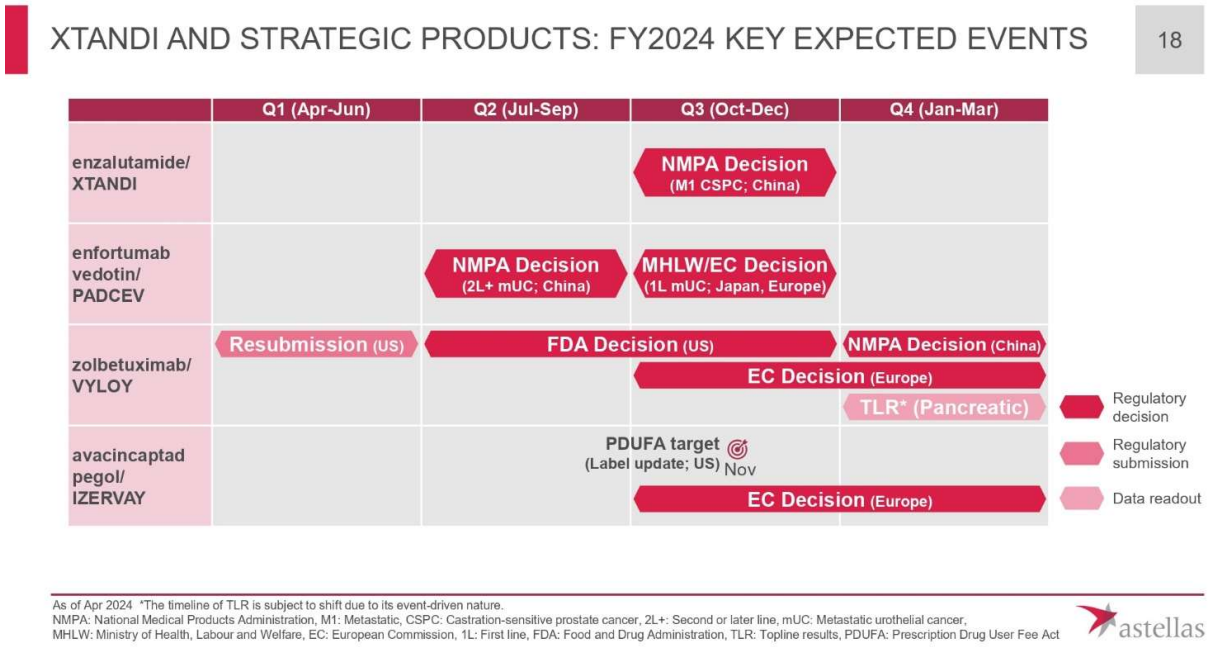
In addition to our FY2024 forecast, we have updated our peak sales forecast. Based on the learnings and data obtained since the launch in May last year as well as the latest market research, we have revised our initial assumptions and lowered our peak sales forecast from the previous range of JPY300 billion to JPY500 billion to the range of JPY150 billion to JPY250 billion. The original assumptions were based on prelaunch market research, but we've updated assumptions based on the findings and data obtained after the launch. Downward revision is mainly due to changes in assumptions for access and price sensitivity, treatment rate, and NK class share. For access, price, and safety, we have made more stringent assumptions to reflect the reality of plan type and patient sensitivity to price. The treatment rate focus has been revised downward to reflect the actual treatment rate in the VMS market as a whole, not just for VEOZAH. We have also changed our outlook for the share of the NK class in the VMS market that we expect to gain.

Although we have lowered our peak sales forecast, we still expect a potential of more than JPY150 billion, and we continue to see this as an important growth driver. We will take necessary actions to achieve new peak sales.

IZERVAY's focus for FY2024 is JPY46.4 billion, an increase of JPY34.3 billion YoY, and we expect full-scale sales expansion. The J-Code coverage was started on schedule on April 1, and we expect to update the label by the end of the fiscal year. We are confident in our ability to grow as we are already seeing signs of an increasing prescribing trend, not only from existing prescribers but also from physicians who began prescribing after waiting for J-Code coverage to become available.

In addition to our regular sales promotion activities, we will continue to conduct disease awareness campaigns aimed at expanding the market and increasing awareness of the IZERVAY brand. We expect quarterly sales growth throughout the fiscal year, and we are targeting a total patient share of about 40% by the end of FY2024.

Finally, the future outlook. We are focusing, as expected, toward our focus of JPY100 billion or more for FY2025, which we announced in our Q2 results. We expect sales to significantly outpace expenses, and we look forward to a full-fledged contribution to profits in the future.



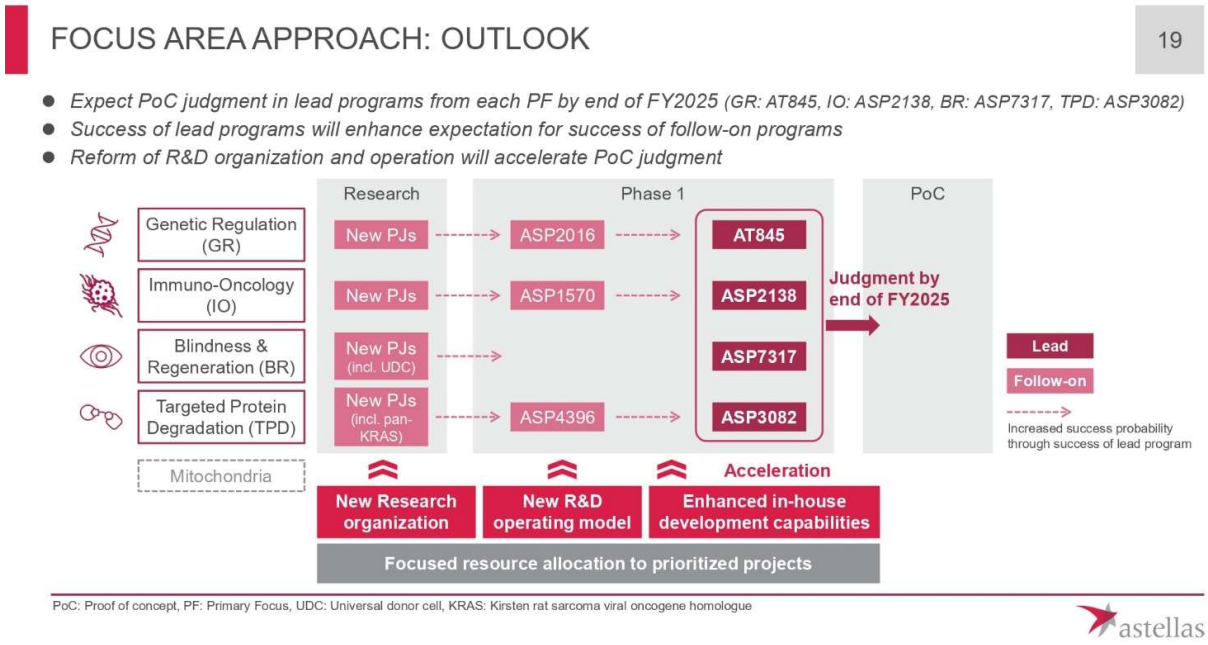
Page 18, I would like to explain some of the key events we expect in FY2024 for expanding other strategic products.

For XTANDI, we expect a decision from the Chinese regulatory authorities in Q3 on its application for an additional indication for M1 CSPC based on the China ARCHES study.

Regarding PADCEV, we expect regulatory decisions in Q2 for the second line and beyond metastatic urothelial carcinoma based on EV-203 in China, and in Q3 for first-line metastatic urothelial carcinoma in Europe.

VYLOY is on track to respond to the complete response letter received from the US FDA in January and plans to resubmit the application in Q1. If accepted, our decision is expected in Q2 or Q3, depending on the classification of the application as determined by the FDA. The regulatory decisions in other regions are expected in H2 of FY2024 in Europe and in Q4 in China. We currently expect top-line results from the Phase II study in pancreatic adenocarcinoma to be available in Q4 as of now. If that data is favorable, we plan to proceed with the application of an additional indication based on the results.

IZERVAY has a target date of November 19 as PDUFA target in the US. In Europe, we currently expect a decision from the authorities in H2 of FY2024. The timeline may change depending on the comments from the regulatory authorities and we will provide updates as appropriate.



On page 19, I will explain the outlook for PoC judgment under the focus area approach.

In the lead programs in each primary focus, for programs such as AT845 for genetic regulation, ASP2138 for immuno-oncology, ASP7317 for blindness and regeneration, and targeted protein degradation ASP3082, will advance to the PoC review stage by the end of FY2025. We expect that the success of these lead programs in obtaining a PoC will enhance expectation for success of follow-on programs, utilizing the same platform, and bring the concept of the focus area approach closer to reality, which is to generate promising new drugs continuously.

To accelerate the program creation and a PoC decision, R&D has made significant reform to its organization and operational model for development projects with proactive delegation to teams to enable faster decision-making. In addition, we are reviewing the use of external resources and strengthen our internal capabilities to promote the development more effectively and efficiently in new modalities and disease areas in which we have little experience. In addition to these measures, we will further strengthen resource allocation to priority projects and focus on PoC decision.

CHANGE IN DEFINITION OF CORE BASIS FROM FY2024

20

<Background>

- The acquisition of Iveric Bio (July 2023) made it difficult to adequately represent profitability under the old definition
- The new definition of core basis better represents profitability and ensures comparability with global pharmaceutical companies

<Changes>

In addition to the old definition's adjustments, "Amortisation of intangible assets", "Gain on divestiture of intangible assets" and "Share of profit (loss) of investments accounted for using equity method" have been newly excluded as new adjustment items

(billion yen)		FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 FCST
Core Operating profit <Old definition>		244.7	286.9	184.6	110.0
New adjustment items	Amortisation of intangible assets (Ratio to Revenue)	28.3 (2.2%)	38.4 (2.5%)	98.8 (6.2%)	140.0 (8.5%)
	Gain on divestiture of intangible assets	24.2	0.2	9.7	-
	Share of profit (loss) of investments accounted for using equity method	0.5	1.3	-3.2	-
Core Operating profit <New definition>		**248.3**	**323.9**	**276.9**	**250.0**

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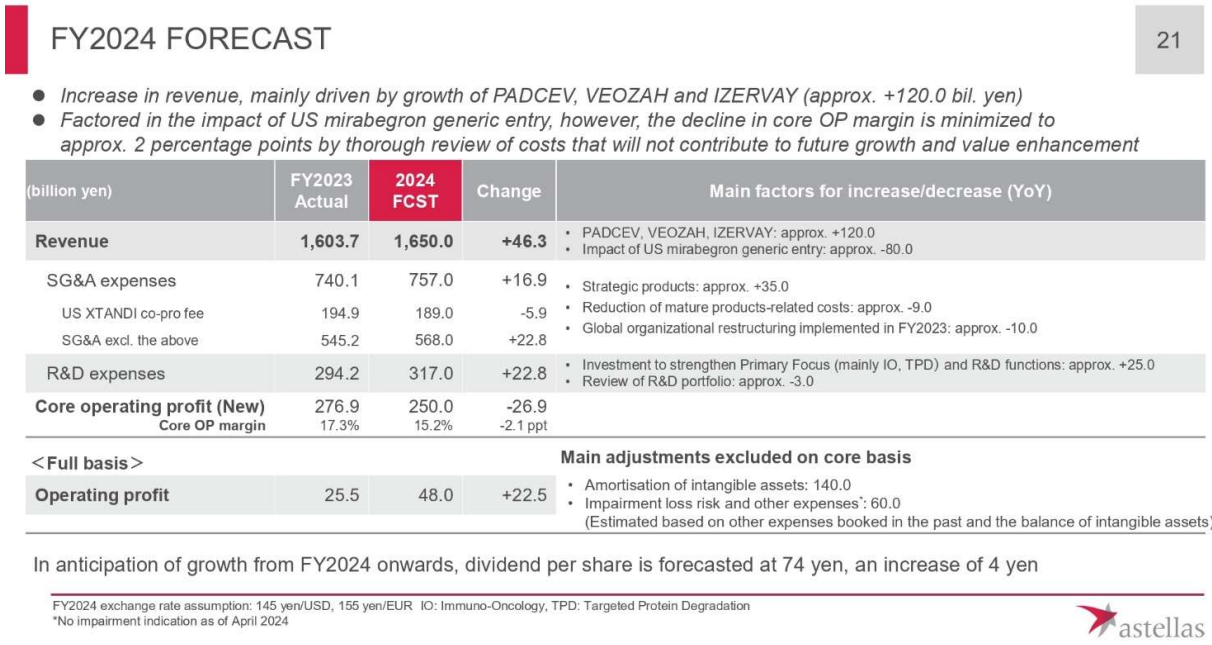
Page 20, I will explain the change in the definition of core basis.

In addition to the old adjustments, amortization of intangible assets, gain on divestiture of intangible assets, and share of profit or loss of investments accounted for using equity methodology, have been newly excluded as the new adjustment items from the old definition starting FY2024. This is because the acquisition of Iveric Bio has resulted in a significant increase in amortization of intangible assets, which makes it difficult to adequately represent profitability under the old definition. We believe that the new definition of core basis will more appropriately show the Company's profitability and ensure comparability with the global pharmaceutical companies.

For reference, the lower part of the slide shows the change in core operating income, reflecting the new definition. Now, you can see that the acquisition of Iveric Bio has significantly increased the amount of amortization of intangible assets and the ratio to revenues compared to FY2023.



Page 21. Now, I will explain our full-year forecast for FY2024.

The focus for revenue is JPY1.650 trillion, an increase of JPY46.3 billion YoY. The impact of the entry of generic mirabegron in the US has been included in the assumptions for the full-year focus of revenue. The decrease in sales of mirabegron is expected to be offset by sales growth of PADCEV, VEOZAH, and IZERVAY, which are expected to increase by JPY120 billion YoY.

SG&A expenses are expected to be JPY757 billion. SG&A, excluding co-promotion expenses for XTANDI in the US, is expected to be JPY568 billion, an increase of JPY22.8 billion YoY. The main reason for this increase is the necessary investments in growth drivers, such as PADCEV, VYLOY, VEOZAH, and IZERVAY, which are expected to increase by about JPY35 billion YoY.

On the other hand, we continue to reduce the expenses of mature products, which is expected to decrease by about JPY9 billion YoY. In addition, we expect to realize cost reductions of about JPY10 billion as a result of global organizational restructuring implemented in FY2023, including a review of sales structure in Japan.

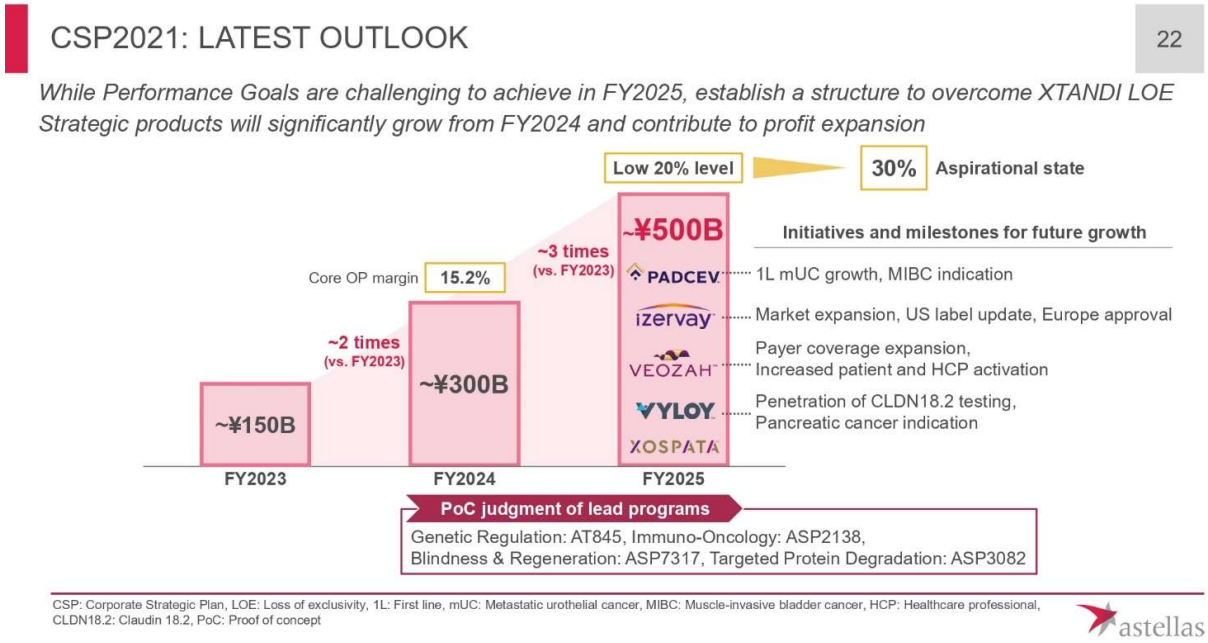
R&D expenses are expected to be JPY317 billion, an increase of JPY22.8 billion YoY. We will continue to invest those strengths in primary focus and R&D functions in general. On the other hand, we will also review our portfolio to reduce costs. We will strictly prioritize allocation of management, resources, and investment in growth areas while thoroughly reviewing expenses that will not contribute to future growth and value enhancement.

As a result, core operating income is expected to be JPY250 billion, a decrease of JPY26.9 billion YoY. And our core operating margin is expected to be 15.2%, a decrease of 2.1 percentage points from the previous year. Although the impact of generic mirabegron in the US will be factored in, we will prioritize expenses thoroughly and minimize the decrease in core operating margins.

The lower part of the slide shows a forecast on a full basis. Operating income is projected to be JPY48 billion YoY. We expect amortization of intangible assets of JPY140 billion to be a major adjustment item that is

excluded from the core basis. In addition, we have factored in other expenses of about JPY60 billion, including the risk of impairment losses.

We're focused on a dividend of JPY74 per share for FY2024, an increase of JPY4 per share. We have revised our dividend increase range in light of lower-than-expected profit growth. But we remain confident about future profit growth and have increased our dividend forecast to JPY4 per share.



On page 22, I would like to explain the CSP2021.

In light of the progress made so far on the three performance targets outlined in the CSP, we believe that it will be difficult to achieve the targets for FY2025. On the other hand, the original theme of CSP2021 is to build a structure that can overcome the patent expiration of XTANDI, and we believe that it is extremely important to firmly establish such a structure during the remaining period.

In terms of revenue, the main growth drivers are PADCEV, IZERVAY, VEOZAH, and VYLOY. We expect total sales of strategic products to nearly double to JPY300 billion in FY2024. In FY2025, we expect this figure to triple to JPY500 billion. We expect profits to grow along with this sales growth, with the core OP margin expected to rise from 15.2% in the FY2024 forecast to the low 20% range in FY2025.

We believe that the initiatives and milestones shown on the right side of this slide will be particularly important for the future growth of our priority strategic products. We will continue to pursue a core OP margin of 30% as our goal by steadily advancing these initiatives. If we succeed in acquiring a PoC for primary focus program by the end of FY2025, we expect to build a pipeline that will enable sustainable growth.

Thank you very much. That's all from me.

Ikeda [M]: Okamura-san, thank you very much. That's all as our explanation from our company.

We now would 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, if you tap details, the Raise Hand button will be shown, so please press it. The emcee will name you one by one. If your name is called, please unmute yourself on your screen. Please mention your name and your affiliation before asking questions.

Thank you for waiting. First, Mr. Yamaguchi from Citigroup Securities, please.

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

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

Yamaguchi [Q]: Thank you. I have a few questions. First, regarding CSP, you reviewed your assumptions. As you explained in the presentation, FY2025, the goals remained the same, but the numbers are a bit challenging. Are you reviewing the assumptions for the numbers? The final numbers will be revisited once again, is there any such possibility?

Okamura [A]: Thank you for your question. What do you mean by revisit?

Yamaguchi [Q]: I mean how I should interpret the current numbers in assumptions which you think you can achieve.

Okamura [A]: CSP2021, we set performance goals in CSP2021. The performance goals themselves, we have no intention to change. This was developed three years ago. So instead of changing through rolling, we'd like to keep the goals as is.

And for the goals, what we likely to achieve, that's what I presented today. In that sense, in FY2024, we have an annual plan already. In FY2025, basically, based on the plan for FY2024, we added scenario planning to show these numbers for you. When we have an annual planning for FY2025, we cannot rule out the possibility that the assumptions have changed but these are the numbers we have confidence about, which we are presenting today. I hope I answered your questions.

Yamaguchi [Q]: Thank you. The second question is about IZERVAY sales forecast. You explained the sales forecast. If I understand what you explained, J-Code was approved effective on April 1, which increased the demand. Also, label update, PDUFA date is November 19, when the volume will increase further. In terms of the impact, it can be a big product. What would be the most impactful element?

Okamura [A]: Thank you for your question. Where should I start? First of all, permanent J-Code has a big impact, I think. Reimbursement procedures will be easier for physicians and HCPs. If they are not accustomed to such a procedure, some of them may be waiting until the procedure is simplified. We can expand the customer base. In that sense, it's very important. On the other hand, for each patient, how much can the drug be utilized? In that sense, I think that's also really important to eliminate the restriction about the usage period for 12 months, since this is a drug you have to use on a chronic basis.

Regarding the numbers in FY2024, it's not reflected so much. Not just in the United States but also in other countries, we'd like to launch IZERVAY in those markets as well. We try to expand the number of countries as

well. These are the three elements that are very important. Instead of saying which is the most important, we'd like to implement those three at the same time.

Yamaguchi [Q]: Thank you. And about mirabegron, it's a sensitive question. It's difficult for me to ask you, but still, I understand that it's included in the sales forecast. According to press release last week, the district court recommends denying your motion according to generic manufacturers. I heard that the injunction in the appeals court worked. On this point, as far as you can share, could you give us your comments?

Okamura [A]: Yes, you're right, as a fact. But the injunction by the appeals court is temporary. How long it's going to be effective, it's not so clear, so it's an injunction. Compared to what we call injunction in general, the duration is very limited.

Yamaguchi [M]: Understood. Thank you very much.

Ikeda [M]: Next is Morgan Stanley MUFG Securities, Mr. Muraoka, please.

Muraoka [Q]: Good afternoon. Muraoka from Morgan Stanley speaking. Thank you very much for giving me the opportunity. Would you show up slide 22? That is core OP margin based upon the new definition is going to be the low 20%. That is where you are going to return to in the next fiscal year. Would you please explain the journey towards that a bit more into details? If these five products show growth, then OP margin is going to be improved automatically. I think that's a simple story. But from the account status, I believe there is a certain distance. Would you please explain a bit more about this?

Okamura [A]: Thank you for the question, Muraoka-san. What you said is exactly what we are thinking.

Muraoka [Q]: I see. In that sense, PADCEV and IZERVAY, those are likely to grow greatly. Are you depending on that, those two-product sales expansion?

Okamura [A]: That is the sales expansion that is likely to hit the bottom line. I don't know if that is the right way to say.

Muraoka [Q]: Okay. Then, when it comes to VEOZAH, after this revisiting in FY2025, is it coming up with the profit or still waiting for the profit from VEOZAH in FY2025?

Okamura [A]: It is not appropriate to disclose the detailed number to you here today. But at least it has to go to the nearly breakeven point, personally speaking. But of course, sales or the revenue itself, we cannot control but we can control the cost. Therefore, even in the middle of the fiscal year, we always would like to refer to the KPIs so that we can flexibly adjust the sales mix. That is going to be the foundation that we have currently. Around FY2025, I hope that this achieves the status of coming up with profit.

Muraoka [Q]: Thank you. Now, about the dividend. Within these one to two weeks among the investors, we discussed, and we also received a lot of questions about the dividend, and you came up with a number of JPY74. In some page, you showed a certain picture, and according to that, in the next fiscal year, the profit will grow so you can increase in dividend at JPY10 basis. Therefore, from next fiscal year, another JPY10 is likely to be added on top of JPY 74 according to the picture that you are drawing. The JPY500 billion for the major products, and core OP margin in the low 20%, then the convention level of the increase is something you think you could achieve. Is that okay to consider in that way?

Okamura [A]: Thank you very much for your question. Of course, I would like to continue the increase the dividend and also would like to increase that range as well. But on the other hand, as you know, XTANDI patent expiration is going to start from FY2027 and afterwards. Therefore, JPY10 this year, JPY2 next year, JPY10 next year, and reduction next year, that's something we would like to avoid. We look at the profit

situation from mid- to long term, and based upon that, we would like to decide the amount of the dividend every year. So FY2025, FY2026, what would happen is something I would rather refrain myself from commenting today. But as I've mentioned, capital allocation perspective, the stable increase of the dividend is our basic direction. It's not the increase or decrease depending on the profit of the year, we can avoid such situation. We would like to always do that in a planned manner.

Muraoka [Q]: If there is a stable profitability, then according to this current situation of your company, JPY4 is appropriate level?

Okamura [A]: Yes, that's right.

Muraoka [Q]: Thank you. Now, about VEOZAH. Affordability was mentioned in your slide. I'd like to confirm. Within one or two years, there would be competitors lowering the price to secure the coverage. Is there any possibility to take such a strategy? Sorry, I may not be catching up. Is such a scenario possible? Is it highly likely or not likely? Could you explain?

Okamura [A]: Yes. Regarding the affordability, what to do with list price, what about the gross to net, that's one thing. But what we'd like to say here is that what is going to be the co-payment of the patients. We are talking about the absolute amount when the original assumptions were made. Initially, we are assuming a small amount of co-payment as an assumption for the patients who use this drug, but that's not really the case in reality. For example, they go to a pharmacy. It's available, but co-pay is high so patients may say, "No, thank you." There are such patients. We can decrease the out-of-pocket payment by the patients. We have to consider it. Lowering the list price itself or increasing the gross to net, there can be a variety of ways. But for us, we shouldn't hurry too much increasing gross to net, the rebate. Then, in the long term, the value of the product would be undermined. We don't want to do this. We'd like to think of a smarter way of taking a variety of actions. That's all.

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

Ikeda [M]: Thank you very much. Next, Goldman Sachs Securities, Mr. Ueda, please.

Ueda [Q]: Ueda from Goldman Sachs Securities. First of all, I'd like to ask you a question about the process to develop your annual forecast. When you announced the results before, you are going to review the process to develop your forecast. Specifically, how did you change? You said you want to be ambitious, but you also paid attention to something achievable. What has been changed compared to the last fiscal year? What is the difference in the probability of achieving your plan?

Okamura [A]: Thank you for your question. I'd like to explain where necessary. Kitamura, sitting next to me, can add comments as well.

First of all, when FY2024, annual plan or budget is being developed, our biggest challenge was that we need to develop a plan which can be delivered for sure. Of course, it must be ambitious, otherwise, the organization would be less motivated. We will use ambitious numbers. But still, it could not be achieved. That should not happen. We would perform a scenario analysis in advance. We referred to bottom-up, but in the end, as corporate as a whole, we will take risks here and here, and in other years, we would not take risks. We incorporate such a process in the early annual plan for FY2024.

Also, it's easy to talk about prioritization but doing this for sure is something tough because we see people and things. But there are three priorities internally. Accordingly, at various places, we determine the priorities. Some we have to endure, and we may have to give up in some areas or we may have to postpone. But we want to allocate human resources and money to what requires such resource allocations. That's the current status. As I said on page 15, mirabegron generics entry, financially speaking, we need to factor in such a

potential risk. We don't have any sign now, but intangible assets are always on the balance sheet. For what reasons projects are terminated, there would be impairment loss so we have to pay attention to those areas. That's how we are planning this time.

Kitamura-san, anything to add?

Kitamura [A]: Thank you. As Okamura said, yes, I agree but I'd like to add two points. Regarding scenario, in principle, it's quite severe. What would be a worst-case scenario and to overcome that, what should be done? There can be good scenarios and bad scenarios as well. Based on rather conservative scenarios, we develop cost planning. It was mentioned earlier, we had very tough prioritization. On the other hand, not just creating numbers in the plan, but we have to think about how to do the operations. It's about the after processes. Specifically, when do we need to make what commitments? By then, what do we know and how to do this? Such a process was discussed in detail by the top management, so we'd like to deliver these numbers for sure. That's all from me.

Ueda [Q]: Thank you very much. The second, this may be related to the operation, just like you mentioned. The forecast for SG&A this fiscal year includes JPY35 billion for the strategic products. Relatively, the amount is larger. Maybe you invest in advance for those products. The next fiscal year and afterwards to think about outlook. What would be the distribution percentage? And this time, once again, is it okay that the current investment is advanced treatment?

Okamura [A]: Okay. For this as well, I'll answer and Kitamura-san will follow. As I've mentioned at the very end slide, core OP listed upon as new definition, that is 30%. Now, for the pharmaceutical companies like our position and the direction is the appropriate amount to aim at. From there, we are going to calculate the cost of goods and so on. Then, automatically come up with the SG&A level to achieve the 30%. With this as a goal, overall, within this range so that we can operate our business, we would like to establish the structure of the system. We would like to have a more masculine-like structure with this target. Anything to add?

Kitamura [A]: Thank you very much. What is quite important, as you see on this slide, in FY2025, for these strategic products, we come up with the sales of more than JPY500 billion. This is critical. In order to realize this, necessary investment is definitely executed. At the same time, just as Okamura mentioned, there will be the increase, so where should the decrease be? That will be the SG&A and other expenses. For example, including digitalization, we can reduce certain costs so we would like to do that. At the same time, FY2025, there are more than 20 months until then. We are going to do the short-term improvement for this fiscal year, and 2025, that is going to be the midterm improvement. The time access will be different, but we are doing so in a simultaneous manner.

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

Ikeda [M]: Thank you. Next, UBS Securities, Ms. Haruta, please.

Haruta [Q]: Haruta from UBS. Thank you very much. First question is about the XTANDI US forecast. That's a question for me. In the guidance this time, FY2025 journey to March, there will be the negative impact, but the remaining calendar year of 2025, that impact will continue. But for 2026, well, in 2025, the drug price is reduced and from there, to what extent will demand improve? Based upon that, you come up with a focus for 2026. 2027 in IRA, if you will be included within the list, then further price decrease by about 30%. For the coming three years, is it okay to expect the coming three years in that way? Could you please explain that?

Okamura [A]: The journey or the route to think about what's coming, I think what you mentioned is quite right, but is there anything else needed to be added? Claus, if you have any, would you please make a comment?

Zieler [A]*: The only thing I would add is that we are very encouraged by the volume growth that we are seeing. I mean, we have been on the market for more than 10 years, and we're growing 4% in paid demand. And that has even strengthened in the last quarter with the publication and the approval of the EMBARK indication. There is demand in the market. And, yes, we have an environment which, over time, will be unfavorable on the price front. But the volume prospects, I think, continue to be very good in terms of long-term growth.

Haruta [Q]: Understood. Thank you very much. The second point is about VEOZAH, about the doctor or HCP intention for the treatment. That's what I'd like to know. There's a market itself because of the hormonotherapy. But now, the VMS recognition as a disease to be treated amongst the HCPs is lowered, and there is no activation by HCPs for the treatment. What is the current status with that regard? That's what I want to learn. Rather than the enthusiasm for the treatment itself, the coverage of the insurance, that itself is a stronger factor for the bottleneck. That's the question.

Okamura [A]: I'd like to comment a bit and then I'd like to ask Claus to make additional comments after. Yes, you are partly right. VMS in the education process for educating the clinical information, we may not have studied much, but opening the practice, we noticed that's the situation. The sales force must ensure disease education even to physicians as well HCPs. Also, in appear using the network, this should also be done as well.

On the other hand, regarding the coverage, if you perform market research, they have the intention to prescribe. They are willing to prescribe. But what kind of patients should come and how they should explain to prescribe, that's a missing link. Sales force and medical reps have to fill this gap. The coverage issue, what we are concerned about is that doctors are willing to prescribe to patients coming to them and prescription could be written under those circumstances. But because there is going to be no reimbursement, some doctors would not prescribe. They wrote a prescription but the patients bring it to pharmacy but it's too expensive, so they may say, no, thank you because of no insurance coverage. They were told to take the advanced procedures so it's too cumbersome. There are doctors who would like to prescribe to their patients, but still, it's not linked to the actual prescription. I think that's the area where we'd like to see faster progress. Doctors themselves need education because they didn't learn in medical school so much about this. And as customers, we want the doctor to prescribe drugs. Still, they don't write a prescription. So we have two dilemmas. Claus?

Zieler [A]*: Yes. What Naoki just described is exactly right. The one factor is the perception from HCPs, that we know from our market research, that they think the coverage is not broad enough for them to prescribe. And it takes time to overcome perceptions in any market, right? Now, we are making good progress on the payer front. We always said we would reach 50% coverage by the end of FY2023. We have delivered on that. We are now aiming for more than 80% coverage by the end of FY2024. I think we're going to be very nicely tracking on that. And over time, we will be able to convince HCPs that coverage is not broad enough for them to prescribe freely, and that is the sales force's job just as Naoki just said. At the same time, we are building a new class, right? We have to educate doctors about the advantages versus the SSRIs or HIT treatments that they're used to prescribe in the past. Those are the two factors, exactly like Naoki said.

Haruta [M]: Understood. Thank you very much. It's now clearer for me. Thank you very much.

Ikeda [M]: Thank you very much. Next, Mr. Hashiguchi from Daiwa Securities, please.

Hashiguchi [Q]: Hashiguchi speaking, thank you very much. On page 22, you talked about XTANDI LOE and you are going to establish a structure to overcome XTANDI LOE. What's your definition? What kind of a situation would mean sufficient structure to overcome XTANDI LOE? When you announced CSP2021, I am seeing the slides. Once again, according to the forecast, as the trend sales and core operating profits in 2030, I think it's going to be a higher level, but you are changing the definition of the core operating profit. Products which you think are going to grow XTANDI. According to the new definition, the profit structure is going to be

different. There may be operating profit for some of the products and not for other products. I'd like you to elaborate on what you're talking about in this regard.

Okamura [A]: Excuse me, I am not quite sure what I should answer. Would you please repeat your question once again?

Hashiguchi [Q]: Let me ask you in a different way. When CSP2021 was announced in FY2021, more than JPY500 billion of the sales from Focus Area projects were projected, then you can overcome the loss of the exclusivity of the XTANDI and you can come up with the long-term growth. Like Okamura-san mentioned today for focus project, currently, there's a bit of a delay in that situation. With that, can you now declare that you're now prepared to overcome XTANDI LOE as of FY2025? As you see it on slide 22, strategic products and also with those sales increase, the XTANDI issue can be overcome or the new definition-wise profit is exceeding the current level. When do you declare that you were able to overcome the issue of the exclusivity of XTANDI? That's the question.

Okamura [A]: Understood. First of all, the sustainable or continuous growth that we think these are the drugs, so the LOE or the patent issue, they always come. There will be the year of discontinuity. I believe I discussed this a lot with Hashiguchi-san in the past, but there is no case that the profit comes out during the vacuum period. What we are aiming at is the current extended sales is about JPY700 billion. From there, we come up with a profit. And that profit, if that is raised from other products, in other words, XTANDI is gone, but we have the other products as alternatives so renversement. Then, as of FY2021, because at the time, we didn't have IZERVAY, but there were six compounds and was added. But anyhow, with those key products or strategic products, profitability structure is different from XTANDI. It's not really about the revenue or the sales, rather operating profit that is gained from XTANDI can be replaced or offset. That is the status we would like to achieve.

At the same time, based upon that from the primary forecast, if we have some other potential products, then with the replacement of the XTANDI, we have another potential product from our primary focus that will lead to the further growth. That's what we are thinking. However, the strategic products status is from the time of FY2021. Also, primary focus potential products are not near, but rather a bit far in the future. And if we can see that, we highly expect with a failure in the clinical trial. In order to offset such situation, we came up with IZERVAY, with acquiring Iveric.

Did you get it? I just wonder if that is a logical explanation.

Hashiguchi [Q]: I understand it quite well. But with IZERVAY now available, according to your explanation, operating profit can be replaced. But you are thinking about the replacement of operating profit based upon this new definition, right?

Okamura [A]: Right. Rather than the accounting-wise profit, I always think about the situation based upon cash flow. For me, IZERVAY, from the cash flow perspective, regardless of the definition of core operating profit is the same thing. But from the investors' perspective, based upon the current core OP definition, you don't understand actually what is happening. We hear that a lot. That's why this time, we decided to change the definition of core OP.

Hashiguchi [Q]: Understood quite well. Thank you very much. Another point for me is about zolbetuximab or VYLOY in Japan maybe. In Japan, initially, you focused on the penetration of the testing that's why you come up with that number for the sales of this year. But CLDN18.2 recognition among HCPs here in Japan is expected to be high compared to Western countries. And if you come up with a forecast here in Japan, in Western countries, after getting the approval, it seems that the sales growth will be relatively slower. Is it okay to see it that way?

Okamura [M]: Thank you for your question. In the HCP community, from the Japanese physicians' perspective, how to think about CLDN18.2, I'd like to have a comment from Taniguchi. What about the plan by the commercial team together with the medical affairs, in collaboration, how to roll out VYLOY in Japan, that is going to be explained by Claus. First, Taniguchi, please.

Taniguchi [A]: Okay. I'd like to talk about CLDN18.2 awareness. From the medical affairs perspective, the awareness is getting higher. Gastric cancer prevalence is high in Japan. There are many cases in our country and Japanese doctors are eager to learn and study. Our new marker, with high sensitivity, they are dealing with this. At the GI physicians meeting, we have a booth and many doctors visit our booth at an exhibition. From that perspective, still, it's very important for them to test. In gastric cancer, HER2 and PD-1 testing was generally done, and CLDN18.2 testing hopefully would be done by the doctors to begin with so we'd like to penetrate the testing. That's very important for the success of VYLOY, as we wrote here.

Claus, please.

Zieler [A]*: We are very encouraged by the fact that the guidelines have already included in Japan CLDN18.2 testing together with the HER testing. So, that gives us a very good basis to communicate to doctors that both tests should be done at the same time when a patient presents. I do think that, in Japan, we actually have a very good environment in terms of getting doctors to understand, be aware, and then also order the CLDN18.2 tests.

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

Ikeda [M]: Thank you very much. Next, JPMorgan Securities, Mr. Wakao, please.

Wakao [Q]: Wakao from JPMorgan Securities. Thank you for your time. First, as Hashiguchi-san asked the question, I'd like to know more about the same topics: CSP2021, XTANDI LOE. You talked about the structure to overcome the XTANDI LOE. If you cannot establish such a structure, what measure are you going to take? FY2025 Strategic products, sales of JPY500 billion, that's next fiscal year. I think the the probability is quite high, but based on the definition, there can be some challenges so strategic products may not go as expected. Then, something like an acquisition like IZERVAY may happen. It may be difficult to acquire those products, but there may be an acquisition of late-stage compounds, which you may consider.

And regarding Focus Area, you need to achieve PoC. If you cannot achieve PoC, another Focus Area would be tried one after another. Should I understand that way? Regarding the focus area, do you have a plan or a way to make further improvements?

Okamura [A]: Thank you for your question. Regarding your first question, for us, in principle, innovations to create a company, if possible, product close to completion in the late-stage phase for companies, we don't want to acquire them. But as you said, things may not proceed as we expect. We say we want to generate innovation so we just shouldn't wait. We decided to acquire IZERVAY this time, as you pointed out. If you look at our balance sheet, next year, it's impossible to acquire a company of JPY500 billion worth. Iveric Bio acquisition was done. For the coming few years, acquiring a big product or a company could be difficult. R&D people sitting right to me must work very hard. Sitting on the left of me is Claus. We delivered Strategic products to the market, so Claus, you have to work hard. Of course, I see you that way.

Regarding the Focus Area, Focus Area is our way of thinking about R&D. You wanted to talk about Primary Focus, right? Within one primary focus, biology, modality, and disease exists by making small changes one by one. This is what we call a pivot, by moving the triangles little by little. Mitochondria is now dissolved. We may terminate a certain Primary Focus and create a different Primary Focus somewhere else. There is flexibility here. That's the good thing about the Focus Area approach.

More specifically, by 2024, I expect it to gain the PoC. But if that would not happen, what should we do? That's also what I'm interested in so I would like to hear it. Let's start with the clinical phase. First of all, Taniguchi, then after that, Shitaka, higher than that level, what you're thinking is something we'd like to hear.

Taniguchi [A]: Thank you. Let me speak first. It's about the clinical development. First, AT845, this is Pompe. ASP2138, this is oncology; and ASP7137, this is the AMD geographic atrophy; and the ASP 3082, this is a KRAS degrader. These four, we would like to get the PoC decision by the end of 2025, at least these four. Of course, other than those, we have other programs that we may be able to decide the PoC in this period of time. But new products or products in earlier development phase, those are also something we'd like to focus on. Shitaka is going to talk about it after me. But from the research, we get something, and we want to have it into the clinical phase so that we can increase the probability of gaining PoC. That's what we are trying to do.

On top of that, as it's been shown in slide 22, for example, PADCEV LCM or line extension, that is also something we are thinking about, and already, in head and neck cancer, the new study is taking place. Other than that, for VYLOY, other than pancreatic cancer, we would like to expand the indication so that we can find other value. Those are considered for LCM. Early-phase and late-phase LCM go together, and with that, we can come up with a higher level of pipeline value. That's what we think. That's why we are doing our best for that.

Shitaka [A]: Now, Shitaka will make an explanation. Just like Okamura mentioned, I would like to transform innovation for the value of the patients, and that's the driver for our growth. Now, the Primary Focus will be turned over, as has been mentioned this time, and we will find another opportunity of the science innovation. That's one way that we can do. Also, within the Primary Focus, several platforms verify one after another based upon the hypothesis that we have. For example, Immuno-Oncology. Unfortunately, Potenza and aAVC couldn't come up with the evidence to verify our hypothesis, but some are already in the dose expansion study. We have ASP2138, and so within Immuno-Oncology, the different factors are utilized and we have something else that we can expect for the next phase. Also, the Targeted Protein Degrader, the situation is the same. The KRAS is the first so that we can launch the product. D-mutated types are now in the clinical phases. The degrader, not depending on the mutation type for KRAS degrader, that is also identified for the clinical phase. Non-KRS oncology and immuno-oncology, where we would like to make use of, within a PF or primary focus, we can verify the different platforms. We can do other ways. These are cases we would like to transform the innovation to the value so that we can grow further. That's what we are aiming at.

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

Ikeda [M]: Thank you. Next, AllianceBernstein, Sogi-san. Ms. Sogi, please.

Sogi [Q]: Thank you. I have a question about PADCEV and VEOZAH. First, about PADCEV. In the 2024 forecast, JPY145 against the US dollar. Based on that assumption, FY2024 sales forecast may be very aggressive according to my impression. First line, market share, what's your assumption about market share to come up with these numbers?

Okamura [M]: Thank you for your question. Straight to Claus.

Zieler [A]*: I expected you to be surprised by our PADCEV forecast because we are extremely confident about that. You will remember that in Q2, we took up the Pat forecast significantly, and we have delivered on that. We're actually a little bit over-delivered on that and we think that trend will continue. Our market research shows a very typical market share in terms of new patients. About half of the new patients would go on PADCEV-pembro first-line combination. We now have three guidelines, three guidelines in the world recommending PADCEV-pembro as the standard of care. That's the ESMO guideline. That's the European Association of Urology guidelines. And the American NCCN guideline, we're also category I. I think we are upending this market. We are changing this market completely. And it is very clear from our feedback from

HCPs, from medical societies, that they see PADCEV and pembro as the first option for patients with bladder cancer, and that is giving us that confidence. I think our track record since Q2 proves us right so far so I would ask you to be confident also in the FY2024 forecast.

Sogi [Q]*: Great. Does that mean that you're assuming that PADCEV will achieve 50% market share during the first year of the new indication in the first line?

Zieler [A]*: In the US, for instance, where we have first line on the market, we already have more than 50% market share.

Sogi [Q]*: I see. Great. That's very impressive. The second question is regarding VEOZAH. Probably, this is also a question to Claus. Thank you for explaining some of the challenges coming from the payer coverage. I also believe that another key challenge is probably the lower-than-expected demand from the patients. I believe that quite a significant DTC to mobilize those patients is quite important for this product. First of all, I'd just like to understand, is that in the right understanding?

Also, the second question is, in order to do that, what is this year's budget for the promotion fee for VEOZAH? And also, if there is any change in your planning to make for the promotion approach based on what you have learned so far.

Zieler [A]*: Okay. That's at least half a dozen questions in one, but I'll try to take them. You are absolutely right that in our initial assumption, we expected an exponential response curve from the DTC and that has not happened. And the more we study this market, the more we believe that we are progressing it in a linear fashion. We've also modeled that versus some analogs. It just seems to be a market that progresses linearly and that has also proven true in Q4. We've increased demand by about 60% in Q4, and we see that demand creation being slower than initially expected but being steady going into the future. So, yes, it does take DTC spend to activate that. Yes, that will have to continue for some time. I mean, please remember we're still within the first 12 months of launch, right? I mean, we haven't even completed the first year of launch. So yes, we will continue on the DTC spending to activate consumers. And we'll be updating you in the next call when we have some fresh market research on how we have affected awareness of HCPs, but also of consumers of the brand, which, if you remember, in December was still only at 25% on the consumer part. So, yes, DTC will be necessary to continue to activate patients, but no, it's not exponential. It's more a linear progression.

Sogi [Q]*: My question is how much you are planning to spend for VEOZAH promotion this year. And also, I mean, if there's any new learning that you have gathered so far that will be applied on how to promote this product.

Zieler [A]*: I'm not going to give you the number you're asking for in terms of the promotional spend. I can tell you that, as I think Naoki said in his presentation, we have monthly KPIs where we look whether we hit the KPIs and then we modulate the spending accordingly.

To your second question, yes, we are learning very quickly and we are adapting the spending mix. As you are aware, DTC is not just TV spend, right? It's TV spend, it's digital spend, it's Google choices. There are various categories in that spending mix, and we are learning and adapting that spending mix as we get real-time data, and that is going on right now. I do think our spending will be more effective in the future because of that learning curve that we're progressing on.

Sogi [M]*: Thank you very much.

Ikeda [M]: Thank you very much. We are already after the expected finishing time but one more question. Mr. Tsuzuki from Mizuho Securities, please.

Tsuzuki [Q]: ASCO, I believe the title is already disclosed. EV-202, the new data is going to be announced there. Is this understanding right?

Okamura [M]: Taniguchi-san, please?

Taniguchi [A]: EV-202 study last year for head and neck cancer, the data was disclosed and announced. The abstract title is now disclosed today. Other cancer types, for example, breast cancer, lung cancer, esophageal cancer, such data of the 202 study is planned to be announced.

Tsuzuki [M]: Understood. Thank you very much.

Ikeda [M]: Thank you very much. Now, time's up. With this, we would like to close today's earnings call. Thank you very much for your participation.

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