



Astellas Pharma Inc.

Financial Results for the Q2 of FY2021

October 29, 2021

Event Summary

[Company Name]	Astellas Pharma Inc.	
[Company ID]	4503-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	Financial Results for the Q2 of FY2021	
[Fiscal Period]	FY2021 Q2	
[Date]	October 29, 2021	
[Time]	14:00 – 15:28 (Total: 88 minutes, Presentation: 36 minutes, Q&A: 52 minutes)	
[Number of Speakers]	5	
	Kenji Yasukawa PhD	Representative Director, President and Chief Executive Officer (CEO)
	Naoki Okamura	Representative Director, Executive Vice President, Chief Strategy Officer (CStO) and Chief Financial Officer (CFO), Chief Business Officer (CBO)
	Bernhardt Zeiher MD Yukio Matsui Ikuno Fujii	Chief Medical Officer (CMO) Chief Commercial Officer (CCO) Head of Corporate Advocacy & Relations
[Analyst Names]*	Hidemaru Yamaguchi	Citigroup Global Markets Japan Inc.
	Kazuaki Hashiguchi	Daiwa Securities Co. Ltd.
	Motoya Kohtani	Nomura Securities Co., Ltd.
	Fumiyoshi Sakai	Credit Suisse Securities (Japan) Limited
	Shinichiro Muraoka	Morgan Stanley MUFG Securities Co., Ltd.
	Akinori Ueda	Goldman Sachs Japan Co., Ltd.
	Seiji Wakao	JPMorgan Securities Japan Co., Ltd.
	Tatsuyuki Arai	BofA Securities Japan Co., Ltd.

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

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Document Notes

This document has been transcribed based on interpreted audio provided by the Company.

Presentation

Fujii: Thank you very much for joining the FY2021 second quarter financial results announcement meeting by our company out of a busy schedule. I'm Fujii from Corporate Advocacy & Relations. I'm delighted to serve as emcee today.

We now would like to begin our meeting here. This is a meeting for investors and analysts. After the presentation, we will have a Q&A session. We will have this meeting in line with the documents posted on our website, so if you are joining by teleconference system, please have the documents at hand.

Today's participants are Kenji Yasukawa, Representative Director, President and Chief Executive Officer (CEO); Naoki Okamura, Representative Director, Executive Vice President, Chief Strategy Officer (CStO) and Chief Financial Officer (CFO), Chief Business Officer (CBO); Chief Medical Officer (CMO), Bernie Zeiher; Chief Commercial Officer (CCO), Yukio Matsui. These 4 are joining. Bernie Zeiher is joining from the US by phone.

This material, all presentations by representatives for the Company, and their answers and statements in the Q&A session include 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 advertisement nor provide medical advice of any client.

You can listen to a simultaneous translation in English in this meeting, but we cannot guarantee the accuracy of interpretation.

We'd like to begin the presentation. Yasukawa, please.

Yasukawa: Good afternoon, everyone. Yasukawa speaking. Thank you very much for joining our FY2021 second quarter financial results announcement meeting out of your very busy schedule today.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.



Page 2 is a cautionary statement regarding forward-looking information. I'm not going to read this slide.

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AGENDA

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I

Q2/FY2021 Consolidated Financial Results
FY2021 Revised Forecasts

II

Initiatives for Sustainable Growth



Page 3 is the agenda for today.

First, I will explain our FY2021 second quarter financial results and revised forecast.

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Q2/FY2021 FINANCIAL RESULTS AND FY2021 REVISED FORECAST: OVERVIEW

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*Revenue increased by 6%, Core OP decreased
In line with assumptions of full-year forecast*

- Sales of XTANDI and Strategic products increased as expected, offsetting sales decrease due to termination of sales and distribution, transfer of products
- SG&A expenses are slightly above full-year forecast
R&D expenses are on track
- As a result, no changes have been made to Core basis FY2021 forecast

Downward revision of full basis profit FY2021 forecast

- Booked fair value remeasurement on contingent consideration for zolbetuximab as other expense, not included in full-year forecast (8.7 bil. yen)



Strategic products: XOSPATA, PADCEV, EVRENZO

Page 4 shows our consolidated second quarter results and an overview of our revised forecast.

Both revenue and profit increased in the second quarter. Sales of XTANDI and Strategic products increased as expected. SG&A costs are slightly above our full-year forecast. Actually, revenue increased and the profit decreased in the second quarter. R&D expenditure is also on track. SG&A cost was slightly above our full-year forecast. As a result, no change has been made to core basis full-year result.

On a full basis, we reviewed our pancreatic adenocarcinoma development plan for zolbetuximab in the second quarter, which led to an increase in the fair value on contingent consideration for zolbetuximab we booked at the time of the Ganymed acquisition. As a result, we booked this fair-value remeasurement of JPY8.7 billion as other expense. This is not something we can assume at the beginning of the fiscal year and was not included in our forecast, so we decided to make a downward revision of our full-year forecast announced in July. I'll explain the background and the details later in the pipeline section.

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Q2/FY2021 FINANCIAL RESULTS

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(billion yen)	Q2/FY20	Q2/FY21	Change	Change (%)	FY21 FCST*	Progress	FX impact
Revenue	615.5	651.7	+36.2	+5.9%	1,323.0	49.3%	+24.5 bil. yen
Cost of sales	119.5	124.7	+5.2	+4.3%			
% of revenue	19.4%	19.1%	-0.3 ppt				
SG&A expenses	242.1	270.5	+28.4	+11.7%	541.0	50.0%	
US XTANDI co-pro fee	60.9	71.1	+10.2	+16.8%			
SG&A excl. the above	181.3	199.4	+18.1	+10.0%			
R&D expenses	111.7	119.1	+7.4	+6.6%	242.0	49.2%	
Amortisation of intangible assets	11.5	12.4	+0.8	+7.2%			
Core operating profit	130.3	125.3	-5.0	-3.8%	270.0	46.4%	+11.5 bil. yen
<Full basis>							
Other income	4.3	2.8	-1.4	-			
Other expense	47.7	38.0	-9.7	-			
Operating profit	86.9	90.2	+3.3	+3.8%	227.0	39.7%	
Profit before tax	89.1	89.1	-0.0	-0.0%	225.0	39.6%	
Profit	72.8	71.6	-1.2	-1.7%	183.0	39.1%	

* Announced in July 2021

On page 5, let me explain our second quarter results.

Revenue reached JPY651.7 billion, up 5.9% YoY. The progress against the full-year forecast was 49.3%. Core operating profit was JPY125.3 billion, down 3.8% YoY. The progress was 46.4%.

The bottom half of this page shows our full basis results.

We booked JPY38 billion as other expense in the second quarter. Operating profit increased to JPY90.2 billion, up 3.8% YoY. Profit was JPY71.6 billion, down by 1.7% YoY.

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Q2/FY2021 FINANCIAL RESULTS: REVENUE

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Revenue increase driven by growth of XTANDI and Strategic products, which offsets sales decrease due to termination of sales and distribution / transfer of products

	Q2/FY20	Q2/FY21	Change	Change (%)
Revenue	615.5 bil. yen	651.7 bil. yen	+36.2 bil. yen	+5.9%

Increase in XTANDI and Strategic products

XTANDI, XOSPATA, PADCEV, EVRENZO **+51.8 bil. yen**



➤ Returned sales of Lexiscan, negatively impacted by COVID-19 in Q1/FY20 **+10.8 bil. yen**

Termination of sales and distribution / transfer of products

Celecox, Lipitor, Eligard **-25.9 bil. yen**



Strategic products: XOSPATA, PADCEV, EVRENZO

Page 6 is an additional explanation about YoY revenue comparison.

For XTANDI, the volume increase has continued since the previous fiscal year. Sales of Strategic products such as XOSPATA, PADCEV, and EVRENZO, also rose as expected to increase the revenue by JPY51.8 billion YoY.

Lexiscan sales, negatively impacted by COVID-19 in the first quarter of FY2020, returned to increase our sales by JPY10.8 billion YoY. On the other hand, sales decreased for mature products, such as Celecox, Lipitor, and Eligard, due to termination of sales and distribution, as well as transfer of products saw revenue declined by JPY25.9 billion YoY for these products combined.

In addition to the positive ForEx impact, revenue increased in the second quarter, also due to the growth of XTANDI and Strategic products, in line with our initial assumptions. We are getting out of the revenue-declining trend up to FY2020 and are now returning to the growth trend.

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Q2/FY2021 FINANCIAL RESULTS: SALES OF MAIN PRODUCTS

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Q2/FY2021 Act and FY2021 FCST (billion yen)

XTANDI	YoY: +42.1 (+19%) Progress against FCST: 48%	✓ Double-digit growth in global sales and in line with forecast ✓ In addition to US, sales expansion in EU following approval of M1 HSPC indication ✓ In China, demand grew higher than expected after reimbursement
267.6		
FY2021 initial FCST: 557.2 → Revised FCST: 554.1		
XOSPATA	YoY: +5.5 (+50%) Progress against FCST: 45%	✓ Global sales increased and in line with forecast, driven by growth mainly in US and EU ✓ Sales contribution from China newly launched
16.5		
FY2021 initial FCST: 36.7 → Revised FCST: 35.4		
PADCEV	YoY: +3.1 (+52%) Progress against FCST: 45%	✓ Revenue in US grew steadily and in line with forecast ✓ The NCCN updated its guidelines, adding PADCEV for cis-ineligible mUC 2L therapy as Category 2A
9.1		
FY2021 initial FCST: 20.1 → Revised FCST: 20.7		
EVRENZO	YoY: +1.1 (+319%) Progress against FCST: 16%	✓ Sales have steadily increased as expected in Japan and continuous growth is expected ✓ Launched in EU in Sep 2021
1.4		
FY2021 initial FCST: 8.6 → Revised FCST: 7.2		
mirabegron	YoY: +4.4 (+6%) Progress against FCST: 48%	✓ Global sales increased and in line with forecast, driven by growth mainly in Japan and Established Markets ✓ In US, Myrbetriq sales are behind forecast due to lower than expected OAB market growth
84.4		
FY2021 initial FCST: 175.2 → Revised FCST: 176.3		



M1: Metastatic, HSPC: Hormone-sensitive prostate cancer, NCCN: National Comprehensive Cancer Network, cis: Cisplatin, mUC: Metastatic urothelial cancer, 2L: Second line, PADCEV: Co-promotion revenue from Seagen, mirabegron (Product name: Betanis/Myrbetriq/BETMIGA), OAB: overactive bladder

Next, page 7 shows the second quarter sales of our main products.

XTANDI global sales increased steadily as expected to reach JPY267.6 billion, up by JPY42.1 billion or 19% YoY, driven by the growth mainly in the US and EU. In Europe, sales increased for the additional indication of M1 HSPC we obtained in April this year. Reimbursement for this indication started in UK, Germany, Spain, Switzerland, the Netherlands, and Croatia. In March this year, reimbursement started in China, where hospital adoption is increasing and demand is growing higher than expected. Reflecting the situation up to the second quarter, we made a slight revision of our initial forecast.

Next, XOSPATA sales increased to JPY16.5 billion, up by JPY5.5 billion or 50% YoY, in line with our forecast. In addition to the US and EU, there has also been sales contribution from China, where it was launched in April this year. New prescriptions have been increasing steadily. We have made a good start with steady progress since the launch in China.

As for PADCEV, co-promotion revenue in the US was JPY9.1 billion, up by JPY3.1 billion or 52% YoY. An additional indication approved in July this year, on top of the existing indications, also contributed to sales expansion. Right after the approval of the additional indications, NCCN updated its guidelines, which many physicians are referring to when they decide their prescription, and NCCN recommended the use of PADCEV for cis-ineligible mUC second-line therapy. Its progress against the forecast may look a little low, but revenue contribution is expected more in the second half. Due to the continuous growth in the US and the launch in Japan and EU expected in the second quarter, we have made an upward revision slightly to JPY20.7 billion.

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EVRENZO sales in Japan was JPY1.4 billion. Along with the HIF-PHI market expansion, sales in Japan are increasing steadily. We are expecting further sales increase in the future, and we are aiming to achieve our full-year forecast. EVRENZO was launched in Europe in September this year. It's now available in Germany, UK, and Austria. When the launch timing was delayed by a little over 1 month compared to our initial forecast, we slightly made a downward revision of our full-year forecast.

Mirabegron global sales increased to JPY84.4 billion, up JPY4.4 billion or 6% YoY, driven by sales mainly in Japan and the Established Markets. Due to lower-than-expected OAB market growth in the US, its progress against the forecast is slow, but global sales are in line with our forecast.

Q2/FY2021 FINANCIAL RESULTS: COST ITEMS

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SG&A expenses increased YoY and slightly above full-year FCST
R&D expenses increased YoY, but in line with full-year FCST

Core basis: Main items for YoY and progress against FCST

Cost of sales % of revenue



YoY: -0.3ppt

- ✓ Decrease mainly due to changes in product mix

SG&A expenses

YoY: +11.7%

Progress

against FCST: 50.0%



- ✓ SG&A excl. XTANDI US co-pro fee: +18.1 bil. yen (YoY +10.0%)
- ✓ FX impact (+8.4 bil. yen)
- ✓ Investment in systems associated with globalization (Approx. +5.0 bil. yen)
- ✓ Increase in sales promotion expenses for new product launch readiness (Approx. +3.0 bil. yen)

R&D expenses

YoY: +6.6%

Progress

against FCST: 49.2%



- ✓ Increase in development cost of zolbetuximab and expanded investment in iota
- ✓ Decrease in development cost of fezolinetant
- ✓ On track with full-year forecast



Page 8 shows YoY comparison and progress against our full-year forecast for cost items.

Cost ratio decreased by 0.3 percentage point YoY due to changes in product mix. SG&A costs in total rose by 11.7% compared to the previous year. SG&A expenses, excluding XTANDI US co-promotion fees, increased by JPY18.1 billion or 10% YoY. 1 factor behind was positive FX impact of JPY8.4 billion.

We also had investments in systems associated with globalization, and an increase in sales promotion expenses for the launch of Strategic products and their growth right after the market launch, which increased SG&A costs by about JPY8 billion. The progress against our full-year forecast is 50%, a little higher than usual years and slightly above our internal plan up to the second quarter.

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R&D expenditure increased by 6.6% YoY. Compared to the previous fiscal year, development cost increased for zolbetuximab, and we expanded iota-related investments. On the other hand, development cost decreased for fezolinetant with the completion of Phase III study patient enrollment. We are in line with our full-year forecast.

FY2021 REVISED FORECAST: OVERVIEW

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- No changes have been made to Revenue
 - Sales of XTANDI and Strategic products are on track
- Costs
 - SG&A expenses are slightly above full-year FCST but within controllable range for the full year
 - ✓ Thorough budget control on a quarter basis
 - ✓ Optimizing personnel globally aligned with transformation of product portfolio
 - R&D expenses are on track
- As a result, no changes have been made to Core OP
- Downward revision of Full basis profit announced in July 2021
 - Booked fair value remeasurement on contingent consideration as other expense (8.7 bil. yen) due to review of pancreatic adenocarcinoma development plan for zolbetuximab



Strategic products: XOSPATA, PADCEV, EVRENZO
Optimizing personnel: Subject to Works Council, consultative, and legal requirements

On page 9, I'd like to explain key points about the revision of our full-year forecast.

As I explained on page 7, Strategic products are progressing on track. No change has been made to our revenue.

As for cost, as was mentioned on the previous page, SG&A expenses were above our full-year forecast in the first half, but will be within the range of assumptions on a full-year basis. We have checked the progress of our budget every quarter, and this fiscal year we are reinforcing these initiatives. We also decided to take away the unused budget from each department on a quarterly basis for thorough budget control by Finance division.

Also, along with the transformation of our product portfolio, we are implementing multiple organizational reform projects globally. By trying to optimize personnel, we are expecting a decrease in personnel cost. In the end, we think we can achieve our full-year forecast.

R&D expenditure is on track. As a result, no changes have been made to the core operating profit.

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In the past, the budget formulated at the beginning of the fiscal year was conservative, and it was taken for granted to make an upward revision in the second quarter. We have reviewed such a stance over the few years, and we have been able to set very ambitious targets from the beginning of the fiscal year.

In the first year towards achieving our CSP, Corporate Strategic Plan 2021, we will aim to achieve our goals set ambitiously against the initial forecast. We're aiming for 100% achievement. As was explained on page 4, on a full basis, we booked as other expense the fair-value remeasurement on contingent consideration for zolbetuximab. Reflecting these expenses, we made a downward revision of our full-year forecast.

FY2021 REVISED FORECAST

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- No changes have been made to Core basis FY2021 forecast
- Downward revision of Full basis profit

(billion yen)	Previous FCST (Disclosed in July 2021)	Revised FCST	Change
Operating profit	227.0	218.0	-9.0
Profit	183.0	174.0	-9.0



On page 10, as I explained so far, the second quarter core basis results are in line with our full-year forecast, so no changes have been made to the core basis full-year forecast announced in April. On the other hand, we are expecting full basis operating profit of JPY218 billion and profit of JPY174 billion, each down by JPY9 billion compared to the previous forecast announced in July

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AGENDA

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I

Q2/FY2021 Consolidated Financial Results
FY2021 Revised Forecasts

II

Initiatives for Sustainable Growth



Page 11.

From here on, I'm going to explain our initiatives for sustainable growth.

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XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT (1/2)

Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132

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Key Events Expected in FY2021

Milestone	Project / Product	Indication / Clinical study	Achieved
Regulatory decision	enzalutamide / XTANDI	M1 hormone-sensitive prostate cancer (EU)	Apr 2021
	enfortumab vedotin / PADCEV	mUC, platinum and PD-1/L1 inhibitor pretreated (US ^{a,b})	Jul 2021
		mUC, cis-ineligible and who have previously received one or more therapy (US ^a)	Jul 2021
		mUC, platinum and PD-1/L1 inhibitor pretreated (EU ^c)	
		Radically unresectable UC that has progressed after anti-cancer chemotherapy (JP ^d)	Sep 2021
	roxadustat / EVRENZO	Symptomatic anemia associated with CKD (EU)	Aug 2021
Regulatory submission	gilteritinib / XOSPATA	R/R AML (China ^e)	
Data readout	fezolinetant	52-week safety results from Phase 3 SKYLIGHT 1, 2 & 4 studies	Jul 2021 (SKYLIGHT 2) Oct 2021 (SKYLIGHT 1)

Red: Updates since the last financial results announcement

a: Priority Review granted, Real-Time Oncology Review pilot program and Project Orbis applied

b: sBLA to convert Accelerated Approval to regular approval

c: Under review based on standard timeline instead of Accelerated Assessment

d: Priority Review granted

e: sNDA to convert conditional approval to full approval



M1: Metastatic, (m)UC: (metastatic) Urothelial cancer, CKD: Chronic kidney disease, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, sBLA: Supplemental Biologics License Application, sNDA: Supplemental New Drug Application

On page 12, let me explain the progress of key events expected in FY2021, which we shared at the beginning of the fiscal year.

What's in red indicates updates since the last financial results announcement.

Enfortumab vedotin, or PADCEV, was approved in Japan in September. As for the progress of approval in EU, it took time to respond to the inquiries from the regulatory authorities, so, as is described in the footnote c. in the left bottom, it's now under review based on standard timeline instead of accelerated assessment. As for the approval timing, we are still expecting approval by the end of the fiscal year.

Roxadustat was approved in EU in August.

With regards to fezolinetant, 52-week data became available in October from 1 of the Phase III pivotal studies, SKYLIGHT 1.

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XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT (2/2)

Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132

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Other Updates since the last financial results announcement

Project / Product	Indication	Updated status
enzalutamide / XTANDI	M1 CSPC	OS data of Phase 3 ARCHES study presented at ESMO in Sep 2021
enfortumab vedotin / PADCEV	mUC, previously untreated	Enrollment of cohort K (combo with pembrolizumab) in EV-103 study completed in Oct 2021
zolbetuximab	Pancreatic adenocarcinoma	Phase 2 study protocol amended to expand the study
roxadustat / EVRENZO	Chemotherapy-induced anemia	Topline results of Phase 2 study obtained in Aug 2021
fezolinetant	VMS associated with menopause	12-week data of Phase 3 pivotal study (SKYLIGHT 2) presented at NAMS in Sep 2021 Phase 3b DAYLIGHT study in patients unsuitable for HRT under preparation to start in Q3 FY2021
AT132 (resamirigene bilparovect)	XLMTM	ASPIRO study put on clinical hold by FDA in Sep 2021 due to a serious adverse event



M1 CSPC: Metastatic castration-sensitive prostate cancer, OS: Overall survival, ESMO: European Society for Medical Oncology, mUC: Metastatic urothelial cancer, VMS: Vasomotor symptoms, NAMS: North American Menopause Society, HRT: Hormone replacement therapy, XLMTM: X-linked myotubular myopathy, FDA: Food and Drug Administration

Now page 13. Here, I would like to explain about important updates of the events other than those shown at the beginning of the fiscal year.

First, from the top, the results of ARCHES study for XTANDI is going to be explained in the next page, and AT132 at the bottom is going to be explained in page 17.

The second row, PADCEV. It completed cohort K enrollment in the EV-103 study in October as scheduled. The study is evaluating combination therapy with pembrolizumab as first-line treatment for patients with cisplatin refractory mUC. We are aiming for accelerated approval in the US in 2022. We expect that the expansion of indications for first-line treatment in the US will be a major growth driver for this product.

Next is zolbetuximab. We have revised the protocol for a Phase II study in patients with pancreatic adenocarcinoma and the number of subjects were increased from 141 to 369. The data pulled in aggregated in a blinded manner is monitored at any time. It was found that the OS event occurred slower than originally assumed and the treatment duration was longer. And based upon the recent literature data on standard therapies in the control arm, we also found that the median OS assumption was needed to be adjusted.

We amended that study protocol to take into account these changes and assumptions and increase the number of the subjects so that the study is more likely to support the approval by the regulatory authority on its own. Based on the changes in acceleration and program timeline and the expanded Phase II study, which may support regulatory approval, we conducted a reevaluation of contingent payment. As a result, we recognized JPY8.7 billion, increasing the fair amount of the contingent payments, as mentioned, which is reflected as other expenses in our full basis quarter 2 operating profit.

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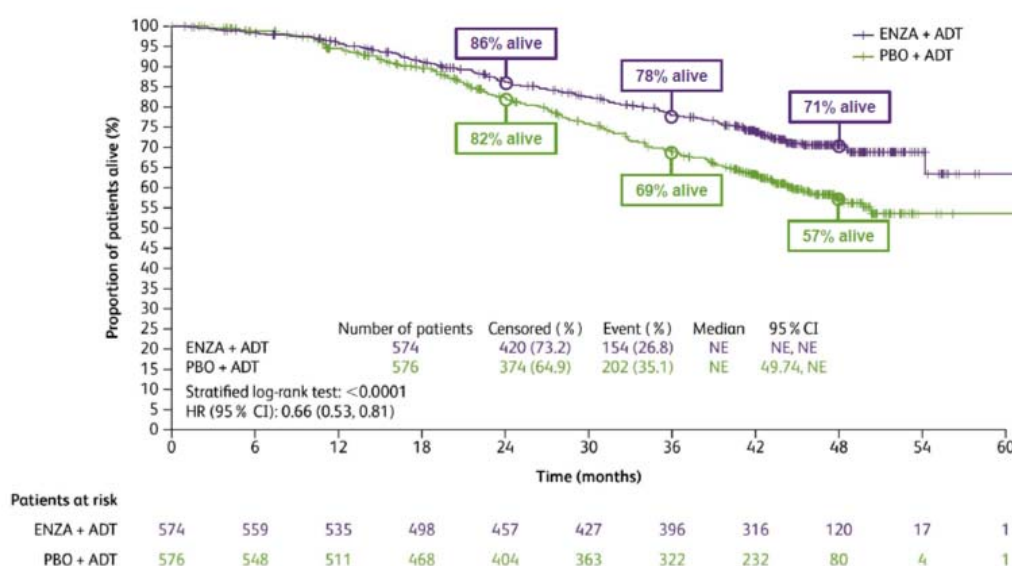
Next is the roxadustat. We obtained top-line results from our Phase II study of chemotherapy-induced anemia in August. We are currently analyzing the details of the study data. And after considering the situations, including the commercial value, we will decide the future direction.

In fezolinetant, apart from the Phase IIIa study conducted to get the drug approval, Phase IIIb, the DAYLIGHT study is scheduled to be started for the purpose of current data that is clinically meaningful and helpful to obtain insurance reimbursement other than the items required by the authorities to obtain approval by December.

ENZALUTAMIDE (XTANDI) (1/2): OS DATA IN PHASE 3 ARCHES STUDY IN M1 CSPC

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OS data presented at ESMO 2021: reduced risk of death by 34%



OS: Overall survival, M1 CSPC: Metastatic castration-sensitive prostate cancer, ESMO: European Society for Medical Oncology, ENZA: enzalutamide, ADT: Androgen deprivation therapy, PBO: Placebo, HR: Hazard ratio, CI: Confidence interval, NE: Not evaluable

Page 14. This slide presents overall survival data from the ARCHES trial of enzalutamide presented at the ESMO in September.

Following the previous ENZAMET study, the ARCHES study also showed the enzalutamide administration significantly prolonged OS in patients with M1 HSPC. The mortality risk was significantly reduced by 34% and the combination arm of androgen deprivation therapy with enzalutamide compared with the androgen deprivation therapy, or ADT, plus placebo.

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ENZALUTAMIDE (XTANDI) (2/2): PHASE 3 STUDY DATA BY DISEASE STAGE

15

*Continued potential in earlier lines
with consistent survival benefit and longer duration of treatment*

Disease stage	Early stage			Late stage		
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	EMBARK	ARCHES	ENZAMET	PROSPER	PREVAIL	AFFIRM
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary endpoint	MFS (Ongoing)	✓ rPFS HR 0.39	✓ OS HR 0.67	✓ MFS HR 0.29	✓ rPFS HR 0.17 ✓ OS HR 0.71*	✓ OS HR 0.63
OS	(Ongoing)	✓ HR 0.66	✓ HR 0.67	✓ HR 0.73	✓ HR 0.77	✓ HR 0.63
DoT	(Ongoing)	✓ 40.2 months	✓ 29.5 months	✓ 33.9 months	✓ 17.5 months	✓ 8.3 months

✓: Data obtained, *: Prespecified interim analysis, Yellow: Data recently disclosed @ESMO 2021



M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, NSAA: Non-steroidal antiandrogen, HR: Hazard ratio, MFS: Metastasis-free survival, rPFS: Radiographic progression-free survival, OS: Overall survival, DoT: Duration of treatment, ESMO: European Society for Medical Oncology

Now page 15. This page is a list of the results of Phase III clinical trials of enzalutamide obtained so far by disease stage.

Enzalutamide has accumulated abundant usefulness data in a wide range of patients from the late stage to the early stage of prostate cancer, and has shown a consistent survival effect. In addition, the administration period of treatment duration exceeded 40 months in ARCHES study, and it was confirmed that the administration period is longer in clinical trials targeting the earlier-stage prostate cancer.

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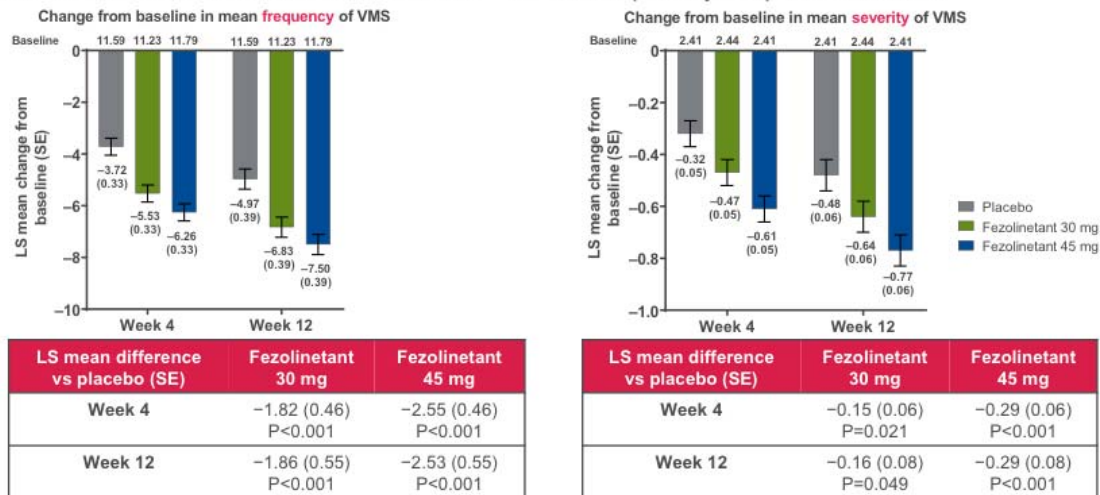


FEZOLINETANT: PHASE 3 STUDY DATA

16

12-week data of SKYLIGHT 2 study presented at NAMS 2021
52-week data of SKYLIGHT 1 study obtained

<SKYLIGHT 2: Co-primary efficacy endpoints> All four co-primary endpoints were met



<SKYLIGHT 2: Safety> No safety signals of concern were apparent for either fezolinetant dose

<SKYLIGHT 1: 52-w data> Obtained in October 2021, which also support the long-term use of fezolinetant

=> Full safety results will be obtained on completion of the Phase 3 program including SKYLIGHT 4 study



NAMS: North American Menopause Society, VMS, Vasomotor symptoms, LS: Least squares, SE: Standard error

Now page 16. This slide introduces the result of the SKYLIGHT 2 study, which was 1 of the fezolinetant Phase III studies that was presented at The NAMS in September.

In terms of efficacy, both 30 milligrams and 45 milligrams significantly improved the frequency and severity of moderate to severe VMS, or vasomotor symptoms, at week 4 and 12 compared to the placebo arm. In addition, improvement in VMS frequency and severity was observed as early as 1 week after administration, and this effect was maintained throughout the 12-week placebo control period. There were no apparent safety signals of concern for either dose.

The 52-week data from the SKYLIGHT 1 trial obtained in October also supports long-term use of fezolinetant. Comprehensive safety assessment results will be obtained upon completion of analysis of 3 Phase III trials, including the SKYLIGHT 4 trial.

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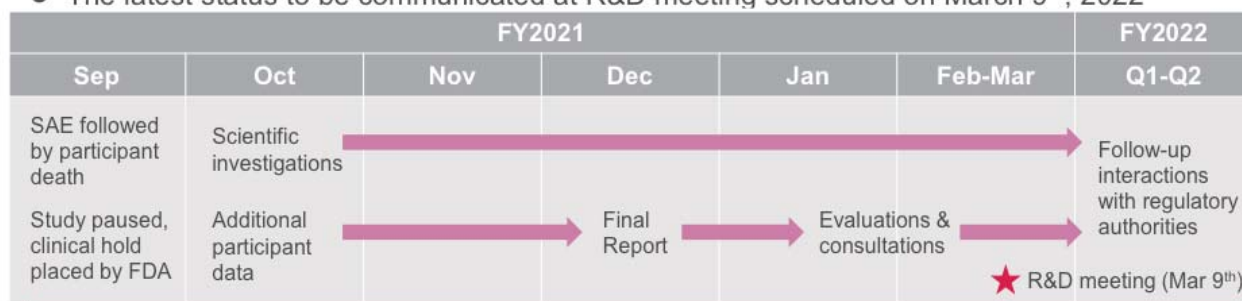


AT132 (RESAMIRIGENE BILPARVOVEC): UPDATED STATUS

17

ASPIRO study in XLMTM put on clinical hold by FDA, due to the incidence of an SAE and subsequent participant death

- Received clinical hold letter from FDA in Sep 2021
- Additional participant data anticipated from the autopsy and follow-up analysis through Dec 2021
- Interactions with regulatory agencies to be initiated in early 2022 based on consultations with KOLs and results from scientific investigations as well as additional participant data
- Future directions to be confirmed after consultations with regulatory agencies on the path forward for AT132
- BLA to be delayed beyond FY2022
- The latest status to be communicated at R&D meeting scheduled on March 9th, 2022



XLMTM: X-linked myotubular myopathy, FDA: Food and Drug Administration, SAE: Serious adverse event, BLA: Biologics License Application

Now page 17. This shows the latest status of AT132.

Serious adverse event occurred in the ASPIRO study, which was resumed in July, and we received a clinical hold letter from FDA. We plan to carry out follow-up analysis, mainly based on autopsy findings, by December to investigate the causes. Based on the data obtained here, expert advice, and a parallel nonclinical scientific research, we plan to begin interactions with the regulatory agencies in early 2022. After consultations with the regulatory agencies, the path forward of AT132 will be decided.

Unlike the indication or description in the CSP, BLA will be delayed beyond FY2022. Since a lot is still unclear at this moment, we plan to hold an R&D meeting in March next year to systematically explain the latest status of AT132 at that time, as well as the overall gene therapy.

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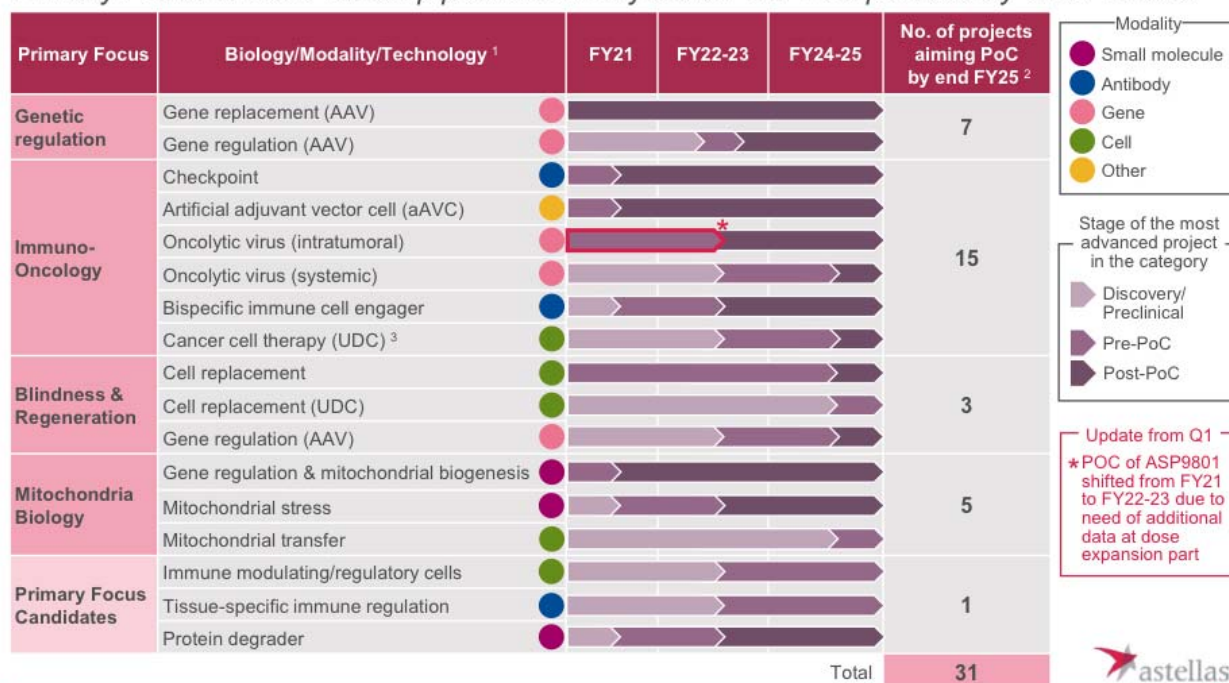
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PROGRESS IN FOCUS AREA APPROACH (1/2): CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS

18

Primary Focuses have robust pipeline to newly build Post-PoC portfolio by end FY2025



1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Oct 2021).

3. The first convertibleCAR program (with autologous cells) IND is planned for late FY2021. CSP: Corporate Strategic Plan, PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

Now page 18. I would like to talk about the progress of primary focus using the table shared at the time of CASB 2021 announcement.

As for oncolytic viruses in immuno-oncology area, the timing of PoC confirmation for ASP9801, which is the lead program, has shifted from FY2021 to FY2022 - FY2023. In the Phase I trial, which was divided into 2 parts, if initial dose-escalation parts obtained clear data even the population is limited, we consider it is possible to determine PoC, so this is the original target. Timing was stated as FY2021. The dose escalation result obtained this time, supposed to move on to the next dose escalation part or recommended Phase II dose expansion part, but the data is insufficient to determine PoC. We decided to make the judgment of PoC in the dose expansion part.

However, the entire study is proceeding as planned, and expectations for an oncolytic virus platform have not changed. We will continue to explain in a timely manner when there is progress in this.

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PROGRESS IN FOCUS AREA APPROACH (2/2): CURRENT STATUS IN PRIMARY FOCUS

19

Primary Focus	Biology/Modality/Technology ¹	Project	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	(See the slides for "XTANDI and Strategic products")
	Gene regulation (AAV)	AT845	Phase 1 study ongoing
Immuno-Oncology	Checkpoint	ASP1948	Phase 1 study ongoing
		ASP1951	Phase 1 study ongoing
	Artificial adjuvant vector cell (aAVC)	ASP7517	<u>FSFT in Phase 2 study in R/R AML and MDS in Oct 2021</u> Phase 1 study in advanced solid tumors to start in Q3 FY2021
		ASP0739	Phase 1 study to start in Q3 FY2021
	Oncolytic virus (intratumoral)	ASP9801	Phase 1 study ongoing (<u>progress to dose expansion part</u>)
	Oncolytic virus (systemic)		
	Bispecific immune cell engager		
	Cancer cell therapy (UDC) (other)	ASP1570	Phase 1 study to start in Q3 FY2021
Blindness & Regeneration	Cell replacement	ASP7317	Screening and enrollment in Phase 1b study put on hold, due to a manufacturing delay
	Cell replacement (UDC)		
	Gene regulation (AAV)		
Mitochondria Biology	Gene regulation & mitochondrial biogenesis	ASP1128	<u>Enrollment discontinued in Phase 2a study, based on the interim analysis for futility</u>
		ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD ongoing
	Mitochondrial stress		
	Mitochondrial transfer		
Primary Focus Candidates	Immune modulating/regulatory cells		
	Tissue-specific immune regulation		
	Protein degrader		

Modality	
●	Small molecule
●	Antibody
●	Gene
●	Cell
●	Other

Underlined: Updates since the last financial results announcement. ¹ Not exhaustively listed.

AAV: Adeno-associated virus, UDC: Universal donor cell, R/R: Relapsed and refractory, AML: Acute myeloid leukemia, MDS: Myelodysplastic syndrome, FSFT: First subject first treatment, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

Next, page 19 shows the current status of the primary focus area projects and the clinical stage.

The underlined part is the progress from the previous financial announcement. A lot of progress has been seen in multiple immuno-oncology projects. For the project ASP7517 of artificial adjuvant vector cells or aAVC, clinical trials for refractory acute myeloid leukemia, or AML, and MDS, myelodysplastic syndrome, entered into Phase II and the first subject, first treatment was started in October.

As has been introduced already, the oncolytic virus project ASP9801 has transitioned from the dose escalation part to the dose expansion part in a Phase I study.

In ASP1128 of mitochondrial biology, patient enrollment was discontinued based on the results of the futility interim analysis in the Phase IIa study.

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PROGRESS IN Rx+ PROGRAM (1/2)



20

Key events expected in FY2021 (announced in Apr 2021)

Sphere *	Program	Event	Achieved
Chronic disease progression prevention	Fit-eNce	Initiation of pilot marketing for at-home service (Fit-eNce Home)	Sep 2021
	Game application for exercise support	Initiation of pilot marketing	
	BlueStar	Initiation of clinical study (Japan)	
	My Holter II	Commercialization of service	Jul 2021
Patient outcome maximization	ASP5354	Topline results for Phase 2 study	

Further updates

Sphere *	Program	Event	Achieved
Chronic disease progression prevention	ECG testing service	Partnering with Nitto and M. Heart	Sep 2021



* Business areas to focus on for realization of Rx+ Story

Next, slide 20. This page summarizes Rx+ program such as the events that are expected to be achieved this year, and are introduced at the beginning of the fiscal year and others.

Fit-eNce, a service that provides an exercise program based on scientific evidence, has already started pilot marketing. But in September, we have started offering Fit-eNce Home, a service that has been improved so that you can exercise at home.

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PROGRESS IN Rx+ PROGRAM (2/2): PARTNERING FOR ECG TESTING SERVICE



21

*Total solution for early detection of atrial fibrillation
using disposable Holter ECG device and AI-Based Analysis Service*

Disposable ECG device "EG Holter"

- Disposable and hygienic; 6 mm thick, 11 g weight, with no cords, waterproof (IPX4)
- M. Heart obtained certification as a medical device (Class II) in Aug 2021
- Nitto will develop and manufacture, and Astellas will aim to sell in Japan after pilot sales



Disposable Holter ECG device "EG Holter"



AI: Artificial intelligence, ECG: Electrocardiography

Combination with ECG Analysis Service

- Promote early detection and appropriate treatment of atrial fibrillation, etc. by providing a total solution combining EG Holter and MYHOLTER II developed by Astellas and M. Heart



Process for analysis using EG Holter



Slide 21. Here, I would like to introduce the alliance with Nitto Denko and M. Heart regarding the ECG testing service.

The EG Holter developed by Nitto Denko is a single-use, disposal, compact, and cordless electrocardiograph. Under this alliance, Nitto Denko manufactures EG Holter, Astellas will conduct pilot sales, and then we will consider subsequent nationwide expansion of the sales.

By adding the convenience of EG Holter to the efficient and highly accurate data analysis of MYHOLTER II, then the electrocardiogram ECG analysis service using AI and that was jointly developed with M. Heart, we hope ECG will become widely spread and will lead to patient benefits such as early detection of AF.

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SUSTAINABILITY: ENVIRONMENT INITIATIVES



22

World's first use of environmentally friendly biomass-based plastic for blister packages of drugs

- The blister package is made of biomass-based plastic, polyethylene derived from sugarcane, as 50% of its raw material. It is an environmentally friendly packaging that match with the concept of "carbon neutrality," which is the idea of balancing greenhouse gas emissions and absorption
- Started commercial production for Irribow Tablet 5μg (indication: diarrhea-predominant irritable bowel syndrome) in Japan
- Considering to switch from the conventional petroleum-derived plastic blister package to the biomass-based plastic blister package for other products as well



Sustainability meeting scheduled on February 28th, 2022



Now, page 22, it's about the sustainability.

As part of our efforts to improve sustainability, we have started to use environmentally friendly biomass-based plastics made from plant-derived raw materials for PTP sheets for pharmaceutical packaging. It is the very first time in the world that the biomass plastic is used for PTP sheets for pharmaceutical packaging.

The blister package is made of the biomass-based plastic, polyethylene, derived from sugarcane as 50% of its raw material. And this package is environmentally friendly just to go in line with the concept of carbon neutral in which the emission and absorption of greenhouse gas is balanced.

Commercial production of this PTP sheet started for Irribow Tablets in the middle of this month. We will consider switching from conventional packages to this these new sheets for other products in the future.

In the CSP2021, strengthening efforts to improve sustainability is set as 1 of the strategic goals. At the CSP announcement in May, we were not able to take enough time to explain Astellas' approach to sustainability, and specifically ESG initiative. In February next year, we are planning to hold a briefing session regarding sustainability.

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PROGRESS TOWARD ACHIEVING CSP2021

23

Revenue, Pipeline Value

- 1** XTANDI and Strategic products:
≥ ¥1.2T in FY2025
 - ✓ Sales growth in line with ambitious forecast
 - ✓ XTANDI: OS data in ARCHES study obtained
 - ✓ PADCEV: Approval in JP, enrollment completion in clinical study for 1L mUC (Cohort K in EV-103)
 - ✓ EVRENZO: Approval in EU
 - ✓ fezolinetant: Presentation of efficacy data of SKYLIGHT 2 study

- 2** Post-PoC projects from Primary Focuses

- 3** Multiple technology platforms

- 4** Focus Area projects:
≥ ¥0.5T in FY2030
 - ✓ AT132: Several scenarios under consideration toward restart of clinical study
 - ✓ ASP7517 (AML and MDS): FSFT in Phase 2 study
 - ✓ Shift to new research organization

Core OP

- 5** Flat SG&A in absolute terms
- 6** Sufficient R&D investments
Core OP margin of ≥ 30% in FY2025
- 7** Steady increase in dividends

- ✓ Investment for new product launch
- ✓ Thorough budget control on a quarter basis

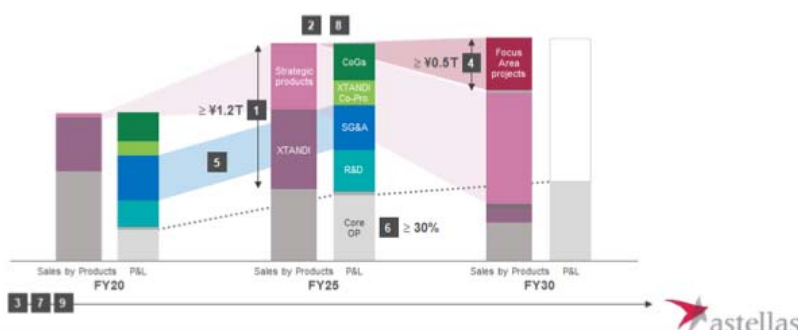
Future Growth

- 8** Rx+:
Breakeven by FY2025

- ✓ Pilot marketing of Fit-eNce Home
- ✓ Partnering for ECG testing service

- 9** Sustainability

- ✓ Use of biomass-based plastic for blister package



Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132

CSP: Corporate Strategic Plan, OS: Overall survival, 1L: First line, mUC: Metastatic urothelial cancer, AML: Acute myeloid leukemia, MDS: Myelodysplastic syndrome, FSFT: First subject first treatment, ECG: Electrocardiography

Page 23. This summarizes the progress made in the second quarter, in line with the CSP2021.

First, about revenue and pipeline value, left top. Sales of XTANDI and revenue of Strategic products are growing as expected against the ambitious targets set as the first year of the CSP2021. In addition, we have steadily achieved the important milestones related to pipeline set at the beginning of the fiscal year as planned.

Next, focus area approach on the lower left. For AT132, we are currently considering multiple scenarios for resuming clinical trials, and we will provide information in a timely manner in the future. In addition, clinical trials of immuno-oncology have progressed.

Next, on the upper right, it's about core operating income. We are continuously reviewing the allocation of management resources to improve the core operating margin, and SG&A expenses are likely to exceed slightly higher than expected. We will continue the budget control of each quarter and throughout-the-year base, and we are aiming at the landing as expected in full year.

Summary: we have confirmed a growth trend as expected according to the target for the first year in the CSP2021. We will now advise the full-year focus for both revenue and core operating income, and we will continue our efforts to achieve the targets set in CSP so that we can achieve sales and profit growth for the full year of FY2021.

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R&D meeting

- Dec 7th 2021, 15:30-16:45 (JST)
 - New research organization structure -
- Mar 9th 2022, 9:30-11:00 (JST)
 - Initiatives for gene therapy -

Sustainability meeting

- Feb 28th 2022, 15:00-16:30 (JST)



Page 24. This is the last slide. We have summarized the schedule of future IR events.

In addition to the gene therapy R&D meeting already explained, and also sustainability briefing session introduced earlier, we plan to hold an R&D meeting in December this year to explain the reorganization of research organization announced in the recent press release. We would like to continue to hold briefing sessions on themes of high interest in the stock market. If you have any requests, please contact the IR staff.

That's all from my explanation. Thank you very much.

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Question & Answer

Fujii: Now we'd like to take your questions.

Operator: Now, Q&A session is going to start. Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi: I'm Yamaguchi from Citigroup. fezolinetant is the topic of my question. SKYLIGHT 1, 2, as you explained before, you're having a good development or flow. As for SKYLIGHT 4, next fiscal year or the beginning of next year, the data is going to become available, but the target—you have finished dosing the patients almost. Right now, any comments you can make verbally now if possible, please.

Yasukawa: As for the serious adverse reactions, we are checking in a blinded fashion. But for the time being, we haven't deducted significant signals. Bernie, any additional comment from you?

Zeiber*: Yes. Thank you for the question. I think the only thing I would add is that we also have a safety monitoring board, and they continue to monitor safety events in addition to our blinded review, and they've identified no issues that would require us to modify the study or stop it. So again, I think the safety profile on a blinded basis seems to be very consistent with what we've seen in SKYLIGHT 1 and 2.

Fujii: Thank you. Next question.

Yamaguchi: This might be difficult for you to make a direct comment, but it's about your competition, generic Zytiga. PARP with Zytiga study result was favorable, and that was announced by the Company in Europe. It may be a bit awkward since there is no direct head-to-head comparison with XTANDI. However, what do you think about this situation as a potential risk for XTANDI? Do you have any particular comment about this?

Matsui: Thank you for the question. Matsui speaking. Let me share with you what we can tell you now. That clinical trial that was conducted, and as a result of the interim analysis, PFS was reported to be favorable. That's what we recognized. However, the detailed data has yet to be announced.

ASCO GU or the coming congress is where that detail will be probably announced. After that, we would like to think. But in oncology, not only PFS, but OS (overall survival) improvement, that is going to be a very critical factor. In that sense, what have we heard so far is there is an improvement in PFS according to the interim analysis. Therefore, we'd like to keep our eyes on it continuously so that we can get the further information. That's one thing we can say.

And on top of that, according to our recognition, Pfizer is also developing a product with the same type of mechanism. And there, combination with XTANDI is also under the study. That's what we've heard. First of all, we would like to wait for the full readout of the data to think about the impact to XTANDI and a countermeasure, if necessary. That's our recognition.

Yamaguchi: Thank you very much. That's all.

Fujii: Thank you very much. Next person, please?

Operator: Daiwa Securities, Mr. Hashiguchi, please?

Hashiguchi: Hashiguchi speaking. Thank you very much. My first question is about AT132. On page 17, you are explaining the situation. An analysis has not been assessed fully yet, as I understood. But the remaining intangible asset assessment, what is the situation right now? As of now, according to your analysis, do you

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still have the remaining value as you're recognizing, or such assessment has not been assessed yet? What is the situation?

Okamura: Thank you for your question. Okamura, I would like to respond. As of now, AT132, future development plan, such as what is going to be the sample size and we have to change the ratio of empty capsids and capsid with transgene. A variety of elements have not been put into place yet fully. As of now, as you can see on the balance sheet, the value of the intangible assets as-is will remain. Based on this assumption, once the future direction is determined, we'd like to reevaluate again.

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

Hashiguchi: Point 2, that is about fezolinetant. DAYLIGHT study introduced on page 13. And especially for the hormone supplemental therapy, what's the definition of that? And on top of that, how will the label change and what will be the impact to future sales?

Yasukawa: Thank you very much. What will be the hormone refractory, or it's unsuitable for HRT? Could you make an explanation about the definition of this, Bernie?

Zeihher*: Yes. Thank you for the question. The trial is designed for patients who might otherwise be unsuitable for hormone replacement therapy. And that could be, for example, if they have a history of breast cancer or a family history of breast cancer, or they've had thrombotic episodes, such as deep venous thrombosis. Or it could be also that the individual will not take hormone replacement therapy because they make a choice.

The reason this is being done, it's less about specifically the label and more for reimbursement in Europe because this population is more likely to be the one for reimbursement in Europe, so this trial is critical to demonstrate efficacy in this population where hormone replacement therapy would not be used.

Yasukawa: Yasukawa speaking. Vasomotor symptom severity and not only for the frequency, mood, depression, anxiety, sexual well-being, and also the sleep are the items to be collected as data. This is not the description in the package insert or labeling, but once that is available, it's going to be a push for the promotion. And depending on the results, what kind of impact or influence it would have, that is going to be different, so I'm not going to tell you any number.

Hashiguchi: Understood very well. Thank you very much.

Fujii: Thank you very much. Next, please?

Operator: Nomura Securities, Mr. Kohtani, please.

Kohtani: Kohtani from Nomura Securities. First question is simple. SKLIGHT 1 study, the data was obtained in October. When can we see the details of the results?

Yasukawa: Bernie, SKYLIGHT 1 presentation at congress, do you have a plan already about SKYLIGHT 1?

Zeihher*: Yes. It is planned for an upcoming congress. We can't disclose exactly when just because it has to be accepted for presentation at that meeting. We are looking at future scientific meetings to submit that data.

Kohtani: SKYLIGHT 1 and SKYLIGHT 2 showed similar profile. Is my understanding correct?

Yasukawa: Yes, your understanding is correct in terms of the results.

Kohtani: The second zolbetuximab, the Phase II study, the number of the patient is expanded and based upon that, you try to do the submission. But as of now, it's in the phase of the blind, so which has a longer survival?

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That's unknown. And May 2019 is FSFT, so it's been long since then. But however, that might be the efficacy of the placebo is also continuing. Why did you change the fair-value remeasurement on contingent?

And also nab-paclitaxel and gemcitabine combination and the fact study is also available. Looking at the result, the longest combination therapy, the overall survival is 8.5 months. Currently, the result is exceeding that?

Yasukawa: Bernie, based upon the data available for you, could you say something that is available or possible for you to explain here?

Zeihher*: Yes. Thank you for the question. As you said, we did review blinded data. These are still relatively small numbers. It is longer than we would have normally expected. What we don't know is, is that driven by longer in just the standard of care or whether it's driven by additional benefit from the zolbetuximab in addition to standard of care.

The driver really to expand the trial is when we first started the study, I think it was before COVID hit. We thought we could actually conduct it a little faster. And if it were very positive, that single smaller study could potentially serve for something like an accelerated approval. Now, with the impact of COVID and wanting to really ensure that we maximize the life cycle of zolbetuximab, and seeing some of the trial at least is not having a short survival or treatment duration, we went and thought that expanding the trial really increases the likelihood that we would have a registration quality study. That was really a key driver. Within the study protocol, we will have interim analyses to make sure that it's not meeting futility criteria, but the goal really ultimately would be to ensure that we have adequate data to be able to file for an approval on the basis of this single trial.

Okamura: As for the fair-value remeasurement on contingent payment, let me make a comment about this. The contingent payment, well, within the contract, it is said that once something is a hit and the payment is placed. The total amount is already fixed. And fair value of contingent payment, well, there is the payment under the condition. And if the probability of the payment is generated, then you think about the current value. The payment for each is decided according to the event.

If that event becomes bigger, it means the timing of the payment becomes earlier or the probability of the payment becomes higher, so either of these 2. And this time, Phase II is expanded and that could be used as a pivotal. Also, on top of that, there is a possibility that the authority doesn't approve that as a pivotal, so you have to do the Phase III study later on.

There are various scenarios available and based upon that, the fair value went up. Therefore, we booked this as other expenses. Please consider it in this way.

Kohtani: It's not clear. Standard care, this is combined and a high possibility of benefit in the combination, is that the reason why?

Okamura: Maybe Bernie should have answered this question, but allow me to answer. We are not assuming that, but we are considering a variety of possibilities. Overall, the study is getting longer or prolonged. That might be a signal, but it's under blinded, so we cannot tell. At any rate, it's getting longer. If possible, instead of just letting it go as-is, by increasing the statistical power in Phase II, we wonder whether we can get the accelerated approval. After considering such scenarios, this is what's happening. That's my understanding.

Zeihher*: We don't want to assume that there's efficacy yet. I mean, because, again, we are looking at it in a blinded way. And also, you don't know because the patients are selected. It's a clinical trial setting, and it's a setting where we've selected patients who expressed Claudin 18.2.

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Whether those have any impact on survival, we don't know, so we are not making strong assumptions that there's efficacy. It's really more about trying to increase the likelihood that if there is efficacy, that we can actually have strong enough data to support regulatory approvals in a timelier fashion.

Kohtani: The Advisory Committee Meeting of Gene Therapy, it took place at the beginning of September, and the future 2 conditions are going to be placed. A high level of the dose to the power of 10, to the power of 14, is not approved and those who have delivered a problem, the gene therapy is not accepted. Considering these restrictions, is there any impact onto the AT132 or other products?

Why there are 3 death cases, 20-40 weeks after the first administration that this took place and there was no immuno involvement? There was no immunity or immune response. Why that leads to the congestion of bile? There is no well explanation about that. Do you have any good explanation about this?

Yasukawa: That is the scientific thing. Did you get the question, Bernie? And could you answer this?

Zeihher*: Thank you. Well, I think you've characterized it well that there is a different problem that we've been seeing with these boys with XLMTM as opposed to other gene therapies. As you said, at the Advisory Committee, there are reports of liver toxicity that's more immune-related and responds to steroids and tends to resolve without a problem. What we observed with XLMTM is different. As you said, we're not seeing immune cells and the liver does not respond to steroids and is associated with cholestasis, the very high bilirubin levels and the progressive toxicity that we've seen.

Our belief, and something we're still investigating is that this is unique to XLMTM and likely a component of the underlying disease. We've worked with some outside investigators and identified that, in fact, the underlying disease of XLMTM is associated with cholestasis. It seems when these children get viral illnesses, they can have very marked increases in their liver enzymes and even bilirubin elevations. So we think this is really more of a – in the setting of XLMTM, they're more susceptible to this cholestatic problem. And when you give them a large dose of the viral vector, that that is triggering the cholestatic event.

Now, what we need to determine through our scientific investigation is, is it all children with XLMTM, or could you treat them when they're younger? Or are there other markers that might predict which children might have this problem? And also part of the other investigation, which I think was mentioned earlier, was there a contribution even of the empty vector, the empty capsids? And do we need to actually refine the drug product to reduce the amount of empty capsids? Basically, what is the contribution of that?

We do not believe that this is something that's common to other diseases that we may treat. For example, Pompe disease, which is our next program. But it would be a potential issue with diseases where there is an underlying liver problem.

I think this is, again, a unique situation with XLMTM and something that we're continuing to actively investigate, and we're happy to give you a further update on that at the time of our R&D meeting in March.

Kohtani: Understood. Thank you very much.

Fujii: Thank you very much. Next person, please?

Operator: Mr. Sakai from Credit Securities, please.

Sakai: Sakai from Credit Suisse Securities. Zolbetuximab and AT132, I have follow-up questions on those. First, zolbetuximab. The fair value was remeasured in pancreatic cancer. Gastric cancer, and esophageal cancer, you have Phase III. Did you also review these plans, or is the competitive environment beginning to change significantly? For the future, so this review is going to be reflected in your plan? That's my first question.

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And you are making a downward revision. Because of the enhanced value, payment will come earlier, that's why you're looking, so this is not a bad thing. Having said so, can you absorb this much amount with your efforts in the Company? What do you think? This is my second question.

Yasukawa: In the first half, gastric cancer Phase III study, SPOTLIGHT ongoing. Right now, we do not have a plan to review the value.

Number 2, on a full basis, it's about a full-basis figure. Absorbing such a figure, there is no such item. JPY8.7 billion has been booked in the second quarter. As usual, full-basis figures, in which month, which year, clinical studies are going to fail, we cannot prove efficacy. We cannot expect or predict that at the beginning of the fiscal year. We'd like to review whenever there is an event. There is no change in that stance.

Sakai: Phase III schedule is not going to change, right?

Yasukawa: For gastric cancer, you're talking about, right, enrollment is almost on track. This is an event-driven study. If the drug is effective more than expected, the event accumulation will be delayed. We cannot mention specifically in which month, which year, but we'd like to continue to watch the situation.

Sakai: Understood. Thank you very much. Rather than AT132, you got acquired from Audentes, about AAV technology. AAV technology itself, the trust or the safety to AAV itself, have you done any analysis or verification about that?

Yasukawa: As has been explained by Bernie, the full depth, we look at the details. And for all these 4 cases, if the findings are the same, or the case 4 is completely different, well, if we learn about that, we can learn if the toxicity is general or patient-specific. We would like to look at the autopsy pathology of the case 4. That is going to be available at the end of the year, and in line with that, preclinical is ongoing. Based upon that result, next year, March, we are going to make the comprehensive explanation.

For the technology, we also think that there might be room for improvement, just like Bernie mentioned. For example, the empty virus capsule, those are still included. With reducing that, the total amount of the virus goes into the bodies will be reduced, so immune-related issue might be also minimized.

Technology modification is also something we would like to consider.

Sakai: Understood. This part is included in intangible, right? AAV technology is intangible? Within the acquisition of Audentes, I believe you did the calculation of the asset, and that is where that AAV is included?

Okamura: Yes, you're right.

Sakai: Thank you very much.

Fujii: Thank you very much. Next, please.

Operator: Morgan Stanley, Mr. Muraoka, please.

Muraoka: Muraoka from Morgan Stanley. Thank you very much for your time. When you announced your mid-term business plan, there are 5 or 6 submission plans in the next fiscal year. I'm talking about the list. As of now, if you have a rough picture, what is going to be the order or sequence of those? If possible.

fezolinetant results will become available at the beginning of the year. Which will come next? zolbetuximab, XOSPATA, and then PADCEV, XTANDI maybe in my view? What is going to be the sequence that we can expect? Any clues on this?

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Yasukawa: Sorry, in the middle, the telecommunication line was not stable. Are you talking about the sequence of the launch?

Muraoka: Not really about the launch, but the readout of the clinical studies and the timing of the clinical study readout and the sequence or the order in the coming 1 year.

Yasukawa: Understood. fezolinetant, as we said from before, from the end of this year to the beginning of next year, SKYLIGHT 4 results will become available. Then in spring, overall safety, overall efficacy analysis results are necessary before submission will be done. Then safety data, you're interested in, could be announced based on that.

And XOSPATA, PADCEV, life cycle management, and zolbetuximab Phase III study, which was talked about earlier, these are all ongoing, but they are event-driven studies. In a pinpoint fashion, which will come first, in which month, we cannot tell you right now.

Event accumulation will be monitored in around which month we can do anything. Once we know that, we will have an earnings call occasion or other forms to explain to you and share the information.

Muraoka: Understood. XTANDI, EMBARK, in the first half or the second half? Is it difficult to give guidance right now?

Yasukawa: EMBARK, we are monitoring the status. We cannot mention which month, in which year yet.

Muraoka: Understood. Thank you very much. Likewise, another event, the ASP3772 pneumococcal, pneumonia vaccine, I think, because PREVNAR 20 is now available, so we cannot go slowly about this. I would like to eagerly hear about the partnering about this. Is there any news about this?

Okamura: When the time comes, I'm going to tell you.

Muraoka: Understood. Thank you. The last question. Prograf, the reduction of the forecast is quite large in EU. International, there's great reduction. Is that tentative, or this might also impact full and will continue toward the next fiscal year as well?

Matsui: Matsui speaking. This time, Prograf, you see that the forecast is reduced. 1 of the reasons for that is that in the Middle East area, the existing patients, partly due to the COVID-19, passed away, unfortunately. That is impacting overall.

There is a great difference depending on the region. And basically, China, international, still continuously, the increase of the transplant is expected. Therefore, the sales is expected. But in Established Markets or Japan, in such markets, there's the impact of generic and also price pressure is another factor of the impact. We see the gradual reduction.

So far, in this couple of years, there's a gradual, little-by-little reduction, so we forecast that this trend would continue.

Muraoka: Understood. Thank you.

Fujii: Thank you very much. Next person, please.

Operator: Mr. Ueda from Goldman Sachs Securities, please.

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Ueda: Ueda from Goldman Sachs Securities. First, about XTANDI, I have a question. In US and Europe, I'd like to know the trends. In the US, it's growing steadily, but is it the real growth? What about the price or the inventory status? Any impact from that?

And in Europe, and just looking at the second quarter compared to the first quarter, it may be a bit sluggish. And full-year forecast has been reduced. I wonder what is happening right now. Could you please explain?

Matsui: Thank you for your question. I'd like to respond. First, in the US, price and the inventory, we are not facing exceptional situations. In M1 HSPC, ARCHES and data has been obtained additionally. In early-stage cancer, prescription increase is expected. Also, duration of therapy would be longer than the actual demand. It's going up because of these factors.

In the US, in principle, as far as we see, it's not a special factor, but as a real demand, it's growing on a real-demand basis.

Next, in Europe, as Dr. Yasukawa, our president said in his explanation, M1 HSPC approval, after the approval, well, in some countries, M0 CRPC, pricing negotiations or negotiations for reimbursement are still going on in some countries.

Because of the COVID-19 impact, the health care cost and insurance cost are strained and negotiations are facing difficulties. Even if there is agreement, the price may be lower than we anticipated in the end. And this is having an impact on the results up to the second quarter, and we're expecting such impact in the latter half of the fiscal year as well.

But in the shorter term, there would be some negative impact, but if we get new indications, the number of patients will increase. In the mid to long term, the negative price, negative factor would be offset by the volume and demand. We can expect further growth.

In particular, specifically, you were talking about Q1 and Q2 comparison. A major factor is as follows. At the end of Q1, the first quarter in June in France, M1 HSPC was approved. Then, from the French authority from July 1, new label package products only should be distributed. We received such instruction.

At the end of June, the inventory we had in the Company, not to make them obsolete, we distributed this into the market. Q1 sales, because of France, a little less than JPY3 billion, there was an excessive shipment because of this and that was included in Q1, resulting in an increase, and that is already absorbed after the second quarter. There is some variance between the 2 quarters. That's all from me.

Ueda: Thank you very much.

The second AT132 is the next question. Just on page 17, you showed the schedule. But the negotiation in the beginning of 2022, you have interaction with the authority, then you have the R&D meeting in March. At that time, the direction of the development is identified and what will be the plan afterwards?

Also, AAV, empty vector is mentioned and the technology to reduce that. Is that going to be developed in your company? Do you also think about the licensing or introduce such kind of technology from outside?

Yasukawa: Well, thank you for the questions about the schedule. The meeting with the authority, we apply, but the schedule is not set as we planned or we favored. With Round 1, if the discussion is completed or not is unknown. March 9, the situation is clear or not, we cannot guarantee. But at a certain time point, we consider this better to explain to you the situation rather than waiting for the final decision. We set up the meeting on March 9 and at the time, we can tell you whatever we know around that time. That's our intention.

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The second. So far, we are working internally for the development of such technologies.

Ueda: Understood. Thank you. Thank you very much. That's all.

Fujii: Thank you very much. Next person, please.

Operator: JPMorgan, Mr. Wakao, please.

Wakao: Wakao from JPMorgan speaking. Thank you. First, about mirabegron. In the US, OAB market growth is slowing. In the second quarter, if I look at the results, individual products are doing well in some cases, but mirabegron in US was rather weak. You made a downward revision. Well, the market growth in US is smaller than expected. Could you elaborate on this point?

GEMTESA from DSP has been launched, so the market has been activated, but could you explain the factors for the current situation? That's my first question.

Matsui: Thank you for your question. I'd like to respond. First of all, the overall market in the US is going to be explained. According to a recent report, in Europe, with the market as a whole, according to IQVIA data, is growing. It's in the recovery stage since April. But, unfortunately, in the US, it's still remaining flat. Compared to before, the patients have not been coming to the office for treatment or prescriptions yet. According to the data, as we recognize, these circumstances, as you pointed out, usually, there can be a concern.

In April, there was a launch by another company. What is going to be the potential impact? This is about another company. We are not going to comment much, but it's within our assumptions. As far as we know, the market share is very limited yet in its usage. Our share is a little slower than planned, but it's still growing steadily.

Probably you're asking this question because of the following reason. Not only on a YoY basis, but on a quarterly basis, comparing quarter 1 and quarter 2, you may be wondering why and you were asking this question in my view. On this point, Medicare coverage gap is having an impact here. As you know, Medicare Part D, the so-called donut hole exists. Like XTANDI with a high drug price, there can be a lot of impact in the first quarter on a calendar year basis. Compared to XTANDI, mirabegron with a lower price, there is going to be a threshold for the donut hole, around USD3,000. That is appearing in the second half gross to net. It's expanding in the second quarter compared to the first quarter. That's why Q1 is negative compared to the first quarter. The volume is not declining QtoQ basis, but gross to net, the timing of the discount payment is the reason why the so-called donut hole, or coverage gap in the third and the fourth quarter—in the fourth quarter, the year will change, but a certain threshold will be exceeded. There's going to be a recovery later in the year.

That's how we see the situation. That's all for me.

Wakao: Thank you very much for that thorough answer. The last question, XTANDI. There was a question at the beginning, that's a PARP inhibitor Zytiga combination. Well, the current available data, according to my understanding, is the castration-resistant prostate cancer with metastasis. And currently, you're thinking about the expansion of the indication and the sales incurred more from the new indications. Currently castration refractory prostate cancer, what's the sales portion or in overall sales of this product? If it's possible, please tell me.

Matsui: Thank you very much for the question. Indication-wise sales, unfortunately, we are not disclosing, so this time, I would like to rather refrain myself from making a comment. Thank you very much.

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Wakao: On the other hand, the sales here, is it better to understand that the sales there is still certain volume? Because in the upper stream, if the sales increases, CRPC sales might be reduced. PARP inhibitor, that might be available in the future. However, the impact of that might not be so great for your product. That's what I thought. What do you think about this?

Matsui: Well, roughly speaking, I think it's about 1/2 of overall portion. As I've already mentioned, the impact will be different depending on the types of the data. As of this moment, we cannot make a further comment.

Wakao: Understood. Thank you very much. That's all.

Fujii: Thank you very much. Next person is going to be the last person to ask questions, please.

Operator: BofA Securities, Mr. Arai, please.

Arai: Arai from BofA Securities. SGA cost, you are above your forecast. The plan in the first half was not disclosed, but specifically against the budget, how much are you progressing above your forecast? I'd like to know the situation.

Usually, towards the second half, SGA costs are going to go up according to the tendency. In usual years, may have certain expenses, so what about expenses you have just this year? You're controlling the budget and trying to optimize personnel. Why do you have a different tendency compared to usual years? Could you explain the background? That's all from me.

Okamura: Thank you for your question. As we said, just looking at expenses, it's more into the second half. To be more precise, more in the fourth quarter. In managing the SG&A expenses, towards the end, we tend to spend a lot. We wanted to review this way from before. By the end of the second quarter, compared to our initial plan or forecast, we are progressing above or ahead. Compared to 50% of the initial forecast, we are a little above compared to that.

On the other hand, up to the second quarter, FX impact existed because of the Japanese yen's depreciation, as Yasukawa said. During the course of CSP, pursuing the benefits, we should make investments from now. Such investments are also being made.

fezolinetant, PADCEV, to come, we need prior investments. In-advance investments for the launch were necessary as well. In 2021 fiscal year, in the first and the second quarters, these may be very specific to this fiscal year in these quarters. In the third and the fourth quarter, nothing like that at all. It will not be gone completely, but for the early spending of the money, we will begin to see benefits gradually.

It's not just spending our money. We may spend a bit, but there would be benefits from what we spend in the first half. And the balance-wise, the benefits will be higher than the investment. When this will be overturned in terms of the balance, as Yasukawa said, very detailed budget control is not what we want to do. But still, because of the situation, if it's planned initially but is not spent, then instead of moving this to the next quarter, it should be used when it should be used to make it meaningful. Between finance and business, there should be discussions, and the money which is not used should be returned to the Central to allocate the money to the sections or departments where the money is needed. Did I respond to your question?

Arai: Yes, very clear. That's all from me. Thank you very much.

Fujii: Thank you very much. With this, we would like to close this session. Thank you very much for your participation.

[END]

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