Astellas Pharma Inc.

Financial Results for the Q3 of FY2023

February 5, 2024

Event Summary

[Company Name]	Astellas Pharma Inc.
[Company ID]	4503-QCODE
[Event Language]	JPN
[Event Type]	Earnings Announcement
[Event Name]	Financial Results for the Q3 of FY2023
[Fiscal Period]	FY2023 Q3
[Date]	February 5, 2024
[Number of Pages]	32
[Time]	16:00 – 17:38 (Total: 98 minutes, Presentation: 34 minutes, Q&A: 64 minutes)
[Venue]	Webcast
[Number of Speakers]	5

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Presentation

Ikeda: Everyone, thank you very much for your participation to this announcement of Q3 FY2023 financial results ended December 31, 2023. I really appreciate your participation. I'm Ikeda, I would like to serve as the moderator. My name is Ikeda, Chief Communications and IR Officer.

We are going to have a presentation followed by a Q&A session. Japanese/English simultaneous translation is available. However, for that translation, the accuracy is not guaranteed by Astellas Pharma Inc. For the languages, please select the preferred channel on the Zoom webinar screen. If you select the original language, you listen to the original language without hearing the translation.

Today's presentation is based upon the material available on our website. This material or representation by representatives for the Company and answers and statements by representatives for the Company in the Q&A session include forward-looking statements based on assumptions and beliefs in light of the information currently available to management and are subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors, please do understand about that, and they contain information on pharmaceuticals, including compounds under development, but this information is not intended to make any representations or advisements regarding the efficacy effectiveness.

The participants here today are Atsushi Kitamura, Chief Financial Officer; Yoshitsugu Shitaka, Chief Scientific Officer; Tadaaki Taniguchi, Chief Medical Officer; and Claus Zieler, Chief Commercial Officer. We have all those four on the stage.

Now, please start the presentation, Kitamura-san.

Kitamura: Hello, everyone. I'm Atsushi Kitamura from Astellas Pharma. Thank you very much for joining our FY2023 Q3 financial results announcement meeting of a very busy schedule today.

This is a cautionary statement regarding forward-looking information. As this was explained by Ikeda earlier, I'm going to skip this page.

AGENDA

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I Q3/FY2023 Consolidated Financial Results
FY2023 Revised Forecasts

II Initiatives for Sustainable Growth

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

Q3/FY2023 FINANCIAL RESULTS: OVERVIEW

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Revenue increased YoY, however, behind the full-year forecast

- XTANDI & XOSPATA: In line with the full-year forecast revised upward in Q2
- PADCEV: In line with the full-year forecast revised significantly upward in Q2
  Potential peak sales revised upward incorporating the robust results of EV-302 study
- VEOZAH: Overall initiatives are progressing, however, demand trails internal expectations
  Full-year forecast revised downward
- IZERVAY: Encouraging first full quarter performance since launch, expect further growth

Cost items

- SG&A and R&D expenses were on track

Operating profit

- Core OP behind the full-year forecast mainly due to the performance of VEOZAH

Full-year forecast for revenue and operating profit revised downward incorporating VEOZAH's current progress

Full-year forecast revised in Nov 2023, Exchange rate assumption: 140 yen/USD,152 yen/EUR

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On page four, I will give you an overview of FY2023 Q3 financial results.

Revenue increased YoY but was behind the full year forecast we revised in Q2.

XTANDI and XOSPATA was in line with the full year forecast revised upward in Q2.

PADCEV was in line with the full year forecast revised significantly upward in Q2. Also, potential peak sales forecast was revised upward, incorporating the robust results of EV-302 study.

On the other hand, regarding VEOZAH, overall initiatives are progressing, but demand trails internal expectations. Full year forecast was revised downward.

IZERVAY demonstrated encouraging first full quarter performance since launch. This progress made us feel confident about its future growth.

SG&A and R&D expenses were on track.

Operating profit was behind the full year forecast, mainly due to the performance of VEOZAH.

Taking these factors into account, revenue and operating profit full year forecast was revised downward.

Q3/FY2023 FINANCIAL RESULTS

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(billion yen)	Q3/FY22	Q3/FY23	Change	Change (%)	FY23 FCST	FX impact (YoY)
Revenue	**1,164.4**	**1,189.1**	**+24.7**	**+2.1%**	**1,608.0**	+58.8 bil. yen
Cost of sales	226.1	219.3	-6.8	-3.0%		+10.2 bil. yen
% of revenue	19.4%	18.4%	-1.0 ppt			
SG&A expenses	471.0	547.0	+76.0	+16.1%	737.0	+26.1 bil. yen
US XTANDI co-pro fee	138.2	146.2	+8.0	+5.8%	187.0	+6.9 bil. yen
SG&A excl. the above	332.7	400.7	+68.0	+20.4%	555.0	+19.2 bil. yen
R&D expenses	206.1	216.3	+10.3	+5.0%	290.0	+6.9 bil. yen
Amortisation of intangible assets	29.2	66.2	+37.0	+126.8%		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	**233.7**	**149.6**	**-84.0**	**-36.0%**	**199.0**	+13.8 bil. yen
<Full basis>						Other expenses
Other income	2.5	8.5	+6.0	+236.6%		• Organizational restructuring cost on a global scale: approx. 18.4 bil. yen
Other expenses	54.9	84.0	+29.1	+52.9%		
Operating profit	**181.3**	**74.1**	**-107.2**	**-59.1%**	**123.0**	
Profit before tax	180.2	73.6	-106.6	-59.1%	121.0	
Profit	**144.8**	**50.3**	**-94.5**	**-65.3%**	**85.0**	

Full-year forecast revised in Nov 2023, Exchange rate assumption: 140 yen/USD,152 yen/EUR

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On page five, I will explain FY2023 Q3 financial results.

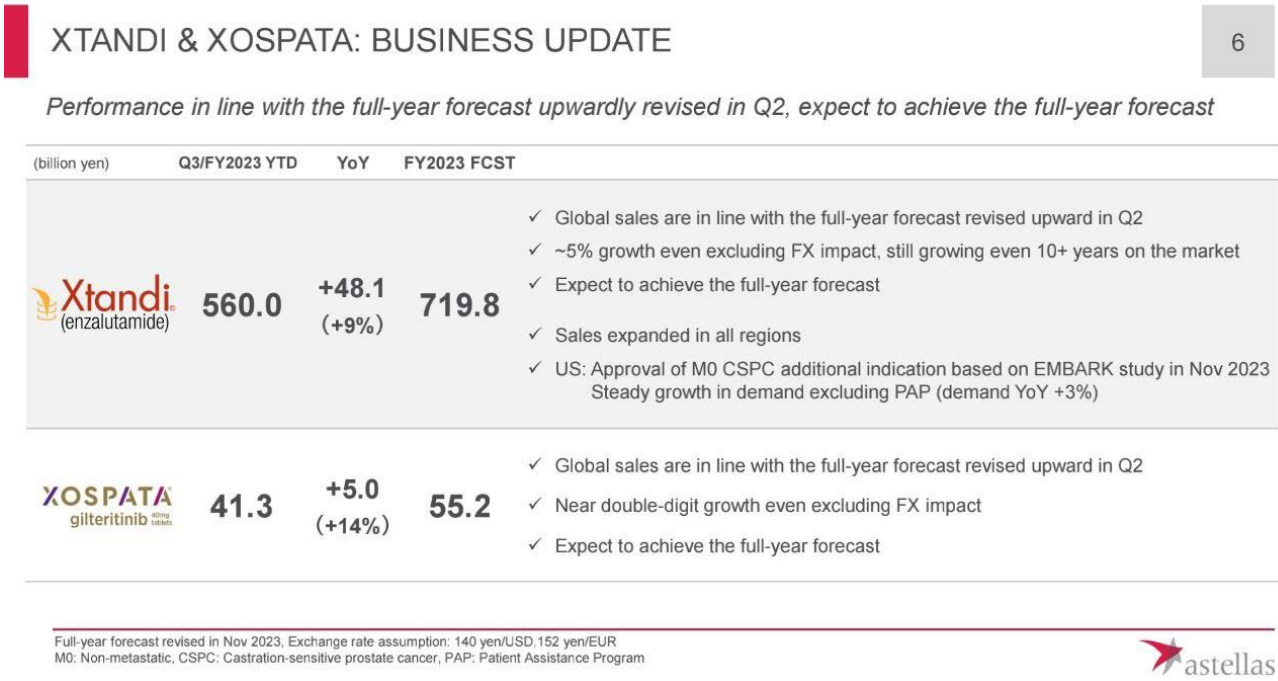
Revenue increased to JPY1,189.1 billion, up 2.1% YoY. ForEx had a positive impact of JPY58.8 billion.

Core operating profit was JPY149.6 billion, down by 36% YoY. ForEx had a positive impact of JPY13.8 billion. Due to the impact of the acquisition of Iveric Bio as well as LEXISCAN generic, core operating profit was significantly lower YoY.

The bottom half of this page shows full basis results.

In the right bottom of the table, we included other expenses booked in Q3. In Q3, we booked JPY18.4 billion as organization and restructuring cost on a global basis. This impact was already factored into our full year forecast we revised in Q1. As a result, operating profit was JPY74.1 billion, down by 59.1% YoY.

Profit decreased to JPY50.3 billion, down 65.3% YoY.

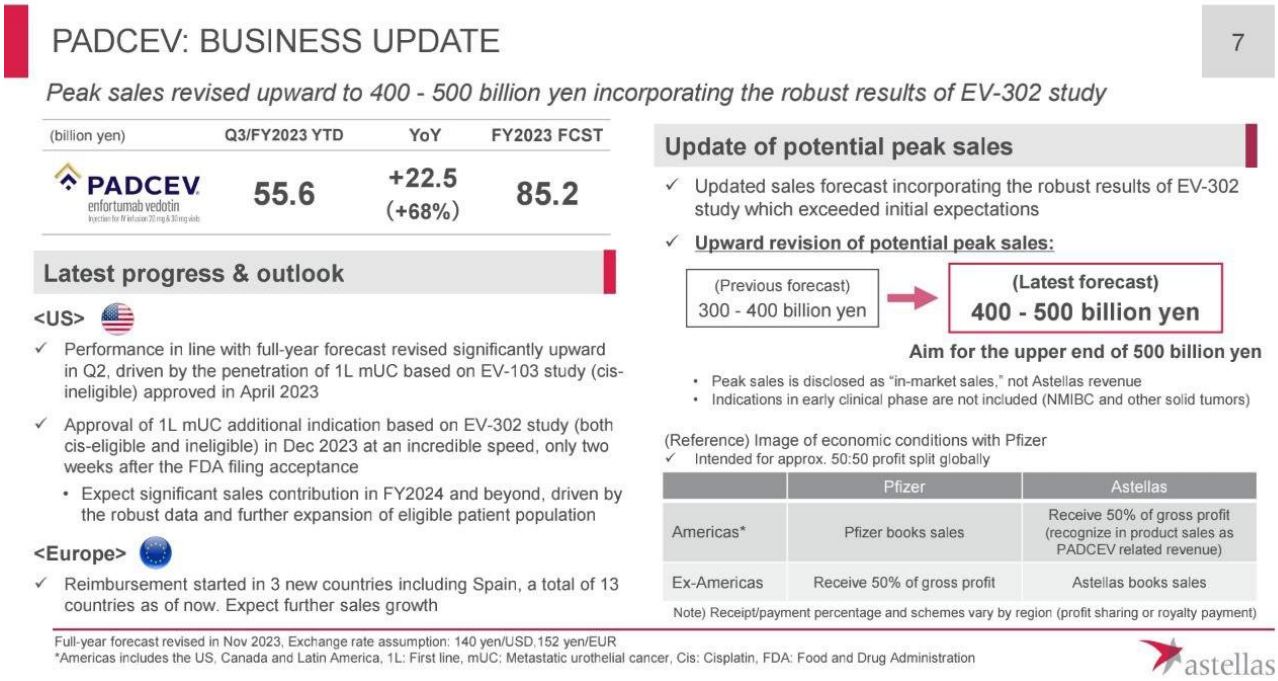


On page six, I will explain the XTANDI and XOSPATA business update.

First, about XTANDI. Global sales increased to JPY560 billion, up by 9% YoY, in line with the full year forecast revised upward in Q2. In the actual business performance, even excluding ForEx impact, XTANDI achieved about 5% growth YoY. Sales expanded in all regions, and XTANDI is still growing more than 10 years on the market. In FY2023, we're expecting sales close to JPY720 billion, exceeding the JPY700 billion mark on a full year basis.

In the US, based on EMBARK study results, M0 CSPC additional indication was approved in November last year. We are expecting contribution to future sales. On the other hand, Medicare Part D redesign will start from January 2025 as one of the measures by the so-called IRA, or Inflation Reduction Act. The redesign is expected to increase the amount to be paid by companies, and we are assuming impact on our sales. We're still examining the specific level of potential impact. We hope to provide guidance in Q4 earnings.

Regarding XOSPATA, global sales increased to JPY41.3 billion, up 14% YoY, in line with full year forecast revised upward in Q2, like XTANDI. XOSPATA is expanding steadily even in the current indication. We're expecting the achievement of our full year forecast.



On page seven, I will explain the PADCEV business update.

PADCEV global sales increased substantially to JPY55.6 billion, up by 68% YoY. Performance is in line with our full year forecast which was revised upward by nearly JPY20 billion in Q2.

US, in particular, contributed the most to global sales expansion. This is driven by the market penetration of first-line cis-ineligible mUC based on EV-103 study approved in April last year.

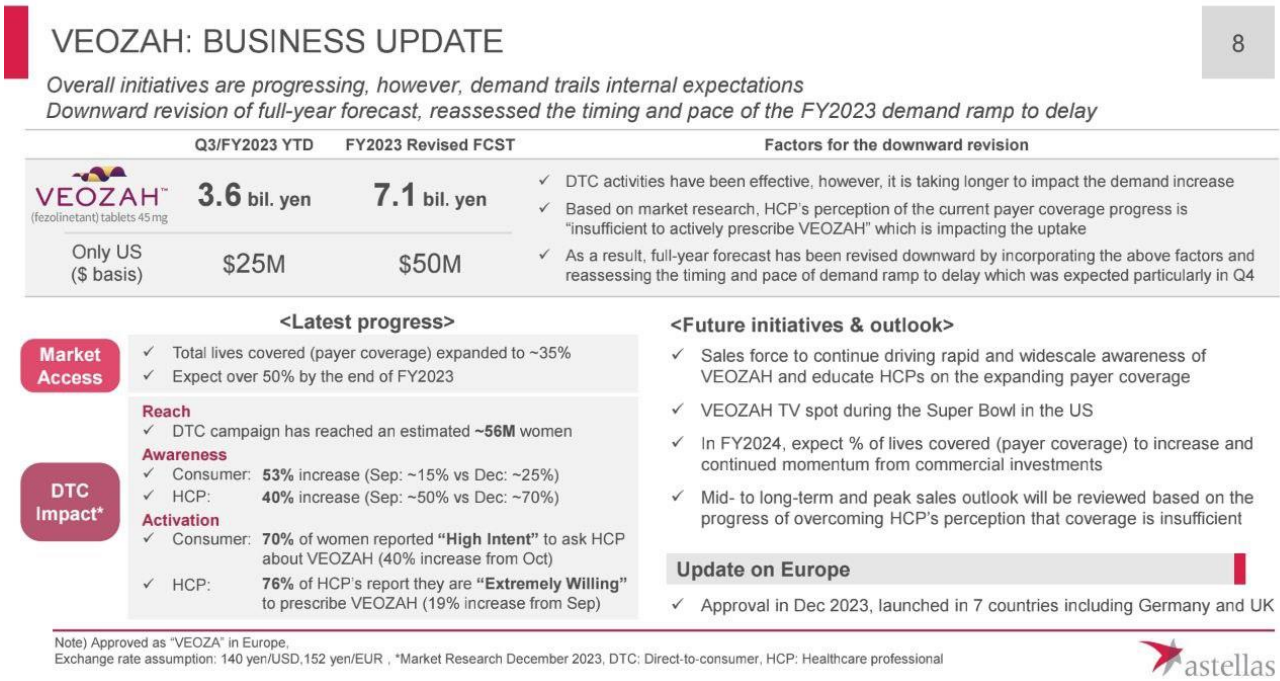
In addition, in December last year, first-line mUC additional indication was approved based on EV-302 study for both cis-eligible and cis-ineligible patients. What's noteworthy is an incredible speed up to approval. Approval was granted only two weeks after the FDA filing acceptance. We believe that FDA also highly evaluated the robust data of EV-302 study. We're expecting significant sales contribution in FY2024 and beyond driven by the penetration of the robust EV-302 study data and further expansion of eligible patient populations.

In Europe, reimbursement started in three new countries, including Spain with a big market. We have obtained reimbursement in a total of 13 countries by now. We are expecting further sales contribution.

Furthermore, we updated potential peak sales forecast for PADCEV. Incorporating the robust results of EV-302 study which even exceeded our initial expectations, we revisited our market share assumptions. We made an upward revision of potential peak sales forecast from JPY300 billion to JPY400 billion to JPY400 billion to JPY500 billion. We will aim to achieve JPY500 billion with PADCEV as an important growth driver.

Peak sales forecast is disclosed as in-market sales, not Astellas revenue. This is calculated as a total of sales booked by Pfizer for the Americas plus sales booked by Astellas for ex Americas. Indications in early clinical phase are not included in peak sales forecast such as NMIBC, or non-muscle-invasive bladder cancer, and other solid tumors. Depending on future progress, there can be an upside for peak sales forecast. Based on progress, we will also update you on peak sales forecast at an appropriate timing.

Just for your reference, you can find the image of economic conditions with Pfizer in the right bottom of this page. Schemes vary slightly by region, but we are assuming profit sharing on a global basis. Both the current progress and the outlook are extremely positive. We're expecting PADCEV to serve as a solid growth driver in FY2024 onwards.



On page eight, I will explain the VEOZAH business update.

Q3 year-to-date sales were JPY3.6 billion or USD25 million. Overall initiatives are making steady progress, such as market access and DTC activities. We feel more confident about the future product potential of VEOZAH.

On the other hand, with regard to FY2023 initial uptake, demand trails internal expectations and the actual results so far are behind our initial assumptions.

There are two main factors for demand lower than expected. First, the impact of DTC activities we started in October last year to the actual demand is lower than expected. The level of interest among consumers and HCPs is rising steadily with DTC activities. We are very confident about the direction of our initiatives. On the other hand, for women who have seen our DTC activities to actually ask HCPs about VEOZAH, the time frame is longer than our initial assumptions. As a result, it's taking longer to impact the demand increase.

Secondly, many HCPs feel that VEOZAH's current payer coverage is not enough. Total lives covered are expanding steadily, but based on market research, more HCPs than we assumed have a perception that the current coverage progress is not enough to actively prescribe VEOZAH, which is impacting the uptake.

The full year forecast of USD375 million we decided to keep in Q2 has been revised downward to USD50 million by incorporating the demand ramp delay due to these factors and by reassessing the timing and pace of the full-scale growth curve we expected in Q4.

Next, I will explain the latest progress.

As for market access, total lives covered expanded to about 35% as of the end of December last year. Payer discussions are ongoing right now. We are expecting over 50% payer coverage by the end of FY2023.

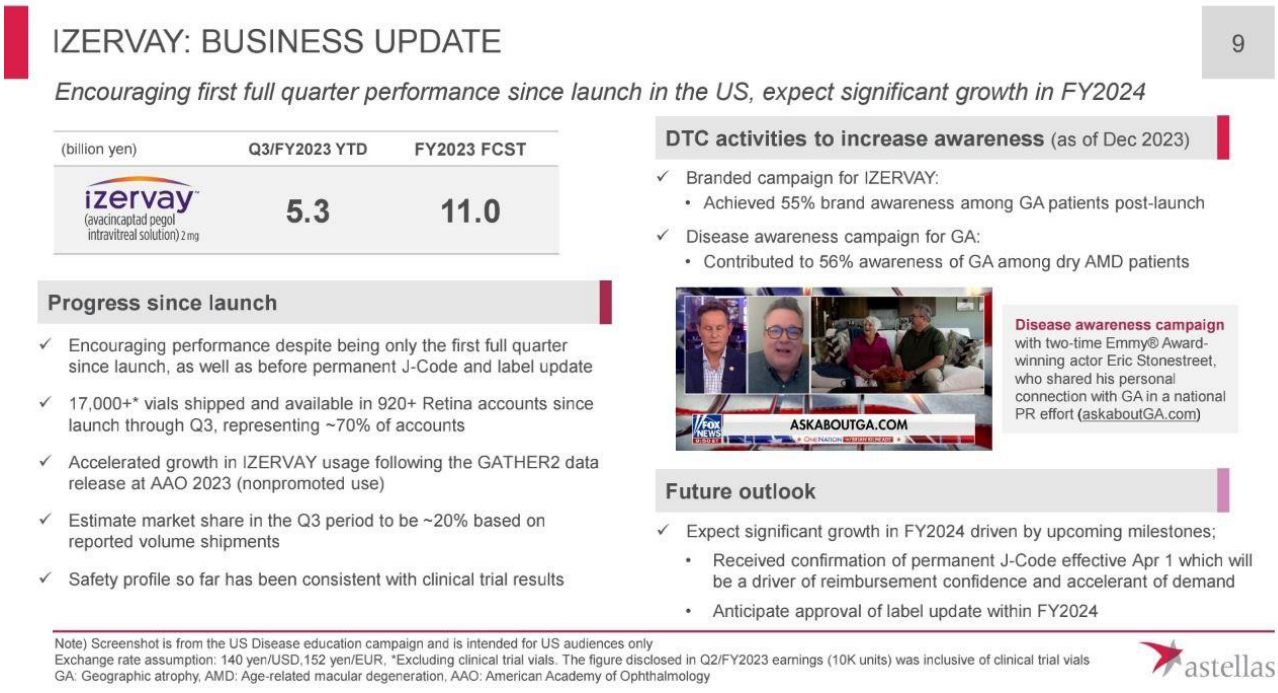
Regarding the effectiveness of DTC activities, we have received a lot of positive response. The level of interest among consumers and HCPs is going up steadily compared to the time before the initiation of DTC activities. In particular, activation of consumers and HCPs is an important progress. According to market research, 70% of women reported high intent to ask HCPs about VEOZAH. Also, 76% of HCPs report they are extremely willing to prescribe VEOZAH. We believe activation is important for the growth of VEOZAH. We'd like to aim further in this regard for the future as well.

As for our future initiatives, in order to address HCPs' perception that payer coverage is not enough, we will promote information provision to HCPs by sales force in an active and timely manner on the progress of the expanding payer coverage.

In DTC activities, we will broadcast VEOZAH TV spot focusing on the product brand during the Super Bowl in the US. More than 100 million people watch Super Bowl every year. Last year, we ran a VMS disease awareness-related TV commercial and received a lot of reaction. We are hoping to reproduce such success.

Regarding the future outlook, we are expecting a further increase in the percentage of lives covered and continued momentum from commercial investments in FY2024. Mid- to long-term peak sales outlook will be reviewed based on the progress of overcoming HCPs' perception that coverage is insufficient, and we will provide guidance at an appropriate timing.

Lastly, an update on Europe. We obtained approval in December last year. The product was launched in a total of seven countries, including Germany and UK. We will aim to increase launched countries and obtain reimbursement in various markets.



On page nine, I will explain the IZERVAY business update.

About the progress since launch, IZERVAY was launched in the US in September last year. Sales in about four months since launch were JPY5.3 billion. This is an encouraging performance of the launch despite being before permanent J-code and label update. This progress was great and made us feel more confident about its future growth.

Since launch, more than 17,000 vials have been shipped and became available in over 920 Retina accounts.

Particularly, the GATHER2 data released at AAO 2023 in November last year was highly evaluated by specialists, and accelerated growth in IZERVAY usage was confirmed after the presentation.

Based on the reported shipment volume data, we estimate market share in the Q3 period to be about 20%. Taking into account the fact that it's just about four months since launch, we think this is an extremely positive number.

Safety profile so far in the real-world settings has been consistent with clinical trial results, according to the report. We remain confident about the product profile of IZERVAY.

Next, about DTC activities aiming to increase awareness of the IZERVAY product brand and GA as a disease is shown on the right-hand side of the page.

Since the approval of IZERVAY, we have been rolling out branded campaign for IZERVAY. We have achieved 55% brand awareness among GA patients post launch.

As for disease awareness campaign for GA, we formed a partnership with two-time EMMY Award-winning actor Eric Stonestreet, who shared his personal connection with GA in a PR effort. These initiatives turned out to be successful and contributed to 56% awareness of GA among dry AMD patients.

Lastly, about the future outlook. We are expecting two major milestones in FY2024. First, we will receive confirmation of permanent J-code effective April 1 this year. The other is that we are anticipating approval of label update within FY2024. We're expecting significant growth in FY2024 driven by these upcoming milestones.

Together with PADCEV and VEOZAH, we're expecting IZERVAY to contribute to sales as an important growth driver for the future.

Q3/FY2023 FINANCIAL RESULTS: COST ITEMS

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SG&A expenses increased YoY due to the impact of the acquisition of Iveric Bio and the investment in VEOZAH, however, progress in line with expectations

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

Cost Items	YoY change	Ratio to Revenue	Progress against FCST	
Cost of sales	-3.0%	18.4% (-1.0 ppt YoY)	-	Cost of sales ratio was as expected
SG&A expenses excl. US XTANDI co-pro fee	+20.4% (+14.6% excl. FX impact)	33.7% (+5.1 ppt YoY)	72.9%	YoY increase excl. FX impact: approx. +49.0 bil. yen ✓ Impact of Iveric Bio acquisition (approx. +20.0 bil. yen. YoY) ✓ Increase in VEOZAH-related costs (approx. +30.0 bil. yen YoY) ✓ Reduction of mature products-related costs (approx. -6.0 bil. yen YoY)
R&D expenses	+5.0% (+1.6% excl. FX impact)	18.2% (+0.5 ppt YoY)	74.6%	Impact of Iveric Bio acquisition: approx. +8.0 bil. yen

Full-year forecast revised in Nov 2023, Exchange rate assumption: 140 yen/USD,152 yen/EUR

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Next, on page 10, I will explain cost items.

As is shown in the table, cost of sales ratio was 18.4%, improving by one percentage point YoY and was on track.

SG&A costs excluding US XTANDI co-promotion fees increased by 20.4% YoY. When ForEx impact was excluded, the YoY increase was 14.6% or about JPY49 billion. As many factors behind, the impact of Iveric Bio acquisition was about JPY20 billion. VEOZAH-related sales promotion costs rose by about JPY30 billion YoY. On the other hand, sales promotion costs related to mature products such as mirabegron decreased by about JPY6 billion YoY. We reduced investments in mature products actively and allocated resources to important growth drivers we should invest in, such as IZERVAY and VEOZAH. We are on track in our spending.

R&D expenditures increased by 5% YoY and increased by 1.6% when ForEx impact was excluded. With the Iveric Bio acquisition, we booked an R&D expenditure of about JPY8 billion and we used it as planned.

FY2023 REVISED FORECAST

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- *Revenue: Downward revision*
  - ✓ *VEOZAH: Full-year forecast revised downward incorporating current progress*
  - ✓ *No change has been made on exchange rates and other products' full-year forecast*
- *Core OP: Downward revision*
  - ✓ *Profit also revised downward aligned with VEOZAH's downward revision*
  - ✓ *Partially mitigated by the review of cost items*

(billion yen)	FY2023 FCST*	FY2023 Revised FCST	Change	Main items of revision
Revenue	**1,608.0**	**1,562,0**	**-46.0**	Downward revision of VEOZAH: 53.3 bil. yen → 7.1 bil. yen (US only: $375M → $50M)
SG&A expenses	737.0	731.0	-6.0	Review of VEOZAH investment timing aligned with reassessing the timing and pace of demand ramp-up
R&D expenses	290.0	286.0	-4.0	Applied accounting treatment recognizing IZERVAY's production cost (R&D expenses) as inventory assets
Core operating profit	**199.0**	**164.0**	**-35.0**	
<Full basis>				
Operating profit	**123.0**	**83.0**	**-40.0**	

*Revised in Nov 2023, Exchange rate assumption: 140 yen/USD,152 yen/EUR

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On page 11, I will explain the FY2023 revised forecast.

We have revised our full year revenue forecast downward by JPY46 billion to JPY1,562 billion, incorporating the current progress of VEOZAH. Foreign exchange rates and revenue of products other than VEOZAH have not been revised from the full year forecast disclosed in Q2.

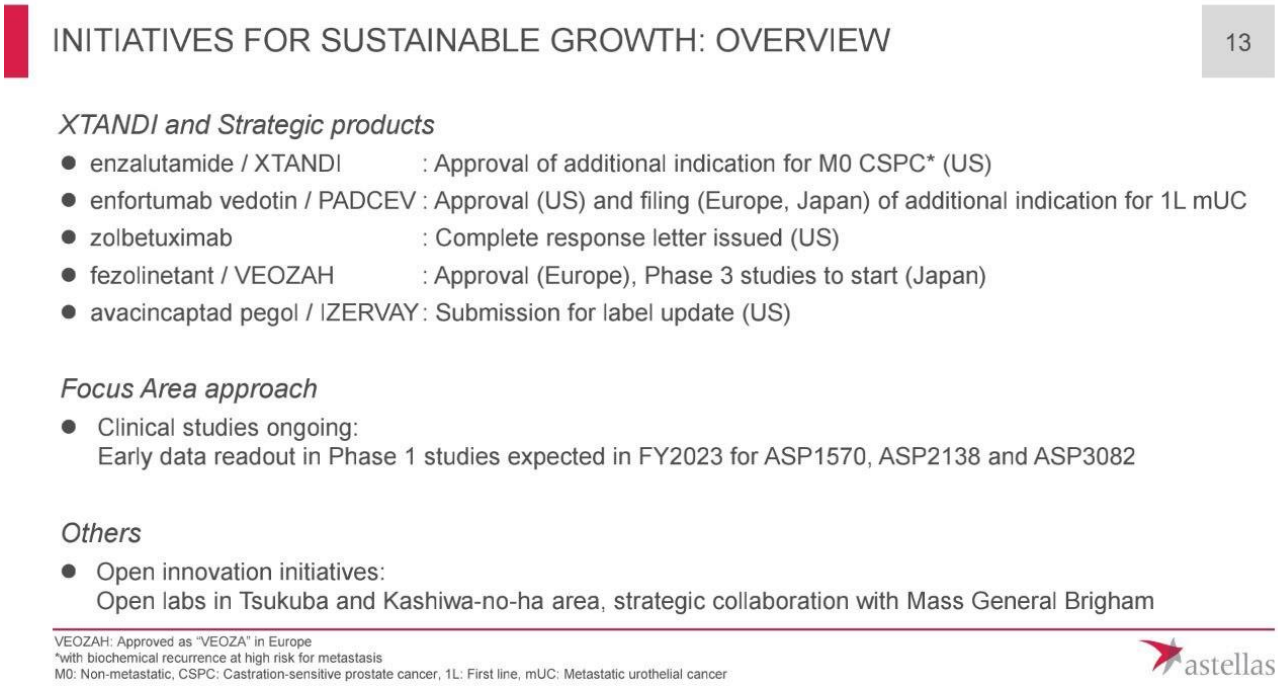
SG&A expenses are expected to be JPY731 billion, a reduction of JPY6 billion. In alignment with reassessing the timing and the pace of demand ramp-up of VEOZAH, we have reviewed some investments timing that we have planned in this fiscal year. We will continue to invest to maximize the product value of VEOZAH, but we will do so after carefully examining the optimum timing for the greatest return on investment.

R&D expenses are expected to be JPY286 billion, with a reduction of JPY4 billion. The production cost of commercial inventory of IZERVAY which was included in R&D expenses in Q2 will be recognized as inventory assets as a result of our reexamination of its accounting treatment, and the impact of this change has been incorporated.

As a result of the above cost review, the impact of the downward revision of VEOZAH has been partially mitigated and the core operating profit is expected to be JPY164 billion.

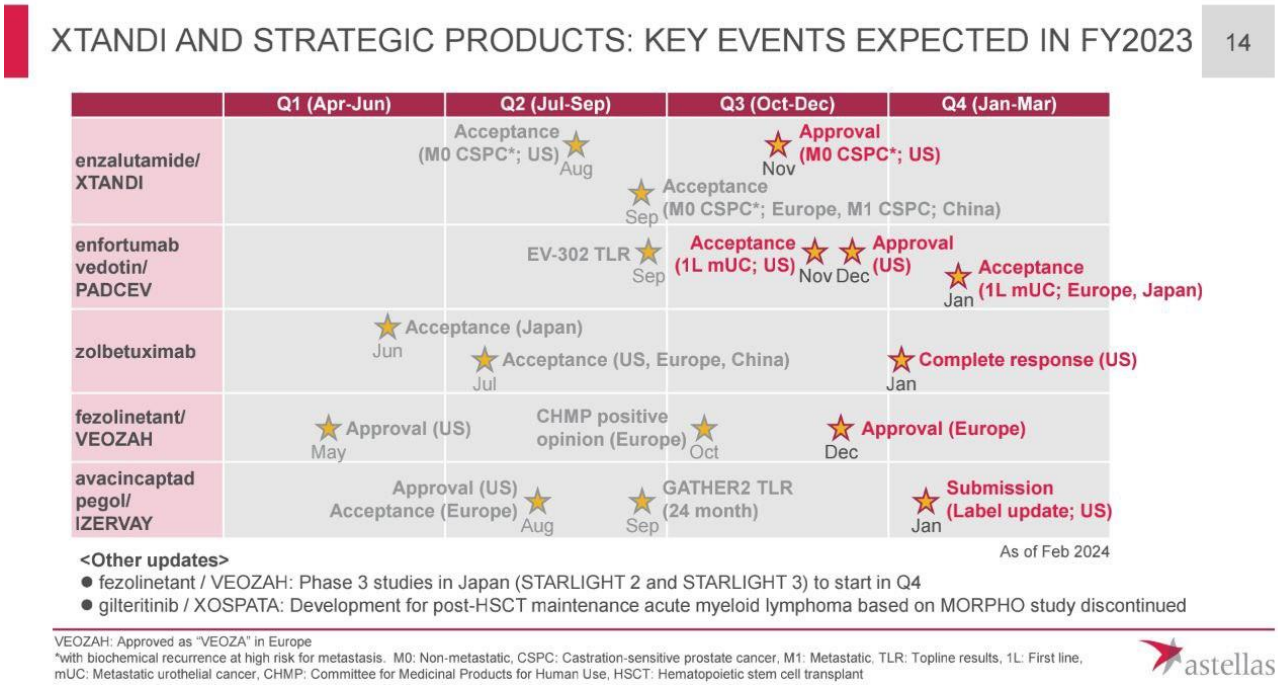
On a full basis, operating profit is estimated to be JPY83 billion mainly due to the core base revision.

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



Page 13 summarizes the main updates regarding R&D since the last financial announcement.

Over the past three months, there have been a number of important progress, particularly with the regulatory submission for XTANDI and key strategic products. Details are provided in the following slides.



Please turn to page 14. Here, I describe the progress of the key events expected in FY2023 for XTANDI and key strategic products. Progress since the last announcement is shown in red.

XTANDI received approval in the US in November last year for the additional indication of M0 CSPC, non-metastatic castration-sensitive prostate cancer with high-risk biochemical recurrence based on the EMBARK study.

Regarding PADCEV, based on the EV-302 study for the additional indication of first-line treatment of locally advanced or metastatic urothelial carcinoma, the filing in the US was accepted in November last year and the approval was granted in December. The filing for additional indications in Europe and Japan were also accepted in January.

As for zolbetuximab, in January we received a complete response letter from the US FDA. I'll provide an update about this later in this presentation.

VEOZAH was approved in Europe last December.

For IZERVAY, we submitted a US label update application in January based on 24-month data from the GATHER2 study.

Other updates are listed outside of the chart.

For VEOZAH, we will conduct Phase III studies with the aim of regulatory submission in Japan. STARLIGHT 2, a pivotal study, and STARLIGHT 3 to evaluate the long-term safety, will be started in Q4.

Regarding XOSPATA, after reviewing the top line results of the Phase III MORPHO study for post-HSCT maintenance acute myeloid lymphoma, together with additional analysis and consideration, we have decided to discontinue the development based on the result of this study.

By accelerating the implementation of measures in each project, we were able to accomplish all the key events planned for FY2023 as of January.

PROGRESS IN LATE-STAGE PIPELINE

4 regulatory approvals for new indication or region received during the quarter

	Indication	Region	
Xtandi (enzalutamide)	M0 CSPC with BCR at high risk for metastasis	US	✓ First novel hormonal therapy for the indication ✓ Approved for monotherapy as well as combination with GnRH analog
PADCEV enfortumab vedotin	Locally advanced or metastatic urothelial cancer (combination with pembrolizumab)	US	✓ New treatment option to transform the current standard of care for decades ✓ Approval in a remarkably short period of time • 3 months after TLR readout in EV-302 study • 2 weeks after sBLA acceptance
VEOZA fezolinetant	Moderate to severe VMS associated with menopause	Europe	✓ First-in-class nonhormonal treatment option ✓ Expansion of opportunities to address unmet medical needs worldwide
CRESEMBA (isavuconazonium sulfate) 372 mg for injection 74.5 mg - 186 mg capsules	Invasive aspergillosis and invasive mucormycosis in pediatric patients	US	✓ High unmet medical needs in pediatric patients ✓ Extension of market exclusivity period by 6 months granted

VEOZAH: Approved as "VEOZA" in Europe
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, BCR: Biochemical recurrence, GnRH: gonadotropin-releasing hormone, TLR: Topline results, sBLA: Supplemental Biologics License Application, VMS: Vasomotor symptoms

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Please turn to page 15. We have made progress in the late-stage pipeline, with four regulatory approvals for new indication or region received during the quarter. I will discuss these in more detail.

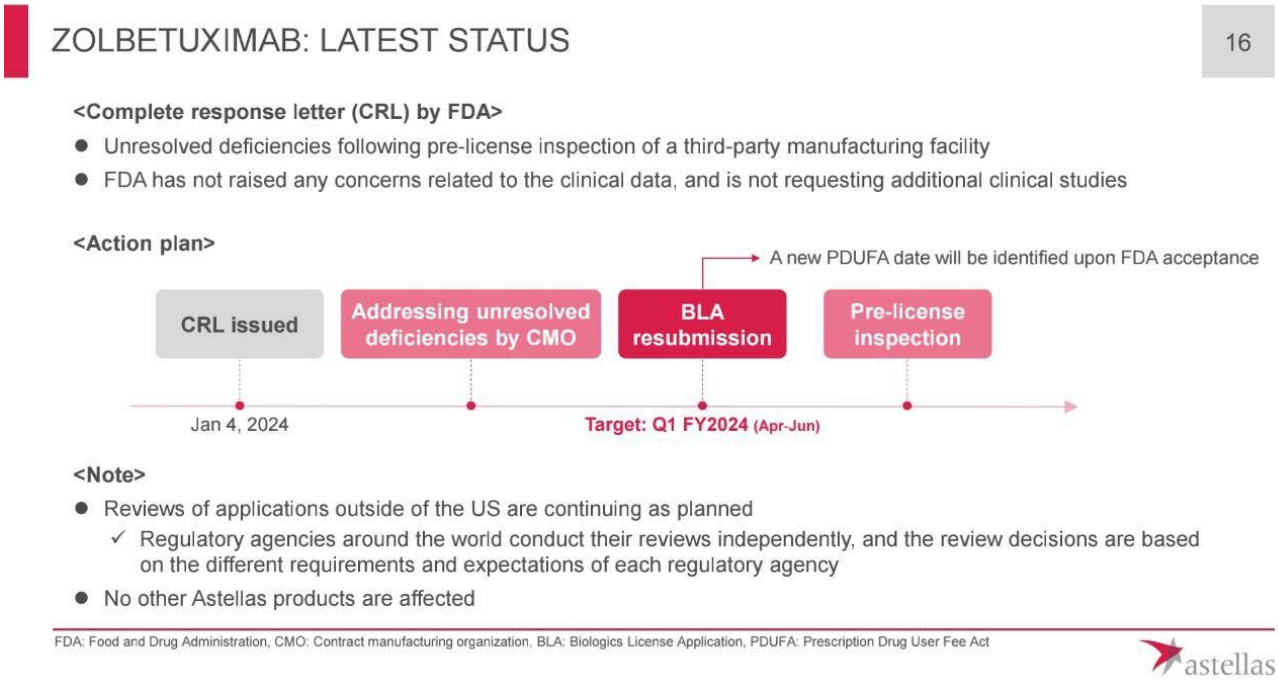
XTANDI, it is the first novel hormonal therapy receiving US FDA approval for M0 CSPC. Based on the result of the EMBARK study, XTANDI is now approved for monotherapy as well as combination with gonadotropin-releasing hormone analog.

Regarding the addition of new indication for PADCEV, we expect that this will be a new treatment option to transform the current standard of care for decades and will bring significant value to patients in the first-line treatment of locally advanced or metastatic urothelial carcinoma. In addition, as I mentioned earlier, PADCEV was approved in less than three months after the top line results readout of EV-302 study and, incredibly, only two weeks after the sBLA accepted by FDA.

VEOZAH was also approved in Europe as the first-in-class nonhormonal treatment. Vasomotor symptoms associated with menopause are known to be a common unmet medical need not only in the US but in many other countries as well, and this approval gives us the opportunity to serve more women suffering from this condition.

CRESEMBA has an additional indication for pediatric patients with very high unmet medical needs. In addition, pediatric exclusivity was granted by the FDA, extending its market exclusivity period by six months in the US.

We hope that these achievements will help maximize the value of each product.



On page 16, I will provide an update on the status of zolbetuximab.

In early January, we received a complete response letter from FDA informing us that FDA could not approve zolbetuximab by the target date due to unresolved deficiencies following the pre-license inspection of the contract manufacturing organization's or CMO facility.

On the other hand, FDA has not raised any concerns related to clinical data and is not requesting any additional clinical studies.

Let me explain our action plan in light of this situation using the diagram in the middle. We are currently working closely with FDA, and the CMO as well, to address the findings. Once Astellas Pharma confirms that the CMO's response is complete, we will resubmit the BLA and a new PDUFA date will be identified upon FDA acceptance. FDA will then conduct an inspection of the facility and decide whether or not approval is granted. The target date for BLA's resubmission is Q1 FY2024.

In parallel to that, reviews of applications outside of the US are continuing as planned. Regulatory agencies around the world conduct their reviews independently, and the review decisions are based on the different requirements and expectations of each regulatory agency. This incurs no impact on other Astellas products. We will keep you updated on any developments as they occur.

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
	Gene regulation (AAV)			
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing toward early data readout in FY2023
	Bispecific immune cell engager	ASP2138	Anti-Claudin 18.2 and anti-CD3	Phase 1 study ongoing toward early data readout in FY2023
		ASP2074	Anti-TSPAN8 and anti-CD3	Phase 1 study ongoing
		ASP1002	Undisclosed	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	Phase 1 study under preparation to start in Q4/FY2023
	Cancer cell therapy			
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells	Phase 1b study ongoing
	Cell replacement (UDC)			
	Gene regulation (AAV)			
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	PPARδ modulator	PMM: Phase 2/3 study ongoing DMD: Next step under discussion
Targeted Protein Degradation	Protein degradation	ASP3082	KRAS G12D degrader	Phase 1 study ongoing toward early data readout in FY2023
Primary Focus Candidate	Immune modulating/regulatory cells			
	Tissue-specific immune regulation			

Modality
- Small molecule
- Antibody
- Gene
- Cell

*Not exhaustively listed. AAV: Adeno-associated virus, MTM1: Myotubularin 1, FDA: Food and Drug Administration, GAA: Acid alpha-glucosidase, DGK: Diacylglycerol kinase, TSPAN8: Tetraspanin-8, IL-2: Interleukin-2, RPE: Retinal pigment epithelium, UDC: Universal donor cell, PPAR: Peroxisome proliferator-activated receptor, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy, KRAS: Kirsten rat sarcoma viral oncogene homologue

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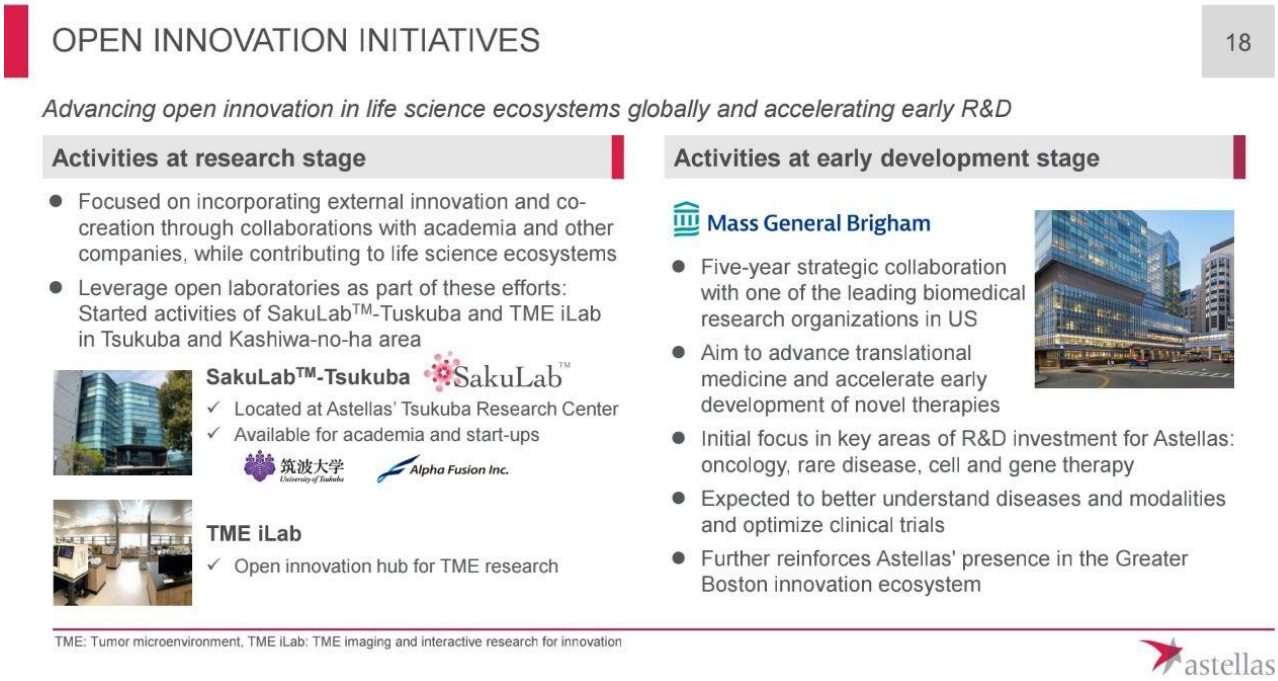
On page 17 I will provide an overview of the current status of the focus area approach projects in clinical phase.

There have been no major changes in the past three months, and each project continues to progress in clinical studies. Of these, ASP1570 and ASP2138 in primary focus immuno-oncology and ASP3082 in targeted protein degradation are aiming to obtain early data readouts in Phase I monotherapy dose escalation study ongoing during FY2023. We are prioritizing the three projects as the leader projects for each approach and expect to obtain data that will lead a POC in FY2024 or later. Since the studies are still ongoing, we are unable to provide specific status at this time, but we will provide updates as soon as they become available at an appropriate timing, such as when we announce financial results.



On page 18, I will explain recent examples of open innovation initiatives, such as the activities at research stage and at early development stage.

As part of activities at research stage, we focused on incorporating external innovation and co-creation through collaborations with academia and other companies and contributions to life science ecosystems.

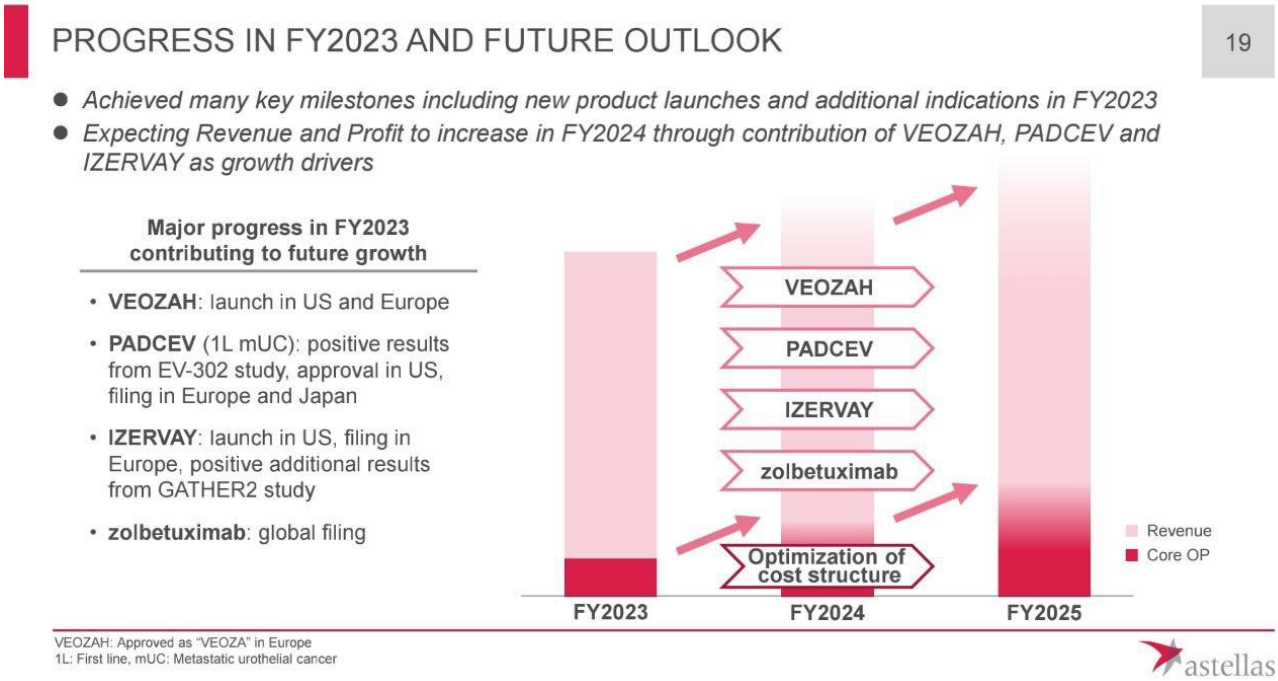
As part of these efforts, we are leveraging open laboratories and have established SakuLab-Tsukuba and TME iLab in Tsukuba and Kashiwa-no-ha areas in Japan.

SakuLab-Tsukuba is an open innovation center established in the Astellas Pharma's Tsukuba Research Center and is equipped with experimental facilities that can be used immediately after move-in. Academia and start-ups that move in here will have the opportunity to network with other users and with Astellas Pharma's researchers in addition to support from various Astellas experts.

TME iLab was established in the Kashiwa-no-ha area as an open innovation center for cancer microenvironments and [inaudible] interactive cancer where researchers from inside and outside the Company can freely discuss and advance their research. The Kashiwa-no-ha area is in close proximity to the National Cancer Center and many of Japanese leading advanced medical facilities in academia, and we expect to promote collaboration by maximizing the advantage of this.

On the right side of the slide are activities at early development stage. We have entered into a five-year strategic collaboration with Mass General Brigham, or MGB. MGB is based in Boston and provides medical education as a teaching hospital at Harvard University. At the same time, MGB is known as one of the top medical research institutions in the world, conducting a wide range of translational and exploratory research. Through this collaboration, the two companies aim to combine their expertise and knowledge to accelerate the early development of innovative therapies. The collaboration has agreed to initially focus on Astellas Pharma's core R&D areas of oncology, rare diseases, and cell and gene therapy. We expect the partnering with a highly specialized academic institution such as MGB will help us to better understand disease and modalities, optimize clinical trials, and accelerate the early development of relevant primary focus areas. We

also expect that Astellas Pharma's presence in Boston area, one of the world's leading life science areas, will be further reinforced, which creates new opportunities for open innovation.



On page 19, I will explain the summary of our progress to date in FY2023 and our outlook.

So far in FY2023, revenue and core operating profit have been below our initial forecast due to the LEXISCAN generic and Iveric Bio acquisition as well as lower-than-expected progress in VEOZAH.

On the other hand, we made significant progress in the development of key strategic products, including the launch of VEOZAH and IZERVAY and the new indication of PADCEV. We have achieved a number of important milestones which we expect to become full-fledged growth drivers from FY2024 onwards.

VEOZAH has been slow to ramp up due to the fact that many physicians feel that insurance coverage is insufficient, which is a barrier to prescribing. In response, we will work to further expand insurance coverage and promote the active and timely provision of information to physicians, which will lead to full-scale growth.

In addition, while ensuring investment in growth drivers, we have begun considering various measures to improve margins, strictly control expenses, and a revision of our planning process. As the CFO, it is my responsibility to ensure that these initiatives are carried out. We'll provide details of these initiatives at an appropriate time in the future.

As a result of the above, we expect to achieve an increase in profit in FY2024. We hope to show that we will be able to achieve sustainable growth from FY2024 onward with the setting FY2023 as a turning point.

That is all. Thank you very much for your attention.

Ikeda: Kitamura-san, thank you very much. That's all for our presentation.

Question & Answer

Ikeda [M]: Next, we'd like to entertain questions from the audience. If you have questions, please press the raise hand button at the bottom of your Zoom screen. If you're joining from your smartphone, you should tap details. The raise hand button will be shown, so please press it.

The emcee is 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 your questions.

Questions, please.

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

Yamaguchi [Q]: I have a few questions about VEOZAH. First, payer coverage is an issue, as you mentioned. Right now, payer coverage is not making progress. There is a delay. What's the biggest reason behind? That's my first question. What's the reason why there is no progress in payer coverage?

Number two, patients' awareness is increasing with DTC, but they are not making visits to HCPs. Why? That's my second question.

Thirdly, you are going to examine the details from now on. At what timing are you going to examine the details?

These are my three questions about VEOZAH.

Kitamura [A]: Thank you very much for your question. First of all, I'd like to briefly respond, then Claus will make additional comments afterwards.

First of all, payer coverage for VEOZAH, it's not really delayed. As of the end of December last year, we made progress up to 35%, and this year, over 50%. So, we are making progress as planned. On the other hand, we are making progress, but from HCPs' perspective there may be no progress. There is such a perception among HCPs, so we'd like to provide information in a timely fashion that we are making progress. We need to do these activities. So, it's not behind, we are making progress in line with the plan, but we have not been able to overcome their perception.

As for DTC awareness, it's on the rise. Why it's not reflected onto the actual demand, there are two major things, in our opinion. First, looking at DTC, people will become interested in VEOZAH and they may want to use it, and they go to HCPs to get the prescription. We thought that it's going to take about two months, but actually it's taking longer in reality. One more point, the HCPs' prescription, it may be difficult to prescribe right now. Because there's such a perception, they are not prescribing so much.

As for the timing to examine the details of the volume and sales, there are a few things I'd like to mention. First, we will implement the action, including payer coverage, when it's going to increase exceeding 50%. Then what way the physicians' and HCPs' perception will change, we have to identify.

Claus, anything to add from you?

Zieler [A]*: Yes. Thank you for your question, Yamaguchi-san. I would like to emphasize what Atsushi just said. Our payer coverage is actually progressing to plan. We have said in the last call and in the call before that, that we were aiming to reach more than 50% payer coverage by the end of the fiscal year. By the end of

December, we had reached 35%. By the end of January, we were already north of 40%. So, we are fully on track if you draw a line in terms of the payer coverage that we set out to achieve.

However, we're seeing that HCP perception is lagging the real coverage, so that's an opportunity for us with our sales force to educate physicians on the options for coverage that exist today. Our sales force is doing that, and we are reinforcing our efforts there. There is a difference between payer coverage progressing and the perception in the HCP community which is not up to date with that progressing coverage, so that's the issue that we have to address now.

As to the DTC, again, as Atsushi said, we're actually very, very happy with how the DTC is working. You can see it on the page that Atsushi presented, with the increase in awareness both in consumers and in HCPs, but we are particularly encouraged with the intention. The increase in high intent of women, that increased from 50% in September to 70% in December. That's a 20-percentage point increase in one quarter. The same for the HCPs, from the mid-60s, we had 64% extremely willing to prescribe in September, that's increased to 76% in December. Again, more than 10 percentage point increase. So, DTC is working, but we are seeing delays, for instance, in the time it takes women to get an appointment with the HCP. That's more than 40 days. So, the timing of the awareness and the intention translating into a consultation and then a prescription is simply longer than we had anticipated. Last call we told you we were estimating two months for that to translate. We're now estimating more likely three to four months. So that's just the delay in women who want to consult, being able to consult and get a prescription from the HCP.

Yamaguchi [Q]: Thank you very much. Then let me ask you one additional question. Regarding the payer coverage, I understand about that quite well, thank you.

So, your view and HCPs' view or perceptions are different. To put it in a reverse way, of course, education is important, but HCP perception, what is the percentage of the physicians who consider that the coverage is sufficient? This is the opposite way to ask you the question.

Zieler [A]*: Exactly right, Yamaguchi-san. We're asking the same question right now. Let us get back to you next quarter with more details on that because we are doing some research on exactly the question, what's the threshold where HCP say, oh, yes, now I feel free to prescribe. Let us wait for that data to come in, and we'll share that with you next call.

Yamaguchi [Q]: Two more questions, just briefly. You have CSP which is ongoing. IZERVAY is added, VEOZAH is slightly behind. You were revisiting peak annual sales forecast. CSP as a whole is going to be reviewed? Do you have such opinion?

Kitamura [A]: Thank you for your question. As of now, CSP2021, we haven't changed our plan. We would like to work on it rigorously. When we announced Q2 results, IZERVAY in FY2025, including the amortization of intangible assets, including that for IZERVAY, considering that impact core operating profit, 30% can be difficult to achieve.

On the other hand, IZERVAY and other products, they will continue to grow beyond XTANDI's LOE for sustainable growth. These are important factors, so we will continue to work on these products.

VEOZAH figures, these will have impact on the achievement of CSP2021. As Claus said before, we have to identify the progress of VEOZAH, and we'd like to closely watch the situation.

Yamaguchi [M]: Thank you very much. That's all my questions.

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

Hashiguchi [Q]: Hashiguchi speaking. Thank you very much. First question is about VEOZAH. Information provision to HCPs will be reinforced, and then these issues could be resolved. Do you think that it's going to be happening? Conditions for patients to receive payer coverage, if these conditions are complicated, you have to simplify these conditions. Otherwise, the coverage ratio may increase, you may not be able to resolve the issues. So, what kind of patients and what kind of background of patients can receive coverage? In order to ease the conditions, rebate can be expanded to simplify the coverage. What's your view about the simplification of this?

Kitamura [M]: Thank you very much. Claus is going to respond.

Zieler [A]*: Thank you, Ashish. I don't think we are changing our approach to payers at this point in time. There's no need for us to do rebating the way you suggest it. Our payer coverage is progressing. It's progressing according to plan. Yes, HCPs have not perceived that yet, but they will over time. We know that HCP perception tends to lag this kind of progress because, of course, it takes time for them to be informed when a payer coverage contract comes in. We are continuing exactly on the same approach, and we're very confident that we will deliver on the more than 50% payer coverage that we aim for by the end of FY2023.

I would suggest that next quarter when we talk again, we concentrate on the question of, has HCP perception caught up with the progress that we're making on payer coverage, rather than now addressing the question of what changes do we have to make to our approach to payer coverage.

Hashiguchi [Q]: Thank you very much. Second question is about IZERVAY, about the update of the label. Toward the back side of the material, it says that in January the submission is done for the label updates. What kind of contents in this label update and to what extent of impact of that is likely to be incurred? Would you please explain about them? At AAO, the data is presented. According to that, from the beginning once in two months of the administration becomes possible, or from 12 months, and the restriction of the administration is going to be now lifted up and released. Seemingly, there might be certain risks for that, but would you please explain your view about that.

Kitamura [A]: IZERVAY labeling update, first of all, briefly, I would like to explain. After that, Taniguchi is going to explain to you the details.

What we are aiming at with this update is the restriction of duration of administration which is currently 12 months. That is what we would like to lift up. And also the once per month schedule is what we would like to extend to once in two months. Of course, ultimately, what kind of label we can gain is depending on the authority review, so we just have to wait. However, our intention is just what I mentioned.

Taniguchi [A]: Let me make some additional comments. For IZERVAY, GATHER2 study is basically, I believe, what you are talking about. GATHER2 study itself is a 24-month study. This shows the separation of the geographic atrophy which is statistically and also clinically significant. So IZERVAY therapy showed that level of the efficacy. Using that data, therefore, just like Kitamura explained, in January, we did a resubmission for the label update.

So, first, this 12-month restriction of the administration is intended to be lifted, and on top of once per month data, once in two months data is now submitted, so that both way of the administration is possible. We are now trying to update at the label. Of course, the final result is depending on the outcome of the authority review, so I'm not going to talk about that, but the review is ongoing currently.

Hashiguchi [Q]: Thank you very much. In the GATHER2 study, well, the first is once monthly, and it was switched to once in two months, and there was no data that administration is once in two months from the beginning. Is your resubmission targeting the once in two months administration from the very beginning of the treatment?

Taniguchi [A]: Ultimately, of course, we have to do the discussion with the authority. We are providing that GATHER2 data, and at the end what is going to happen can be updated later on.

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

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

Muraoka [Q]: Thank you very much. I also have a question about VEOZAH and IZERVAY. First, about VEOZAH, prescription will start in two months, but it's taking three or four months as was presented. In other words, your sales plan, according to your sales plan for this fiscal year, it's going to increase firstly and it's behind. In January/March period it's going to increase, and then there's going to be a faster increase from April/June. It's just the timing being shifted at a later time point. Is that the right picture I can draw? Can I have such a simplified understanding? For example, according to the table you showed before, you need to sell JPY20 billion in April/June period. Do you still have such plan? That's my first question.

Kitamura [A]: Regarding VEOZAH, I'd like to briefly comment. Regarding the initial forecast for FY2023, before starting DTC activities, we wanted to sell a certain volume, and after DTC activity initiation, relatively rapidly, it will drive the after demand. These were assumptions. Regarding the first point in the previous call, it didn't come so much. Now, regarding the pickup after the initiation of DTC activities, as you pointed out, the timing of resulting after demand is shifted and being delayed and HCPs' perception may be a barrier to prescription, so there is one additional parameter. What is going to happen to this is something we have to watch.

Muraoka [Q]: Thank you very much. HCPs' perception, you were talking about it continuously. Have you missed any other factors? No such possibility?

Zieler [A]*: This is Claus speaking. Thank you for your question, Muraoka-san.

I do believe the two factors that we have mentioned are the ones that play a role here. One is the HCP perception of coverage, which is lagging behind our real progress, and the other is the timing in the activation of the DTC, so how much time when a woman decides to consult a physician, how much time does it take for her to make an appointment and to actually get a prescription. That timing is just longer than we had anticipated previously.

So those are the two factors we've identified, and we believe that the HCP perception factor will normalize over time. Of course, the question of how much time does it take for a woman to book an appointment, I think that's probably going to be a static factor from now on. I hope I answered your questions, but to confirm, those are the two factors that we identified.

Muraoka [Q]: Understood. Thank you very much. Now, the second is going to be about IZERVAY. December, JPY2.9 billion, so compared to SYFOVRE, the situation is getting better. There's a strong growth in the US. Now the question is about EU. SYFOVRE is facing difficulty in the European market. That is not the company's reasons, but the company is saying this is due to the authority. So, what about you, Astellas Pharma? In terms of the European market, are you looking at it in the same way as Apellis, or do you think that is some sort of a misunderstanding and therefore you can get the approval in the European market? On top of that, the intangible asset is 150 billion other than US. So, if you face the difficulty in Europe, to what extent of the impairment risk it would incur?

Kitamura [A]: Thank you for the question. That is about the European approval, therefore, I make a brief explanation, which is followed by Taniguchi.

SYFOVRE, negative opinion is issued, and we have, of course, recognized that. We cannot assume the decision by the authority; therefore, we work within the information available of us now. But if we're looking at the

clinical trial study, as you know, IZERVAY is aiming at GA for which the treatment is not available these days, and the consultation with the authority is on track. But of course, we cannot assume the kind of judgment or decision they will make.

Taniguchi [A]: I would like to make some addition just briefly. As Kitamura explained, European IZERVAY submission and actual review are ongoing. I cannot talk about the other company's situation. However, for us, for IZERVAY, Two Phase III pivotal study was conducted in GA. Geographic atrophy progress was suppressed at the 12-month point in a statistically significant manner, and this is only one kind of such drug. The data was announced in November. Twenty-four months post administration, GA progress was statistically significantly suppressed. Again, in that sense, this is a very first drug. Safety perspective, we have a consistent data, robust data. In looking at both the GATHER1 and GATHER2 data, the data is consistent with the safety information that is already available. Ultimately, including Europe and looking at globally, this two pivotal study safety and efficacy balance is reviewed for the final decision. So, what we can say here is that in Europe, the review is ongoing in a smooth manner.

Muraoka [Q]: Thank you very much. Apellis mentioned that the unconceivable outcome or endpoint was requested by the authority in its new arms, but your data shown is in line with the expectation or the request of the authority in Europe? Based upon the consultation with them, you understand it in that way, right?

Taniguchi [A]: So far there was no critical point out or mentioning from the authority. There are 120-day queries and answers are being prepared. Therefore, if we can make some update about this at an appropriate timing, I would like to inform that.

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

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

Ueda [Q]: Ueda from Goldman Sachs Securities speaking. My first question is about PADCEV. You made an upward revision of the peak sales forecast. The FX assumptions have changed a lot from the previous time. On a local currency basis, what's your view? What are the changes in your opinion on a local currency basis? EV-302 study, based on that, you explained the situation. So, what's your opinion resulting in the upward revision of peak sales forecast?

Kitamura [A]: Thank you. What has changed the peak sales forecast of PADCEV significantly, rather than FX rate, it's EV-302 data, in our opinion. If you look at page 35, you can see a large number of eligible patients. As for 1L mUC, we were able to obtain our approval. This is a big driver for us.

Zieler [A]*: If I could add, I think you have to think about PADCEV in three steps. First, we got approval of the second-line+ indication. So, second line, a doctor had to treat first basically with cisplatin or with avelumab. That was the basis of our launch. Then, in April this year, only in the US, we received approval of the EV-103, which is a first-line indication but only for part of the population, only for the part of the population that is cisplatin ineligible. So that's only part of the first-line indication. And that is what provided already such good growth in this year in the US, and we updated you on that in the last quarterly call. We revised our FY2023 forecast upwards on the basis of that very strong uptake in that partial first-line indication in the US.

Now, in combination with pembro, we have the full first-line patient population available to us, so both cisplatin ineligible, but also cisplatin eligible. That really opens up the whole field of first-line treatment for a doctor. Given that we had such a strong echo in the ESMO Congress when we presented the data to physicians, we really think that this has the potential to change practice in a very significant way, and that is what's causing now our optimism and our upward revision because we now have this very strong data for the entire first-line population that a doctor can see.

I hope this stepwise fashion of thinking about the PADCEV patient populations helps on why we have updated you first with an upward revision for FY2023 results in last quarter based on fast uptake of EV-103, which is only partial first line, and now we are updating you for the peak sales because of the robust data of EV-302, which gives the doctor access to all patients in first line with PADCEV and pembro combination. So, I hope that explains.

Ueda [Q]: Second question. Toward the end of the examination by Kitamura-san, the planning process change is part of your consideration, I think that's what you mentioned. Currently, what kind of issues do you see for the planning process, and in what way would you like to revise? What's your perspective about this?

Kitamura [A]: Thank you for the question. First of all, I'm not saying that the current way is not good at all, rather that we would like to reinforce the current process. Especially regarding new products, including timing, there are always uncertainties, so we would like to look at them in a range or based upon scenario and when we have beforehand what kind of actions we should make. In that sense, scenario planning is something we can review, and in a timely manner, we need to make the appropriate decision-making. Depending on the necessity, we are going to accelerate reallocation of the resource. That's also something we'd like to do. So basically, it's about scenario setting and also the speed of decision-making. Those are something we see more room that we can work on to reinforce it further. That's all.

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

Ikeda [M]: Thank you very much. Next is JPMorgan, Wakao-san, please.

Wakao [M]: Wakao speaking, thank you very much.

First, it's about VEOZAH. Thank you for the explanation so far. There's a delay compared to the initial plan; I understand about that. FY2025, JPY300 billion that you are aiming at, and I believe, currently, it's very difficult to achieve. So how do you view it?

Next is about how to use the expenses. For this fiscal year, partly, you reduced some. Next fiscal year and afterwards, VEOZAH SG&A, how are you going to allocate that? There's a delay, so would you like to catch it up in the case you think about increased SG&A, or are you not going to increase that with efficient usage of the expenses, or will there be a reduction in SG&A overall?

Kitamura [M]: I would like to ask Claus to answer this question.

Zieler [A]*: Thank you, Wakao-san, for your question. Yes, we have a delay, but we're still very confident in the potential of this drug. There is a huge unmet medical need in this market, and we are tapping that unmet medical need as a pioneer. We're creating the market. That takes some time. So, our investment will continue until we see that our assumptions may have to change. Right now, I can tell you, our investment level is appropriate, both on the [field force] side and on the DTC side, and we intend to continue that also in the future, including in FY2024 as appropriate to drive the value of this brand.

Let me just confirm, Wakao-san, that I've answered your question?

Wakao [Q]: In other words, there's a possibility that you would increase the SG&A costs and so on for next fiscal year and afterwards?

Zieler [A]*: I believe that our current investment in VEOZAH is appropriate.

Wakao [M]: Understood.

Zieler [A]*: Barring events, I don't see movement up or down in a major way. Does that clarify?

Wakao [Q]: It's very clear. Now, second question is about the IZERVAY competition. There is about 20% of the market share. Currently, with the competition, compared to that, what's your current status of your product? The market itself is growing, so it seems that there is no fierce competition about getting the market share. But for SYFOVRE, how it's evaluated, how do you evaluate that compared to SYFOVRE in terms of getting market share?

Kitamura [M]: Claus, could you answer this question?

Zieler [A]*: Thank you again for your question. I would give you the following consideration. We've been on the market promoting IZERVAY since September. Until end of fiscal year Q3, that gives us four months on the market. In the last three months, so in the full quarter, October, November, December, we achieved what we estimate to be a 20% market share. That's based on the public information available of what SYFOVRE has shipped and what we have shipped. If we put all that together, we estimate approximately 20%. That's overall market share.

Taking into account that we entered the market six months after SYFOVRE, that means the new-to-brand market share in the last quarter must have been significantly higher than 20%. So, our estimation is that we are extremely competitive in the new patient capture with IZERVAY because that's the only way you would get a 20% market share within essentially the first full quarter on the market.

Wakao [Q]: I might have missed, but I'd like to ask you the last question. Medicare Part D redesign was mentioned. I'd like to hear more about the redesign, Medicare Part D to start from 2025 and the impact on your products.

Kitamura [M]: Claus is going to respond.

Zieler [A]*: So, I believe Atsushi, when he explained, was referring to XTANDI because that's the major impact we see from the Part D redesign that the Biden administration has put into legislation. When we think of Part D redesign, the first thing to consider is that this takes effect in calendar year 2025, so from first of January 2025. We are now talking about fiscal year Q4 of FY2024. That's the first consideration.

The second consideration is that this is a very complex change which affects both Medicare as a government institution reimbursing, it also affects the plans in the US, it affects what manufacturers have to pay, and it affects what patients have to pay. So, you have four factors going on at the same time. Patients have to pay less, plans have to pay more, manufacturers have to pay more, and Medicare is shifting what they pay. Trying to really estimate, pinpoint estimate, how all these factors play out is going to be very, very difficult.

What we have done so far is just mathematical calculations based on the publicly available information from who pays more and who pays less. We have not simulated, or we're in the process of simulating, how does behavior now also change in the marketplace as patients pay less and other players have to pay more. That's a very, very difficult exercise to do. So please understand that right now, all we are informing about is the factual mathematical calculation of what we know from the changes that kick in on first of January in 2025.

Wakao [Q]: So, there can be quite a certain level of negative impact. Should we assume that? You're still calculating the details, right, but do you have any assumption?

Zieler [A]*: From the simple mathematical calculations, we assume that not only Astellas Pharma, but all manufacturers, will have a certain extent of negative impact affecting gross to net. But as I said, there may be counteracting factors, based on how behaviors change in the market, which we cannot estimate at this point in time.

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

Ikeda [M]: Thank you very much. Next, UBS, Haruta-san, please.

Haruta [Q]: Haruta speaking from UBS. Question is about IZERVAY. The vasculitis issue, there's one case of vasculitis in the past. After that, there are any such cases? Is there any report of vasculitis or so after that? If that happened, what kind of feedback did you get? In the case of SYFOVRE and IZERVAY as well, if the frequency is low because unmet medical need is high, the market itself is growing, is there any feedback from the doctors? If there is any, I would like to learn about that.

Kitamura [A]: Thank you very much. As for the safety profile, it is consistent with the clinical study result. There is one case of off-label usage, but the second case afterwards, retinal vasculitis was not reported. There was no post-launch adverse event report of such. So, the result is consistent with the result we gained from the clinical trial.

Haruta [Q]: Then complement inhibitor for that mechanism itself in AAO questionnaire shows a bit of a negative way to look at it. Is there any change about that? AAO, there is a report about the negative perception on this complement inhibition. Is there any change about that?

Company Representative [A]: Let me respond to that. As Kitamura explained, I think the question is basically about safety. So far for IZERVAY, there is no report of retinal vasculitis at all. In the clinical trial as well, we've done GATHER1 and GATHER2, and there is no report of the retinal vasculitis. That's where we are.

The drug itself, regarding IZERVAY, C5 is targeted. RNA aptamer is the modality, and other competitor, peptide. And us, this is the intraocular administration and the kit for that. There is the appropriate provisioning. So, there is such a difference although the same target is targeted. However, based upon the available information for us, it seems there was no negative impression on to our product.

Haruta [Q]: Understood. Thank you very much. Zolbetuximab, CRL was received. There is a slight delay in your schedule. As of now, peak sales impact is none. This is may be about the situation after approval. For gastric cancer, CPS less than five is going to be the target in this market. Is that what you're going to target? Claudin 18.2 biomarker, how are you going to increase the awareness of this? Do you have any information you can share right now?

Kitamura [M]: Thank you. Claus is going to respond.

Zieler [A]*: Thank you. It's a very good question. The companion diagnostics for the testing for Claudin 18.2 varies considerably from market by market. We have markets, particularly in East Asia, where Claudin 18.2 testing awareness is very high, and we do not foresee problems with including that in testing. We have other markets, more Western markets, where we have to educate doctors much more on Claudin 18.2 testing.

Now, the program we've designed addresses both the awareness with doctors once we are able to promote the product, but we also have a program working with pathologists and the labs that have to do the testing because you actually need the awareness on both sides, right? You need it with the prescribing physician, you also need it with the pathologist and the lab that has to do the testing. So those programs are in place, and we are ready to educate physicians as soon as we get approval.

Haruta [Q]: Thank you very much. Any comment on the patient segments?

Zieler [M]*: Could you repeat your question, please?

Haruta [Q]: Claudin 18.2 is going to be important. In particular, CPS under five is the target population which could enjoy benefit from your product. What do you think of this? Target population with CPS under five, is that the target population with your drug?

Zieler [A]*: We will target the population in accordance with our label. Now, if you're looking for specifics within that population, we would have to get back to you with more details. I'm sorry, maybe I'm not 100% understanding your question.

Haruta [M]: Thank you very much.

Ikeda [M]: Thank you very much. Next, Bank of America Securities, Mamegano-san, please.

Mamegano [M]: Thank you very much. Mamegano is my name. Can you hear me?

Company Representative [M]: Yes.

Mamegano [Q]: Thank you very much for the confirmation. I have two questions. First of all, VEOZAH. This may be a bit of a future thing. The competitor from Bayer, elinzanetant, the clinical trial is said to be successful and probably next year is going to be launched in the market. What's your view about the competition? The market is still on the process of the expansion, so is this competition going to work positively for your product? What kind of deal do you have? Also, is there any benefit for first-comer or not? That's the first question.

Kitamura [A]: Probably last time, Okamura mentioned the same kind of thing. Having the competition there is both positive and negative. First, the market is getting bigger. That is one big positive impact. First, the market is getting bigger and how we can gain market share is one important thing. So, we would like to increase our owner brand awareness, although we are not the first-comer. Claus, do you have any additional comment? No? Thank you. That's all.

Mamegano [Q]: Thank you very much. Second question regarding the early data readout. You can get that for three projects within this fiscal year. So, for this early data readout, you are planning to get POC. But for those early data readouts, when are they going to be disclosed? When can we know about this early data readout?

Kitamura [A]: Thank you for the question. As we mentioned, it's appropriate timing. Taniguchi is going to give you the response.

Taniguchi [A]: Thank you. Regarding the early data readout, basically, Phase I dose selection, dose setting, 1570, 2138, and 3082, we are doing the dose selection study for those three. Based upon the result, I would like to decide the most appropriate dose. We are on the phase now. First, we decide the clinical dosage. Once that is fixed, we would like to consider about disclosing that in some publication also. As of now, we haven't decided when and which congress we will present or not, so I cannot give you any specific answer. But for the early data readout, that is completely on the plan.

Mamegano [M]: Thank you very much.

Ikeda [M]: Thank you very much. Next, Sanford C. Bernstein, Mrs. Sogi, please.

Sogi [M]: Thank you very much. First, before asking questions, Kitamura-san, four months after you joined the Company, this is your first earnings call, business and pharma business. You're catching with these difficulties. I was surprised positively, so I wish you good luck. I have high expectations in you.

Kitamura [M]: Thank you very much.

Sogi [Q]: I have a question, two questions about VEOZAH and one question about IZERVAY. First, about VEOZAH. Private health insurance coverage, so seven months after the launch, between seven to nine months during this magic period, you need to increase the coverage. Otherwise, it's going to be difficult in the later period. This year, by the end of March, just 50% in private insurance coverage. I'm concerned about it. Next year, next fiscal year and beyond, how much can you grow from 50%?

About VEOZAH, promotion costs may remain high for a long period of time. That's my concern. From last year, an increase of JPY30 billion due to VEOZAH. Considering this factor this year, of course, DTC started in October and after, but you are not doing activities on a full year basis, you have a lot of money for DTC activities. In 2024, JPY50 billion or so may spend. It may not be over in just 2024. Bayer's product will enter the market and you will continue these activities further. Then this product will be breakeven in 2026 or 2027, according to my assumption. I'd like to hear your view on this.

Last but not least, I have a question about IZERVAY. SYFOVRE in February last year was launched. On a full year basis, USD275 million were the sales, according to JPMorgan presentation. Even that factor, USD160 million or so could be reached by IZERVAY, but you mentioned JPY11 billion which is much lower than USD160 million. Competitively, new-to-brand share is being captured by your product. Why compared to SYFOVRE if it's lower?

Kitamura [A]: Thank you for your question. First, about VEOZAH, two questions about VEOZAH and one question about IZERVAY, for the details, Claus is going to respond.

But regarding IZERVAY, as we mentioned, from April and beyond, the J-code will become available and label update will be made and approved, so there is room for a lot of growth. The numbers may look weaker, but next fiscal year and beyond, it's going to grow well.

Zieler [A]*: Adding to the IZERVAY comment from Atsushi, I firmly believe that we are very competitive with our new patient capture with IZERVAY versus SYFOVRE. You have to consider that in a disease where there was no treatment, the first to market will capture the so-called bolus patients, so the patients that are waiting, and that gives them a base that they can carry forward.

Now for us to capture, as I said, 20% of the overall market in the first full quarter after launch, our new brand capture has to be extremely competitive. It's difficult to estimate right now because we don't have the data. I think you're being a little bit too careful on what we are capturing in the US market with IZERVAY right now. That would be my IZERVAY comment.

On VEOZAH, I believe your question was, when do we break even and what's the investment going forward and what's the curve? I would beg you for some patience as we figure that out. Again, I think you are being very critical with the numbers and your projection of breakeven. I do think we will pleasantly surprise you with some news, but what we need to do before we can pleasantly surprise you is we need to understand exactly how the pickup curve in the next quarter or so really develops because that gives us a robust basis for informing you on what is the trend that we anticipate for FY2024 and beyond. I would like to wait for that data before we start talking about what's the year that we break even and what's the projection of the sales. So, if you permit me, let's try to debate that in three months' time.

Sogi [Q]*: That's great. I actually have another question regarding the commercial health payer coverage. So, you are expecting the coverage to achieve 50%, but usually, the major boost of coverage should happen between seven and nine months after launch, and that is exactly the time we are in right now. I'm a little bit wondering how much more it would go after this 50%, after this magic period of seven to nine months.

Zieler [A]*: Yes. We are exactly in that period, that seven to nine months, as you said. There are quite a few contract negotiations that are going on right now. I don't want to speculate, and I don't want to give

information that's not appropriate, but we are exactly in the period that you described with some negotiations going on which could make a major impact. So, let's leave it at that for now, and let's talk in three months what progress we've made on the payers.

Sogi [M]*: Great. Thank you very much.

Ikeda [M]: We're a little behind, but I would like to take one more question. Nomura Securities, Mr. Matsubara, please.

Matsubara [M]: Matsubara from Nomura Securities. Can you hear me?

Ikeda [M]: Yes.

Matsubara [Q]: I have a question about IZERVAY. In your presentation, after GATHER2 study data presentation, prescription increased and the study said that compared to placebo there was no improvement of the visual acuity in GATHER2 but a GA area was suppressed and also safety is highly evaluated.

Secondly, about zolbetuximab, the reexamination period is up to Q2. But regarding the findings, the issues are going to be resolved Claudin 18.2 bispecific antibody is under development by you. So how are you going to differentiate zolbetuximab as that antibody, bispecific antibody?

Kitamura [M]: This is about GATHER2 study. Taniguchi is going to respond.

Taniguchi [A]: First from me about IZERVAY. GATHER2 data was presented and the question is why. As we mentioned earlier, GATHER2 data is important because as of 24 months, the primary endpoint, GA progression, was suppressed, statistically speaking, for the first time. That's a very meaningful data in that regard. As for safety, it's consistent with the past data, there was no onset or report of retinal vasculitis, so the results were consistent with the past results. Physicians might have felt relieved by looking at that data, as we can imagine. Because of this, the results were taken positively. How they capture the data will become available into the future as well.

Next, about zolbetuximab. CMO, or contract manufacturing organization, with that vendor, the findings by FDA, we are discussing to address the findings as soon as possible. On the part of CMO, they also regard this as very important and they are doing their best to address the situation. So, as I mentioned before, next fiscal year, in Q1, we can resubmit our filing, and that's what we are aiming for as we are proceeding with the discussions.

ASP2138, Claudin 18.2 and CD3 bispecific antibody, ASP2138, and how do you differentiate this from zolbetuximab? That was your question, right? Claudin target is the same, but 2138 is T-cell engager, CD3 exists. So according to expectations, we have to look at the data from now on, but for more broader patient populations, this drug can become more meaningful. Phase I study is ongoing right now. If you look at the safety and efficacy to discuss how this drug is going to be used or this drug can be used in combination as well as the indications, we are discussing right now. Once the future direction is determined, we'd like to share more with you.

Matsubara [Q]: Understood. Thank you very much. Additionally, the visual acuity improvement by IZERVAY, is there any particular comment from the HCPs?

Taniguchi [A]: Putting aside if it is from doctors or not, but as you know, although it's a post hoc analysis, but for IZERVAY, 12 months after the treatment, for example, visual equity, there are more than 15-letter improvements for BCVA and there is a 56% separation. On top of the IZERVAY GATHER2 data is including the [inaudible] analysis under the annualization. Such kind of data is probably referred to by the HCPs as well.

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

Ikeda [M]: Thank you. We are behind this time to close the session. Therefore, with this, we would like to close today's earning call. Thank you very much for your participation.

[END]

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