Astellas Pharma Inc.

Financial Results for the Q1 of FY2023

August 1, 2023

Event Summary

[Company Name]	Astellas Pharma Inc.
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[Time]	16:00 – 17:21 (Total: 81 minutes, Presentation: 32 minutes, Q&A: 49 minutes)
[Venue]	Webcast
[Number of Speakers]	5

Naoki Okamura	Representative Director, President and CEO
Yoshitsugu Shitaka	Chief Scientific Officer
Tadaaki Taniguchi	Chief Medical Officer
Claus Zieler	Chief Commercial Officer
Hiromitsu Ikeda	Head of Corporate Communications

[Analyst Names]

Hidemaru Yamaguchi	Citigroup Global Markets
Kazuaki Hashiguchi	Daiwa Securities
Naomi Kumagai	Mitsubishi UFJ Morgan Stanley Securities
Akinori Ueda	Goldman Sachs
Shinichiro Muraoka	Morgan Stanley MUFG Securities
Madoka Sato	Schroder Investment Management
Kasumi Haruta	Credit Suisse Securities
Taito Kurose	Nikkei Inc.
Shinya Tsuzuki	Mizuho Securities

Presentation

Ikeda: Thank you very much for your participation on this earning call for Q1 FY2023 financial results ended June 30, 2023. I am Ikeda, Head of Corporate Communications, serving as the moderator for today. For today's meeting, you can join either the Zoom webinar or live streaming. After our presentation, a Q&A session will take place, and the questions will be entertained through the Zoom. In other words, you can ask the questions from live streaming. The participants here today are Naoki Okamura, Representative Director, President and CEO, Yoshitsugu Shitaka, Chief Scientific Officer, Tadaaki Taniguchi, Chief Medical Officer, and Claus Zieler, Chief Commercial Officer.

Today's earning call includes a Q&A for which simultaneous translation in both Japanese English are provided. For the simultaneous translation, accuracy is not guaranteed by us. If you are joining by the Zoom webinar, from the Zoom screen please select your favorable language. If you select the original language, then you can hear the original voices, not interpreters. For today's presentation material, that is available on our website. That is the material for these earnings calls.

This material or presentation by representatives for the Company and answers and statements by Representatives for the Company in the Q&A session includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and is 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 representations or advertisement regarding the efficacy or effectiveness of the products. Next, the presentation will be started. Okamura-san, please.

Okamura: Hello, everyone. I'm Naoki Okamura from Astellas Pharma Inc. Thank you very much for joining our FY2023 Q1 financial results announcement meeting out of your 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

3

I Q1/FY2023 Consolidated Financial Results

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.

Q1/FY2023 FINANCIAL RESULTS: OVERVIEW

4

Revenue

- Revenue decreased 2% YoY, due to the impact of Lexiscan generic
- XTANDI and XOSPATA expanded as expected, while PADCEV exceeded expectations
- VEOZAH's initial uptake in line with expectations

Cost items

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

Operating profit

- Core OP increased 17% YoY (incl. FX impact)

Revenue and core operating profit were behind expectations due to the impact of Lexiscan generic
On the other hand, core business that will contribute to future growth were on track

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On page four, I will give you an overview of FY2023 Q1 financial results. Revenue decreased by 2% YoY. This is mainly due to the impact of Lexiscan generics. Generics were launched by multiple companies at a timing earlier than we expected. Pricing pressure went up rapidly, resulting in a substantial decrease in our sales. We are assuming that this impact is not temporary but will be a downside factor throughout the current fiscal year. On the other hand, XTANDI and XOSPATA expanded as expected, while PADCEV exceeded our expectations. Also, the initial uptake of VEOZAH, launched in May, was in line with our expectations. I will explain our main products on page six and seven in detail.

Q1/FY2023 FINANCIAL RESULTS: OVERVIEW

4

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Next, on cost items. SG&A and R&D expenses are both on track. As a result, core operating profit increased 17% YoY, including Forex impact. Revenue and core operating profit were behind our expectations in terms of the progress against our full year forecast due to the impact of Lexiscan generics I mentioned earlier. On the other hand, core businesses contributing to our future growth progressed steadily.

Q1/FY2023 FINANCIAL RESULTS

5

(billion yen)	Q1/FY22	Q1/FY23	Change	Change (%)	FY23 FCST*	Progress	FX impact** (YoY)
Revenue	**381.8**	**375.0**	**-6.8**	**-1.8%**	**1,520.0**	**24.7%**	+17.5 bil. yen
Cost of sales	88.9	68.9	-19.9	-22.4%			-11.1 bil. yen
% of revenue	23.3%	18.4%	-4.9ppt				
SG&A expenses	153.4	168.2	+14.8	+9.6%	661.0	25.4%	+8.0 bil. yen
US XTANDI co-pro fee	43.1	44.6	+1.4	+3.4%	176.0	25.3%	
SG&A excl. the above	110.3	123.6	+13.3	+12.1%	485.0	25.5%	+5.5 bil. yen
R&D expenses	74.0	64.6	-9.4	-12.7%	251.0	25.7%	+2.4 bil. yen
Amortisation of intangible assets	10.7	9.1	-1.7	-15.6%			
Gain on divestiture of intangible assets	0.2	0.1	-0.1	-68.5%			
Core operating profit	**55.3**	**64.9**	**+9.6**	**+17.4%**	**290.0**	**22.4%**	+18.2 bil. yen
<Full base>							
Other income	16.3	3.9	-12.4	-76.0%			Other expenses
Other expenses	38.4	23.1	-15.4	-40.0%			• Fair value increase contingent consideration due to FX impact (zolbetuximab): 7.6 bil. yen
Operating profit	**33.1**	**45.8**	**+12.6**	**+38.2%**	**288.0**	**15.9%**	• Impairment loss on the transfer of the Meppel plant: 7.3 bil. yen
Profit before tax	31.7	46.8	+15.2	+47.9%	289.0	16.2%	
Profit	**24.8**	**33.1**	**+8.3**	**+33.5%**	**227.0**	**14.6%**	

* Exchange rates for initial FY2023 FCST: 130 USD/yen,140 EUR/yen
** Incl. the impact of elimination of unrealized profit remaining in Q1/FY22 (12.8 bil.yen). FX impact on core operating profit excluding this impact: +5.4 bil. yen

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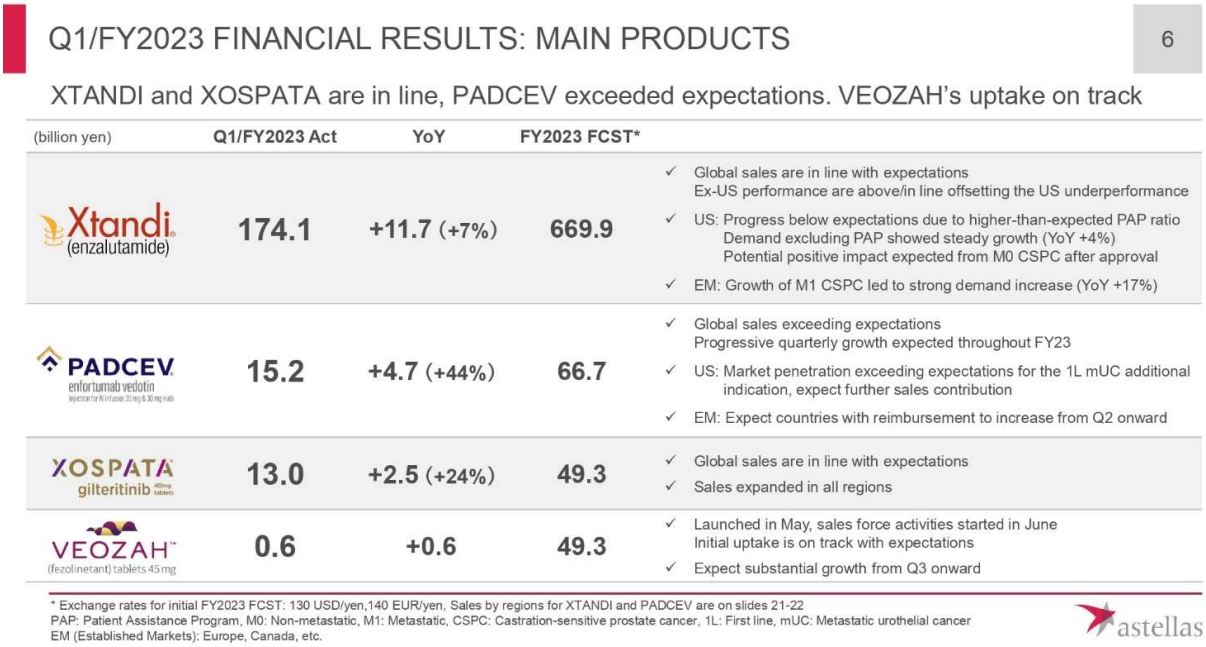
On page five I will explain FY2023 Q1 financial results. Revenue decreased to JPY375 billion, down 1.8% YoY. The progress was 24.7% against the full year forecast. Core operating profit was JPY64.9 billion, up by 17.4% YoY. The progress was 22.4%. The progress of both revenue and core operating profit looks a little weak due to the larger impact of erosion by Lexiscan generics than expected. On the other hand, we are expecting

VEOZAH and PADCEV sales to expand towards the latter half of the current fiscal year. Accordingly, operating profits are expected to increase towards the latter half of the year as well.

You can see the Forex impact on the right-hand side of the table. Revenue was affected positively by JPY17.5 billion and operating profit by JPY18.2 billion. This includes the Forex impact of elimination of unrealized profit remaining in Q1 of FY2022, which was JPY12.8 billion.

The bottom half of this page shows full basis results. In the right bottom of the table, we included other expenses booked in Q1. We booked JPY7.6 billion due to fair value increase of contingent consideration for zolbetuximab because of Forex rate fluctuations. The contingent consideration for zolbetuximab is booked as liabilities in Europe. From the end of FY2022 through the end of FY2023 Q1, the forex rate] fluctuated towards the lower yen, which resulted in a fair value increase of contingent consideration. In May, we issued a press release about the conclusion of an agreement regarding the transfer of a manufacturing plant and business based in Meppel, the Netherlands. As a result, we booked JPY7.3 billion impairment loss, mainly due to these two factors. Other expenses reached JPY23.1 billion in Q1. As a result, operating profit was JPY45.8 billion, up by 38.2% YoY. Profit increased to JPY33.1 billion, up 33.5% YoY.



On page six, I will explain FY2023 Q1 results for main products. First, XTANDI. Global sales grew to JPY174.1 billion, up by 7% YoY. Ex US performance offset the US underperformance. Global progress as a whole is in line with our initial assumptions, even excluding Forex impact. In the United States, progress was below expectations due to higher-than-expected ratio of PAP, our patient access program to provide drugs for free. On the other hand, volume, excluding PAP, showed steady growth of 4% YoY. So, demand increased. In the latter half of the current fiscal year, we are expecting approval of the additional indication M0 CSPC. We are hoping this will bring a potential positive impact to grow sales. Established markets exceeded expectations and contributed the most to the expansion of global sales. Mainly in Germany, Spain and Italy, prescription for M1 CSPC continued to grow. Demand substantially increased by 17% YoY. We confirmed that there is no clear impact of competitive Zytiga generics as of now.

I would like to touch on the profit margin of XTANDI by region once again. In the United States, about half of the sales are paid to Pfizer as co-promotion fees. In ex-US regions, about 10% to 20% level royalties, the

amount of which increases in line with the sales, are paid under economic conditions. Therefore, sales expansion in regions other than the United States contribute more to the overall profit margin improvement. There tends to be more focus on the United States, which is the biggest market, but from the perspective of the profit, sales expansion in other regions is also extremely important. We will continue to focus on initiatives for the entire globe.

As for PADCEV, global sales increased to JPY15.2 billion, up by 44% YoY, driven by good performance in the United States. We can also expect an upside from our initial forecast globally as a whole. We are expecting sales to increase continuously also in Q2 and beyond. In the United States, market penetration is exceeding expectations at a speed faster than expected for the first-line additional indication approved in April. It's well received by physicians, and we are expecting further sales increase. In established markets, we are expecting reimbursement to start in Q2 and beyond in big markets like Germany, France, Italy and Spain, where we are expecting continuous growth like the United States for the future, as well.

Q1/FY2023 FINANCIAL RESULTS: XTANDI (REGION)

Xtandi (enzalutamide) 21

(billion yen)	Q1/FY2023 Act	YoY	FY2023 FCST
Global Sales	**174.1**	**+11.7 (+7%)** Excl. FX impact [+1.9 (+1%)]	**669.9** (YoY +1%)
US (Unit: $)	$632M	$-15M (-2%)	$2,635M (+4%)
Established Markets (Unit: €)	€365M	€+26M (+8%)	€1,419M (+1%)
Japan	14.4	+0.3 (+2%)	58.2 (+6%)
Greater China	4.4	+0.8 (+23%)	14.5 (+31%)
International Markets	13.8	-0.1 (-1%)	55.9 (+1%)

Established Markets: Europe, Canada, etc., Greater China: China, Hong Kong, Taiwan,
International Markets: Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Korea, Australia, Export sales, etc.

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Q1/FY2023 FINANCIAL RESULTS: PADCEV (REGION)

PADCEV enfortumab vedotin 22

(billion yen)	Q1/FY2023 Act	YoY	FY2023 FCST
Global Sales	**15.2**	**+4.7 (+44%)** Excl. FX impact [+3.9 (+37%)]	**66.7** (YoY +50%)
US (Unit: $)	$76M	$+20M (+35%)	$341M (+59%)
Established Markets (Unit: €)	€16M	€+7M (+79%)	€82M (+70%)
Japan	2.2	+0.3 (+13%)	9.9 (+18%)
International Markets	0.1	+0.1	0.9

Established Markets: Europe, Canada, etc.
International Markets: Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Korea, Australia, Export sales, etc.

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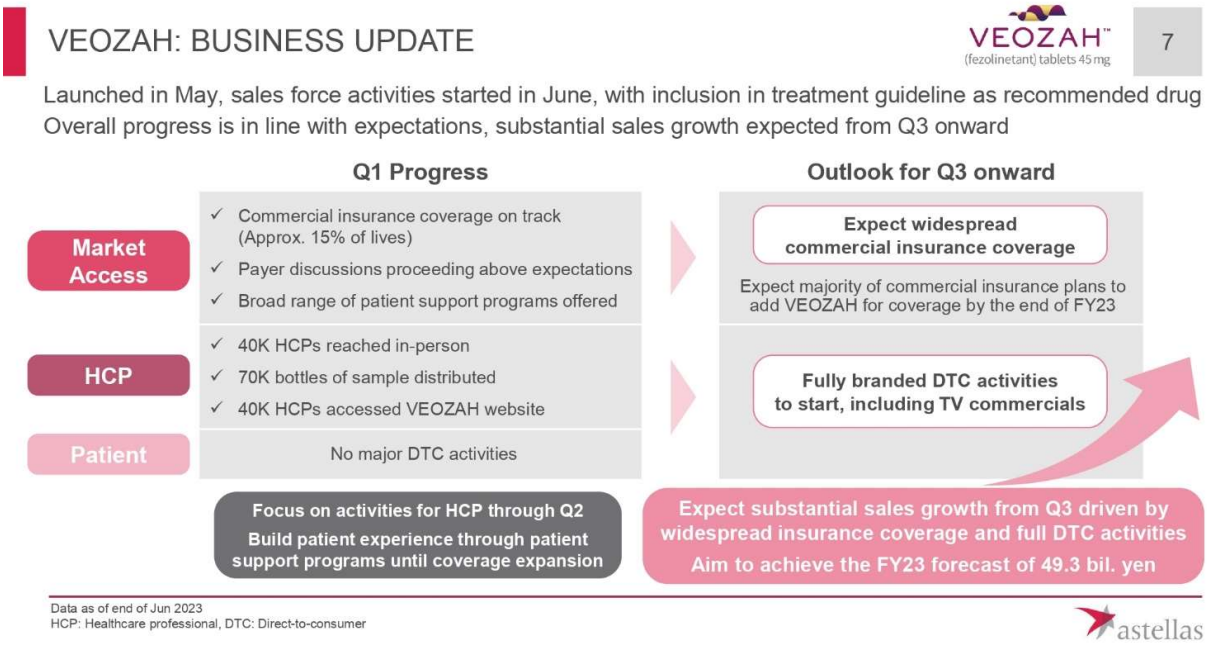
By the way, you can find XTANDI and PADCEV sales by region on page 21 and 22.

Regarding XOSPATA, global sales increased to JPY13 billion, up 24% YoY. Sales expanded in all launched regions, performing in line with expectations overall.

VEOZAH was launched in the United States in May. Q1 sales were limited, with JPY0.6 billion, but the initial uptake is on track. I will explain the details on the next page.



On page seven, I will explain the details of VEOZAH. In our full year forecast, we're expecting full-scale sales growth of VEOZAH from Q3 onward. In order to ensure the growth, we are now focusing on market access enhancement and activities for HCPs, and are closely monitoring the trends. The left side of this page shows the progress in Q1. First, on market access. Generally speaking, it takes three to six months until the start of commercial insurance coverage. So, the current 15% of lives is on track. Aiming to expand the coverage, we are discussing with payers right now. Payers are requesting for meetings earlier than initially scheduled, showing stronger interest than expected. We will continue to discuss with the payers, and we are expecting coverage by a majority of commercial insurance by the end of the current fiscal year.

Next, with regards to our activities for HCPs and patients, up until Q2 we are not implementing fully branded DTC activities for patients. But rather, we are focusing on our activities for HCPs in order to make them fully understand the orders of safety and efficacy profile so that they can prescribe the product appropriately to their patients. VEOZAH has been included in the VMS treatment guidelines as a recommended drug since June. We hope this will contribute to the enhancement of HCPs awareness and intention to prescribe.

We have started sales force information provision activity since June. In just one month of activities, we have been able to reach 40,000 HCPs in person and distributed 70,000 bottles of tablets for seven days of samples. Samples are not captured in the prescription data and not booked as sales, but we are hoping that samples taken by patients will lead to the actual prescription. Including TV commercials, full DTC activities for patients are scheduled to start from Q3 onwards.

We said that the overall progress so far is on track, but we recognize that, after looking at the weekly prescription data, some of you may think that the uptake is slow. This is due to a gap between the prescription data and the actual prescription by physicians on typical market access issues during the market entry by new products. In clinical settings, patients prescribed with VEOZAH by physicians are not covered by insurance plans in some cases. Even when they are covered by insurance, prior authorization may be required for a prescription. This prior authorization process takes a certain amount of time. Once authorized, patients can receive VEOZAH. At this time, it is finally captured in the IQVIA prescription data. As of the timing of one month after the launch, due to these reasons I just explained, about one fourth of the patients prescribed with VEOZAH have been able to actually receive VEOZAH according to our estimation. As of now, we have

confirmed many applications for prior authorization. We are hoping that authorization will make progress and many patients will be able to start treatment with VEOZAH.

We are expecting substantial sales growth from Q3 onward, driven by widespread insurance coverage and full DTC activities. We have not changed our full year forecast of JPY49.3 billion. We will aim to achieve this figure continuously.

Q1/FY2023 FINANCIAL RESULTS: COST ITEMS

8

Cost of sales ratio was as expected
SG&A and R&D expenses were on track

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	-22.4%	18.4% (-4.9ppt YoY)	-	✓ Main factor for the decreased YoY was the impact of foreign exchange related to the elimination of unrealized profits in Q1/FY2022 (12.8 bil. yen) ✓ Cost of sales ratio was as expected
SG&A expenses excl. US XTANDI co-pro fee	+12.1% (+7.1% excl. FX impact)	33.0% (+4.1ppt YoY)	25.5%	✓ Increase in VEOZAH-related costs (approx. +5.0 bil. yen) ✓ Reduction of mature products-related costs (approx. -1.0 bil. yen) ✓ Cost reduction progressed as expected, actively making necessary investments ✓ As a result, in line with initial full-year forecast
R&D expenses	-12.7% (-16.0% excl. FX impact)	17.2% (-2.2ppt YoY)	25.7%	✓ Booked one-time expense for using PRV in Q1/FY2022 for the application of VEOZAH (13.1 bil. yen) ✓ In line with initial full-year forecast

PRV: Priority Review Voucher

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Next, on page eight, I will explain cost items. Cost of sales decreased substantially YoY, as we booked the Forex impact of JPY12.8 billion related to the elimination of unrealized profits in Q1 of FY2022. Cost of sales ratio was as expected. SG&A cost, excluding XTANDI US core promotional fees, increased by 12.1% YoY. When Forex impact was excluded, SG&A expenses increased by 7.1% YoY. The progress was 25.5% against the full year forecast. As we mentioned during the FY2022 financial results announcement meeting, we position FY2023 as a year to make active investments for future growth. Sales promotion expenses related to VEOZAH launched in the United States in May increased by about JPY5 billion YoY. On the other hand, we are trying to reduce sales promotion costs related to material products, such as mirabegron, which resulted in a cost reduction by about JPY1 billion YoY. As a result, we were able to reduce costs as expected and actively make necessary investments. SG&A costs were in line with our initial forecast. R&D expenditure decreased by 12.7% YoY and fell by 16% when Forex impact was excluded. There was a substantial decreased YoY due to the booking of onetime expense of JPY13.1 billion for using a priority review voucher in Q1 of FY2022 for the application of VEOZAH. The progress was 25.7%, in line with our full year forecast.

FY2023 REVISED FORECAST

- *No changes have been made to Core basis FY2023 forecast*
  - ✓ Plan to reassess in Q2, considering the impact of the Iveric Bio acquisition

- *Downward revision of Full basis profit*
  - ✓ Planned one-time expenses related to organizational restructuring on a global scale, including the review of Japan commercial structure: approx. 20.0 billion yen
  - ✓ Impairment loss related to the Meppel plant business transfer: approx. 7.0 billion yen

(billion yen)	Initial Forecast	Revised Forecast	Change
Operating profit	288.0	259.0	-29.0
Profit	227.0	204.0	-23.0

Organizational restructuring: Subject to Works Council, consultative, and legal requirements

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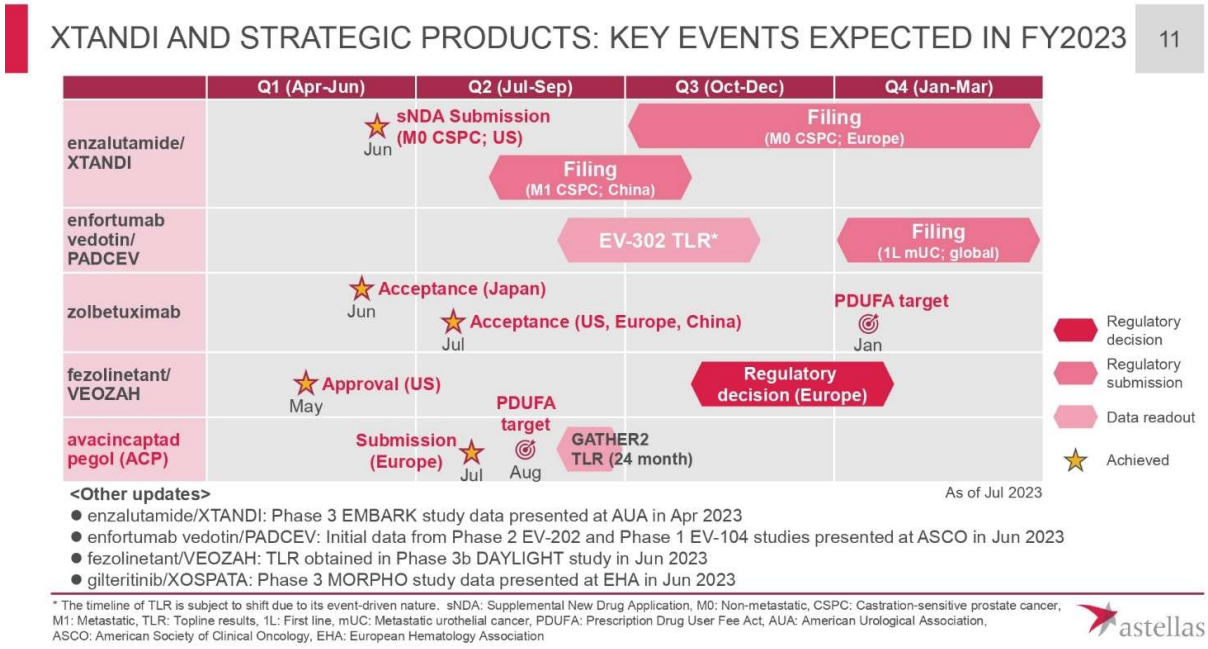
On page nine, let me explain the FY2023 revised full year forecast. No changes have been made to the core basis FY2023 forecast. We plan to reassess our forecast as a whole in Q2, considering the impact of the Iveric Bio acquisition into our results. On the other hand, we have made a downward revision of full basis profit. We are planning to book as other expenses about JPY20 billion, onetime expenses related to organizational restructuring on a global scale, including the review of Japan commercial structure. As we announced in the press release today, we have booked in Q1 JPY7.3 billion impairment loss related to the Meppal plant and business transfer, which we didn't factor in at the time of our full year forecast. This transaction is done in euro, so it's subject to the impact of Forex fluctuation every quarter. We are expecting about JPY7 billion loss. Mainly due to these factors, we have made a downward revision of full basis profit. Full basis operating profit is expected to decrease from the initial forecast of JPY288 billion by JPY29 billion to reach JPY259 billion. We are expecting profit to decrease from the initial forecast of JPY227 billion by JPY23 billion to reach JPY204 billion.

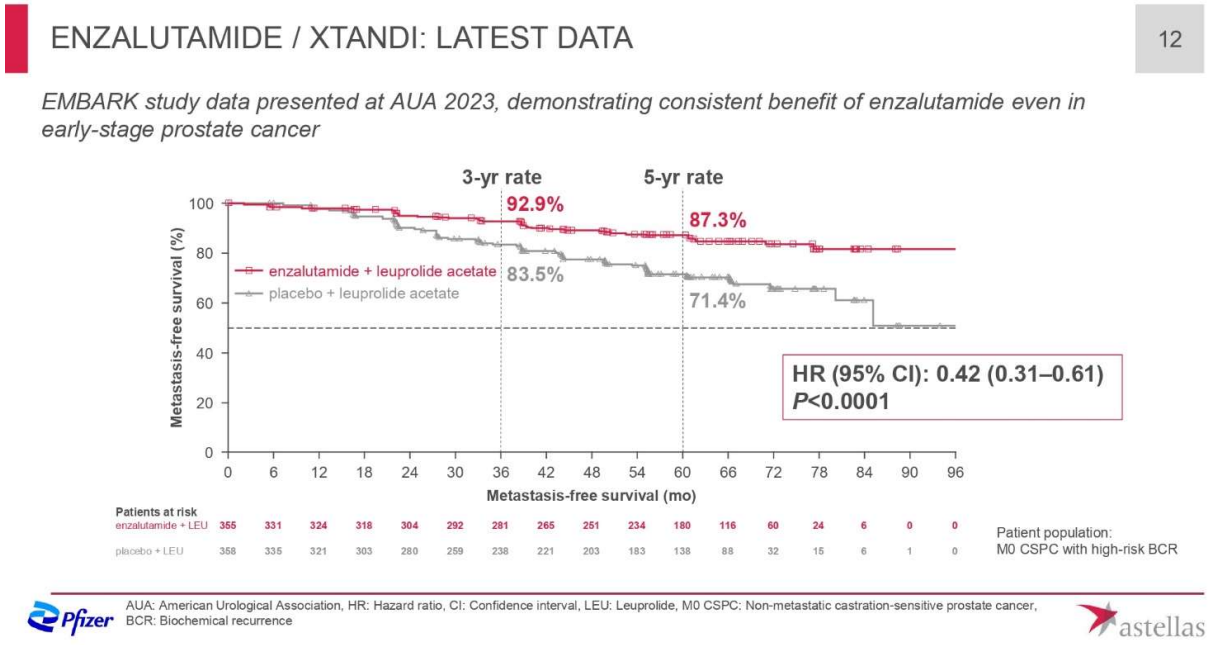
Slide 10. Now let me explain our efforts to achieve sustainable growth.



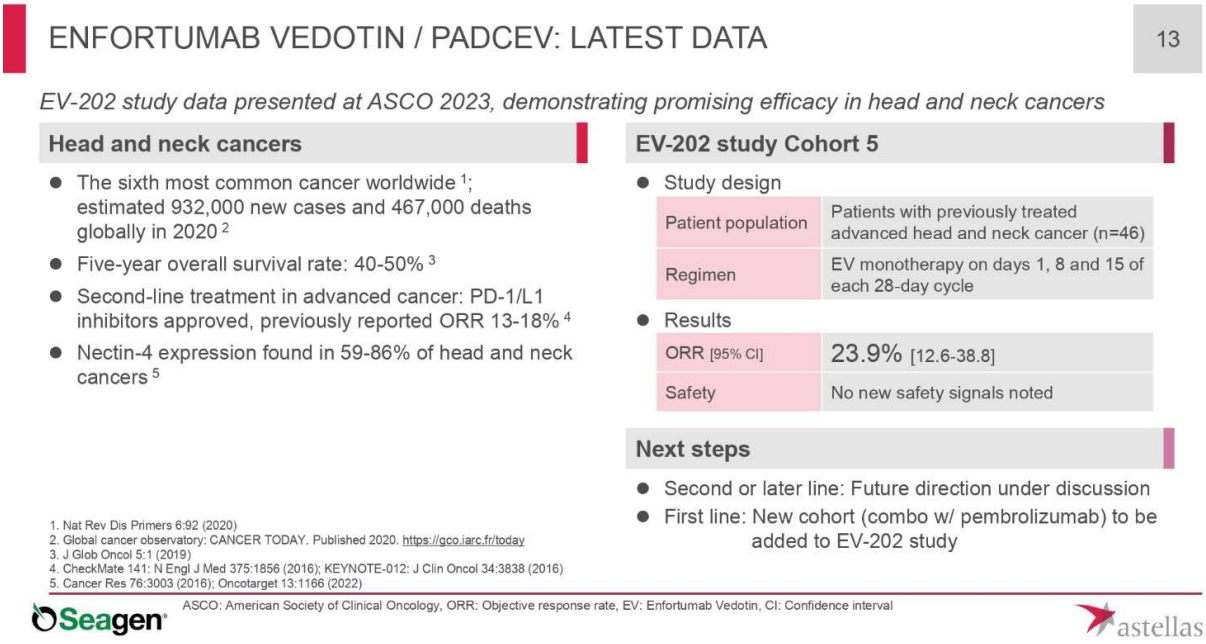
On slide 11, I would like to explain about key events expected in 2023 for XTANDI and key strategic products. The progress made in the past three months is shown in red. For XTANDI, we've submitted a supplemental NDA for M0 CSPC non-metastatic castration sensitive prostate cancer based on the EMBARK study in the US in June. For zolbetuximab, the application for gastric and GEJ adenocarcinoma was submitted in Japan, the US, Europe and China, partially ahead of the schedule that we had. The US application was accepted for priority review in July, and the PDUFA date was decided as January 12, 2024. VEOZAH was approved by the

US FDA in May. As you see at the bottom of the table, avacincaptad pegol, or ACP, was newly added to the pipeline following the acquisition of Iveric Bio. Details will be explained later in another slide.

Other updates are listed outside of this chart. XTANDI and PADCEV's data presentation will be explained on subsequent slides. As for VEOZAH, positive top line results were obtained from the Phase IIIb daylight trial. These results will provide additional data to support the Health Technology Assessment, or HTA, and reimbursement dossier in Europe. Regarding XOSPATA, the data from the Phase III MORPHO study in maintenance therapy after hematopoietic stem cell transplantation was presented at the EHA. Although the primary endpoint was not met for the cohort as a whole, a subsequent subgroup analysis showed a result suggestive of efficacy in patients with MRD, or measurable residual disease. We are currently discussing the next steps on future development and submission, and we will provide an update when a further progress is made.

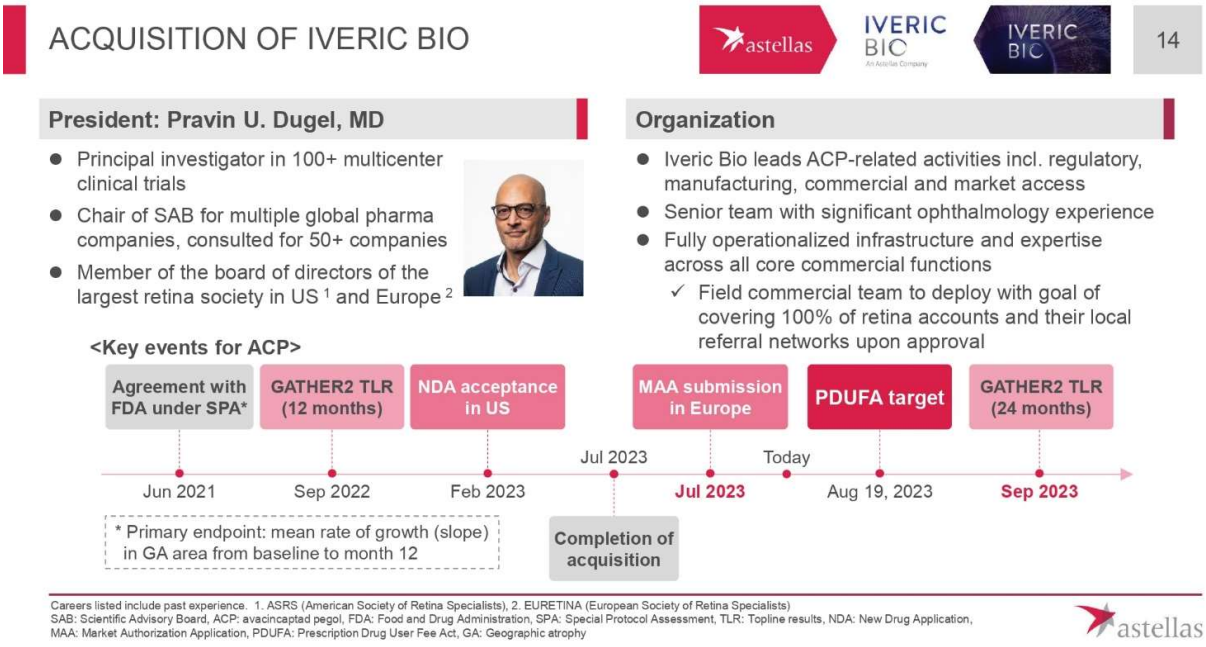


On page 12, I will discuss the EMBARK trial data for enzalutamide/XTANDI presented at AUA at the end of April. The data from the EMBARK study of enzalutamide/XTANDI presented at the AUA meeting at the end of April described on page 12. In the study, the patients with M0 CSPC and a high risk of biochemical recurrence were treated with either placebo enzalutamide in combination with leuprolide, or enzalutamide alone. The graph shows the results of the primary endpoint, metastatis-free survival, or MFS, comparing the enzalutamide combination to the placebo combination arm. The MFS was statistically significantly improved with enzalutamide combination therapy, with the hazard ratio of 0.42, or 58% reduction in risk of disease progression or death compared to placebo. XTANDI has demonstrated a high level of efficacy in clinical trials in each stage of prostate cancer, from the most advanced M1 CRPC to M1 CSPC. The results of the EMBARK study for earlier stages of breast cancer show the result of the highest efficiency as consistent with that of previous studies.



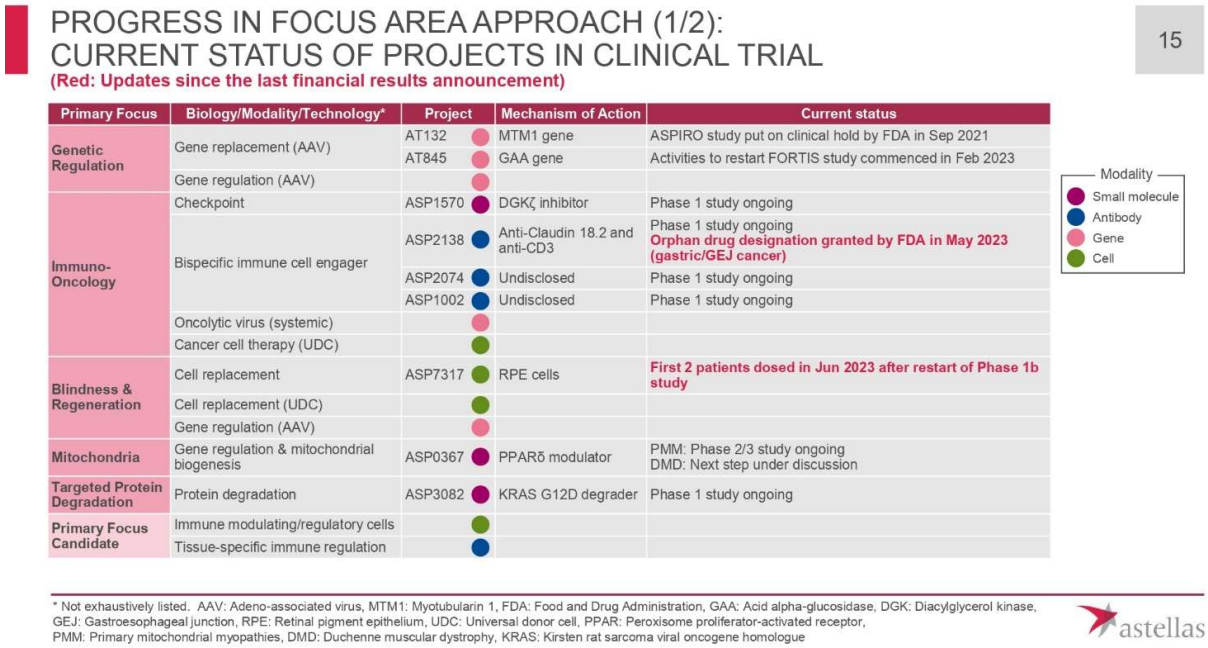
On page 13, I will discuss the data on PADCEV and head and neck cancer presented at ASCO in June. As shown on the left side of the slide, head and neck cancers are known for their high prevalence and poor prognosis. Advanced head and neck cancer is medically treated mainly with chemotherapy. Currently, PD-1/L1 inhibitors are approved as a second-line therapy, but the objective response rate, or ORR, reported previously is ranged from 13% to 18%, indicating a high unmet medical need. Nectin-4, the target molecule of PADCEV, is reported to be expressed in 59% to 86% of head and neck cancers. The EV-202 trial is a Phase II study valuating the antitumor activity of PADCEV in a variety of solid tumors other than urothelial carcinoma. As you see on the right side of the slide, we presented the results of the study evaluating the efficacy and safety of PADCEV monotherapy in previously treated patients with advanced head and neck cancer. The ORR was 23.9%, which is promising in second or later line setting, where high response rates have been difficult to achieve in the past. The safety profile was consistent with the previous results and no new signal as were observed.

Based on these results, we are currently considering how to proceed for the head and neck cancer development. We are discussing the future direction of the second or later line treatment, as well. We will inform you when a specific direction is decided. We are also planning to add a new cohort of combination with pembrolizumab to the EV-202 trial for the first-line treatment. We will update the data and our future steps for cancers other than head and neck cancer at the appropriate time after the analysis results are available.



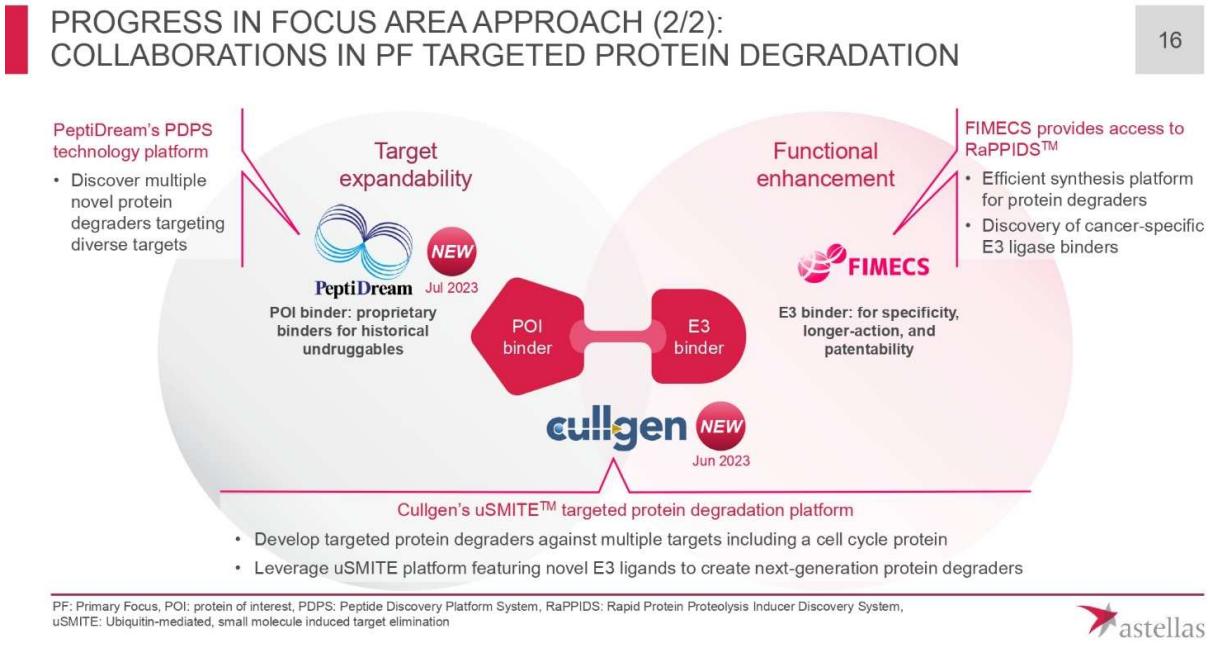
Slide 14 provides an update on the recently completed acquisition of Iveric Bio. First, at the top, this is the post-acquisition organization. The President will be Pravin U. Dugel. He's an ophthalmologist with outstanding expertise and has served as President prior to the acquisition. He has extensive experience as a clinical principal investigator and has been asked by many companies, including global pharmaceutical companies, to advise them. He is versed with drug development, as well. He's also highly respected by colleagues in his specialty and has a long list of accomplishments at academic, enough to have built an extensive network in the medical community. As shown in the upper right corner of the slide, Iveric Bio will continue to lead ACP-related activities for the time being, while Astellas will provide support as needed to ensure smooth progress in dealing with the authorities and launching the product. Iveric Bio has a senior leadership team with significant ophthalmology experience, and which has a commercial faction with highly specialized personnel for rapid post-approval ramp-up. The field sales team will cover a wide range of local referral networks, including the retinal specialists who will administer the drugs and the laboratories to provide the test.

The bottom half of the slide shows a timeline of key events for ACP. I will explain the new events indicated in red. In July, based on the results of the pivotal GATHER study, we did submission in the EU following the United States. In September, we expect to receive top line results for 24 months of data from the GATHER2 trial, which will include monthly data for up to 24 months, as well as data from bimonthly dosing starting at month 13. Finally, with the PDUFA date in the US just in front of us, we have recently received a number of inquiries regarding the likelihood of approval. As shown on the left side of that figure, the GATHER study is being conducted based on the protocol agreed on with the FDA, in which the primary end point recommended by the FDA as clinical meaningful is adopted. Of course, approval is not 100% guaranteed, but the results have met the primary endpoints agreed upon in advance with the FDA, and we see no reason to believe that the ACP will not be approved at this time. We hope to have good news for you in the near future.

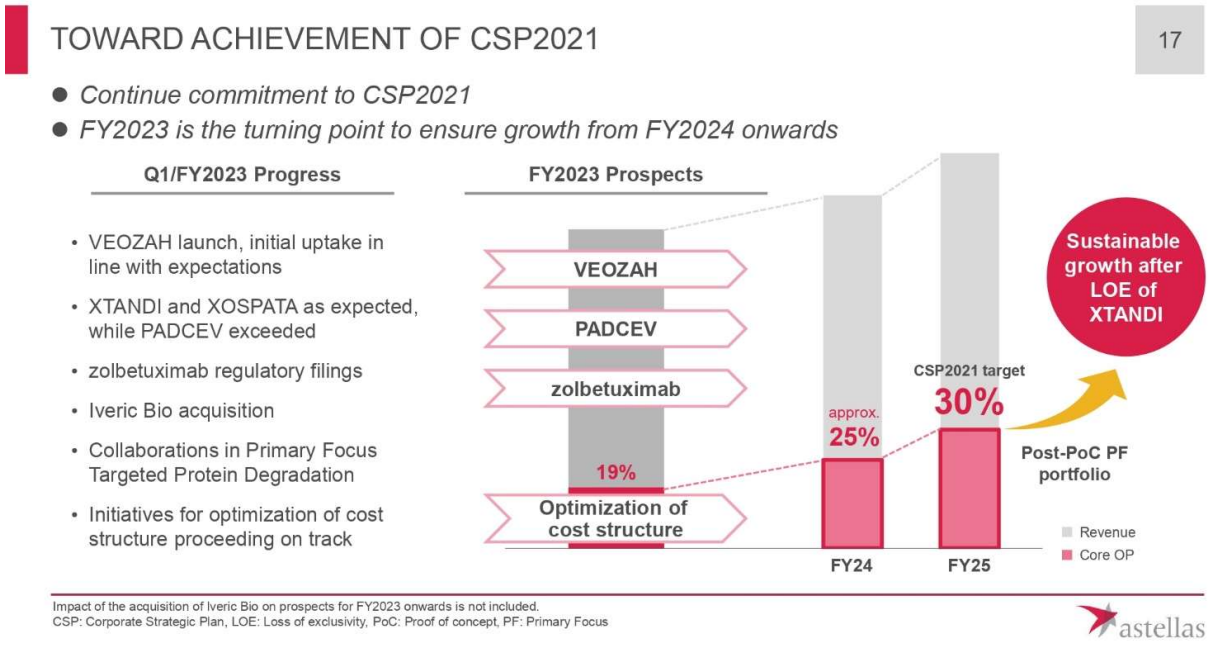


Primary Focus	Biology/Modality/Technology*	Project	Mechanism of Action	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	GAA gene	Activities to restart FORTIS study commenced in Feb 2023
	Gene regulation (AAV)			
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing
	Bispecific immune cell engager	ASP2138	Anti-Claudin 18.2 and anti-CD3	Phase 1 study ongoing **Orphan drug designation granted by FDA in May 2023 (gastric/GEJ cancer)**
		ASP2074	Undisclosed	Phase 1 study ongoing
		ASP1002	Undisclosed	Phase 1 study ongoing
	Oncolytic virus (systemic)			
	Cancer cell therapy (UDC)			
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells	**First 2 patients dosed in Jun 2023 after restart of Phase 1b study**
	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
Primary Focus Candidate	Immune modulating/regulatory cells			
	Tissue-specific immune regulation			

From here, page 15, I would like to explain our progress and focus area approach. Status of projects in clinical trials that have been updated in the past three months are shown in red. In the primary focus, immuno-oncology, ASP2138 was granted open drug designation by the FDA for the treatment of gastric and GEJ cancer. This is a bispecific antibody targeting claudin 18.2 and CD3, and it is expected to be a successor to zolbetuximab. For ASP7317 in blindness and regeneration, two patients were treated in June after the resumption of clinical trials. The project team's proactive efforts to accelerate the enrollment of patients, such as increasing the number of clinical trial sizes, are bearing fruit. We will continue to take steps to accelerate the process and aim to identify our POC as soon as possible.



Page 16, that explains collaborations and primary focused targeted protein degradation. As shown in the middle of the figure, the protein degrader is composed of a target protein binder, an E3 binder and a link connecting them. By changing the target protein binder, it can be applied to various targets and diseases. Also, target protein binder, it is possible to improve the specificity and duration of action to enhance the function of the protein degradation. In addition to the collaboration with FIMECS, which was introduced at the R&D meeting last December, we have recently entered into a new collaboration with the PeptiDream and Cullgen. PeptiDream has proprietary technology to create special cyclic peptides with a high binding capability and selectivity for targeted molecules. This technology can be used to target a wide variety of targets that are difficult to bind to with conventional small molecules and is expected to lead to the creation of new protein integrators. Cullgen has an innovative technology platform for the creation of novel protein integrator. Through this collaboration, we aim to create a protein integrator for multiple targets, including cell cycle proteins. Cullgen also has expertise in the creation of novel E3 binders, which we expect will be utilized to create a new generation of innovate protein degraders. We will continue our collaboration FIMECS, which has unique E3 binders, and create innovative protein degraders for various targets by appropriately leveraging the strength of each company. We will continue to proactively invest management resources into collaboration and others to achieve a leading position in protein degrader.



Page 17, at the end, I would like to summarize the progress made in Q1 of the current fiscal year toward the achievement of CSP2021. The impact of the acquisition of Iveric Bio has not been incorporated into the current focus shown here. We will explain this point at the announcement of Q2 financial results. So, please wait for a while. Regarding XTANDI and strategic products, there was a lot of progress, such as VEOZAH's launch, and the initial uptake is in line with expectations. Sales of XTANDI, PADCEV and XOSPATA increased, and zolbetuximab was flat globally. In addition, through the acquisition of Iveric Bio, we acquired ACP, which is expected to become a new revenue pillar for us. We have steadily developed each primary focus, including targeted protein degrader, in line with our strategy. Also, initiatives for optimization of cost structure are proceeding on track. In FY2023, we will proactively promote investments and initiatives for the future and position the year as turning point to ensure growth in FY2024 and beyond. We will continue to aim to achieve our full year profit targets and the targets of that CSP2021. That is all for now. Thank you so much for your attention.

Ikeda [M]: That's all as a presentation. We now would like to entertain questions from the audience. You can ask questions only through the Zoom webinar. You cannot ask questions through live streaming. If you have a question, please press the raise-hand button at the bottom of the Zoom screen. If you're joining from your smartphone, if you tap Details you will see the raise hand bottom. The MC is going to name you, so please unmute yourself on your screen. Please mention your name and affiliation and then ask your question. Today, we have Claus, our Chief Commercial Officer. As I said at the beginning, on the main Zoom screen, if you select the original language, you can listen to the original sound without going through the simultaneous translation. You can change the language or sound at this time if you want. Questions, please?

Ikeda [M]: Thank you for waiting. Citigroup Securities, Mr. Yamaguchi, please?

Yamaguchi [Q]: I have two questions. First of all, regarding ACP, I'm looking forward to August 19. As you know, there is a leading product ahead of you. There are intraocular inflammation, although it's a rare event, of course, it's a different drug, but it may be due to the procedure. How do you see this issue? In order to prevent these issues from happening for ACP, there may be a lot of uncertainties, but I'd like to hear your comment. This is my first question. Thank you very much.

Okamura [M]: In principle, it's about a competitive product. So we'd like to refrain from commenting on their product. But as far as we have captured the information, and as far as we can share, Taniguchi is going to explain.

Taniguchi [A]: So, I'd like to comment and respond to your question. In our position for the time being, safety for ACP, we have the database for ACP safety, and we are discussing with the FDA, as well. Regarding the other company's' products, there are adverse events, future issues, such as retinal vasculitis, or retinal occlusive vasculitis, or hematologic occlusive retinal vasculitis, which are reported. But looking at our database in GATHER1 and GATHER2 studies, we don't see such adverse events. If you look at our database, that's the situation right now. So, in terms of the safety concern, we cannot respond from that perspective as of now. But the PDUFA date is approaching. So, in our discussions with FDA, as soon as possible we'd like to obtain the approval for this product, which we'd like to concentrate on. And at the same time, in the post-marketing settings, the safety is extremely important. So, we will do our best as we proceed going forward. Thank you very much.

Yamaguchi [Q]: The second for VEOZAH, just like you mentioned, the actual is different from the IQVIA data, but in order to interpret that you gave us that information. Thank you very much. Still, I have a question. The initial approach that you thought about is 40,000 patients you were able to achieve. According to your material, there are about 100,000 early adopters, and you provide the information thoroughly to them. That's the first point. But this 40,000, I believe that this is an efficient number. And for the early adapt adopters, the information is sufficiently provided. What do you think about the situation? And 70,000 sample bottles means the assembly of 70,000 prescriptions. And it costs approx. JPY50 thousand per bottle. The amount is quite large, and all that is going to be placed with the prescription. So, what would be the timing that actually you come up with the revenue from this?

Okamura [A]: Thank you for the question. First of all, 40,000. If my memory serves me right, by the end of September, 65,000 is the number of the target to be conducted. But in June, just one month, 40,000 doctors we were able to meet, meaning that this uptake speed is quite high. In other words, the information is provided in a very accelerated manner to those specialists. And the bottles, in other words samples, this is different from ordinary bottles. One week's portion of the tablets are within one bottle, and there are 70,000

bottles in total. So, if I multiply by 550 on this, it is not right. But just like I mentioned, first, usage of the sample is quite important to experience the benefit of this drug, so that this drug can be actually prescribed. That is something we are expecting. So, in this perspective, this as an entry usage of sample is something we are highly expecting. However, as it's been explained, insurance coverage has to be there. Otherwise, even when the sample phase is finished and we go to the prescription, and the prescription is made, the drug cannot be given or gained. So, rather than this provisioning of the samples, enhancement of the insurance coverage is the fact that is contributing to the actual sales. That is the answer from me. But Claus, you are the specialist, you like to make some additional comment on this point?

Zieler [A]*: Can you hear me? Okamura-san, you've covered it very, very well. So, we are very much encouraged by the interest in the marketplace, both from the HCP side, from the payer side and from the patient side. So, covering 40,000 physicians in one month. We started on the first of June. It is actually a very, very speedy coverage. So, we're very pleased with the result.

Yamaguchi [M]: Thank you very much.

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

Hashiguchi [Q]: Hashiguchi speaking. Thank you for your time. I also have a question about ACP and VEOZAH. Regarding ACP, as Dr. Taniguchi said, there is a competitive product ahead of you. And I think what you said is very similar to what the competitor is saying. As of now, in your clinical studies, you don't see these events, but there are multiple such reports in real clinical settings. And the cause is not so clear. And doctors are careful about prescriptions right now, in many cases. Regarding ACP, even if you get the approval, where is the concern of adverse events? You have to communicate the cause of the adverse events to the physicians. Otherwise, doctors will become very careful about the prescription of ACP, and that situation may continue for some time. So, regarding safety, how are you going to communicate this once you're able to get the approval? What's your plan?

Okamura [A]: Thank you for your question. What shall I say? What's not happening to ACP, what shall we do? It's very difficult to say on something that has not happened. But as Hashiguchi-san said, it's a product from a competitor with a similar mechanism, having adverse events. So, it may happen that doctors will become careful about prescribing our product. In the real-world settings, whether a similar adverse event will go or not by using a product, we have to monitor to eliminate the concern of physicians. There is no other way. It may be procedural issues, and there can be other reasons behind it. Iveric experts will use their network of retinal specialists to think about the procedures to prevent adverse events from occurring. They also have their experiences as physicians, so they will take all possible measures. So, it's not something to prevent, as it could occur, but they are going to see whether such an event could occur for ACP.

Hashiguchi [Q]: For VEOZAH insurance coverage, to what extent it is expanded and how it's going to be expanded, that is touched upon. But the impact on the business performance, gross to net, how it would be? That is going to be quite important. There are many payers where the conditions haven't been really fixed. So regarding gross to net, is there a gap compared to your expectation? Or is it in line with or better than your expectation? Would you please share that point?

Okamura [A]: Regarding growth to net, basically, we are not making any comments. Therefore, I would not make any comment. But, Claus, is there anything you would like to say? A word about this? Claus, do you have any comment?

Zieler [A]*: So, we are approaching the payer discussions very constructively. As I mentioned to you, payer interest is very high. And we are proceeding, on the one hand, as speedily as necessary. On the other hand, as carefully as necessary because, as you know, these negotiations are always a balance between speed and the discounts that you settle on. So far, as I mentioned to you, we've been very happy with payer interest,

and we are fully on track with the payer coverage, the way we imagined it. And I think that's all we can say at this point. As Okamura-san said, we expect the majority of payers to have their lives covered by the end of the fiscal year.

Hashiguchi [M]: Thank you very much.

Ikeda [M]: Thank you very much. Next, Mitsubishi UFJ Morgan Stanley Securities, Ms. Kumagai, please.

Kumagai [Q]: Regarding ACP, Iveric Bio's commercial team has about 90 people according to the material presented for the acquisition. How many are salespeople? Is that enough to cover specialists? And do you have a plan to increase the head count?

Okamura [A]: Thank you for the question. We are not disclosing the details of the headcount. But already, until the PDUFA date, it just three weeks to go until the PDUFA date. So, we shouldn't think about a plan to increase the headcount from now. But rather, with the headcount we have, we have the assumption to cover the necessary physicians. That's the structure right now.

Kumagai [Q]: Next, about VEOZAH, I expected it would be started much earlier, but it will be Q3 and afterwards. That's because of an insurance coverage matter? And after samples are provided, what is actually the feedback you received from the patients?

Okamura [A]: Thank you for the questions. For the first question, first, the HCPs to have a better understanding about this drug. Therefore, before their good understanding, those who look at the DTC campaigns and start to talk about the products with the HCP is the worst case scenario for us. So, first, we would like to focus on the communication, and also approach the HCPs first. Of course, within these three months the insurance coverage has to be proceeded. Otherwise, even the patients who come to be adopters and the prescription is written, but will be rejected, and that is meaningless. Therefore, at the same time, we perceive that a market exists that is important. However, focusing on HCP first is very important. And next, feedback from the patients. I don't have any feedback. But Claus, for the patients, do you have information about feedback from those who actually use it as the product, or use it as samples?

Zieler [A]*: So, we don't have statistically significant feedback that we can report on today. We have anecdotal feedback, which is positive, but nothing that would be statistically represented.

Kumagai [M]*: Okay, thank you.

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

Ueda [Q]: Ueda from Goldman Sachs Securities. I also have a question about ACP first. Regarding safety, when you think of the future potential in the labeling, what should we focus on in the labeling? Could you please explain? And also, the initial uptake, given the situation, there can be a mild penetration. Do you have any image about the uptake?

Okamura [M]: Thank you for your question. First, about the label and all the discussions with the regulators, FDA, now, as far as we can share, Taniguchi is going to explain. And then, commercialization and the initial uptake after commercialization, that is going to be explained by Claus later, again as far as we can.

Taniguchi [A]: Regarding the label, what kind of discussions we have had with FDA by now, as far as we can share, I'd like to explain. As you know, the ACP filing is based on the GATHER1 and GATHER2 studies. These two studies are the basis for filing our submission. Right now, we are in the final stage. Including the label, what content would be included are also being discussed. In reality, GATHER1 and GATHER2, primary endpoints and other designs were agreed in advance with FDA as we proceeded. And both studies, primary

endpoints were achieved. So, discussions are ongoing without any major issues. As for safety, we have submitted the data of both studies. We'd like to deliver this drug to the patients as soon as possible. Claus-san?

Zieler [M]*: Yes, I believe your question was about launch preparations. Did I understand that correctly? And how we start the ramp-up of the commercialization? Yes. So, we met with the Iveric team just after the closing dates. And I must say we were very satisfied with their preparations of the launch, both in terms of the physicians they want to cover. They have clearly identified the retinal physicians that do the administration of the product, and the material is ready. The different payer and trade schemes are ready. So, we were very satisfied with the preparation of the launch. So, then it is, I think, after the PDUFA date, very traditional contacting the physicians to explain the ACP product profile, the details of administration, preparing the patient to come in the intervals of injection, all the details that need to be communicated to the physicians before they can start administrating the product. So, in that sense, as I said, sales force materials have all the different elements there. We expect SP ramp-up, and the preparation was at a very high level.

Ueda [Q]: Thank you very much. Let me move on to the next question. That is about PADCEV. First line is approved and the progress after that. Concerning the number of the patients, I think you can accelerate further. But according to your presentation, the current progress level is better than the plan. For the market that is extremely large, at what point of time do you think you can gain further growth? So, current status, and also for future perspective, would you please give us your opinions?

Okamura [M]: US PADCEV first line current status and the future perspective. Claus-san, please share with us your opinion.

Zieler [A]: Yes. Thank you for your question. So, as you stated correctly, the performance exceeded our expectations, with the launch of the so-called Cohort K data in first-line patients. These are first line cis-ineligible patients. So, it's not the full first line patient population. Growth surprised us. We're very, very pleased with the progress that we've made. It is important to note that we have another study that will enlarge the patient population to the full first-line patient population in combination with another drug. So, as we proceed, we will be able to target the entire first line population. But in the Cohort K, in this ineligible patient population that we're targeting now, take-up has been faster than expected, and we expect that to continue throughout FY2023.

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

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

Muraoka [M]: Hello. Muraoka, from Morgan Stanley. Thank you very much. Can you hear me?

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

Muraoka [Q]: Oh, thank you. The Iveric acquisition is going to be reflected onto your guidance or plan at the next earnings call. I know that, but it's a huge amount. Goodwill, and also depreciation could be as much as JPY50 billion, in my view. I don't want to ask you to give me that particular figure, but there would be many M&A transactions for the future core operating profit. The definition could be changed. You can exclude intangible fixed assets to start a new operating profit model. Have you considered such a way?

Okamura [A]: Thank you for your question. It doesn't mean that we are not discussing such a possibility. I am serving as CFO, but I'm in an interim position, so I shouldn't talk too much here. But whether we change the definition or not, investors and analysts will calculate by adding or subtracting on their own. To understand the development of our main business, we use the core operating profit definition. Changing the definition would not mean much. And that's based on my gut feeling. But if there is a big M&A transaction, which could

be probably once in 10 years or so, but depreciation of demand could fluctuate? No, that's not the case. So, I don't think it's so important. In our CSP in 2021, we tried to achieve it. Compared to what we are discussing, in essence, whether to change the definition or not, that's not so important, honestly, in my view.

Muraoka [Q]: Thank you very much. Sorry to go further with nominal and substantial areas, but achieving the core operating profit targets in CSP, if you try to achieve it based on the current definition, this depreciation can be very cumbersome. After depreciation and amortization, can we still achieve the FY2025 goals? If VEOZAH is going to sell well, no problem. But you're going to proceed with confidence, correct?

Okamura [A]: For such details, when we announced our results for Q2, I will explain, but after M&A transaction, a big amortization or depreciation, we shouldn't just give up. So, please give us some more time so that we can consider. Thank you.

Muraoka [Q]: Now another question is about the VEOZAH, the way of thinking of it. From the third party's perspective, every week, weekly prescription data by the third vendor is going to be the critical information for us. But around what time in the future do you think that current number is going to parallel to the actual number booked by yourself? For example, three months later, the actual number you calculated is going to be consistent with the third party's information? Probably, you have some assumption about that. In order to look at the situation, such information is going to be helpful.

Okamura [A]: Well, I'm not a specialist enough to give you some tips here. Claus might have some comments on this, as well. But whichever case, this has been only four weeks since launch. So, I think it's not so meaningful to stick to that information. I don't know if that is the right way to say as a person who is doing business, but there might be some more data that will be available. And at that time, what will be the relationship of this number and that number? That kind of discussion might be viable. This is the comment setting the scene for you. Claus, could you make some comments? IQVIA prescription data and our considering actual demand and actual sales, that relationship, is there any magic way that we can see a clear picture of the relationship between these two?

Zieler [A]*: Yes, there's usually not too much magic in life. I understand your question. But let me put your question into perspective. The full impact of the inflection curve of VEOZAH we will see when we start activating the direct-to-consumer campaigns. So, that is when we expect women, in response to the direct-to-consumer campaigns, to consult a physician. At that point, the physicians will be fully informed on VEOZAH. And then we also have the payer coverage that will have progressed at that point. And then we see a relevant number of scripts. So, that ramp-up is what we expect to start in Q3. And that is when we get the trend rates that tell us whether our expectations are met or not. At this point in time, in this Q1 where we've only been really promoting for the month of June, but even in Q2, the script levels are going to be low. And yes, we can debate about IQVIA reflecting correctly or not, but it's not going to give us what you're looking for. What you're looking for is the inflection curve. Is it where we expect it to be or is it not where we expect it to be? And, unfortunately, we'll have to wait until DTC campaigns kick in in Q3, until we have that information. So, I think it's probably more prudent to wait until we have that picture rather than go into the relative script levels of IQVIA reported versus our estimations at the low levels of scripts that we see today. I hope that answers your question.

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

Ikeda [M]: Thank you very much. Next, Schroder Investment Management, Sato-san, please.

Sato [Q]: Sato from Schroder. I have two questions. First, full base profit is revised downward. You are going to implement the organizational restructuring after paying a onetime expense of JPY20 billion. What is your plan you'd like to achieve after spending that money? And next, what about the status of the hiring of the CFO? Are you able to hire and find a good person as new CFO by the end of the current fiscal year?

Okamura [A]: Thank you for your question. Regarding your first question, you're talking about the situation in Japan, for which we issued a press release. For details, we are not disclosing the details. And what is going to be the target to support their career? What is going to be the target population for the career change support program? We are not going to disclose it yet. Well, we had an early retirement plan before. The level and the size is going to be similar to that one when doing financial calculations. What we'd like to do? Claus may explain more later on. It used to be having branches and sales offices in different regions in Japan, allocating MRs to have frequent visits to DRs for mature products as well, that has been the sales activities in the past. We had such products appropriate for such a model, but we are now beginning to change to different types of product portfolio. So, where we should make a big change? That is the issue all the time. Even now, we have Suglat. Suglat requires sales reps. You may say so. But we are considering a variety of things. We have a lot of assumptions. Are we going to change at the very last minute? Or, even though the product has become mature, but while it's used in market, are we going to change the way we do business in organization and in the market? We are aiming to achieve our target by FY2025 of CSP2021, and FY2023 should be a turning point. So, in terms of the headcount, it's going to decrease. For those who stay in the Company, how are they going to engage in sales activities for the future? What kind of tools, what kind of technologies and what kind of digital tools are they are going to use have a more efficient and effective interaction with the customers? It's not just about Japan, but this is what we are considering globally. Particularly, in terms of the big difference compared to what we have done before, Japan has a big difference. That's resulting in the measures we are thinking about. It's not going to be just the reduction in the headcount, but those who stay and remain will engage in activities not the same as the conventional sales rep activities. So, it's going to be a small sized group of experts who would stay. Claus may comment later. And for CFO, as I said at the previous meeting, the requirements are very high for us. So, we cannot say that there are many candidates. But we have a few specific candidates we have been able to identify by now. So, we cannot commit to a particular timing, but not far away into the future, we would be able to share the information with you.

Sato [Q]: Thank you very much. Claus-san, I'd like to listen to him, but I think JPY20 billion would be used not just for Japan, but also for global organization. If you have certain ideas, could you explain as well?

Okamura [A]: Yes. The balance, most of the JPY20 billion will be used for Japan. We are not going to do something major globally. But having said so, one of the highlights today is LEXISCAN. There are generics in the United States and sales force covering hospital. What should they do? We do have such an issue we have to consider in established markets, in international markets, in commercial pipelines. At a slightly different timing, we'll make progress. So, accordingly, we are changing organizations in response. And also, focusing on regions, we had management styles, but we are changing to a global management style, and the layers, which increased, how can we reduce the number of layers to go into a flat organization model? That's another thing we have to consider this time. Thank you very much.

Zieler [A]*: Yes. Thank you, and thank you for your question. So, Okamura-san accurately described the situation of what we are trying to achieve. This is the result of a portfolio review that we did in our Japan portfolio. And we identified a tighter focus on priority products and the combination of face-to-face and other channels that would optimally serve our customers. As you know, the customers nowadays use a number of the channels to get information on products, not only the traditional MR visit model. And we want to serve our customers that way. And then, that means building the right building blocks between the human element on the commercial side, on the medical side, and then the digital channels that doctors also use today, from e-mail to webinars. And orchestrating that in a seamless fashion, that's what we're trying to achieve, specifically in the Japanese commercial organization. But it does apply worldwide. Now, as you know, digital channels has been ongoing for a long, long time. So, it's not a new topic. But what we are realizing is that, with COVID, and with the maturity of some products, some of these trends have accelerated and, specifically in Japan, there's a good opportunity now to reset the organization in that seamless face-to-face and digital combined way of reaching the customer. So, that then impacts certain roles in the organization which would exist today, and that is what you see in the restructuring costs that we've put into the full profit picture.

Sato [M]*: Very clear. Thank you so much.

Ikeda [M]: Thank you so much. Next, Credit Suisse Securities, Ms. Haruta, please.

Haruta [Q]: Two questions about ACP. So, in the presentation material, you mentioned about the submission in EU, or Europe. In the past, the EU development and sales was under consideration. But for this, are you going to use your own personnel to do the development and sales of this product in EU?

Okamura [A]: Thank you for the question. Iveric Bio versus Astellas, will it be the way to think or not? That's one point for the discussion. But within Astellas, of course, a non-US organization is available. Regulatory affairs, part of the medical affairs, they can also work for the European business. But when it comes to ophthalmology specialists, we don't have any particular persons who have the good network with. So, if we use them, we hire a new person, we have to think about it. We have to come up with some particular position for that, as well.

Well, I didn't mention much about the non-US market situation because we wanted to see if we could really submit or not. So, we didn't mention much about the sales organizations, or other organization in other countries. But of course, if the product is good, we would like to provide that to the patients. So, we've been thinking about it for a while. Thank you.

Haruta [Q]: Secondly, regarding a procedure there were procedural issues. And also the performance of the product issue for those sales, for the competitive product, when the doctors bring the product into the syringe for the intravitreal injection, it may cause a problem. In your manufacturing process, it's a prefilled syringe and no such issues are going to occur? For your ACP, what kind of risk do your foresee? Could you explain?

Okamura [A]: Thank you for your question. Today, we don't have experts. So I don't think we may be able to give you useful information. This is what is happening with the competitor product, and what is the cause. I don't think it's meaningful to discuss this in detail. I don't want to comment very much, but Taniguchi may have some useful information. So, I'd like to ask him.

Taniguchi [A]: Thank you very much. As for the procedure, the difference is, for example, a needle, when you use a needle for the injection and the vial will be supplied, the needle from the vial Iveric and Astellas products, we are going to supply those. So, there are differences in small details. But in reality, the difference in the product, C3-targeting is the competitor. We target C5. So, that's the difference in terms of the target. And also, the modalities, that's also different. RNA aptamer is ours, and the competitors is different. So, there are such differences in reality. And how they would be linked to the results, we don't know yet.

What we can do is to make doctors administer this product correctly and appropriately to the patients. So, we need education regarding the details of the procedure and safety management, and also safety information must be captured so that they can address it appropriately every time. We will do our best. That results in a good relationship of trust with physicians and patients, medical and commercial would work together to create such a situation.

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

Ikeda [M]: Thank you very much. Next Nikkei Newspaper, Mr. Kurose, please?

Kurose [Q]: Thank you. Kurose from Nikkei Newspaper. Thank you very much. Just one question. That's about the introduction of this career change support program. The numbers are not disclosed. But about what percentage of overall medical reps are here in Japan? And also, the sales activities are changing with introducing digital tools. But what about the background of this system introduction, the digital usage is enhanced, and the business activities are changed? What's the background of this?

Okamura [A]: Thank you for the question. First of all, the size as we mentioned, when we did the earlier retirement system in the past, the size is almost the same. Thus, they are numerators. And the current numbers that comes into the denominator, I believe you have knowledge, so you can do the calculation on your own. And just like you mentioned, the technical advancement around the time of the COVID pandemic, we were not able to see the doctors, but still we had to provide the information, we had to collect the information. Considering that, the way of doing the sales activities will be changed now toward the future. Another point is that our product portfolio itself is changing. In the past, we needed to have contact with the customers. But rather, further advanced customer interaction is more necessary for selling the account products and future products. So, there are such changes impacting.

Kurose [M]: Thank you very much, understood quite well.

Ikeda [A]: Comment from the IR, we have here in Japan, with a number of 1,650.

Kurose [M]: Thank you for the information.

Ikeda [M]: We are running over a bit, but we'd like to take one more question. Mizuho Securities, Tsuzuki-san, please.

Tsuzuki [Q]: First, about Iveric. Because of Iveric's products, you have more interactions with the FDA in person and product.

You work with PeptiDream and Cullgen, but do you have any outlook for or ASP3082 and pan-KRAS?

Okamura [M]: First, about the interaction with FDA, for ACP, Taniguchi is going to respond as far as he can.

Taniguchi [A]: As I touched on earlier, August 19 is the PDUFA date. That's the target. Setting aside if we have more interactions because of the recent safety concerns, we have very frequent interactions with the FDA. We are now in the final stage. It's not increasing because of the safety issue, according to understanding. We will continue to have close discussions with the FDA, so that we can deliver this drug to the patients as soon as possible. That's how the team is working on it.

Okamura [A]: Second question, TPD, our Focus Area approach, basically our thinking is as follows: biology and modality combination, and in which patients is it better to proceed.

We will make such a decision. And the flagship would go into a clinical stage. We get a POC for the clinical. And then the others will come into the clinical stage. That's our basic thinking. If you don't get the POC for ASP3082, it's difficult to think of everything that will go into the clinical stage. Shitaka, in charge of Research, is going to respond.

Shitaka [A]: Thank you for the question. In December last year, we had R&D meeting. The situation has not changed since. Regarding ASP3082, as planned, the dose escalation study is now ongoing. Regarding pan-KRAS, we have to look at the situation of the competitors. As we announced before, we are aiming for IND within FY2023. Thank you very much.

Ikeda [A]: Thank you very much. Earlier, we mentioned 1,650 employees in the Japanese commercial organization, but it's not the number of sales reps. 1,650 is the member of employees in the entire commercial organization in Japan.

There are some people who would like to ask questions, but we would like to close today's earnings call. Thank you very much for your participation.

[END]

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Document Notes

1. *Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.*

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