Astellas Pharma Inc.

Financial Results for Q1 of FY2022

August 1, 2022

Event Summary

[Company Name]	Astellas Pharma Inc.	
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[Number of Speakers]	4	
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	Yukio Matsui	Chief Commercial Officer (CCO)
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	Motoya Koutani	Nomura Securities Co., Ltd.
	Seiji Wakao	JPMorgan Securities Japan Co., Ltd.
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	Akinori Ueda	Goldman Sachs Japan Co., Ltd.

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

Presentation

Kikuoka: Hello, everyone. I am Minoru Kikuoka from Astellas Pharma Inc. Thank you very much for joining our FY2022 Q1 financial results announcement meeting out of your very busy schedule today. This is a cautionary statement regarding forward-looking information. As Ikeda explained this earlier, I'm going to skip this page.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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

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

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AGENDA

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I Q1/FY2022 Consolidated Financial Results

II Initiatives for Sustainable Growth

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This is the agenda for today. I will cover these topics in this order from the next page.

Q1/FY2022 FINANCIAL RESULTS: FX IMPACT AND ONE-TIME FACTORS（FULL BASIS）

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Affected the significant FX impact incl. elimination of unrealized profit due to the sharp depreciation of yen in Q1
Financial results were on track when excluding FX impact and one-time factors

(billion yen)	Q1/FY21	Q1/FY22	1. FX impact	Q1/FY22 (excl. 1)	2. One-time Factors	Q1/FY22 (excl. 1&2)
Revenue	**326.1**	**381.8**	**+35.5**	**346.3**		**346.3**
Cost of sales	62.2	88.9	+18.5*	70.4	XTANDI: Royalty payment adjustment for prior year (+1.8)	68.6
% of revenue	19.1%	23.3%		20.3%		19.8%
SG&A expenses	137.1	153.4	+16.7	136.7		136.7
US XTANDI co-pro fee	34.5	43.1	+6.7	36.4		36.4
SG&A excl. the above	102.6	110.3	+10.0	100.3		100.3
R&D expenses	58.3	74.0	+7.5	66.5	One-time expenses (+13.1)	53.4
Amort./Equity	5.7	10.4	+0.2	10.2		10.2
Gain on divestiture of intangible assets	-	0.2	-	0.2		0.2
Core OP	**62.8**	**55.3**	**-7.4**	**62.7**		**77.6**
Other income	0.4	16.3	+14.1	2.2		2.2
Other expenses	27.1	38.4	-	38.4	fezolinetant: Increased fair value of contingent consideration (+13.6)	24.8
Full OP	**36.1**	**33.1**	**+6.7**	**26.5**		**55.0**

No changes have been made to Full-year FCST as there are no items that are beyond expectations
Expect to have a positive FX impact for the full year

* Incl. FX impact on elimination of unrealized profit (+12.3)
Amort./Equity: Amortisation of intangible assets/ Share of profit (loss) of investments accounted for using equity method

On page four, let me first explain the significant impact of Forex and one-time factors on our Q1 results.

Due to the sharp depreciation of the yen in Q1, we were affected by the significant Forex impact, including the Forex impact on elimination of unrealized profit. There were also one-time factors as well. When these impacts are excluded, our financial results are on track. Our actual business is progressing steadily.

First, as you can see in the middle column, Forex had a positive impact of JPY35.5 billion on our revenue. On the other hand, Forex impact increased each cost item. There was a negative impact on our core operating profit, but this time, particularly for COGS. In addition to the cost increase due to Forex impact in proportion to sales amid the yen's depreciation, Forex impact on the elimination of unrealized profit was JPY9.1 billion on a group consolidated basis due to the sharp rise of foreign currencies near the end of June, mainly the rise of the US dollar, and JPY4.2 billion, mainly due to the surprise of the Russian Ruble on sub-consolidation basis in Europe. This doubled towards the end of the period. The total was JPY13.3 billion, substantially up by JPY12.3 billion compared to JPY1 billion in the previous fiscal year. So, excluding the Forex impact and the elimination of unrealized profit, core operating profit was JPY62.7 billion at the same level YoY.

For full basis operating profit, Forex impact was positive due to the booking of net foreign exchange gains as other income. Full basis operating profit was JPY26.5 billion, excluding this impact.

Next, as you can see on the right, we had one-time factors such as the booking of JPY1.8 billion as XTANDI royalty payment adjustment for prior year and JPY13.1 billion as one-time expenses of R&D expenditure.

Excluding the Forex impact and these one-time factors, core operating profit was JPY77.6 billion, progressing in line with our initial assumption. For full basis operating profit, we booked as other expenses, JPY13.6 billion of increased fair value of contingent consideration for fezolinetant in Q1 when we submitted our filing.

We didn't factor this into our full-year forecast because of uncertainty whether this will occur or not at the beginning of the fiscal year. This booking of expenses was a reflection of the results of positive progress in development. Excluding this impact, full basis operating profit was JPY55 billion. With regards to Forex impact, the elimination of unrealized profit is a one-time factor. Based on the assumption that the current Forex rate levels will continue with the yen's depreciation, we are expecting a positive impact on our core operating

profit on a full-year basis. As there are no items beyond our expectations, we decided to keep our full-year forecast as is.

And this time, due to a very big Forex impact on the elimination of unrealized profit, let me explain the background on our philosophy in more detail.

If you have been watching Astellas from before, you may know this. For a company with a big rate of internal transactions overseas, mainly in Ireland for us due to IP or production strategies, in case of big Forex fluctuations, resulting in a big difference between the average rate during the period and the term and rate, the elimination of unrealized profit is a temporary phenomena to occur with appropriate account processing.

This time, in addition, amid geopolitical risks, we were securing proper inventory in Russia in executing the most important mission for us as a pharma company to ensure the delivery of drugs to patients. Then came the sharp appreciation of the Russian Ruble, leading to similar events on sub-consolidation basis in Europe for the first time.

It's impossible to predict these events in advance. We cannot hedge them in our business operation as usual. Costs booked in relation to the term and processing, and this is not related to cash at all. So personally, I don't think we should hedge. We appreciate your understanding.

On page 23, in the appendix, you can find a brief explanation and the impact on group consolidation and sub-consolidation in Europe, so please refer to that page later.

Having said so, with appropriate accounts settlement processing, JPY55.3 billion core operating profit and JPY33.1 billion full basis operating profit we announced today are the correct figures. But in account settlement, there are always one-time factors, and they were unusually standing out this time. So, it's up to the judgment of investors in the end, but we wanted to explain to you our Q1 profit and loss in our actual business as we understand. That's why we included this slide at the beginning of the presentation.

Recently, as you know, we often see volatile movements of the stock price of not only our company, but also others soon after the announcement due to system trading using algorithm, et cetera. Therefore, next time and beyond, so that we can announce our results and explain our thinking behind to the market and investors without much time difference, we'd like to announce our results and organize this kind of meeting at 3:00 PM or later when the Tokyo Stock Exchange closes its trading session for the day. We appreciate your understanding.

Q1/FY2022 FINANCIAL RESULTS: OVERVIEW

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Revenue increased 17% YoY and was on track when excluding FX impact

- Sales of XTANDI and Strategic products increased 26% YoY
- Cost of sales ratio increased YoY due to significant FX impact
- SG&A expenses were on track and decreased YoY when excluding FX impact
- R&D expenses were on track

Operating profit

- Core OP decreased YoY, same level as previous year when excluding FX impact, progress on track
- Full basis decreased YoY
  - Booked net foreign exchange gains as Other income (14.1 billion yen)
  - Booked impairment losses on intangible assets:
    Termination of research and development for AT702, AT751, AT753 (22.0 billion yen)
  - Booked fair value remeasurements on contingent consideration for fezolinetant US NDA submission as Other expenses (13.6 billion yen)

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Strategic products: PADCEV, XOSPATA, EVRENZO
NDA: New Drug Application

Please turn to page five.

Revenue increased YoY in Q1. Revenue was on track when Forex impact was excluded. Sales of XTANDI and Strategic products increased 26% YoY, contributing to the revenue increase. As was explained on the previous page, COGS ratio rose YoY. SG&A expenses were on track and decreased YoY, excluding Forex impact. R&D expenditure increased YoY, but was on track and used in line with our expectations. As a result, core operating profit progressed as expected, excluding Forex impact. Full-basis operating profit decreased YoY.

Q1/FY2022 FINANCIAL RESULTS

(billion yen)	Q1/FY21	Q1/FY22	Change	Change (%)	FY22 Initial FCST	Progress	FX impact
Revenue	**326.1**	**381.8**	**+55.6**	**+17.1%**	**1,443.0**	**26.5%**	+35.5 bil. yen
Cost of sales	62.2	88.9	+26.6	+42.8%			+18.5 bil. yen*
% of revenue	19.1%	23.3%	+4.2 ppt				
SG&A expenses	137.1	153.4	+16.3	+11.9%	598.0	25.7%	+16.7 bil. yen
US XTANDI co-pro fee	34.5	43.1	+8.6	+25.1%			
SG&A excl. the above	102.6	110.3	+7.6	+7.4%	416.0	26.5%	+10.0 bil. yen
R&D expenses	58.3	74.0	+15.7	+26.9%	254.0	29.1%	+7.5 bil. yen
Amortisation of intangible assets	6.0	10.7	+4.8	+80.2%			
Gain on divestiture of intangible assets	-	0.2	+0.2	-			
Core operating profit	**62.8**	**55.3**	**-7.5**	**-12.0%**	**290.0**	**19.1%**	-7.4 bil. yen
<Full basis>							(Other income) Net foreign exchange gains: 14.1 bil. yen
Other income	0.4	16.3	+15.9	-			
Other expenses	27.1	38.4	+11.3	+41.7%			(Other expenses) Impairment losses on intangible assets (AT702,AT751,AT753): 22.0 bil. yen
Operating profit	**36.1**	**33.1**	**-2.9**	**-8.2%**	**269.0**	**12.3%**	
Profit before tax	35.8	31.7	-4.2	-11.6%	267.0	11.9%	fezolinetant increased fair value of contingent consideration: 13.6 bil. yen
Profit	**30.7**	**24.8**	**-5.9**	**-19.1%**	**208.0**	**11.9%**	

* Incl. FX impact on elimination of unrealized profit (+12.3 bil. yen)

Next, on page six, I will explain FY2022 Q1 results.

Revenue increased to JPY381.8 billion, up by 17.1% YoY. The progress against the full-year forecast was 26.5%. Core operating profit was JPY55.3 billion, down by 12% YoY. The progress against the full-year forecast was 19.1%.

The bottom half of this page shows our full basis results. In Q1, we booked JPY16.3 billion as other income and JPY38.4 billion as other expenses. Operating profit was JPY33.1 billion, down 8.2% YoY. Profit was JPY24.8 billion, down by 19.1% from the previous fiscal year. The progress against our full-year forecast is remaining at low levels, but this is due to a big impact of Forex and one-time factors I explained at the outset.

Q1/FY2022 FINANCIAL RESULTS: XTANDI AND STRATEGIC PRODUCTS

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Sales of XTANDI and Strategic products increased 26% YoY

(billion yen)	Q1/FY2022 Act	YoY	FY2022 Initial FCST	Progress	
Xtandi (enzalutamide)	162.4	+29.5 (+22%)	642.5	25%	✓ Global sales are in line with expectations ✓ Signs of sales recovery in US from Q4 slowdown
PADCEV enfortumab vedotin-ejfv	10.6	+6.4 (+152%)	36.5	29%	✓ Global sales are above expectations • New patients starts far exceeded expectations in Japan • Clinical trial orders booked ahead of schedule in US ✓ Possibility of exceeding initial full-year forecast
XOSPATA gilteritinib	10.5	+2.2 (+26%)	46.2	23%	✓ Global sales are almost in line with expectations ✓ US performed below expectations due to inventory burn
Evrenzo roxadustat	0.7	+0.1 (+19%)	9.9	7%	✓ Sales in Japan and Europe are below expectations ✓ Expect reimbursement to start in European countries in 2H/FY2022

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Strategic products: PADCEV, XOSPATA, EVRENZO
PADCEV (US): Co-promotion revenue from Seagen

On page seven, let me explain Q1 results for XTANDI and Strategic products.

Sales of Xtandi, PADCEV, XOSPATA, and Evrenzo increased by 26% YoY, continuing a strong growth.

As for Xtandi, global sales increased to JPY162.4 billion, up by JPY29.5 billion or 22% YoY. I will explain the details, including the situation in the US on the next page.

PADCEV global sales increased to JPY10.6 billion, up JPY6.4 billion or 152% YoY. Despite some one-time factors, it's progressing well overall. We are expecting an upside from the initial forecast. I will explain the details on the next page, together with Xtandi.

XOSPATA global sales increased to JPY10.5 billion, up JPY2.2 billion or 26% YoY. Global sales are almost in line with our expectations. Based on this progress, we think we can achieve our full-year forecast. US with the biggest sales amount is performing below expectations, but is affected by the high inventory level at the end of the previous fiscal year. The actual business is trending as expected.

Evrenzo sales reached JPY0.7 billion, up by JPY0.1 billion or 19% YoY. Sales in Japan and Europe are below expectations due to the factors, which haven't changed much from the previous quarter. Continuously, there is an impact of intensifying competition in Japan. In Europe, not much progress has been made yet compared to the assumptions in differentiation from the existing standards of care in Europe. On the other hand, we are expecting reimbursement to start in European countries in 2H of FY2022. So we are hoping for sales expansion in the future.

Q1/FY2022 FINANCIAL RESULTS: BUSINESS UPDATE FOR XTANDI AND PADCEV

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Global sales grew as expected, mainly from M1 CSPC contribution

<US> Performed below expectations, but showed signs of sales recovery

- Impact from generic competitor pressure continued, no significant expansion
- Signs of PAP rate settling, still slightly higher level than expected
- New patient starts are in upward trend, expect positive impact

<ex-US> Performed above expectations, especially contribution from Europe

- In Europe, M1 CSPC showed strong growth, and countries with reimbursement increased, contributing to demand increase
- Positive price impact, higher price than assumed was agreed upon (Germany)

Sales grew in all regions, global sales growth exceeding expectations

<US> Performed as expected, even excluding revenue from clinical trial orders

- Strong growth from cis-ineligible mUC 2L therapy

<JP> Market penetration far exceeding expectations since launched in Nov 2021

- Highly evaluated by physicians, new patient starts and market share higher than expected

<Europe> Approved in Apr 2022, currently launched in 8 countries, strong initial uptake

- Expect further increase in launch countries and reimbursement start

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EM (Established Market): Europe, Canada, Australia, GC (Greater China): China, Hong Kong, Taiwan, INT (International Market): Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea
M1: Metastatic, CSPC: Castration-sensitive prostate cancer, PAP: Patient Assistance Program, mUC: Metastatic urothelial cancer, 2L: Second line
PADCEV (US): Co-promotion revenue from Seagen

On page eight, I will explain Xtandi and PADCEV in detail.

First about Xtandi, US performed below expectations, but other regions performed above expectations to offset the downside in the US. Global sales grew as expected. Also with a positive Forex impact, our record-high quarterly sales were achieved. Sales increased, mainly from early-stage M1 CSPC, metastatic castration-sensitive prostate cancer, contributed to sales growth.

In the US, with concern over the slowdown in the previous quarter and the high level of interest from the stock market, we are seeing signs of sales recovery. Regarding generic competitors, which affected Xtandi in the previous quarter, impact from generic competitor pressure still continues, but we don't see significant expansion of the generics.

As for the patient assistance program called PAP, which affected our business in the previous quarter, the ratio of PAP is still slightly higher than expected, but there are signs PAP tap rates settling from June. For both generic competitors and PAP, inflation and economic recession are factors behind. We think that patients are shifting to cheaper generics and PAP for free drug provision.

It's difficult to make an accurate forecast of these elements, so we are continuing to monitor them as a potential risk.

On the other hand, new patient starts are in an upward trend partly due to the achievements from disease awareness activities for new patients we have been implementing since the previous fiscal year. Initial forecast is still challenging, but we are hoping that increasing new patient starts and M1 CSPC prescriptions will lead to sales expansion.

Regions other than the US performed above expectations, especially with big contributions from Europe. In Europe, in M1 CSPC, which was additionally approved in April last year, the number of countries with reimbursement for M1 CSPC increased, including Italy, with a big market, contributing to volume increase. In the reimbursement negotiations in Germany, higher price than we assumed was agreed upon, so we are expecting this will be an upside factor throughout the current fiscal year. Ex-US regions other than Europe are

also performing in line with or above expectations, so we're expecting further expansion in each region in the future.

Next, on PADCEV, sales grew in all regions, and global sales growth is exceeding expectations.

In the high-performing US, the results include revenue from clinical trial orders, but even excluding that factor, in the actual business trend, US is performing as expected. Prescription is increasing from second-line therapy, which is contributing to growth.

In Japan, sales are increasing at a pace far exceeding our expectations since the launch in November last year. Many prescribing physicians are highly evaluating PADCEV. New patient starts were higher than expected, leading to a higher market share than our forecast. We're hoping for a continuous growth into the future.

Also in Europe, since the approval in April this year, PADCEV has been launched in eight countries, including Germany. By now, initial uptake is stronger than expected. We are expecting further increase in launch countries. We are expecting reimbursement to start in 2H of FY2022 or later.

Q1/FY2022 FINANCIAL RESULTS: COST ITEMS

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Cost of sales ratio increased YoY due to significant FX impact
SG&A expenses were on track and decreased YoY when excluding FX impact
R&D expenses were on track

Core basis: Main items for YoY and progress against FCST

Cost of sales % of revenue YoY: +4.2 ppt	✓ FX impact on elimination of unrealized profit: +3.2 ppt (+12.3 bil. yen) ✓ XTANDI royalty payment adjustment for prior year: +0.5 ppt (+1.8 bil. yen)
SG&A expenses **(excl. XTANDI US co-pro fee)** YoY: +7.4% Progress against FCST: 27%	✓ SG&A excl. FX impact: -2.4 bil. yen (YoY -2.3%) ✓ Global optimization of personnel aligned with transformation of product portfolio (Approx. -3.0 bil. yen) ✓ Reduction of mature products-related costs (Approx. -2.0 bil. yen) ✓ Investment for new product launch readiness (Approx. +2.0 bil. yen)
R&D expenses YoY: +26.9% Progress against FCST: 29%	✓ FX impact (+7.5 bil. yen) ✓ Increase in one-time expenses that already factored into full-year FCST (+13.1 bil. yen)

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On page nine, I will explain cost items compared to the previous fiscal year and full-year forecast.

COGS ratio increased by 4.2 percentage points YoY. As I explained at the beginning, there was a significant Forex impact on elimination of unrealized profit, which increased COGS ratio by 3.2 percentage points or JPY12.3 billion YoY. Xtandi royalty payment adjustment for the prior year also became a factor to increase COGS ratio, increasing COGS ratio by 0.5 percentage points or JPY1.8 billion.

SG&A expenses, excluding US Xtandi co-promotion fees, rose by 7.4% YoY. But when Forex impact was excluded, SG&A expenses decreased by JPY2.4 billion or 2.3% YoY and were in line with expectations. Costs decreased by about JPY3 billion YoY due to global optimization of personnel aligned with transformation of product portfolio. We are also trying to reduce costs related to mature products such as mirabegron, which decreased our cost by about JPY2 billion YoY. We are making active investments for new product launch

readiness, resulting in an increase by about JPY2 billion from the previous year. We will continue to allocate our resources to strategic products with higher priority.

We are making a thorough review of costs, which would not contribute to corporate competitiveness and value enhancement. We will continue to control our SG&A expenses stringently. R&D expenditure increased by 26.9% YoY. Forex impact increased our R&D costs by JPY7.5 billion. In addition, we also booked one-time R&D expenses, which increased our R&D expenditure. Due to the booking of JPY13.1 billion as one-time expenses in Q1, the progress versus our full-year forecast is high at 29%, but we already factored in this one-time cost into our full-year forecast at the beginning of the fiscal year, so we are expecting landing as expected on a full-year basis.

Let me add one point on this page. In addition to increasing geopolitical risks, which I touched on at the beginning, there is much more uncertainty in business, such as associated increase in material costs, energy and power shortage, and inflationary concern. Under these circumstances, we recognize it's becoming more important than ever not just to control expenses, but also to respond with BCP for a stable continuation of business because we are a pharma company. So, for good readiness against various risks under the direct leadership of our CEO, Yasukawa, we will address the situation in a structure that enables swift response.

AGENDA

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I Q1/FY2022 Consolidated Financial Results

II Initiatives for Sustainable Growth

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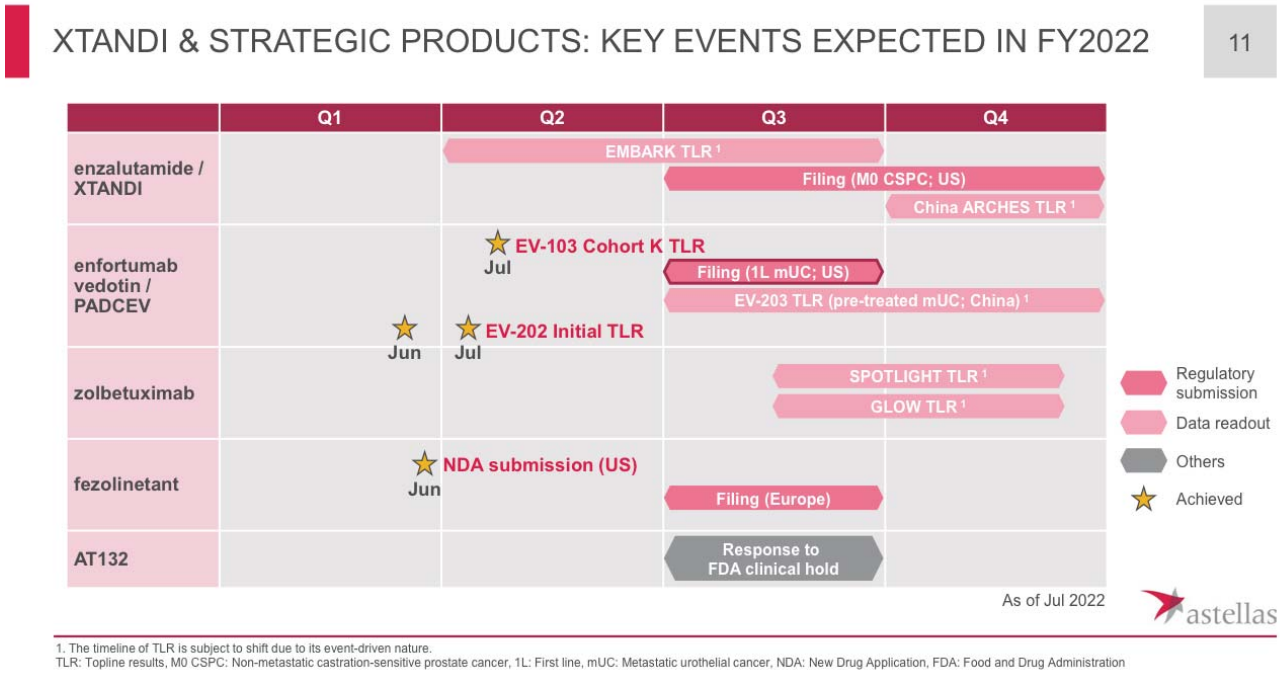
Slide 10. Now I'd like to explain about our initiatives for sustainable growth.



Page 11. Regarding XTANDI and Strategic products, key events expected in FY2022 will be explained here.

Events that have been achieved are marked with a star. For PADCEV, we received topline results in July from the EV-103 study cohort K for the first-line for metastatic urothelial cancer. Results are explained in the next slide.

In addition, we obtained topline results in June and July for two cohorts of the EV-202 study, which is being conducted for several solid tumors other than urothelial cancer. We are currently reviewing the status of other cohorts and scrutinizing the future development plan with our partners. We will explain the results of each cohort at an appropriate time.

We submitted an application for approval of fezolinetant in the US in June, and the preparation for the submission in EU is currently proceeding as planned. The progress of fezolinetant as a whole will be explained in a later slide.

ENFORTUMAB VEDOTIN (EV) (1/2): TOPLINE RESULTS FOR EV-103 STUDY COHORT K

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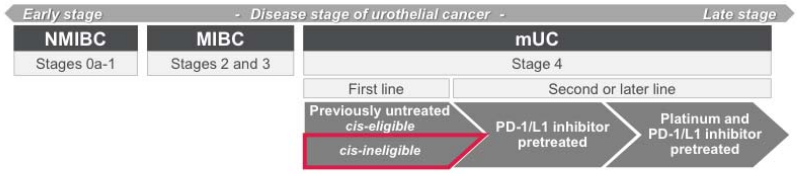
Positive topline results obtained, showing consistent efficacy and safety with previous data [1]

- First-line treatment for advanced urothelial cancer (cis-ineligible, combination with pembrolizumab)
- Plan to discuss results with FDA aiming sBLA submission in 2022 under Accelerated Approval



<Cohort K in EV-103 study>

Patient segment	Patients with unresectable la/mUC who are unable to receive cisplatin-based chemotherapy in the first-line setting
Study arm	• EV + pembrolizumab combo (n=76) • EV monotherapy (n=73)
Primary endpoint	ORR (per BICR)
Secondary endpoint	DoR, PFS, OS, safety, etc.

<Topline results (Combo arm)>

ORR [95% CI]	64.5% [52.7 to 75.1]
DoR	Not reached (median cannot be calculated due to continued response in many subjects)
Safety	Tolerable and manageable, and no new safety concerns emerged

Seagen

[Ref] Previously reported ORR data for gemcitabine + carboplatin treatment in first-line setting [2]: 42-46%

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1. EV-103 dose-escalation cohort and expansion Cohort A. 2. IMvigor130: Galsky et al., AACR 2021 Abstract CT042; KEYNOTE-361: Powles et al., ASCO GU 2021 Abstract 450; DANUBE: Powles et al., EAU 2021
FDA: Food and Drug Administration, sBLA: Supplemental Biologics License Application, NMIBC: Non-muscle-invasive bladder cancer, MIBC: Muscle-invasive bladder cancer, cis: Cisplatin,
la/mUC: Locally advanced or metastatic urothelial cancer, ORR: Objective response rate, BICR: Blinded independent central review, DoR: Duration of response, PFS: Progression-free survival, OS: Overall survival, CI: Confidence interval

Page 12 is about PADCEV.

I will discuss the topline results of the EV-103 study Cohort K, which was presented in the press release last week. Cohort K evaluated the combination therapy with the PD-1 inhibitor, that is pembrolizumab as first-line therapy in patients with advanced urothelial cancer and cisplatin ineligible. The objective response rate, ORR, the primary endpoint, was 64.5%.

The combination of gemcitabine and carboplatin is currently the standard of care for first-line treatment of advanced and cisplatin urothelial cancer. Although head-to-head comparisons are not appropriate due to differences in patient demographics and study design, the ORRs in some previous reports have been in the mid to high 40% range, and we believe that the results of this study demonstrate the high efficacy of the combination of PADCEV and pembrolizumab. The median duration of response cannot be calculated at this time because of the large number of patients who are still responding to treatment. As for safety, there were no unknown findings that are of concern.

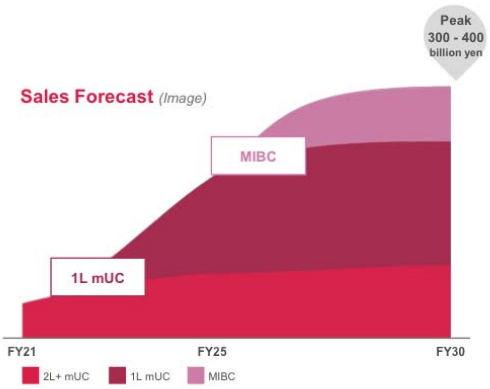
Overall, the efficacy and safety results are consistent with those seen in the dose escalation cohort and expansion cohort A of the EV-103 study, which was conducted under a similar protocol in the past. The details of the data is planned to be presented at a future site meeting.

Based on the results of the dose escalation cohort and expansion Cohort A that I mentioned earlier, we received a breakthrough therapy designation from the FDA February 2020 for this combination therapy. We are planning to discuss with the regulatory authorities aiming at Accelerated Approval within 2022.

ENFORTUMAB VEDOTIN (2/2): OVERVIEW

13

The most significant growth driver is 1L mUC indication, which is expected to account for more than half of total sales in the future



Patient segment		Pivotal study	Mono/ Combo [1]	OS	PFS	ORR	DoR	Target filing timing	Number of eligible patients [2]
MIBC	cis-ineligible	EV-303	Combo	(Ongoing)				FY2025 or later	10,000
	cis-eligible	EV-304	Combo	(Ongoing)				FY2025 or later	37,000
mUC, previously untreated (1L)		EV-302	Combo	(Ongoing)				FY2024	76,000
		EV-103 Cohort K	**Combo**	(Ongoing)		**64%**	**Not reached**	**2022 [3]**	**8,000** (US, cis-ineligible)
		EV-103 dose escalation cohort & Cohort A	Combo	26.1 mos	12.3 mos	73%	25.6 mos		
2L+ mUC	PD-1/L1 inhibitor pretreated	EV-201 Cohort 2	Mono	14.7 mos	5.8 mos	52%	13.8 mos	Approved	1,600 (US, cis-ineligible)
	Platinum & PD-1/L1 inhibitor pretreated	EV-301	Mono	12.9 mos	5.6 mos	41%	7.4 mos	Approved	38,000
		EV-201 Cohort 1	Mono	12.4 mos	5.8 mos	44%	7.6 mos		

Clinical studies in other patient segments are also ongoing:

- Non-muscle-invasive bladder cancer (NMIBC): EV-104 (Phase 1)
- Other solid tumors [4]: EV-202 (Phase 2)

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1. Combination with pembrolizumab. 2. Based on internal estimates. 3. US 4. Hormone receptor positive/HER2 negative breast cancer, triple-negative breast cancer, squamous non-small cell lung cancer (NSCLC), non-squamous NSCLC, head and neck cancer, gastric adenocarcinoma or esophageal adenocarcinoma or gastroesophageal junction adenocarcinoma, esophageal squamous cell carcinoma. mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, 1L: First line, 2L+: Second or later line, cis: Cisplatin, mono: Monotherapy, OS: Overall survival, PFS: Progression-free survival, ORR: Objective response rate, DoR: Duration of response

Page 13. I will explain the position of EV-103 cohort K in the overall growth of PADCEV.

The figure on the left shows PADCEV's sales forecast for each target patient group. The most significant growth driver is in the middle of the chart, first-line treatment of metastatic urothelial cancer indication, which is expected to account for more than half of total sales in the future. Of this first-line treatment, the majority of sales will be in the US, and we estimate that about 1/2 of that will come from the cisplatin-ineligible patient population that is the target of EV-103 cohort K. If we are able to file as expected, we expect the growth of PADCEV to further accelerate in the next fiscal year and beyond.

FEZOLINETANT: LATEST STATUS

14

<Regulatory submission> NDA submitted to US FDA on June 22

<Data presentation> Latest data presented at ACOG and ENDO

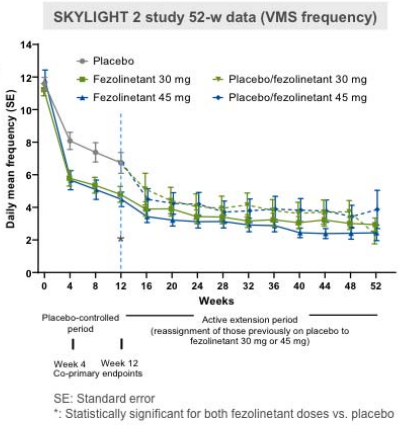
- SKYLIGHT 1 study 12-w data: Consistent results with those of SKYLIGHT 2 study
- SKYLIGHT 2 study 52-w data:
  - ✓ Maintained improvement in VMS frequency and severity throughout 52 weeks
  - ✓ Reduction in VMS frequency and severity after re-randomization from placebo to fezolinetant
  - ✓ Consistent safety profile with that of 12-week placebo-controlled period

<VMS education and awareness activities (US)>

- HCP: Sequentially launched VMS educational/awareness website (KnowVMS.com) and omni-channel online and in-person approach
  - ✓ Reached 132k unique HCPs
- Consumer: Launching DSA (Disease State Awareness) campaign in August (TV from October)

<Upcoming events>

- SKYLIGHT 4 study 52-week data to be presented at NAMS in October
- Conference call after NAMS presentation will be held on October 17



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NDA: New Drug Application, FDA: Food and Drug Administration, ACOG: American College of Obstetricians and Gynecologists, ENDO: Endocrine Society, VMS: Vasomotor symptoms, HCP: Healthcare professional
NAMS: North American Menopause Society

Page 14 is the update of fezolinetant.

As previously announced, we submitted NDA for fezolinetant in the US on June 22. We are currently waiting for the contact from the FDA on acceptance.

Next, we presented the latest data at ACOG, American College of Obstetricians and Gynecologists in May and the Endocrine Society of America, or ENDO, in June. At ACOG, we presented 12-week data from the SKYLIGHT 1 study. The results of this study were confirmed to be consistent with a 12-week data of the SKYLIGHT 2 study presented last year. At end, we presented 52-week data from the SKYLIGHT 2 trial. We've confirmed that VMS frequency and severity through our 52 weeks maintained, reduction in VMS frequency and severity after randomization from 12-week placebo to fezolinetant, and consistent safety profile of 56 weeks with that of 12-week placebo-controlled period.

The VMS disease education and awareness activities in the US are also making progress. For healthcare professionals, we have sequentially launched a series of online and in-person omnichannel approaches, including the operation of the VMS educational and awareness website, Internet advertising, and booths at academic conferences.

To date, we have reached approximately 130,000 health care professionals and have made a steady progress in promoting the understanding of the mechanisms of VMS and its burden. In addition, for consumers, a disease data awareness campaign will be launched in August. Furthermore, TV commercials will be utilized starting in October to promote understanding of VMS as a disease.

Finally, we will introduce upcoming events related to fezolinetant. We are planning to present data from the SKYLIGHT 4 study, which evaluates the long-term safety of fezolinetant at the NAMS in October. A conference call will be held on October 17, following the NAMS to provide an update on the status of the study, including the SKYLIGHT 4 and other published data, as well as details on disease awareness activities.

PROGRESS IN FOCUS AREA APPROACH (1/4): CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

15

(Red: Updates since the last financial results announcement)

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	4
		AT845	**FORTIS study put on clinical hold by FDA in Jun 2022**	
	Gene regulation (AAV)			
Immuno-Oncology	Checkpoint	ASP1570	Phase 1 study ongoing	12
	Artificial adjuvant vector cell (aAVC)	ASP7517	Phase 2 study in R/R AML and MDS ongoing Phase 1 study in advanced solid tumors ongoing	
		ASP0739	Phase 1 study ongoing	
	Oncolytic virus (intratumoral)	ASP9801	Phase 1 study ongoing	
	Oncolytic virus (systemic)			
	Bispecific immune cell engager	ASP2138	**FSFT in Phase 1 study in Jun 2022**	
	Cancer cell therapy (UDC)			
Blindness & Regeneration	Cell replacement	ASP7317	**Screening and enrollment in Phase 1b study anticipated to restart in Aug 2022**	3
	Cell replacement (UDC)			
	Gene regulation (AAV)			
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD ongoing	4
	Mitochondrial stress	ASP8731	Phase 1 study ongoing	
	Mitochondrial transfer			
Primary Focus Candidates	Immune modulating/regulatory cells			1
	Tissue-specific immune regulation			
	Targeted protein degradation	ASP3082	**FSFT in Phase 1 study in Jun 2022**	
			Total	24

Modality
- Small molecule
- Antibody
- Gene
- Cell
- Other

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1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Jul 2022)
AAV: Adeno-associated virus, UDC: Universal donor cell, FDA: Food and Drug Administration, 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

On page 15, we will discuss the progress in Focus Area Approach.

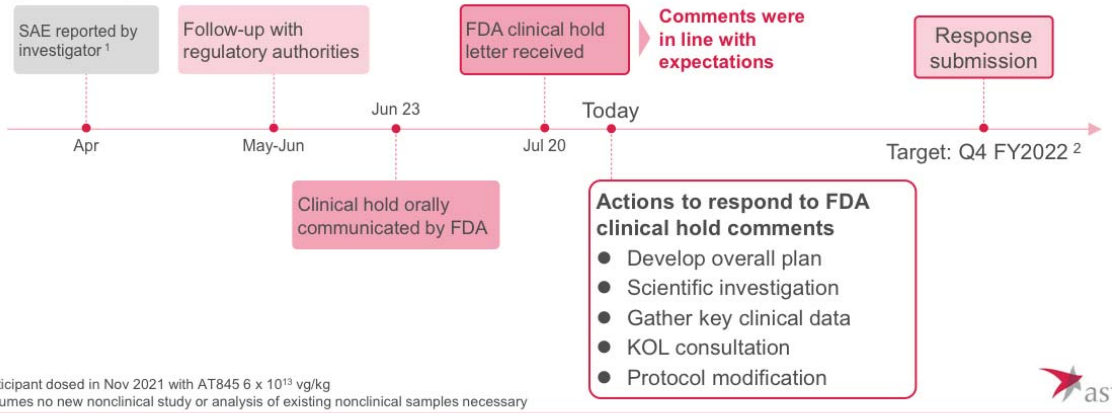
This slide shows in red the progress made in the past quarter for the projects in the clinical trial with the FA or Focus Area Approach.

The following slides provide details on AT845, ASP7317, and ASP3082. Other progress includes ASP2138, our lead project for bispecific immune cell engager in immuno-oncology Primary Focus, which achieved first patient dosing in Phase I in June. The rightmost column shows the number of projects aiming PoC by the end of FY2025. There was no change from the total number of 24 reported in this April's financial announcement.

PROGRESS IN FOCUS AREA APPROACH (2/4): AT845

16

- FORTIS study placed on clinical hold by FDA, following the reporting of an SAE of peripheral sensory neuropathy
- Remain committed to the safe and effective development of AT845 for Pompe disease, and to gene therapy



1. Participant dosed in Nov 2021 with AT845 6 x 10^{13} vg/kg
2. Assumes no new nonclinical study or analysis of existing nonclinical samples necessary

FDA: Food and Drug Administration, SAE: Serious adverse event, AE: Adverse event, KOL: Key opinion leader

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Slide 16 is the update of AT845.

As we have already informed you, FORTIS study is placed on clinical hold by FDA following their reporting of an SAE of peripheral sensory neuropathy in one subject.

I would like to begin by briefly explaining the background of the situation. In April, the investigator reported an SAE in a subject who was administered AT845 in November last year. In response to this, we provided information to the authorities and responded to their inquiries several times. On June 23, clinical hold was orally communicated by FDA. On July 20, we received a clinical hold letter from the FDA. The comments in the letter were in line with our expectations. We are currently developing an overall plan to fully respond to the FDA's comments. Based on this plan, we will proceed with clinical data collection, scientific investigation, and KOL consultation.

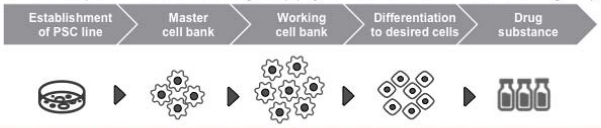
We expect to submit our response to the FDA by the end of FY2022 if no new nonclinical studies or sample analysis is required. We are facing various challenges, but we will remain committed to the development of gene therapies, including AT845, which could be an innovative therapy.

PROGRESS IN FOCUS AREA APPROACH (3/4): ASP7317

17

Clinical study of ASP7317, the lead program of cell therapy, anticipated to restart

- ASP7317
  - ✓ Human embryonic stem cell-derived retinal pigment epithelial cells
  - ✓ Target disease: Geographic atrophy secondary to age-related macular degeneration, Stargardt disease
- The clinical study was voluntarily put on hold due to the manufacturing process changes and the introduction of new cutting-edge analytical methods for product release in accordance with technology advancements in a cell-therapy field
- Established capabilities enabling supply of cells that meet the high quality standard through activities for resumption



- ✓ **Manufacturing**: Improving ratio of cells with desired characteristics
- ✓ **Analysis**: Quality testing with high sensitivity and reproducibility
- ✓ **Specification setting**: Building rationale based on multiple preclinical data

- Screening and enrollment anticipated to restart in Aug 2022
- Acceleration of research and development for subsequent cell therapy programs
  - ✓ Expected to be able to provide cells with higher quality for clinical studies without delay, by leveraging established capabilities

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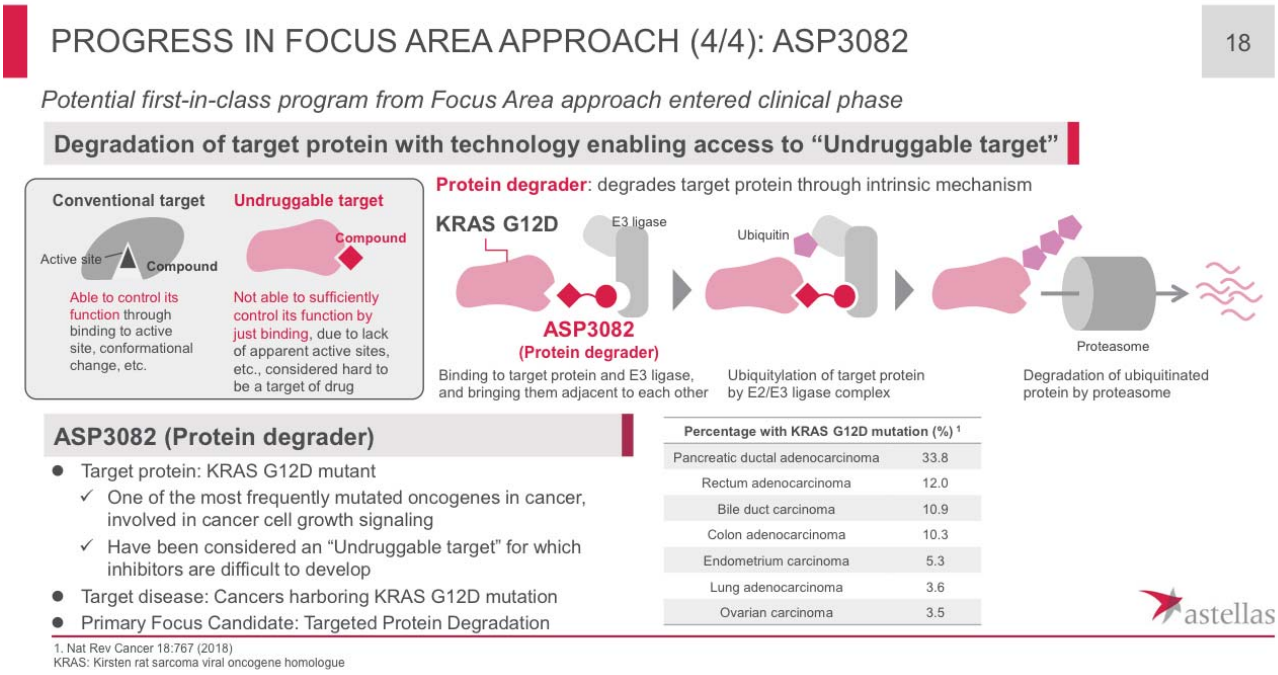
PSC: pluripotent stem cell

On page 17, I will explain the latest status of ASP7317.

In this project using human embryonic stem cell-derived retinal pigment epithelial cells, we had been changing the manufacturing process and introducing cutting-edge analytical methods in order to respond to recent technological advances in the field of cell medicine. Due to the time required to study the manufacturing process, quality testing, and establishment of quality standard as well as to provide other to the FDA, Astellas has been voluntarily putting on hold the enrollment of new subjects in clinical trials since last year.

Through these activities, we have established capabilities enabling supply of cells that meet high-quality standards. There are three of them: manufacturing technology to improve the ratio of sales with the desired characteristics, analytical technology for quality testing with high sensitivity and reproducibility, and specification settings based upon the various preclinical data and the rationale.

The necessary steps have now been completed, and subject screening is anticipated to resume in August. In some cases, similar issues were identified early in other cell therapy programs leading to smooth responses. We hope that the capabilities established this time will be utilized in subsequent programs to accelerate the research and development of cell therapy.



Next, new project, ASP3082.

First of all, an undruggable target is a molecule that is considered hard to be a target of conversion compounds. Even if a compound binds to an undruggable target, it is difficult to control this function by itself and cannot access sufficient action.

We have focused on protein degrader, utilizing an intrinsic mechanism in the body as a technology to assess undruggable targets. The protein degrader we are currently developing has a structure with a site that binds to the target protein and a sight on the opposite side that binds to E3 ligase, which is a ubiquitin ligase. This brings the target protein into close proximity to the E3 ligase where it undergoes ubiquitylation. The target protein is then degraded by the proteasome, an enzyme that selectively degrades ubiquitinated proteins. Once this technology is established, we believe it can be applied to a variety of undruggable targets by converting the binding site to the target protein.

The target protein of ASP3082 is KRAS G12D mutant. As shown in the table on the right, it is one of the most frequent cancer-driver gene mutations found in various types of cancer, but has been considered an undruggable target. Astellas has long been strong in chemical synthesis and was able to create a compound that binds to KRAS G12D at an earlier stage. However, the problem was that simply binding to KRAS G12D did not fully control its function and did not produce the expected effect. Therefore, we created ASP3082, which induces selective degradation of KRAS G12D by utilizing the mechanism of protein degrader. This is expected to have a growth inhibitory effect on cancer cells with KRAS G12D mutations.

PROGRESS IN Rx+ PROGRAM

Rx+ 19

Key events expected in FY2022 (announced in Apr 2022)

Category	Program	Event	Result
Digital health Other services	EG Holter/AI Software	Initiation of sales pilot	**Achieved (Jun 2022)**
Digital therapeutics	BlueStar	Initiation of clinical study (Japan)	
Drug-device combination	pudexacianinium chloride (ASP5354)	FSFT in Phase 3 study	

- Implantable medical devices (iota):
  Prepare for IDE submission in FY2022, toward initiation of clinical study in FY2023

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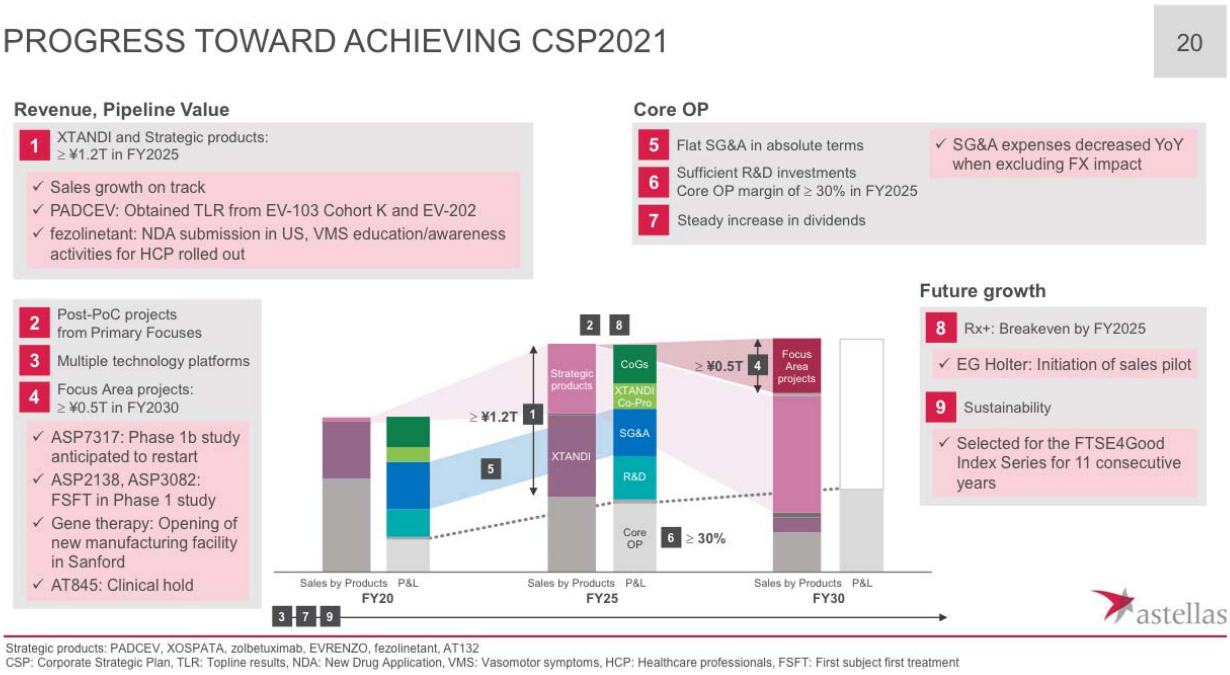
AI: Artificial intelligence, IDE: Investigational Device Exemption, FSFT: First subject first treatment

Next, I will explain the progress of Rx+ program.

At the top of the chart, in June, we began pilot sales of EG Holter, a single-use ECG testing sets that we are collaborating with Nitto Denko and M. Heart. This service aims to provide a total solution combining a highly convenient ECG testing with the EG Holter designed and developed by Nitto Denko, and data analysis with MYHOLTER II jointly developed by M. Heart and Astellas, leading to early detection and appropriate treatment of AF and others.

This is the first time for Astellas' Rx+ plans program to sell its products on an e-commerce site. After verifying the business model through these pilot sales, we will consider full-scale development as well.



Page 20. This summarizes the progress made in Q1 in line with the CSP2021.

On the top left, Xtandi and the strategic products showed sales growth on track. We also achieved important development milestones with PADCEV and fezolinetant.

In the [focus area project], left bottom, we made progress in clinical trials for our oncology projects with an aim of being first in class. In the cell therapy and gene therapy projects, we continue to build capability by resolving the various challenges we face in tackling cutting-edge science.

In terms of core operating profit, top right, by thoroughly reviewing the rigorously controlling costs and the resource allocation, SG&A expenses, excluding the impact of foreign exchange fluctuations, decreased YoY, while we continue to aggressively make necessary investments. Overall, we made progress as expected toward achieving the performance targets of CSP2021.

UPCOMING IR EVENT
(SECURITIES ANALYSTS AND INSTITUTIONAL INVESTORS)

21

fezolinetant meeting

- Oct 17th 2022, 9:30-10:45 (JST)

Enfortumab Vedotin meeting (EV-103 Cohort K)

- To be announced

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This is the last slide.

This is the schedule of upcoming events for securities analysts and institutional investors. We are planning to hold a fezolinetant meeting on October 17. We are also planning to hold a meeting on the data from the EV-103 study Cohort K of PADCEV after presentations. Details will be announced at a later date. We would like to continue to hold meetings on topics of high interest from the stock market.

If you have any requests, please contact our IR department. The presentation is finished with this.

APPENDIX

Appendix, here. I'm not going to talk about the details. But, therefore, those who are not familiarized with this situation, let me explain about this, why the situation happened.

FX IMPACTS ON ELIMINATION OF UNREALIZED PROFIT

23

- In elimination of unrealized intercompany profit included in inventories as a part of the consolidation accounting process, FX fluctuation could cause impacts on cost of sales

Overview of cost of sales

Beginning inventory | Cost of sales | Mfg cost / Purchase | Unrealized profit | Ending inventory

elimination of unrealized profit

Record cost of sales | Profit from intra-group transactions

Theoretically no impacts on P/L as the cost of sales offset the intra-group profit

(example of unrealized intercompany profit) Co. A sold product to Co. B. At the year-end, the product had not yet been sold to 3rd parties.

Company A: Profit from intra-group transactions 70; COGs 30

Sales 100, COGs 30 →

Company B: Inventory 100; Unrealized profit 70

FX impacts related to inventories held by foreign affiliates

Local currency: Unrealized profit $70 → Record cost of sales $70 = Profit from intra-group transactions $70

Translated to yen → JPY

@current rate | @average rate

(1) In case current rate (@120) is weaker than average rate (@110)

8,400 yen > 7,700 yen

Recorded COGs is larger → COGs +700 yen

(2) In case current rate (@100) is stronger than average rate (@110)

7,000 yen < 7,700 yen

Recorded COGs is smaller →COGs -700 yen

Impacts on FY22Q1 Group consolidation (JPY) :cost of sales +9.1 billion yen
Sub-consolidation at ABV (euro) :cost of sales +4.2 billion yen (mainly due to stronger RUB)

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Mfg cost: Manufacturing cost

When the cost of sales is calculated, as you know, the top left, the time beginning inventory and the purchase and cost added for the calculation of the cost of sales, and out of this, as you see, left, at the time of the consolidation. For example, from the manufacturing side with the high profitability, if the goods are sold to the group company, For example, 30 cost of goods is sold with a 70, then internal profit 70. At the time of consolidation process, this is posted as the cost of sales. And as you find on the left, this is what is unavoidable. That is unrealized profit. That is the flow. So, in place of the booking in the mid of the fiscal term, the beginning

inventory and the ending inventory, that is a [VS] item. Therefore, the [term] end rate is applied for this elimination proportion. So, as you see that the JPY7,700 to JPY8,400, with the yen depreciating greatly, then cost of sales to be offset or eliminated is bigger. Therefore, the COGS is larger. But in the case of the stronger yen, then the recorded COGS is smaller. This time, the US dollar has an impact, at the same time, the drastic increase of the Russian rubles.

On the cost of sales, group consolidation JPY9.1 billion and sub-consolidated euro in Europe, cost of sales is positive JPY4.2 billion.

That is all from me. Thank you very much.

Ikeda: Thank you very much. That's all for our presentation. Next, we'd like to entertain your questions.

Question & Answer

Ikeda [M]: You can ask questions through the teleconference system. You cannot ask questions through the livestreaming system. If your turn comes, the operator will name you, so please wait on the phone if you requested for questions.

If you want to ask a question, please press zero one. The operator will name you one by one, so please wait. If you want to cancel your question, please press zero two.

Thank you for waiting.

Please connect with the person who is going to ask the first question.

First, Mr. Yamaguchi from Citigroup Securities.

Yamaguchi [Q]: Yamaguchi from Citigroup. I have a few questions.

You explained the details about the elimination of unrealized profit. I'd like to confirm in Q1, you had this much impact. And Forex is not going to fluctuate. Q1 impact will remain in Q2 and Q3, and it's going to be diluted. This JPY13 billion or so is going to remain without a fluctuation of the Forex. The elimination of unrealized profit, this is the cash, so you're not ignoring this. This amount is going to remain, but is there going to be a positive impact on the top line because of the yen depreciation, and you can absorb the impact, correct?

Kikuoka [A]: Yes, you're right.

From the end of the previous fiscal year, there is a difference, and we had unrealized profit. The inventory level, if the inventory level is going to trend at the same level, then the same amount is going to stay, but we cannot identify what is going to happen to the Russian ruble by [selling], it's going to be offset.

How much this is going to remain is not clear yet. On the other hand, as you pointed out, if it's going to trend at the same level this time as well, unrealized profit in areas other than unrealized profit in proportion to sales, cost will go up. But the profit margin in local currency would not change. So, the positive impact of Forex will only emerge. The Forex impact is going to be diluted into the future, as you said. For us, on a full consolidated basis, the net foreign exchange gains could be expected in some cases. Core operating profit on full basis operating profit, the yen's depreciation level is going to continue at the current level. If that's the assumption, we will have a positive impact into the future.

Yamaguchi [Q]: Understood.

Second, Xtandi. I had a good understanding about that thanks to your explanation. You explained about the US situation. But full year, US CER increase of the revenue is looked at. So, there has to be the acceleration in the US business. There are several positive factors. Q1, I understood very well, but Q2, Q3, afterwards, your forecast is very aggressive. How are you going to try to catch up with that? Matsui-san, could you make a comment about this?

Kikuoka [A]: That's what I was planning. So Matsui is going to talk about it.

Matsui [A]: Yamaguchi, thank you very much for your question. Q2, Q3, the challenges are, as explained by Kikuoka, the PAP percentage is difficult to predict and also new patients, to what extent we can enjoy the

increase of new prescriptions that matter. And PAP, that's touchable. We cannot do anything about that. But with regards to the increase of the patients, as has been mentioned in the past as well, currently, together with Pfizer, we are working so that the patients go to the hospitals to get the diagnosis. In order to educate for that, we are working for the communication activities together with them. We will enhance such activities further so that the patients have early access to this drug so that they can use our drug in an earlier phase. Through these activities, we would like to catch up the forecast of Q2, Q3. There are many activities [we are] planning, but what I mentioned is considered to be one of the largest.

Yamaguchi [Q]: You have been doing these activities from some time ago. There has been some impact of COVID-19, but you are beginning to feel some effect in your collaboration with Pfizer?

Matsui [A]: Internal assessment for these investments. And ROI within marketing mix is being seen, how effective these activities happen based on certain assumptions we are assessing.

In such an evaluation, we are finding a positive impact, so we'd like to continue to collaborate with Pfizer in this respect.

Yamaguchi [Q]: Thank you. R&D, that is one-time or temporary, but there is a bit of the gap, but more specifically, what actually happened?

Kikuoka [A]: I didn't mention clearly about that in the presentation, so please do understand the situation. As of now, what we can say is that would explain about that at an appropriate timing. Thank you very much for your understanding.

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

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

Mr. Hashiguchi, please.

Hashiguchi [Q]: Hashiguchi speaking. Thank you very much.

My first question, on page 18, ASP3082 and about this technology.

You have entered the clinical stage, but Primary Focus Candidate is still the stage for that. Why is it still a candidate? And regarding the Targeted Protein Degradation, what is going to be the possible application of this technology?

There is a circle and diamond in the figure. Any difference compared to typical small molecules? What about the features of this modality, as far as you can comment?

Kikuoka [A]: This is an early development project, Bernie. Hopefully, you will comment on this, please.

Zeiher [A]*: The question. First, I believe there are two components. The first part of the question relates to why is this a Primary Focus Candidate.

When we declare something to be a Primary Focus, it means that we have confidence in the platform and can produce multiple candidates. This is the first one, as was mentioned, using this protein degrader technology. And as we gain more confidence that we can continue to use this technology to target other proteins, we're going to consider upgrading it. It doesn't really change any individual project. It's just more of an internal decision as to at what point we develop more resources and continue to work on other proteins where it may be appropriate to pursue this technology.

The second part of your question, I think you were asking what's different about this versus a typical small molecule inhibitor. I think the main difference here, as shown on slide 18, is the fact that typically with a small molecule, you're binding to one protein, and you're usually binding in an active site or in another site that actually changes the confirmation of the protein. In this case, the molecule that we've developed has two binding sites. One of those will bind to KRAS and specifically the mutated KRAS G12D, and the other is going to bind to E3 ligase, which makes it somewhat a larger small molecule, but it is still a synthetically produced small molecule. That is the difference versus the normal approach, and by binding to that E3 ligase, it targets the protein for degradation. In that way, it's a different mechanism by which it's inhibiting KRAS because ultimately, what you're doing is removing the protein from the cell so that it can no longer contribute to the cancer phenotype.

Hashiguchi [Q]: Now the second question, that is about the promotion of Dansharism. That is one of the themes for this fiscal term. We just finished Q1, so there might be less to talk about here. But so far, what kind of experience do you have? What kind of opportunities you have? Do you see any challenges? If there is any new information, would you please share that with us?

Kikuoka [A]: Thank you very much for the question. Just like you mentioned, this is about the change of mindset. That's the starting point. Actually, employees are giving us their very positive response about the Dansharism from the individual base to function based. There are new plans for the activities in the business as well. From July 15 to August 5, Dansharism challenge program has been conducted, so we are starting activities of sharing the programs that we are going to do, we are currently doing. Each business unit group team will have opportunities for discussions. This is also called the grassroots activities, so we are trying to make rules and a new mindset.

Well, for Dansharism itself, we still create the white space for the employees through nurturing the mindset. And I would like to have the environment for innovation and improve intellectual productivity.

So, at this moment, it's very early to talk about the cost impact, but I think this is well rooted in the environment of the work for our employees. As for the grassroots activities, they're now prevailing. We are trying to avoid unnecessary process or procedures. If some voices are raised, the management needs to listen to them. This is employee-level information. But from the management and also head of things, perspective as well, we need to look at the situation where, For example, reporting is quite complicated. Like the finance and corporate planning, we are issuing multiple reports. And if there is something overlapping, we should simplify them or we reduce the time necessary for the meeting.

We would like to introduce the efficiency in corporate, and that is part of the management responsibility. So there are things that are taking place in the field or employee level, and also topline initiatives. With those in combination, we would like to continuously work on that.

Hashiguchi [M]: That's all for me as well. Thank you very much.

Ikeda [M]: Next person please. Mr. Koutani from Nomura Securities.

Kotani [M]: Kotani from Nomura Securities. I have a lot of questions. I'd like to focus on three questions. First about Xtandi.

Due to inflation, there may be some impact due to inflation. But honestly speaking, I'd like you to elaborate on that point because Johnson & Johnson is a competitor, Erleada. It's a similar drug with, there is a difference in the indication. It's performing well, and the drug price is not so much, so it should have been affected by the inflation. I wonder why Xtandi alone is affected by inflation. If you look at the prescription trend, I don't see signs of recovery. How are you judging that it's going to recover?

Looking at the end customer level, inventory, you are judging that it's recovering.

Matsui [A]: Thank you for the question. First, the impact of inflation may not be seen for other competitors. It may be seen just with Xtandi. The impact of inflation we are seeing is as follows.

In the oncology area, cancer fund. This is our guess, and we cannot say anything clear. But probably, since January this year, usually, cancer fund support could be extended to patients, but the number of such patients is decreasing, resulting in an increase in PAP according to a guess.

Koutani [Q]: Is this seen just with Xtandi?

Matsui [A]: Also with other drugs, the same thing is happening as well. As we have confirmed, PAP right now, for Johnson & Johnson drug, you took it up as an example. I haven't captured all the drug situation, but for some cancer-related drugs in Q1 calendar basis, it's increasing since January, affecting the revenue and profits.

We heard some reports by other companies as well. For us, macroeconomic aspect, from that perspective, support related to funds and the funding in the foundation is also part of the issues and PAP program by companies in order to enable access to the drugs, patients are applying for that. That's one impact.

Under these circumstances, why is access difficult? Because there are many elderly patients with prostate cancer. If the average age is 65 years old, because of their job and because of their income level, they may no longer be working.

Slight inflation of the drug price because of the increase of auto pockets can be very difficult for some patients. They want to have an option to minimize their out-of-pocket payments. That's why there's an increase in generics. That's part of the current situation.

Secondly, on what prescriptions are recovering according to analysis, it depends on which period to look at. We don't see a dramatic growth yet, so the volume is just a slight increase in trend. But in a worst-case scenario, prescriptions would not go up for a long time into the future. We don't think so. We are confirming an upward trend.

According to the data we have internally, we look at the long-term prescription patterns internally. This is how we're interpreting on our end. That's all from us.

Koutani [Q]: By the way, cancer fund, the resource for that is from donation, and inflation has a negative impact on that as well?

Matsui [A]: This is just our assumption. It's inflation, or macro economy might be the reason for that regardless of pharmaceutical companies with several reasons. The donation from various sources might have been reduced. That's what we assume, although there was no proof for that.

Koutani [Q]: Understood. The second EV-202 study, the initial topline result is available now. But I don't know if you make access or not. So how should we interpret the situation?

Those enrolled in the study have already received SOC standard of care for each cancer type. After that, that is the progress. So, ORR 20-30% is a good result. Once the result is out, again, you are going to have a placebo-controlled study as well. What's your plan for this?

Zeiher [A]*: Yes, Koutani-san. Thank you for your question about EV-202. We apologize, we don't have more data to share at this time. But please understand this is a complicated study with seven different tumor types that are being explored, and we've received topline data from two of the tumor types. Now we're analyzing

that data. We also need to consider standard of care, which you need to, every tumor type continues to evolve, and then having discussions with our partner, Seagen, on what might be the path forward or whether we would proceed with a particular tumor type.

We hope to be able to explain that in the not-too-distant future. In many cases, as you said, we will need to perform placebo or standard-of-care-controlled trial. But there may be opportunities for open-label studies to also enable us to do accelerated approval. It really just depends on the magnitude of the results and the specific tumor type. For each of these, as we gain clarity on the results and potential path, we will have appropriate disclosures and share that information with you.

That's the end of my answer.

Koutani [Q]: This is the KRAS G12D drug for ASP3082. There is high activity for KRAS G12D. So it would bind to the CTC like GTC.

Lumakras as a monotherapy is effective enough. Amgen's Lumakras has been approved.

What about ASP3082? It's a very hot mechanism, protein degradation.

Is G12D alone not enough in animal studies or is selectivity not so high, so that's why you have to do this selectively? I'd like to know why.

Zeiher [A]*: Yes. Thank you, Koutani-san, for the question. So, you mentioned KRAS is a very, well, it's a target that the industry has pursued for many years, but not with much success. Amgen and Mirati had some breakthroughs. There is a different mechanism using covalent binding at the active site. The protein degradation approach that we're taking to G12D, we think, has the potential to have monotherapy activity. Obviously, that's the thing that we are evaluating in our initial trials. Much like other KRAS programs, there may be potential to combine in the future, but we are looking at this stage for monotherapy type activity.

Company Representative [M]: Thank you very much. Next person, please. JP Morgan, Wakao-san.

Wakao [Q]: JPMorgan, Wakao. There are two questions. Xtandi, US.

We understand that the volume and price this time, it's difficult to increase the price, but the price, is it okay to understand that do you think the price increase is very difficult? In M0 CSPC, the study was successful. And if you gain the indication for that, is it possible for you to increase the price? So the price perspective, I would like to know your focus for Xtandi in the US.

And Lexiscan is suspended, and there is such a request, and what happened to that?

Ikeda: Matsui is going to answer that.

Matsui [A]: Thank you for your question Wakao-san.

The first question is about the extended price increase and the possibility of that for the future. Environment-wise, as you know, in the US, the price sensitivity is quite enhanced. Therefore, increase of the price is quite difficult. That's for sure. Having said that, the less than inflation rate level, the level of the price increase is ongoing not only with us, but other companies as well, so we are not going to deny the price increase. From the strategic perspective as well, we cannot say that we would increase, we would not increase. But from my perspective, under this current environment compared to the past years, it is difficult to increase the price. However, for the future indications, depending on the profile and also value, increase of the price is also possible even in the US market.

The second, what was your question? That is about the litigation?

Wakao [Q]: I think you requested for the suspension of Lexiscan. The result will be available around July, I believe you mentioned.

Matsui [A]: Yes, this preliminary injunction, that is actually what we've done, and the result, Forexample, the local courts, we believe that that response or the answer will be given to us from the local court. But, so far, we haven't received anything from them. Suppose that we have a negative result out of this, as has been communicated from our IR team already, we already appealed to the Federal Court, and there, the injunction request is planned to be applied. So far, that is where we are.

Wakao [Q]: So from the local court decision was communicated to you?

Matsui [A]: The answer is no for that. That's all.

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

Ikeda [M]: Next person. Mr. Sakai from Credit Suisse Securities.

Sakai [Q]: About Xtandi, I have two questions. First, about Xtandi.

At least IMS IQVIA prescription trend I see, and your quarterly data on the sales in Q1, it's difficult to link the two. This has been pointed out from before.

As Matsui-san said, the prescriptions you're checking internally. According to such trend, there is a recovery trend and also growth.

It's not captured by IQVIA for specialty retail, and the volume there still exists a lot for Xtandi.

This was mentioned from before, so I'd like to know the current status.

Matsui [A]: Thank you very much. Regarding this capturing, according to our understanding, about 30% has not been captured or grasped as of now, according to our estimation. And any impact because of this, I cannot say clearly right now.

At least, the actual demand and prescriptions, the volume is increasing. The inventory has a certain degree of impact within the normal range. The inventories are still a little less or more at the end of the term. In June, it was a little more than usual. But excessive inventory exceeding or deviating from usual, not at all, according to my understanding. Gross to Net assumptions are also changing, reflecting the environment and for prescriptions, it's not growing so much. This is below our expectations, as we explained earlier, but there is an increase. That's what we recognize.

Sakai [Q]: It is my understanding that it is from the previous quarter, the fourth quarter of the term that ended, and now the first quarter, is that the increase what you look at?

Matsui [A]: Yes. So for each quarter, we are looking at the trend, and we see the gradual trend of the recovery.

Sakai [Q]: Understood.

Another question is the question from time to term ask, it's zolbetuximab current status. Claudin 18.2, that is a biomarker.

In the US, the gastric cancer and GE junction cancer, adenocarcinoma, well, Opdivo is now approved for that indication in the US, but the competition situation is getting very severe.

Of course, there is the advantage of your product. As you've shown in page 11, the SPOTLIGHT and GLOW studies, well next year, January and March, the data will be available. I think this is the same as the previous presentation. But I believe this is basically event driven, but how do you see the outlook? I believe you have already started the educational awareness activities for Claudin 18.2. Would you please explain about the current situation?

Zeiher [A]*: First, to just provide some update on the clinical program, as you said, the SPOTLIGHT and GLOW studies are event-driven studies. We anticipate readouts from both of those in Q3 to Q4.

It's actually unusual to some extent that we will have two pivotal studies reading out very close together, and these should support global submissions, often in oncology. Well, if you're pursuing accelerated approval, sometimes there's only, or under something like a breakthrough designation, you may only have open-label data, and even if you're seeking full approval usually, you only have one pivotal study. So, this is actually a very comprehensive program. We think this should help to address many questions that could come up in gastric cancer because it's on two different chemotherapy backgrounds. We're hopeful that we're seeing very similar results and that it can offer benefit.

As you mentioned, it is a targeted therapy, which is going to be for patients with tumors that express Claudin 18.2, and there would be a companion diagnostic that would be needed to identify those patients. We think that will also be important.

Maybe Matsui-san wants to comment on any educational activities we're doing around Claudin 18.2.

Matsui [A]: Okay. On top of that, let me make just a couple of comments.

Again, because this is before the approval. So awareness activities and education activities are only what we can do. Not only commercial, but also the medical side is currently carrying out such activities.

This Claudin 18.2, the interest towards that is on the increase currently amongst the oncology field. Still, our activities haven't been full-fledged. We just partially started activities, but what we feel out of the activities done so far is that the positioning of Claudin 18.2 is on the increase among specialists, and that level is more than we expected.

That's basically the information I have. In the sense, including the result of the clinical results, and also just like Bernie commented, CDx in other words, company diagnostics, from that perspective, further education activities, awareness activities are what we would like to reinforce.

Sakai [Q]: To confirm, with the results of the two studies. If you have results just from one study, is it possible to file your submission just based on the results from one study? Is that going to be possible?

Zeiher [A]*: Yes. Thank you for the question. Yes, we do believe it's possible to file with just one positive study. Where it could have impact is, geographically, the background chemotherapy that's used in different regions is different. SPOTLIGHT uses the modified FOLFOX 6 as the backbone chemotherapy. That's more common in Western countries. The GLOW study uses CAPOX, which is more common in Asia. So, depending on which study is positive, it could influence some of the uptake, given the differences and usage of the backbone chemotherapy.

Sakai [M]: Understood, thank you very much.

Ikeda [M]: Next person, please.

Mr. Muraoka from Morgan Stanley MUFG Securities. Mr. Muraoka, please.

Muraoka [Q]: I'm Muraoka from Morgan Stanley.

I want to ask Kikuoka-san this question first. Looking at the P&L, there were a lot of elements. I understand how it was. Cost management and cost control. There are lessons learned from the January to March period. What is your personal assessment of Q1 results? Do you think you can give a full mark?

Kikuoka [A]: It's difficult to assess this myself. As I explained, excluding Forex impact, YoY, it's negative YoY. But, honestly speaking, in Q1 of the last fiscal year, the level was high. The budget is given at the CXO level and the division head level. On an individual basis, we try to have a stringent control not only myself, but also from finance, even if they hit us internally, cost ownership and financial discipline are the words we are using to promote this control.

We have to avoid any misunderstanding internally because this is the selection and concentration. As I explained during the presentation, strategic areas for the future and cost reductions into the future must be the result from the streamlining investments we have to promote. The costs, which are becoming something like a legacy, must be prevented as much as possible.

In various aspects, we have to control costs in a stringent fashion. We run multiple projects. If they can reduce the budget, the money could be used elsewhere. Before, we didn't control so strictly in some cases. So including such areas, I may be repeating myself, but if we are seen like a cost cutter, it may not work so well internally in the Company. Necessary expenses have to be spent, but we'd like to prevent unnecessary cost. We think that idea is spreading to a certain degree within the Company.

As is mentioned in the context of Apple, for the future streamlining activities like ERP investments into the future, by rolling this out globally, it's being standardized. Then, including the ease of use in each region and including education, it took time to stabilize. But finally, we have been able to do this to complete one round. This will lead to higher efficiency for sure. Given that the situation is still short in duration, I have to study and learn more by myself, but I think we achieved a certain degree of achievement.

Muraoka [Q]: Thank you very much.

And the regional sales, China, international, they made a greater growth probably due to Xtandi. Can it be explained by Forex? Or are there other factors? Just a word would be fine.

Matsui [A]: Muraoka-san, thank you so much for your question.

First of all, about China. Your question is about QoQ growth. That is better than we expected. Which way should we answer your question?

Muraoka [Q]: I ask you from both perspectives.

Matsui [A]: First of all, QoQ compared to last year Q1, the result is better. That's because in China as a whole, there are two factors.

First of all, Xtandi growth. That's one thing.

The second biggest factor for this is tacrolimus. Due to the COVID-19 impact, the end of last fiscal year, Shenyang factory is where we ship our products. There, the cluster of COVID-19 took place and the shipment became impossible, so the distributed inventory was greatly reduced. But in this fiscal year, it's recovered.

That's one factor. Also, last financial year, Q1, the VBP, volume-based procurement, in China, targeting tacrolimus, that has prevailed in health care professionals. Therefore, the inventory level was greatly suppressed, so those were the major reasons. Compared to the previous fiscal year, there was a great increase.

Against the budget this fiscal year, why the progress is better than what I've expected. Tacrolimus, this drug has just a narrow therapeutic window, and the difference between generic and original products is likely to take place. There are a lot of concerns about that from patients and health care professionals. Even after the expiration of the patent, it's still used continuously. So volume-based procurement was not covered, not really including the product.

But in the province level, rather, in order to reduce the budget, they are trying to work on the province level of VBP. The plan to do this was already opened, disclosed, and that impact was incorporated into the budget this fiscal year. But as you know, in China, the zero COVID-19 approach took place. That's why the provincial government does not have to work on this health care situation. Rather, they spend more time for COVID-19 countermeasures. What's been planned hasn't been really progressed. These factors, all in all, worked favorably for us. This is the reason why our business in China is good.

While in the international market, a big driver for this is just like you mentioned, Xtandi, and more exactly, what's good about Xtandi. Russia, For example, considering the sanction status, because uncertainty is high, they would like to supply products as much as possible. Therefore, there is a larger scale of the bid that took place in H1 of the fiscal term that had a positive impact on the shipment.

That's the biggest favorable factors for international market. That's all.

Muraoka [Q]: Understood. Thank you very much. That was quite a substantial answer. Thank you very much.

Ikeda [M]: Thank you very much. We are running over, but maybe one last person to ask questions before we close.

Mr. Ueda from Goldman Sachs Securities.

Ueda [Q]: Ueda from Goldman Stocks Securities.

Just briefly, I'd like to ask you two questions about numbers on page 4. fezolinetant increased fair value of contingent consideration for fezolinetant, which was not planned. What was the progress leading to the increased fair value of contingent consideration for fezolinetant? And second, about the elimination of unrealized profit, JPY13.3 billion on page 23. But on page four, JPY10.3 billion, so I'd like to know the difference between the two figures.

Kikuoka [A]: Regarding JPY13.6 billion, we had the filing in this period. There was a higher likelihood of the launch, so regarding the contingent consideration, there was an arrangement when we purchased this drug. Based on the calculation formula, this was remeasured.

Further increase in the fair value, they can be a little bit. But with this, we have reached almost the upper limit. Second, yes, you're right. Actually, I checked with my colleagues. On an apples to apples basis, in Q1 of FY2021, we had JPY1 billion.

How to look at the Forex was a question.

In comparison to FY2021, if you are to look at the budget rates, it's different. But because of the comparison against FY2021 to be in line in the previous quarter, in the previous Q1, we had JPY13.3 billion because of the JPY1 billion difference compared to Q1 of the previous fiscal year.

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

Thank you very much.

Ikeda: Thank you.

I'm sure that you still have questions, but its time. With this, we would like to close today's earnings calls.

Thank you very much for your participation.

[END]

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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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