



Astellas Pharma Inc.

Financial Results for FY2022

April 27, 2023

Event Summary

[Company Name]	Astellas Pharma Inc.	
[Company ID]	4503-QCODE	
[Event Language]	JPN	
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[Event Name]	Financial Results for FY2022	
[Fiscal Period]	FY2022 Annual	
[Date]	April 27, 2023	
[Time]	16:00 – 17:31 (Total: 91 minutes, Presentation: 39 minutes, Q&A: 52 minutes)	
[Venue]	Webcast	
[Number of Speakers]	5	
	Naoki Okamura	Representative Director, President, and CEO
	Yoshitsugu Shitaka	Chief Scientific Officer (CScO)
	Tadaaki Taniguchi	Chief Medical Officer (CMO)
	Claus Zieler	Chief Commercial Officer (CCO)
	Hiromitsu "Hiro" Ikeda	Head of Corporate Advocacy and Relations
[Participant Names]	Hidemaru Yamaguchi	Citigroup Global Markets
	Kazuaki Hashiguchi	Daiwa Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Akinori Ueda	Goldman Sachs
	Naomi Kumagai	Mitsubishi UFJ Morgan Stanley Securities
	Seiji Wakao	JPMorgan Securities
	Kasumi Haruta	Credit Suisse Securities
	Motoya Kohtani	Nomura Securities
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Presentation

Ikeda: Thank you very much for your participation in this Astellas Pharma Inc. earnings call for FY2022 financial results ending March 31. I'm Ikeda, Corporate Advocacy and Relations. I'm serving as the moderator today.

This meeting is going to be provided with Zoom webinar and live streaming. You can attend this in other ways. After the presentation, we'll have a Q&A session, but questions are accepted only from Zoom webinar and not from live streaming.

The participants today are Naoki Okamura, Representative Director, President, and CEO; Yoshitsugu Shitaka, she is CScO or Chief Scientific Officer; CMO, Chief Medical Officer, Tadaaki Taniguchi; CCO or Chief Commercial Officer, Claus Zieler. In total, we have four participants here on our end.

Including Q&A, this session will be held with simultaneous translation in Japanese and English. Accuracy of interpretation cannot be guaranteed by ourselves. Those attending the seminar, please select the favorable language from the Zoom screen. When you select the original language, then you can listen to the original sound without translation.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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

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Today's presentation is going to be made based upon the presentation materials on our website. 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 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 advertisements regarding the efficacy and effectiveness of these compounds.

Now, Okamura-san, please start the presentation.

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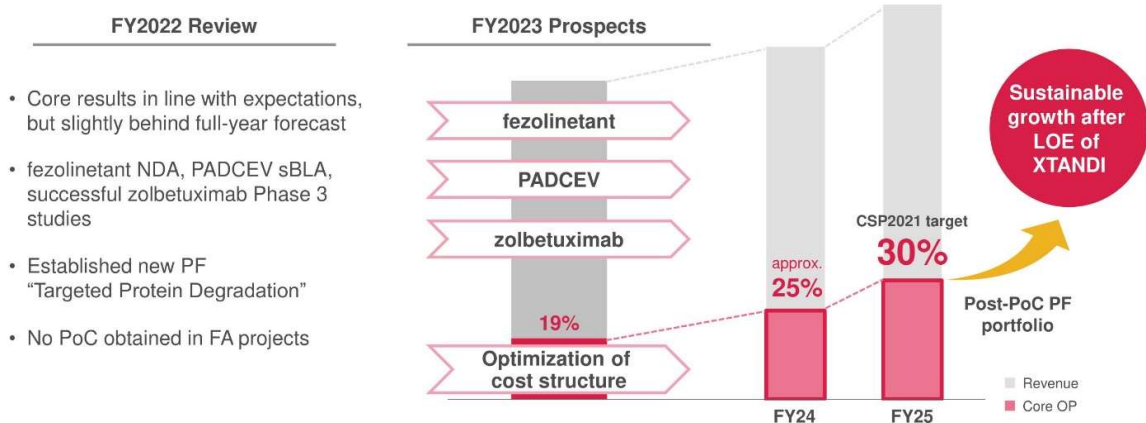


Okamura: Hello, everyone. I'm Okamura from Astellas Pharma Inc. Thank you very much for joining our FY2022 financial results announcement meeting out of your very busy schedule today.

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

TOWARD ACHIEVEMENT OF CSP2021 3

- Continue commitment to CSP2021
- FY2023 is the turning point to ensure growth from FY2024 onwards



Approval of PADCEV sBLA for first-line metastatic urothelial cancer in US is Apr 2023.
 CSP: Corporate Strategic Plan, NDA: New Drug Application, sBLA: Supplemental Biologics License Application, PF: Primary Focus, PoC: Proof of concept, FA: Focus Area, LOE: Loss of exclusivity



Page three. Today, before explaining the details of the financial results, I'd like to explain the FY2022 review as a whole; FY2023 initiatives for achieving the Corporate Strategic Plan, CSP2021; and prospects for FY2024 and beyond.

FY2022 quarterly basis results are almost in line with our expectations, but slightly behind our full year forecast. These were the results of our aggressive efforts to tackle the stretched full year forecast. In development, we achieved important milestones with products we expect to become major growth drivers for the future, such as fezolinetant, PADCEV, and zolbetuximab.

In our focus area approach, our active creation efforts have borne fruit. Targeted protein degradation was selected as a new primary focus. On the other hand, each project aimed for PoC, but unfortunately, no PoC was obtained in these projects.

We take these results seriously and turn them into learning opportunities to be leveraged for FY2023 initiatives so that we can ensure growth towards achieving CSP2021. FY2023 is the turning point for CSP2021. We will continuously keep a strong commitment to the achievement of our targets.

We position FY2023 as a turning point to ensure growth for FY2024 and beyond. As important initiatives in FY2023, we can highlight the four items shown on this page.

First, regarding fezolinetant, we have high expectations for it as a blockbuster. We will make proactive investments with higher priority in order to realize rapid market penetration and sales expansion after launch.

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As for PADCEV, we're hoping that first line treatment of metastatic urothelial cancer will be a major growth driver. We are expecting sales expansion in the United States and also progress in development for global submission.

With regards to zolbetuximab, we will proceed with global submission, and in parallel, make investments for market penetration after launch.

Fourth, we will aim for sales expansion with new products and new indications, and at the same time, we actively promote investments to optimize the cost structure for the future.

To improve operating profit margin in FY2024 and beyond, we will thoroughly pursue operational excellence. As a result, we are forecasting a similar level of the core operating profit margin in FY2023 compared to the previous year. When these investments initiatives bear fruit, we think we can achieve about 25% core operating profit margin in FY2024 and 30% in FY2025, our target in CSP2021.

AGENDA	4
I FY2022 Consolidated Financial Results	
II Initiatives for Sustainable Growth	
III FY2023 Forecasts and Key Expected Events	



Now, I'm going to explain the details from the next page. Page four is the agenda for today.

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FY2022 FINANCIAL RESULTS: OVERVIEW

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Revenue increased 17% YoY and was in line with expectations, but slightly behind full-year forecast
XTANDI, PADCEV and XOSPATA expanded as expected with full-year forecasts

Cost items

- Cost of sales ratio was as expected
- SG&A expenses were on track and decreased YoY when excluding FX impact
- R&D expenses were on track

Operating profit

- Core OP increased 17% YoY and was in line with expectations, but slightly behind full-year forecast



I will start with FY2022 consolidated financial results. Page five.

Revenue and profit increased in FY2022. Revenue increased 17% YoY. It was almost in line with our expectations, but slightly behind our full year forecast. XTANDI, XOSPATA, and PADCEV expanded in line with the full year forecast. I will explain the product details later on page seven.

Next on cost items. Cost of sales ratio was as expected. SG&A expenses were on track and decreased YoY when FX impact was excluded. R&D expenses were on track. As a result, core operating profit increased by 17% YoY. Like the revenue, it was almost in line with our expectations, but slightly behind our full year forecast.

FY2022 FINANCIAL RESULTS

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(billion yen)	FY2021	FY2022	Change	Change (%)	FY2022 FCST ¹	Achievement	FX impact (YoY)
Revenue	1,296.2	1,518.6	+222.5	+17.2%	1,529.0	99.3%	+164.4 bil. yen
Cost of sales	253.0	288.4	+35.3	+14.0%			+13.3 bil. yen (Incl. the impact of elimination of unrealized profit remaining in Q4/FY2021: +7.8 bil.yen)
% of revenue	19.5%	19.0%	-0.5 ppt				
SG&A expenses	548.8	630.3	+81.4	+14.8%	642.0	98.2%	+80.3 bil. yen
US XTANDI co-pro fee	139.3	175.5	+36.2	+26.0%	186.0	94.3%	
SG&A excl. the above	409.5	454.8	+45.3	+11.1%	456.0	99.7%	+50.4 bil. yen
R&D expenses	246.0	276.1	+30.1	+12.2%	278.0	99.3%	+27.5 bil. yen
Amortisation of intangible assets	28.3	38.4	+10.2	+35.9%			
Gain on divestiture of intangible assets	24.2	0.2	-24.0	-99.1%			
Core operating profit	244.7	286.9	+42.2	+17.2%	290.0	98.9%	+40.1 bil. yen
<Full basis>							Ref. Other expenses (booked in Q4/FY2022)
Other income	15.3	3.6	-11.6	-76.1%			• Fair value increase of contingent consideration(zolbetuximab) ² :38.6 bil. yen
Other expenses	104.3	157.5	+53.2	+51.0%			• Impairment losses on intangible assets :60.3 bil. yen(EVRENZO:47.1 bil. yen, FX-322:8.6 bil. yen, Adaptimmune:4.6 bil. yen)
Operating profit	155.7	133.0	-22.7	-14.6%	137.0	97.1%	
Profit before tax	156.9	132.4	-24.5	-15.6%	135.0	98.0%	
Profit	124.1	98.7	-25.4	-20.4%	105.0	94.0%	

1. FY22 FCST were announced in Oct 2022, provided that full basis is the revised forecast announced on April 11, 2023.
2. Booked in Q4/FY2022 due to internal decision-making to submit for approval of zolbetuximab



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On page six, I will explain FY2022 financial results.

Revenue increased to JPY1,518.6 billion, up 17.2% YoY, achieving 99.3% of the full year forecast. Core operating profit was JPY286.9 billion, up by 17.2% YoY. The achievement of our full year forecast was 98.9%. You can see the FX impact on the right-hand side of the table. Revenue and profit increased even when FX impact was excluded.





The bottom half of this page shows our full basis results, provided that full basis profit forecast is the revised forecast announced on April 11, 2023. In the right bottom of the table, we included other expenses booked in Q4. As we decided to file our submission, we booked JPY38.6 billion as fair value increase of contingent consideration for zolbetuximab.

The other day, we made a press release about the expected booking of about JPY58 billion impairment losses and other expenses in Q4. We examined the numbers in detail and booked JPY60.3 billion, including impairment losses of JPY47.1 billion due to the review of future sales forecast for EVRENZO. Overall, other expenses reached JPY157.5 billion in Q4. Operating profit was JPY133 billion, down by 14.6% YoY, achieving 97.1% of our full year forecast. Profit decreased to JPY98.7 billion, down 20.4% YoY, achieving 94% of our full year forecast.

FY2022 FINANCIAL RESULTS: MAIN PRODUCTS

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XTANDI, PADCEV, XOSPATA showed solid growth in line with full-year forecast

(billion yen)	FY2022 Act	YoY	FY2022 FCST*	Achievement against FCST	
 Xtandi (enzalutamide)	661.1	+126.8 (+24%) Excl. FX impact [+45.4 (+9%)]	670.0	99%	<ul style="list-style-type: none"> ✓ Global sales showed growth in line with FCST ✓ US: Total demand growth offset by affordability challenges including fluctuating PAP rates and generic competitor share. Despite the challenging environment, XTANDI continues to be the leading branded NHT across all indications ✓ Europe: Strong demand increase, achieved the upwardly revised FCST
 PADCEV enfortumab vedotin Injection for IV infusion 20 mg/4.30 mg vials	44.4	+22.7 (+104%) [+17.2 (+79%)]	45.4	98%	<ul style="list-style-type: none"> ✓ Global sales expanded significantly, driven by Europe and Japan ✓ US: Despite steady growth in actual demand, revenue from clinical orders was below expectations, resulting in underachieving the FCST ✓ Europe: Launched countries increased to 21 and obtained reimbursement in 7 countries
 XOSPATA gilteritinib 400mg tablets	46.6	+12.5 (+37%) [+6.6 (+19%)]	45.8	102%	<ul style="list-style-type: none"> ✓ Global sales achieved FCST ✓ Sales expanded in all regions, performance in line with expectations ✓ High market share in US, Europe and Japan
 Evrenzo roxadustat	3.2	+0.6 (+23%)	5.0	64%	<ul style="list-style-type: none"> ✓ Progress was significantly behind FCST ✓ Japan: Market share was lower than expected due to competitive pressure ✓ Europe: Launched with reimbursement in Italy in Q4

* Announced in Oct 2022
FCST: Full-year forecast, PAP: Patient Assistance Program, NHT: Novel Hormonal Therapy



Please turn to page seven. I will explain FY2022 results for major products.

First, XTANDI. Global sales grew to JPY661.1 billion in FY2022, up by 24% YoY. Even when FX impact was excluded, it was nearly a double-digit growth. The results were almost in line with our expectations, but slightly behind our full year forecast. By region, the US was behind, which became a factor for the underachievement of global sales. Levels of the PAP, Patient Assistance Program, ratio and the share of Zytiga generic competitors remained high, which affected our sales.

On the other hand, despite the challenging environment, XTANDI continues to maintain the overwhelmingly leading position in the branded market across all indications. In Europe, we achieved a full year forecast, which was substantially revised upward in Q2 as mainly in Germany and Italy, M1 CSPC prescription increased, and

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demand substantially increased by 20% YoY. In the midterm plan five years ago, we announced the peak sales forecast of JPY400 billion to JPY500 billion, but XTANDI substantially exceeded those expectations and grew to a product exceeding JPY600 billion in sales.

As for PADCEV, global sales expanded significantly to JPY44.4 billion, up by 104% YoY, driven by Europe and Japan in particular. The results were almost in line with our expectations, but slightly behind our full year forecast. In the United States, despite steady growth in actual demand, revenue from clinical orders was below expectations, resulting in the underachievement of the forecast.

On the other hand, both Japan and Europe achieved the full year forecast, which was substantially revised upward in the Q2. In Europe, launched countries increased to 21 and reimbursement was obtained in seven countries. In Japan, new prescriptions exceeded our expectations, contributing to sales expansion.

Regarding XOSPATA, global sales increased and achieved full year forecast. Sales expanded in all regions, performing in line with expectations, particularly in US, Europe, and Japan. High market share was achieved in the current indications.

As for EVRENZO, progress was significantly behind our full year forecast. We booked impairment losses, and the sales trend was much lower than expected. Intensifying competition continues to be a factor behind in Japan. In Europe, the situation still continues where we have not been able to differentiate from the existing standards of care. In Q4, we obtained reimbursement in multiple countries, including Italy, which we hope will contribute to sales in FY2023.

FY2022 FINANCIAL RESULTS: COST ITEMS

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Cost of sales ratio was as expected

SG&A expenses were on track and decreased YoY when excluding FX impact

R&D expenses were on track

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

Cost Items	YoY change	Ratio to Revenue	Achievement against FCST	
Cost of sales	+14.0%	19.0% (-0.5ppt YoY)	-	✓ Cost of sales ratio was as expected
SG&A expenses excl. US XTANDI co-pro fee	+11.1% (-1.3% excl. FX impact)	29.9% (-1.6ppt YoY)	99.7%	<ul style="list-style-type: none"> ✓ Optimization of commercial-related personnel globally (YoY approx. -8.0 bil. yen) ✓ Reduction of mature products-related costs (approx. -8.0 bil. yen) ✓ Investment for new product launch readiness (approx. +12.0 bil. yen) ✓ Cost reduction progressed as expected, actively making necessary investments ✓ As a result, SG&A expenses were on track
R&D expenses	+12.2% (+1.1% excl. FX impact)	18.2% (-0.8ppt YoY)	99.3%	<ul style="list-style-type: none"> ✓ Booked one-time expense for using PRV in Q1 for the application of fezolinetant (13.7 bil. yen) ✓ In line with full-year forecast, including the expense above

PRV: Priority Review Voucher



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

Cost of sales increased by 14% YoY, along with the revenue increase. COGS ratio was down by 0.5 percentage points YoY to 19%, in line with our expectations. SG&A costs, excluding XTANDI's US co-promotion fees, increased by 11.1% YoY, but when FX impact was excluded, SG&A expenses decreased by 1.3% or JPY5.1 billion YoY.

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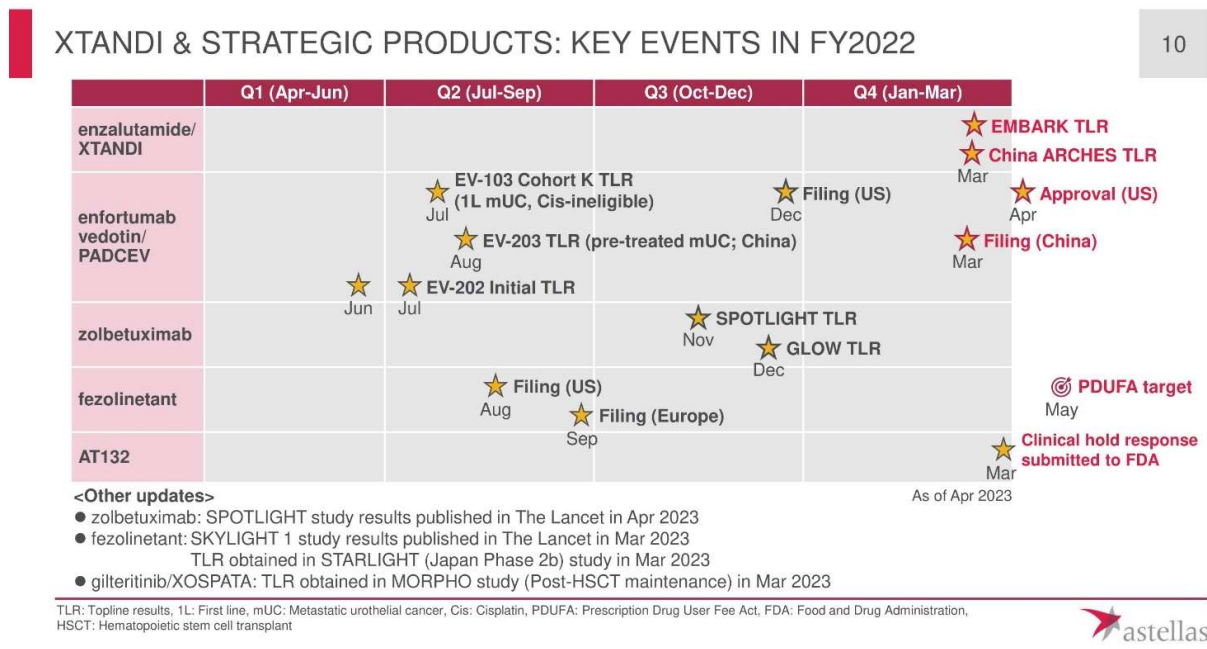
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The ratio to revenue decreased by 1.6 percentage points YoY to 29.9%. The achievement rate was 99.7%, with spending in line with our full year forecast. Personnel costs fell by about JPY8 billion YoY with global optimization of commercial-related personnel. We are trying to reduce sales promotion costs related to mature products such as mirabegron, which decreased our cost by about JPY8 billion YoY.

On the other hand, we are making active investments for new product launch readiness for PADCEV and fezolinetant. Sales promotion expenses rose by about JPY12 billion YoY. As a result, we are able to reduce costs as expected and necessary investments were made actively. SG&A costs were controlled in line with our initial assumptions throughout the year.

R&D expenditure increased by 12.2% YoY, but 1.1% when FX impact was excluded. There was an impact from the booking of onetime expense of JPY13.7 billion for using a priority review voucher in Q1 for the application of fezolinetant. When this cost is excluded, the R&D expenditure decreased YoY. The achievement rate was 99.3%, in line with our full year forecast, including the expense for using a Priority Review Voucher.



From here on, I will explain our initiatives for sustainable growth. Turning to page 10. I will explain key events we achieved in FY2022 for XTANDI and strategic products. Progress in the past three months is shown in red.

Regarding XTANDI, we obtained positive top line results from both Phase III EMBARK study in M0 CSPC and Phase III China ARCHES study in M1 CSPC Chinese participants. I will explain the details related to the EMBARK study on the next page.

This is an achievement in FY2023, but with PADCEV, we obtained accelerated approval from the US FDA in April for the additional indication of locally advanced or metastatic urothelial cancer and cisplatin-ineligible patients in the first-line treatment. In China, our filing for previously treated metastatic urothelial cancer was accepted in March.

As for fezolinetant, we received a notification from US FDA that the review period would be extended by three months to secure time to complete their review. The new PDUFA date is set for May 22.

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Regarding AT132, we submitted a series of responses to the clinical hold by the FDA by in March. We are discussing with regulatory authorities continuously. As other updates, we published Phase III study results for zolbetuximab and fezolinetant, respectively, in the prestigious medical journal, *The Lancet*.

For fezolinetant, we obtained positive top line results in Japanese Phase IIb study, STARLIGHT study. We will discuss the future development and submission plan with the regulatory authorities.

With regards to XOSPATA, we obtained positive top line results for Phase III MORPHO study for maintenance therapy after the hematopoietic stem cell transplantation in March. Unfortunately, we couldn't achieve primary endpoint. We will analyze the data in detail again and consider the future plan.

In FY2022, as a whole, we were able to achieve all important events in light of the initially announced plan, except for the delay in obtaining top line results due to the delay in accumulating events in the EMBARK study.

ENZALUTAMIDE/XTANDI: LATEST STATUS

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- Aiming for regulatory submission in US as well as Europe, based on the positive topline results from EMBARK study
- Revised potential peak sales upward to 700 billion yen

EMBARK study

- Study design

M0 CSPC
(high-risk
BCR)

Placebo +
leuprolide (LEU)

enzalutamide + LEU

enzalutamide mono

→

Undetectable
PSA

Week 37

Yes →

No →

Suspend
treatment
(reinitiate if
PSA rises)

Remain on
treatment

- Topline results
 - Met primary endpoint of MFS (enzalutamide + LEU vs. placebo + LEU)
 - Positive trend in key secondary endpoint of OS (not yet mature)
 - Met other key secondary endpoints
 - MFS (enzalutamide mono vs. placebo + LEU)
 - Time to PSA progression
 - Time to first use of new antineoplastic therapy

Future plan

- EMBARK data presentation: AUA 2023 on Apr 29
- Regulatory submission: targeting mid-2023 in US and 2H FY2023 in Europe

Update of sales forecast

- Updated sales forecast by incorporating sales trend so far, M0 CSPC submission plan in Europe and FX rate trend
- Potential peak sales: over 700 billion yen*
 - Sales contribution from M0 CSPC: 40-50 billion yen

* Previous forecast: 600-700 billion yen

M0 CSPC: Non-metastatic castration-sensitive prostate cancer, BCR: Biochemical recurrence, PSA: Prostate-specific antigen, MFS: Metastasis-free survival, OS: Overall survival, AUA: American Urological Association

On page 11, I will explain an overview of the EMBARK study and related updates.

In this study, M0 CSPC patients with high risk of biochemical recurrence received placebo plus leuprolide, enzalutamide plus leuprolide, or enzalutamide monotherapy. If PSA is not detected 37 weeks after the initiation of the treatment, participants will suspend treatment until their PSA rises again.

Regarding the primary endpoint of MFS, the enzalutamide combination group demonstrated a statistically significant improvement compared to the placebo group. Furthermore, in OS, a key secondary endpoint, a positive trend was observed. OS data is not yet mature, so we will continue monitoring for the final analysis.

Also, for other secondary endpoints shown in the right middle on the slide, statistically significant improvement was also demonstrated. The results in detail will be presented at AUA 2023 on April 29, US time. Based on the study results, we are planning to file a submission targeting mid-2023 in the United States. Also, in Europe, we will have discussions with the regulatory authorities, targeting our submission in 2H of FY2023.

Also, we updated the sales forecast by incorporating the sales trend so far, the newly decided submission plan in Europe, and the recent FX rate trend. We issued guidance to forecast potential peak sales of JPY600 billion

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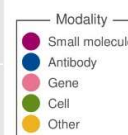


to JPY700 billion, but made an upward revision to JPY700 billion or higher. We estimate the contribution of M0 CSPC indication to be JPY40 billion to JPY50 billion. We will update the peak sales forecast for other strategic products at an appropriate timing.

PROGRESS IN FOCUS AREA APPROACH (1/2): CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL (Red: Updates since the last financial results announcement)

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Primary Focus	Biology/Modality/Technology ¹	Project	Current status	No. of projects aiming PoC by end FY25 ²
Genetic Regulation	Gene replacement (AAV)	AT132	ASPIRO study put on clinical hold by FDA in Sep 2021	2
		AT845	Activities to restart FORTIS study commenced in Feb 2023 Preliminary data from FORTIS study presented at WORLD Symposium in Feb 2023	
Immuno-Oncology	Gene regulation (AAV)			7
	Checkpoint	ASP1570	Phase 1 study ongoing	
	Artificial adjuvant vector cell (aAVC)	ASP7517	Terminated	
		ASP0739	Terminated	
	Oncolytic virus (intratumoral)	ASP9801	Terminated	
	Oncolytic virus (systemic)			
	Bispecific immune cell engager	ASP2138	Phase 1 study ongoing	
ASP2074		FSFT in Phase 1 study in Mar 2023		
Blindness & Regeneration	Cell replacement (UDC)	ASP1002	FSFT in Phase 1 study in Mar 2023	3
		ASP7317	Screening and enrollment in Phase 1b study restarted in Aug 2022	
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD terminated due to operational reasons	3
		ASP8731	Terminated	
Targeted Protein Degradation	Protein degradation	ASP3082	Phase 1 study ongoing. Fast Track Designation granted by FDA in Feb 2023 (pancreatic adenocarcinoma)	1
Primary Focus Candidate	Immune modulating/regulatory cells			-
	Tissue-specific immune regulation			
Total				24 → 16



1. Not exhaustively listed.

2. Estimated based on standard development timelines, assuming 100% probability of success (as of Apr 2023). Total number indicates change from Apr 2022.

AAV: Adeno-associated virus, UDC: Universal donor cell, FDA: Food and Drug Administration, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy



From page 12, I will explain the progress in our focus area approach. Projects in the clinical trial stage with updates in the last three months are shown in red. AT845 in primary focus, genetic regulation, will be explained on a later slide.

In immuno-oncology, ASP7517 and ASP0739, artificial adjuvant vector cells aAVC, and ASP9801, intratumoral oncolytic virus, were terminated based on the clinical study data obtained so far. Bispecific immune cell engager, ASP2074 and ASP1002 achieved the first subject dosing in March as planned.

In mitochondria stress, ASP8731 for sickle cell disease was terminated based on the data obtained so far. In targeted protein degradation, ASP3082 was granted first track designation by the FDA in February for existing treatment-resistant pancreatic adenocarcinoma with KRAS G12D mutation. We are hoping that this will lead to the acceleration of the project.

The right-hand side of the table shows the number of projects aiming for our PoC determination by the end of FY2025. As of now, we have 16 projects due for termination after PoC in the clinical study stage, as well as the project termination in the research stage, as well as delay. It's a pity that no PoC was obtained in primary focused projects, but we will continue to create projects in research stage and aim for PoC in the clinical or study stage so that we can obtain PoC.

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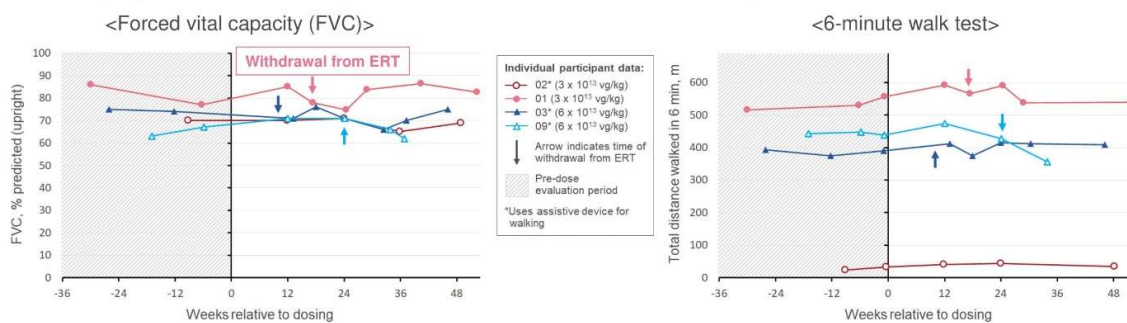


PROGRESS IN FOCUS AREA APPROACH (2/2): AT845 PRELIMINARY DATA FROM FORTIS STUDY

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- Three of four participants have discontinued enzyme replacement therapy (ERT)* following administration of AT845¹
- Their measured functional outcomes have been stable while off ERT

*ERT: only approved treatment for Pompe disease; a chronic treatment delivered in bi-weekly infusions



- Activities to restart FORTIS study commenced in Feb 2023, with dosing anticipated to resume in Q2 FY2023

1. As of Sep 15, 2022



On page 13, regarding AT845, I will introduce you to data from the FORTIS study that was recently presented.

At the time of data evaluation, four subjects received AT845 and were being followed up. Three of the four subjects chose to discontinue standard therapy that is enzyme replacement therapy or ERT, following the administration of AT845. ERT is currently the only approved treatment for Pompe disease, but it requires a chronic treatment delivered in bi-weekly infusions. We hope AT845 will replace it with a single dose.

The study showed that major functional outcomes such as FVC or forced vital capacity in the six-minute walk test have been stable after withdrawal from ERT, for up to 51 weeks in the longest-evaluated subjects. The clinical hold was lifted in February, and the activities are now underway with the aim of resuming dosing in Q2. The plan is to determine the PoC, along with the data from subjects who will be administered after the resumption.

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PROGRESS IN Rx+ PROGRAM: SUMMARY OF FY2022

(Red: Updates since the last financial results announcement)



Key events expected in FY2022 (announced in Apr 2022)

Category	Program	Event	Progress
Digital health Other services	EG Holter	Initiation of pilot marketing	Jun 2022: Initiated sales pilot
Digital therapeutics	BlueStar	Initiation of clinical study (Japan)	Jan 2023: Partnership agreement with Roche Diabetes Care Japan, aiming for approval as a combined medical product with a blood glucose monitoring system Initiation of clinical study in Japan planned in FY2023
Drug-device combination	pudexacianinum chloride (ASP5354)	FSFT in Phase 3 study	Jan 2023: Collaboration on exclusive commercialization in US with Stryker, a medical device company with strengths in surgical visualization technology Preparation to initiate Phase 3 trials in FY2023

FSFT: First subject first treatment



On page 14, we summarize the main progress made in FY2022 with regard to the Rx+ program. Progress made in the last three months is shown in red.

A partnership agreement was signed with Roche Diabetes Care Japan or Roche DC Japan for BlueStar digital therapeutics with diabetes patients. In addition to tracking blood glucose data of diabetes patients using the blood glucose monitoring system of Roche DC Japan, BlueStar is combined with it, aiming to provide a new solution to support disease management. In Japan, the Company plans to begin clinical trials in FY2023 with the aim for approval as a combined medical product.

ASP5354 has entered into an exclusive US commercialization agreement with Stryker, a medical device company with a strength in surgical visualization technology. Through this partnership, Stryker will assist in the visualization of the ureter during surgery by providing a video system optimized for ASP5354 and Stryker will promote awareness and use of the system in clinical practice through collaboration on sales, marketing, and surgical training with them. Phase III clinical trials are planned to be initiated in FY2023.

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- *Revenue to be the same level as previous fiscal year*
Sales contributions of fezolinetant and PADCEV offsetting decrease in sales of Lexiscan
 - ✓ *SG&A expenses to increase YoY mainly due to investment in fezolinetant and zolbetuximab*
 - ✓ *Implementation of continued pursuit of operational excellence to achieve Core OP margin of 30% in FY2025*
 - ✓ *R&D expenses to decrease YoY due to decrease in development costs for Strategic products while continued investment to be made in Primary Focus*
- *As a result, Core OP to be the same level as previous fiscal year*
- *In anticipation of our growth from FY2024 onwards, dividend per share is forecasted at 70 yen, an increase of 10 yen*



Next, let me talk about focus and the key expected events in FY2023. Page 16.

Revenue is forecasted to be the same level as the previous fiscal year in FY2023. As a premise for the full year revenue forecast, we have factored in the impact of the most recently confirmed the shipment of generic Lexiscan products. The decrease in sales of Lexiscan is expected to be offset mainly by the launch of fezolinetant and the sales contribution from the additional indication of PADCEV for the first-line treatment in the US.

The product focus for FY2023 is explained in detail on page 18. Now, let me explain the expenses or cost items.

We expect SG&A expenses to increase YoY, and this will be a year of investment to ensure growth in FY2024 and beyond. We will expand investments mainly in fezolinetant and zolbetuximab. In addition, in order to achieve a core margin of 30% in FY2025, as stated in our CSP2021, we will continuously pursue operational excellence. We have been working for scrutinization to optimize cost structure toward FY2024 and FY2025. Specific projects and initiatives are still under consideration. We will provide details as we move forward. We expect R&D expenses to decrease YoY. We will expand investment in primary focus.

On the other hand, we anticipate a decrease in development expenses for our Strategic products. As a result, we expect core OP to remain at the same level as the previous fiscal year. In anticipation of mid- and long-term growth in FY2024 and beyond, we are forecasting a JPY10 dividend increase to JPY70 per share for FY2023.

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FY2023 FORECAST

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(billion yen)	FY2022 actual	FY2023 forecast	Change (%)	
Revenue	1,518.6	1,520.0	+0.1%	FY2023 FCST (FX rate) USD: 130 yen EUR: 140 yen FX impact: -40.8 bil. yen
SG&A expenses	630.3	661.0	+4.9%	
US XTANDI co-pro fee	175.5	176.0	+0.3%	
SG&A excl. the above	454.8	485.0	+6.6%	
R&D expenses	276.1	251.0	-9.1%	
Core operating profit	286.9	290.0	+1.1%	FX impact: -8.7 bil. yen
<Full basis>				
Operating profit	133.0	288.0	+116.5%	
Profit	98.7	227.0	+130.0%	



On page 17, I will explain the performance focus for FY2023.

Revenue is projected to be JPY1,520 billion, an increase of 0.1% YoY. The yen is expected to appreciate against the US dollar compared to the previous fiscal year, which will have a negative impact on our performance, but we expect to absorb the impact and achieve the same level of sales revenue.

SG&A expenses are expected to be JPY661 billion, an increase of 4.9% YoY. Excluding co-promotion expenses for XTANDI US, SG&A expenses are expected to be JPY485 billion an increase of 6.6% YoY. R&D expenses amounted to JPY251 billion, down 9.1% YoY. As a result, our operating income is expected to be JPY290 billion, up 1.1% YoY. As with revenue, we expect to be able to absorb the negative impact of foreign exchange rates.

The lower part of the slide shows our full basis forecast. Operating profit is projected to be JPY288 billion, In FY2023, we have included in other expenses, an increase of about JPY2 billion in fair value increase and the contingent consideration of fezolinetant and zolbetuximab.

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FY2023 FORECAST: MAIN PRODUCTS

18

Expect continued growth led by PADCEV, with sales contribution from fezolinetant

(billion yen)	FY2023 FCST	YoY	Main growth factors
 Xtandi (enzalutamide)	669.9	+8.8 (+1%) Excl. FX impact* (+30.7 (+5%))	<ul style="list-style-type: none"> ✓ US: Expect continued growth within the current indication; and potential approval of M0 CSPC additional indication by the end of FY2023 ✓ Japan: Expect sales growth driven by M1 CSPC ✓ China: Reimbursement for M0 CRPC additional indication started in Mar 2023
 PADCEV enfortumab vedotin injection for IV infusion 200mg/5.50mg vials	66.7	+22.3 (+50%) (+23.5 (+54%))	<ul style="list-style-type: none"> ✓ US: Expect substantial growth driven by the additional indication of 1L mUC ✓ Europe: Expect increases in countries with reimbursement ✓ Japan: Expect continued growth within the current indication
 XOSPATA gilteritinib 400mg tablets	49.3	+2.7 (+6%) (+4.3 (+10%))	<ul style="list-style-type: none"> ✓ US and Europe: Expect continued growth in the large markets ✓ International Markets: Expect sales to expand from the increase of launched countries and reimbursement start

- fezolinetant: Factored into FY2023 forecast (40-50 billion yen), detailed guidance will be provided after approval

Regional forecasts for XTANDI and PADCEV are on slides 31-32. * Aligning the exchange rate to FY2023 forecast exchange rate
M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer 1L: First Line, mUC: Metastatic urothelial cancer,
International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc



Page 18 is the focus for major products in FY2023.

First, expected forecast for FY2023 is JPY669.9 billion, an increase of JPY8.8 billion YoY. Excluding the impact of FX, this would be an increase of 5% over the previous year.

In the US, although we continue to expect the impact of PAP and Zytiga generics, recent data shows an upward trend in the number of new patients and expect an increase of new patients further. We also expect to receive approval for an additional indication for M0 CSPC in FY2023. Although the contribution to sales in this fiscal year will be limited, we expect synergistic effects on the existing indications by activating promotion activities.

In Japan, we expect sales to expand mainly driven by the growth of M1 CSPC. In China, reimbursement for the additional indication of M0 CSPC started in March 2023, which is expected to contribute to sales. On the other hand, sales growth in Europe is expected to be moderate, because although driven by an increase in prescriptions of M1 CSPC, with volume growth in the single-digit range, it will be offset by the negative impact of an increasingly competitive environment and price pressure.

PADCEV's forecast of FY2023 is JPY66.7 billion, an increase of JPY22.3 billion YoY. Excluding the impact of FX, this represents an increase of 54% over the previous fiscal year. In the US, we expect substantial sales course driven by the additional indication, which was approved this month. We have already gained a high market share in second- and third-line treatment, and we expect first-line treatment to be a growth driver going forward.

We also received information today that NCCN guidelines, which are mainly what physicians refer to when making prescription decisions, have been updated to recommend the use of PADCEV as first-line treatment for mUC, based on the result of the EV103 trial. We look forward to its contribution for our future.

In Europe, we expect further growth by obtaining reimbursement in big markets such as Germany, France, Italy, and Spain. In Japan, we expect continued growth as we seek further market penetration in the current indications.

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The regional forecast of XTANDI and PADCEV are shown on pages 32 and 33.

The forecast for XOSPATA for FY2023 is JPY49.3 billion, an increase of JPY2.7 billion over the previous fiscal year. In the huge markets such as US and Europe, we expect continued growth through market penetration of FLT3 testing in the market. In the International Market, we expect an increase in the number of countries where FLT3 will be launched and reimbursed, and we expect sales to grow.

Finally, for fezolinetant, which is expected to be approved in the near future, we have factored in JPY40 billion to JPY50 billion in FY2023 forecast. Naturally, this figure includes the impact of the three-month extension of the PDUFA date. The impact of the three-month extension does not simply mean that 1/4 of the originally projected sales of FY2023 will be reduced.

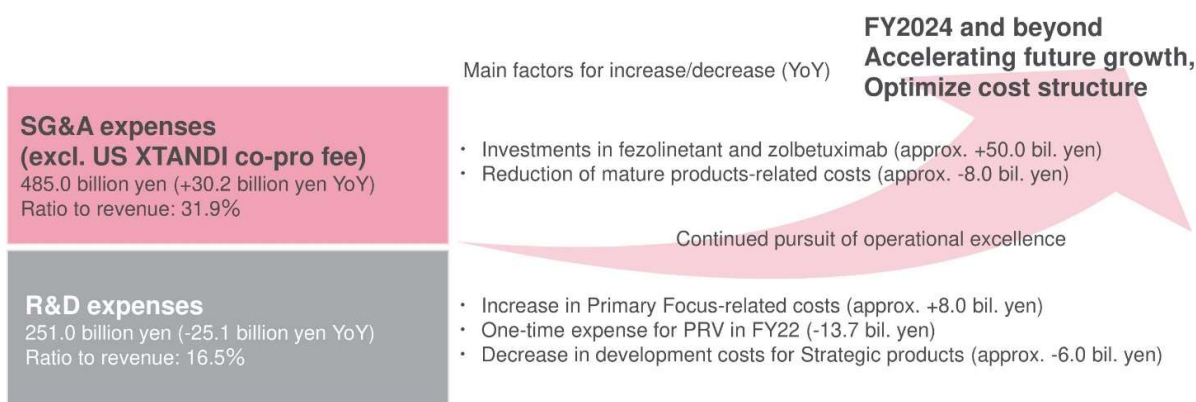
We expect a certain period of time from the launch of product to reimbursement, so we are projecting a linear growth in each quarter. In other words, we estimate that sales will be reduced by about half from our original forecast of FY2023 because the last three months is when we expect the greatest contribution to sales but this will be postponed to the next fiscal year.

Last year, we gave the guidance that we could expect fezolinetant sales to be mid-double-digit billion yen in the first year, but please understand that we would have expected even higher than JPY40 billion, JPY50 billion if it had been approved in February. We would appreciate if you could wait until the approval for further details and assumptions. We plan to hold a briefing after the approval to provide guidance on specific amounts, focus, and sales strategies to achieve them.

FY2023 FORECAST: COST ITEMS

19

Allocate limited resources in a disciplined manner to drive sustainable growth from FY2024 onwards



On page 19, I will explain the cost items for FY2023.

Excluding the co-promotion fee of XTANDI in the US, SG&A expenses are expected to be JPY485 billion, an increase of JPY30.2 billion YoY. As explained on page 18, we expect fezolinetant sales of JPY40 billion to JPY50 billion in FY2023. Although the PDUFA date has been extended by three months, we have set the highest priority on fezolinetant in FY2023 in order to achieve rapid market penetration and a further sales expansion in FY2024 and beyond.

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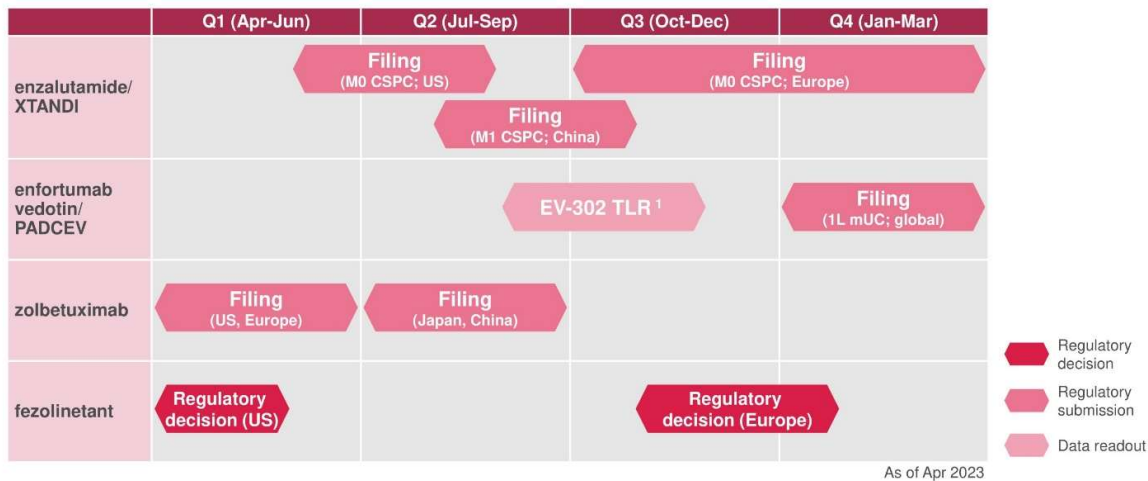
We will continue to make proactive investments in additional investment. In addition to this, we will also make investments in anticipation of the launch of zolbetuximab. We expect investments in these two products to increase by approximately JPY50 billion YoY.

On the other hand, we'll continue to reduce cost for mature products and expect a decrease of approximately JPY8 billion YoY. SG&A expenses will increase in FY2023 due to the proactive investment in fezolinetant, but at the same time, we will aim to optimize cost structure. Although we cannot give specific details or a sense of scale at this time, we will get the achievement of a core OP margin of 30% in FY2025, by making sure of this approach contributing to FY2024 onwards.

R&D expenses are expected to be JPY251 billion, a decrease of JPY25.1 billion YoY. Investment in primary focus will continue to increase. We expect an increase of approximately JPY8 billion YoY mainly due to expanded investment in target protein degradation and gene therapy.

On the other hand, a one-time expense for Priority Review Voucher of JPY13.7 billion for fezolinetant will be a factor for the decrease compared to the previous fiscal year. In addition, development costs for fezolinetant and XOSPATA are expected to decrease by approximately JPY6 billion YoY. We will invest proactively for further growth, and we will continue to review the costs and now contribute to the improvement of competitive merchant value. This year will be the year of further growth and optimization of cost structure of FY2024.

XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2023 20



1. The timeline of TLR is subject to shift due to its event-driven nature.
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, M1: Metastatic, TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer



Page 20 is about key events we expect to see in XTANDI and Strategic products in FY2023.

XTANDI. We plan to file for additional indication for M0 CSPC based on the EMBARK study; in the US, between June and August, and in Europe in 2H of FY2023. Also, for the filing for additional indication of M1 CSPC in China around August to October based on China ARCHES study. PADCEV top line results from Phase III EV302 study are expected to be available in September to November.

The target indication for this is the first line of cisplatin eligible mUC, and if the result comes on schedule and the data positive, we expected to be able to file globally in Q4.

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The global submission for zolbetuximab for the treatment of gastric and GEJ adenocarcinoma is expected in Q1 in the US and Europe and in Q2 in Japan and China. Fezolinetant, a decision on the profile is expected by May 22 and PDUFA date. In Europe, we expect a decision from the regulatory authorities between November and January next year.

FOCUS AREA APPROACH: KEY EVENTS EXPECTED IN FY2023

21

Expecting Phase 1 entry in 4 projects and several progress in Phase 1 studies toward PoC judgment

Primary Focus	IND	Phase 1	
		Early data readout ¹	Dosing resumption
Genetic Regulation	1 project		AT845
Immuno-Oncology	2 projects	ASP1570 ASP2138	
Blindness & Regeneration			ASP7317
Targeted Protein Degradation	1 project (pan-KRAS)	ASP3082	

1. Dose escalation/monotherapy
PoC: Proof of concept, IND: Investigational New Drug



Page 21. Here are the main events expected in FY2023 for primary focus projects.

A total of four projects from genetic regulation, immuno-oncology, and targeted protein are expected to enter the Phase I stage. The details of each will be explained at the time when they go into the Phase I stage.

The projects that have already entered the clinical study phase, initial data for the monotherapy dose escalation part of the Phase I studies are expected for the inhibitor against DGK ζ , ASP1570, the bispecific antibody ASP2138, and the KRAS G12D degrader ASP3082. For AT845 and ASP7317, the first dose is expected to be administered after the resumption of clinical trials.

Although we do not have any projects planned to achieve or obtain PoC in FY2023, we expect to obtain initial clinical data for several projects, which we hope will lead us to PoC in FY2024 and beyond.

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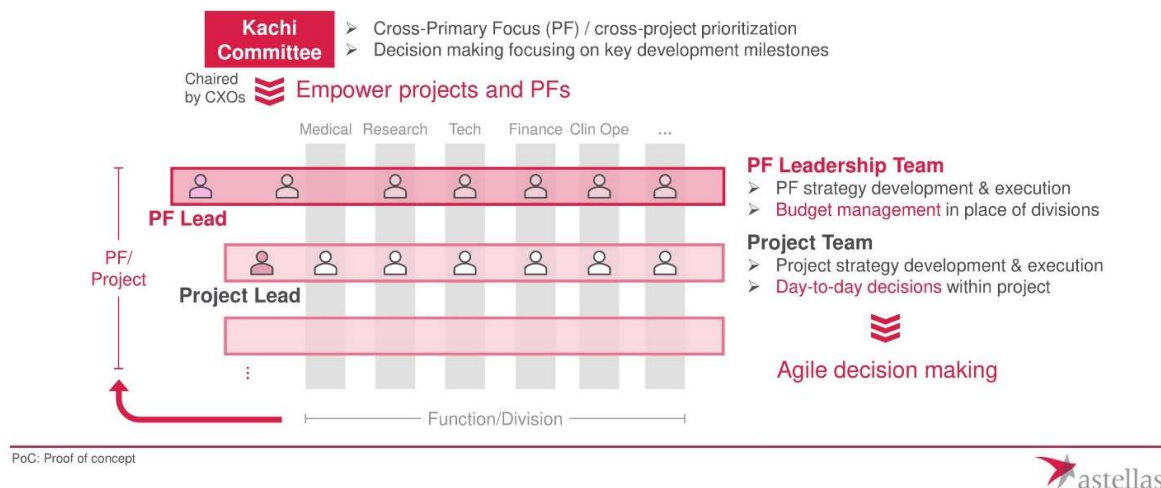
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NEW R&D OPERATING MODEL

22

To achieve meaningful PoC as early as possible, enable agile decision making by empowering projects and Primary Focuses throughout the project lifecycle



Page 22. I will explain our new promotion system for R&D projects.

R&D operating model, in other words, newly introduced in April with the aim of accelerating the PoC acquisition. At the R&D meeting held about a year ago, we explained that we have reorganized our research organization structure from a traditional, function-based hierarchical structure to purpose-based and agile organizations. As a result, the new primary focuses and the projects are being actively created by the research organization, so actual results will be gaining too much.

This time, we have expanded its concept to include clinical development and shifted the focus of activities around the function and access to the objective axis, the primary focus project axis, and organized to enable agile decision-making through empowerment.

The leadership team from each primary focus consisting of a percentage for each function established is establishing and making strategic planning for each primary focus. Furthermore, it manages budget and oversight and prioritize projects from research to clinical phases. Day-to-day decision-making for each project is delegated to each project team. Also, organizational structure was reformed in which layers between each project lead and CXO in charge was reduced.

At the Company-wide level, we have established a new meeting body called the Kachi Committee, which is the governance body, chaired by the CXO in charge. The Kachi Committee is responsible for prioritizing among the primary focuses and digital making focuses on key development milestones. We think the empowerment to each project, the primary focus needs to decrease the timing of visiting our corporate wide governance body, and the system is a designed to enable rapid decision-making on a project-by-project basis. This will accelerate the decision of our PoC in the future.

We reiterate that we remain committed to achieving CSP2021, and we proactively invest in promoting initiatives for the future in FY2023, making it a turning point to ensure growth from FY2024 onwards. We'll commit to achieve core margin of 30% in FY2025 and promote to build our portfolio of late-stage development products through our new R&D operating model to ensure a sustainable growth after the loss of exclusivity of XTANDI.

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fezolinetant Meeting

- To be held after approval
(Details will be delivered later)



Page 24. This is the last slide for me. This is about upcoming events.

We expect the fezolinetant will be approved in the very near future, and we plan to hold an information sharing meeting after approval. The detail will be informed when the time comes. We hope you will be able to attend.

Thank you very much. This is all from me. Thank you for your attention.

Ikeda: That's all from us as a presentation.

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Question & Answer

Ikeda [M]: We are now going to take your questions. The first question is from Mr. Yamaguchi from Citigroup.

Yamaguchi [Q]: Fezolinetant, I have a question. You're going to explain the details into the future, but I'd like to ask you a few questions as of now. I'd like to ask you about the three months' delay. This is due to a process issue. It's not about because of the questions about the drug itself. Is my understanding correct?

Okamura [A]: Yes, your understanding is correct. We were not told that there have been any particular new data, but the data we submitted is to be reviewed by FDA, and they need more time. So, predetermined three-month extension was communicated to us.

Yamaguchi [Q]: Understood. Second question, it's about the sales. You made an explanation verbally. This JPY10 billion and JPY100 billion is in between of that. According to your explanation, we have that number. With this three-month delay, as a result, you reduced it. That result is between JPY40 billion to JPY50 billion. I believe that was your explanation. Is my interpretation right?

Okamura [A]: Yes, that is right.

Yamaguchi [Q]: Then, in media also, just like you mentioned, tail heavy is likely to be happening. Therefore, the impact on sales is larger. The sales would have been increased, but the SG&A, which is around JPY50 billion. What do you think about it? With this delay of three months, is there a further increase or decrease on this?

Okamura [A]: This three-month delay of sales cannot reduce the initial investment for SG&A. Therefore, the same level of the investment will be necessary. On top of that, this three-month delay means that the peak that we can achieve might be reduced. In order to avoid such kind of feeling, rather I would like to get into the market as early possible for catch-up.

At the time of the full year, this level of the SG&A will be necessary support. Suppose there is such a number. Rather, in the FY2023 budget, we booked further larger amounts compared to that.

Having said that, we haven't decided if we are going to use it all from the beginning because this is a new treatment therapeutic area for us. SG&A resource mix probably might be different from the past. Not only field sales, but other digital channels will be introduced for the communication of the information. Looking at the situation, we would like to do some detailed adjustments.

Yamaguchi [Q]: As for the insurance, with regards to fezolinetant, there may be many patients with private insurance because of their age. In spite of the three-month delay, negotiation with the payers have to start before approval. Feedback, it may take some time in terms of the timing, but insurance-related feedback from the payers, anything you can comment right now?

Okamura [A]: We are going to explain such details at the meeting we are going to hold after the approval.

Yamaguchi [Q]: Understood. It's not related to the financial results announcement, but Naoka Okamura-san is now CEO and CFO, wearing two hats right now. Regarding the new CFO, what's the situation right now?

Okamura [A]: It's vacant. As you know well, CFO, we have an external posting to search for candidate. Of course, we also have our own list. From our side, some are approaching us. How should I explain? More than

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10 candidates have been identified by now. If possible, in 2023, by the time we announce the Q1 results, I hope that our CFO will join us. That's the sense of speed. In my view, that's all from me.

Ikeda [M]: Next, Daiwa Securities. Mr. Hashiguchi, please.

Hashiguchi [Q]: Toward the end of your presentation, CSP2021 achievement is something you mentioned that you commit to. According to the page 23 slide, in such target, OP margin 30%, that is only the number described here. The regional performance target, I think there are mainly three of them. XTANDI and Strategic products exceeding JPY1.2 trillion and JPY50 billion in 2025 and afterwards, in a focus area and such. There were other targets that were established.

On this slide, it seems that you have less emphasis on the other targets. Is the core OP is still your sole target this time? I would like to hear the current progress for other targets than this core OP. How do you think about it?

Okamura [A]: Mr. Hashiguchi has a good understanding about the CSP2021 performance goal. This 30% is the number three target, and we are not giving up on the number one and number two target. On this slide, the context here is that fezolinetant, PADCEV, and zolbetuximab growth is where we are going to invest for FY2023. Because of that, core OP rate in 2023 will end up at 19%.

With the coming two years, the target number three, 30% core OP, is committed to be achieved. This is just focusing on the number three target on the slide. Sales is smaller and core OP 30% alone is achieved. In that case, the absolute value of the profit is going to be smaller. The performance target of number one and two, we are still committed to. Thank you very much because this is the end of the fiscal year earnings call. That's why you focused on the target number three. That's all.

Hashiguchi [Q]: Focus area approach outlook is something I'd like to ask you about. One or two may be successful in the end. Then, JPY500 billion in the end would be in your sight sufficiently. But, when you develop your CSP, at that time, there can be a variety of scenarios.

Based on the simulation, the median amount could be JPY500 billion. Based on the progress by now, as a median value, it may be declining. Is it better to think that way? Focus Area Approach in around 2030, how much revenue can you generate? What about the probability of achieving such a scenario? I'd like to hear your view, Okamura-san.

Okamura [A]: As you remember, our performance goal number two is 2025 at the end of that year, pipeline value we internally calculate is the definition. From those from outside in society, there is no way to calculate this. We say we have this much value being accumulated, but you cannot examine the details. What did we do? The Monte Carlo simulation was performed. The pipeline in FY2023, how much revenue it can generate? We calculate the power as an example for 2030.

What I want to say here is that revenue in FY2030, if there is a one-year delay, the revenue will decline that much. The revenue will fall much. In terms of the value, it may not be affected so much. In that sense, FY2030 revenue, what are we explaining there, I wonder whether it was a good idea or not. Instead of the sales amount in FY2030, the pipeline value in 2025 after the sum of the net present value, after adjusting the probability.

We don't have PoC. You may say so, yes, you're right. By being able to obtain PoC, the value of the project will go up a lot. What we try to do with Focus Area Approach is the primary focus. Triangle project would be generated out of there.

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Also, multiple projects will come out one after another. Flagship would be in the clinical study. Others may not go into the clinical studies. Once it's successful, we'd be able to be aggressive in subsequent follow-up projects. If you can get a PoC, that project value would go up. The subsequent project value would also follow. What about the FY2030 revenue, JPY500 billion could be a difficult go. Sometimes, I feel that way, but 2025 pipeline value, from that perspective, it's not impossible in my view.

Hashiguchi [Q]: Now in CSP, the SG&A is being maintained as absolute value, and there will be increase in this fiscal year, but the next fiscal year or even after that for us, what kind of perspective should we have?

Okamura [A]: This fiscal year, fezolinetant sales might not contribute so much, but we have to spend our money for SG&A. We have to set the preparation for zolbetuximab. That's fine. That's why we have to experience the increase of the cost. Because of that, we are thinking about not investing in others.

That is not the case for FY2024 and FY2025, so that we can improve our profit and loss structure, we would like to do some methods if that is available so that we can invest in that area as well. I would like to secure a certain portion. That's why I came up with this number of the core OP of 19%.

Of course, we couldn't find such other method, then the profitability would go up. So, SG&A maintains the absolute level, same level. That doesn't mean that we have the same level every year. But, as the landing point of FY2025, while the sales increases, but observe value of this SG&A, it would be suppressed so that we can increase the core OP rate.

That's the way of the calculation. You don't need to worry much, we are showing, we experienced the effect of this SG&A control. We started to learn that how we can control the SG&A well.

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

Muraoka [Q]: I also have a question about fezolinetant. I understand we need to wait for the meeting, but I'd like to ask you about how we should think about it. Q1, there is almost going to be no sale or revenue. But, in Q2 and beyond in principle, there's going to be a linear growth of sales, over 12 months or JPY40 billion to JPY50 billion. Is that the right image? Or, somewhere, including the insurance coverage, there's going to be a turning point to have JPY40 billion, JPY50 billion in the end? Could you give me a clue? Regarding the detailed numbers and also how we will develop a relationship with the payers?

Okamura [A]: Regarding the detailed numbers and also how we will develop a relationship with the payers, that is going to be explained at the meeting after approval in more detail and more accurately. When you say linear, what is going to be the size of the three-month delay? What about the size of the impact? That's a metaphor when I say why don't you use mass?

On a full year basis, there's going to be a linear growth of sales in Q1, one triangle or 1357 and 16 triangles on our full year. If there's going to be a three-month delay, the seven triangles would come to the next quarter. So, 7 out of 16 will be gone. It's almost half. This is a metaphor.

The sales plan we developed from day one towards March 31, I'm not saying that there's going to be a linear growth. Then, somewhere, there's going to be an inflection point to grow more towards the end. I may be repeating myself, but for the detailed plan, that is going to be explained at a meeting after approval.

Muraoka [Q]: Another point in the plan, Lexiscan 27270 is the sales plan, and the generic is launched according to your explanation. What about then, in this case, the downside risk? Is it necessary to consider that? What should be the precondition in this case? Could you give us some guidance?

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Okamura [A]: This is about the United States. Once generic becomes available, the market is dominated by the generic. That is the general situation. We have several of our own reasons, so we would not go down to complete zero. Rather, we believe that we can continue a certain level of the sales.

That is per condition. That's why this number. Of course, there might be a certain level of downside risk. But, to a certain extent, we've been using our own insight, and we come up with this number. Claus Zieler is here. If he has additional comments, we are very happy to hear that. What about you, Claus?

Zieler [A]*: You explained it very well. We have multiple generics on the US market. We have confirmed their shipment. It is now a question of confirming that the penetration of the generics will be in accordance to our estimate. Of course, there can always be deviations from those estimates as time goes by.

Muraoka [Q]: The results of this year, I'm afraid of any shortage. But, mirabegron, you are expecting a decrease in revenue, but actually, it was increasing. Is that because of the competition on the unit price again? For FX?

Okamura [A]: We may need to examine the details, but based on my gut feeling, it may be because of FX.

Muraoka [Q]: I see. So any particular reason?

Okamura [A]: Once again, we will check again the corporate advocacy, and we will contact you at a later date after confirming the details.

Ikeda [M]: Next, Goldman Sachs Securities. Mr. Ueda, please.

Ueda [Q]: First, I'd like to ask you a question about assumptions about PADCEV. In the United States, first line was approved, and it's now included in the guidelines recently. Looking at the numbers in your plan, it may not be accelerated so much. The denominator is getting larger. I understand that, but what's your assumption? Are you having a conservative look? What is going to be the speed of market penetration for the first line? If you could answer these questions, it would be highly appreciated.

Zieler [A]*: The growth of PADCEV is, of course, driven by the approval in first line in the United States that we obtained in the beginning of April. That is a substantial increase of the available patient pool in the United States. Our share assumption would be over 20% of that first-line patient pool in the United States. On the basis of that trajectory, we have built a model that would add more than 100 million to PADCEV in the US.

Ueda [Q]: Second question, and that is about the premise of the plan. The plan for this fiscal year, how do you see the cost ratio? If there are some factors that might worsen the ratio of the cost, would you explain it?

Okamura [A]: As for the representation of the certain factors, was in the cost of the sales ratio, let me answer that later on.

Ueda [Q]: Okay. Then, in the meantime, let me ask you, this is again about the premise of their plan. Gain on divestiture of intangible assets such as Mycamine transfer, for example, are there any one-time cost/profit factored into a core basis in FY23?

Okamura [A]: Only Mycamine, JPY9 billion.

Ueda [Q]: Thank you, that's all from me.

Okamura [A]: And the question about the sales cost ratio. Well, basically, the product mix will be changed. Roughly speaking, this cost of sales ratio as for the ratio basis, it is going to be the stable level.

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

Kumagai [Q]: First question about SG&A costs, JPY50 billion-plus. Most of this is related to fezolinetant. After approval, there can be more detailed guidance. What kind of items are included here? Anything you can tell us?

Zieler [A]*: The session that we will have after approval, if I may ask you to wait until then.

Kumagai [Q]: AT845. Looking at the six-minute walk test, there seems there is no improvement, but is it good enough because it's maintained for AT845? There seems to be no dose dependence. Could you explain how to interpret this?

Okamura [A]: Taniguchi, Chief Medical Officer is going to explain.

Taniguchi [A]: First of all, six-minute walk test. There's an arrow, as you can see here, the standard of care is the ERT, enzyme replacement therapy, which is discontinued in three subjects. Even without ERT, the walking distance has not changed. In that sense, it's a clinically meaningful data.

For these patients, Q2W, they come to hospitals for IV infusion to receive ERT. Because they have troubles with their bodily conditions, it would cause a lot of trouble for them. Just one gene therapy administration to maintain their function, that's a very meaningful and significant for them. At this academic society meeting, this data drew a lot of attention.

Those responses must be closely looked at from now on. Needless to say, at all doses, for the time being, we see a certain level of response and effectiveness, including safety. You have to take that into account to determine the optimal clinical dose.

Kumagai [Q]: In the immuno-oncology program, three projects are discontinued. That is because you want to reallocate the resource for the remaining projects. How do you view the immuno-oncology projects now?

Taniguchi [A]: Regarding immuno-oncology, within this primary focus area, we put further focus on this. Again, these three projects were discontinued as it was decided because the study results met the discontinuation criteria that was set from the beginning. That's why we decided to discontinue.

This type of decision-making is quite difficult. We've introduced these criteria for the discontinuation, and we just followed that, so that we can reallocate the resources for the more promising areas, especially for Immuno-Oncology, ASP2138, needless to say, bispecific antibody, is in the middle Phase I study. There are other two bispecific antibody projects went into the Phase I study, so we can expect further for these areas.

Ikeda [M]: Next, JPMorgan Securities. Mr. Wakao, please.

Wakao [Q]: First, as was mentioned by others for their questions, SG&A costs to be returned to the FY2021 level, it was like JPY410 billion. There is a difference of JPY75 billion compared to JPY485 billion. Fezolinetant expenses, you're going to use this fiscal year are going to fluctuate. So, JPY50 billion may not be necessary as of 2025. You're going to reduce the cost to reach JPY410 billion with operational excellence.

Okamura [A]: The FX rate while JPY410 billion and 2023 FX rate can be very different. Even if we say it's the same amount in terms of the absolute value, the FX is going to yen's depreciation, it's very difficult to make them comparable. That's the same level. In terms of the operational structure, sales amount would be in various currencies. After distribution sales in various currencies, there are also expenses in various currencies. If there's going to be any inflation because of the currencies, there's going to be inflation in costs as well.

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Wakao [Q]: The second one is related to the already asked questions. It's about the performance of their Primary Focus. We mentioned this will lead to the sustainable growth. As of now, the purchasing, acquiring those on the later stage is not something you are thinking about. Would there be a certain timing aware that you need to do certain sort of the acquisition of such from outside, considering the XTANDI cliff, then you have to think about something like that, but also you have the primary focus. You need to think about the certain time issue. Do you have any time limit for working for the Primary Focus?

Okamura [A]: That's a really good question. That is a question relating to the success of the CSP2021. This Focus Area approach, the way we are coming up for the innovation is also relating to your question. Now, we have CSP2021, not thinking about others, we just pursue CSP2021 to do the activities that was decided in 2021 April. That is not the course that we are doing. Of course, the change of the environment taken into consideration. For example, XTANDI US is materialized, Lexiscan is available. However, generic came into the market earlier than we expected. We have to deal with such factors.

It is true that the PoC is not really obtained as was expected in our primary focus area. Of course, we have to work harder internally. Depending on the situation, we would like to introduce something outside of the company. We have such a variety of things on our list, so that we face the timing where we have to get something from outside, we have the preparation ongoing here. It's not something that a certain point of time, we are going to do M&A. If something comes up, then in that case, we will let you know.

Ikeda [M]: Next, Credit Suisse Securities, Ms. Haruta.

Haruta [Q]: First question, about XTANDI. Peak sales, JPY700 billion or more, you made an upward revision. Peak sales trend for the future. How should we think about it? Within this year, in the United States, Inflation Reduction Act, your drug may be subject to the drug price reduction list, then there can be a possibility of the price reduction from 2026 towards LOE, peak sales want to emerge. Because of the IRA inflation reaction act, what are your assumptions? What's your view on this?

Okamura [A]: Regarding this issue, it's very complicated. It contains a lot of complexities. First of all, the FX rates are changing. We talked about JPY500 billion, JPY600 billion range. We already reached JPY600 billion. We want to say that there's going to be normal growth? No. We are saying that it's going to grow even further into the future. That's one thing. EMBARK data is approved, so there is a possibility of an upside as an addition, that's why you are changing to JPY700 billion as our guidance.

The impact of IRA, needless to say, US commercial people are mainly developing a variety of scenarios and doing a variety of analyses. Do you think about what kind of ways can mitigate the risk? What should be the priority? From then, they are going to do this and they are doing such an analysis. As you pointed out, XTANDI, products like XTANDI of the site, it may be on the list. We are including that possibility in our assumption.

On the other hand, whether it's going to be included in the list or not, we don't know yet until that time comes. If it's listed, what is going to be the price negotiation? After that, it's very unclear right now. What kind of price or the authorities are going to propose an offer? We don't know yet. Regarding the proposed price, what kind of opportunities would be given to us to protect that? What kind of data can we do? How much can we push back to achieve success?

We don't know yet. We shouldn't speculate. You shouldn't share our views right now, rather, maybe you can wait for some more. Once we know more facts, we should explain more perfectly. I think that would be better.

Haruta [Q]: Second question, Primary Focus, decision-making, you have established a new operating model, but what was the decision-making problem in the past? With this new way, how will it be improved? For the agile that you're making, this primary focus is those on the face for the getting PoC. In this agile decision making, in what way will you do the clever decision making?

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Okamura [A]: For this operating model, Taniguchi took the initiative, so he's going to explain.

Taniguchi [A]: Let me explain. As you see here, what's changed greatly is this governance. Governance is consolidated to one. So far, we have governance for the R&D and governance for the corporate wide. There are two, but it was consolidated as a Kachi Committee.

In that way, a more agile and appropriate decision is possible to be made. Also, there are necessary members there always. Including us, the appropriate CXO executive members will be the members for the right decision making, then we can commit to the project budget, and also timeline.

The second point is that this PF leadership team, you see. So far, this PF leadership team was not officially established. How well at each level, there is a team and for each portfolio, primary focus portfolio was looked at. This time, it is going to be delegated to this leadership, for the budgeting as well.

Also, prioritization in the therapeutic areas will be also done by these teams. Including the future investment and also new strategies will be considered by this leadership team. Underneath, there is the project lead that is about PF lead, and under that, there is a project lead. We have lower layers.

Day-to-day decision-making can be done on each team level, which leads to the accelerated decision-making. At the same time, to this project lead, the certain level of the delegation is done. With that role and responsibility of those lead will be clarified that leads to the agile and appropriate decision making and also appropriate investment.

Of course, we have the functional access as well that focuses on the center of excellence in particular therapeutic areas and the capability levels belong to those areas would go up. This is a complete metrics model that we came up with.

Ikeda [M]: Next, Mr. Kohtani from Nomura Securities.

Kohtani [Q]: First fezolinetant, SPOTLIGHT study details was published in a paper in April. Looking at that paper, if you take a closer look, 45-milligram fezolinetant, two patients with endometrial or adenocarcinoma, there's thickness in one patient and one patient on placebo. FDA may be taking a close look at this data in the paper. According to the paper, within the risk specified range, so there should be no problem. But I'd like to confirm, with fezolinetant in terms of safety, does FDA have any particular concern about its safety?

Okamura [A]: Taniguchi is going to explain.

Taniguchi [A]: First, regarding fezolinetant, thank you very much for explaining the details. Needless to say, FDA or any regulatory authority would take a very close look at safety in addition to efficacy, no difference among different regulators.

Safety portion, as you mentioned, regarding cancer cases, they are reviewing all these details. Right now, review is not ongoing, so we cannot share the details today. But, the target date is May 22, that's the PDUFA date, and review is making progress towards that date right now.

Kohtani [Q]: Second question about the launch of fezolinetant linear launch. The number is higher than I've expected. My question is this mid three-digit is what Mr. Yasukawa mentioned. That is around October.

After that, such kind of site is utilized for realization of access for the HCPs and also the disease awareness activities for the patients are also taking place. The launch factor is the reimbursement price and also the level of the awareness amongst the doctors, the price may not be that high, I expect. You have the clear view about those factors, and that's why you came up with this number. That is my understanding. Is that right?

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Okamura [A]: Each individual factor, I'd rather not talk about it here, but naturally saying, ideally, February 22, the authority would have made a decision and looking at that timing, we came up with a number. In that respect, various factors are now clarified to a greater extent. That's why we came up with this number.

Kohtani [Q]: ASP5354 congratulations for your collaboration with Stryker, infrared visualization for surgical operation, that company was the first. It's more advanced as an ideal partner in my view. This Phase III study design, I took a look. In Phase II, it's limited to just some procedures, but this is the overall abdominal procedures. This is a company for artificial hip device companies. There can be damage. Are they talking about that area as well? This is my last question.

Okamura [A]: Stryker, for near infrared image visualization, at least in the United States, it has overwhelmingly larger share compared to others. Even outside of the United States, they are very aggressive in other markets as well. In that sense, we think there are an ideal partner for us. To target procedures for the clinical studies, what is the scope? I don't have the established good data in front of me, so we will check and come back to you. Or Taniguchi can explain.

Taniguchi [A]: In the clinical studies, I'm sure you have seen the protocol, the pelvic as well as the abdominal surgeries and urea can be visualized to prevent the damage to the ureter. That's the objective. As an endpoint, visualization is mainly the important area as an endpoint. That's what we agreed. We need to agree with the authorities as we proceed.

Kohtani [Q]: Regarding the hip joint, any mention about the artificial hip joint?

Taniguchi [A]: No such discussions as of now. In principle, ureter damage can occur with a hysterectomy, gynecological procedures, OB/GYN procedures, or general surgical procedures. The intraoperative ureter damage is a bigger number of cases, so we should start with what's occurring more frequently. That's what we'd like to focus on.

Ikeda [M]: We are coming to the time to close the session. The following will be the final question, from Nikkei Newspaper. Mr. Yamada, please.

Yamada [Q]: A lot of questions were already asked, so that is only just one question. Primary Focus, there is no PoC obtained yet for that. I have one question. R&D organization is revisited, and you are going to change the governance. Governance is going to be changed, and this leads to the agile decision making, which is wonderful. The PoC, again, not obtained to this extent as that because the governance alone is a problem. CSP2021 was established, and it's been awhile since then. Looking back the management and also the development, what kind of challenges are you seeing in front?

Okamura [A]: First of all, from me, I would like to talk about my own view. After that, I would like to hear from Shitaka and Taniguchi.

This is not only the matter of the governance, but the governance issue has a certain weight, which means that we have to understand the status and the situation for the early and precise decision-making. For that purpose, team is important. What about the organization of the Astellas so far? It is a functional organization, and there are many layers. The people are supposed to be in the decision-making process has the long distance to the level who has the authority of the decision-making.

In that organization, although you have a good discussion within a team, nothing can be decided because we have to escalate it back to the boss, and then, you have to bring it down back to the team once again. Then, decision come up with different opinions leading to the different decision making. That's why we thought the team should have the ownership and having a delegation to make it agile. So yes, the governance itself is changed in this way, but the impact of that is greater than you just consider as the organizational change.

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Yamada-san, I think you are asking how we should find the candidate or how we can make use of the modality in the effective way. I think in that case, Shitaka and Taniguchi can answer you.

Shitaka [A]: Shitaka, in charge of Research, I would like to answer you first. Again, we have a Focus Area approach, our Primary Focus. As you see on the page 12, as the list of such projects that we have, we came up with the platform, and we come up with the products one after another, from that is what we are aiming at.

Unfortunately, within these two years, there's nothing we were able to prove from this platform, just like Taniguchi mentioned, bispecific platform or immuno-oncology cellular therapy platform or gene therapy, or TPD target protein degrader. We have such a leader programs of the platform. Those are in the phase of obtaining a PoC.

In other words, we are on a critical phase now. From there, we can get the push for certain platforms. In that case, we can think about the next program, and probability of success for them is likely to be increased greatly. In the past two years, the result is unfortunate, but the lead program for each program is facing the very critical point. That's my understanding.

Taniguchi [A]: Shitaka made comments, as he said, the platforms are being reinforced in various projects towards IND. They are proceeding towards IND right now. Then, what about the clinical side? What we are focusing on right now is reinforcing the early development team.

We have the pipeline, as you know, we had many in the late phase development. We used to focus on those for the past few years. That's not long, and we think that's very important. We have to be very serious to tackle the focus areas in early development. We need to accelerate what you are suggesting. We are changing the organization to that end and new talent are being hired and acquired from inside and from outside, so that we can accelerate further. That's what we are thinking about.

Ikeda [M]: Some of you are still waiting to ask questions, but the time is up. We'd like to close this meeting here today. Thank you very much for joining this meeting today.

[END]

Document Notes

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

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