



Astellas Pharma Inc.

Financial Results for the Q1 of FY2024

August 1, 2024

Event Summary

[Company Name]	Astellas Pharma Inc.	
[Company ID]	4503-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	Financial Results for the Q1 of FY2024	
[Fiscal Period]	Q1 of FY2024	
[Date]	August 1, 2024	
[Time]	16:00 – 17:20 (Total: 80 minutes, Presentation: 28 minutes, Q&A: 52 minutes)	
[Venue]	Webcast	
[Number of Speakers]	4	
	Atsushi Kitamura	Chief Financial Officer (CFO)
	Tadaaki Taniguchi	Chief Medical Officer (CMO)
	Claus Zieler	Chief Commercial Officer (CCO)
	Hinomitsu Ikeda	Chief Communications & IR Officer (CCIRO)
[Analyst Names]	Hidemaru Yamaguchi	Citigroup Global Markets
	Seiji Wakao	JPMorgan Securities
	Akinori Ueda	Goldman Sachs Securities
	Kasumi Haruta	UBS Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Kazuaki Hashiguchi	Daiwa Securities
	Shinichiro Hyogo	Mitsubishi UFJ Trust and Banking Corporation
	Miki Sogi	Sanford C. Bernstein
	Tony Ren	Macquarie Capital Securities

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptsasia.com



Presentation

Ikeda: Everyone, thank you so much for your participation in these financial results ended June 30 financial call. I'm going to serve as the moderator here for today. I'm Ikeda from Chief Communications and IR Officer.

Today, we are going to give you the presentation first that is followed by a Q&A session. The presentation material is on the website.

Including Q&A, the Japanese-English simultaneous translation is available. For the translation, the accuracy of that is not going to be guaranteed by Astellas Pharma Inc.

This material or representation by representatives for the Company and answers and the statement by representatives for the Company in the Q&A session includes the forward-looking statements based on assumptions and beliefs in light of the information currently available to management and are subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors. They contain information on pharmaceuticals, including compounds under development. But the information is not intended to make any represented issuance or advertisement regarding the efficacy or effectiveness of these variations from more than approved uses in any fashion nor provide medical advice of any kind.

Participants are Chief Financial Officer, CFO, Atsushi Kitamura; Chief Medical Officer, CMO, Tadaaki Taniguchi; Chief Commercial Officer, CCO, Claus Zieler. These three are participants from our end.

Now I would like to start the presentation. Kitamura-san, please start.

Kitamura: Hello, everyone. I'm Atsushi Kitamura from Astellas Pharma. Thank you very much for joining our FY2024 Q1 financial results announcement meeting out of your very busy schedule today.

This is a cautionary statement regarding forward-looking information. As this was explained by Ikeda earlier, I'm not going to read this page.

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



I Q1/FY2024 Consolidated Financial Results

II Initiatives for Sustainable Growth



Page three is the agenda for today.

Starting from the next page, I will explain these topics in this order.

Q1/FY2024 FINANCIAL RESULTS: OVERVIEW

Solid start toward achieving the FY2024 initial forecast*Revenue*

- **Increased YoY (+26%)**
- XTANDI: Contributed to overall growth, driven especially by the US
- Strategic Brands: Expanded to **75.0 bil. yen** in total
Robust growth of approx. **+50.0 bil. yen** YoY (**3 times** increase)

Cost items

- SG&A and R&D expenses: Invested as planned for future growth
- Timely cost management with a focus on ROI

Core Operating profit

- **Increased YoY**, with significant contributions from the expansion of XTANDI and Strategic Brands

Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA
ROI: Return On Investment



On page four, I will give you an overview of FY2024 Q1 financial results.

First, overall, we have made a solid start towards achieving the FY2024 initial forecast. In Q1, revenue increased by 26% YoY. XTANDI contributed to overall revenue growth driven especially by the US. Sales of

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Strategic Brands as a whole expanded to JPY75 billion in total, increasing three times YoY with a robust growth of about additional JPY50 billion.

SG&A and R&D expenses were invested as planned for future growth. In parallel, we executed timely cost management with a focus on ROI.

Core operating profit increased YoY with significant contributions from the expansion of XTANDI and Strategic Brands.

Q1/FY2024 FINANCIAL RESULTS

5

(billion yen)	Q1/FY23	Q1/FY24	Change	Change (%)	FY24 FCST*	FX impact (YoY)
Revenue	375.0	473.1	+98.1	+26.2%	1,650.0	+45.4
Cost of sales	68.9	91.1	+22.2	+32.2%	326.0	+6.1
SG&A expenses	168.2	206.9	+38.7	+23.0%	757.0	+20.8
US XTANDI co-pro fee	44.6	61.6	+17.0	+38.2%	189.0	+7.3
SG&A excl. the above	123.6	145.3	+21.7	+17.5%	568.0	+13.5
R&D expenses	64.6	86.8	+22.2	+34.4%	317.0	+6.9
Core operating profit**	73.3	88.3	+15.0	+20.5%	250.0	+11.6
< Full basis >						
Amortisation of intangible assets	9.1	35.0	+25.9	+285.9%		Note) Amortisation of IZERVAY's intangible assets started from Q2/FY2023
Other income	3.9	4.9	+1.0	+25.2%		Other expenses
Other expenses	23.1	10.4	-12.7	-55.0%		• Fair value increase of contingent consideration (zolbetuximab) due to FX impact: 5.5
Operating profit	45.8	50.7	+4.9	+10.6%	48.0	
Profit before tax	46.8	50.5	+3.6	+7.8%	43.0	
Profit	33.1	37.6	+4.5	+13.5%	30.0	

* Announced in Apr 2024, exchange rates of initial FY2024 FCST: 145 yen/USD, 155 yen/EUR. Actual exchange rates of Q1/FY2024: 156 yen/USD, 168 yen/EUR
 ** The definition of core-basis is changed from Q1/FY2024. In addition to the old definition's adjustments, 'Amortisation of intangible assets', 'Gain on divestiture of intangible assets' and 'Share of profit (loss) of investments accounted for using equity method' are newly excluded as new adjustment items. All figures above reflect this change.



On page five, I will explain FY2024 Q1 financial results.

Revenue reached JPY473.1 billion, up by 26.2% YoY. Core operating profit rose to JPY88.3 billion, up by 20.5% YoY. Even excluding ForEx impact, revenue and profit increased.

The bottom half of this page shows full basis results. In the right bottom of the table, we included other expenses booked in Q1. We booked JPY5.5 billion because of fair value increase of contingent consideration for zolbetuximab, mainly due to ForEx impact. As a result, operating profit was JPY50.7 billion, up by 10.6% YoY. Profit increased to JPY37.6 billion, up by 13.5% YoY.

Support

Japan 050.5212.7790
 Tollfree 0120.966.744

North America 1.800.674.8375
 Email Support support@scriptasia.com





Q1/FY2024 FINANCIAL RESULTS: XTANDI AND STRATEGIC BRANDS

6

XTANDI contributed to overall growth, driven especially by the US

(billion yen)	Q1/FY2024 Act	YoY	FY2024 FCST [*]	
 Xtandi	224.2	+50.2 (+29%)	757.0	<ul style="list-style-type: none"> ✓ Global sales off to a strong start, driven by higher-than-expected US performance ✓ US: Demand exceeded expectations, driven by the impact of EMBARK (M0 CSPC) and market growth

*Strategic Brands expanded to **75.0 bil. yen** in total. Robust growth of ~ **+50.0 bil. yen** YoY (**3 times** increase)*

(billion yen)	Q1/FY2024 Act	YoY	FY2024 FCST [*]	
 PADCEV	38.4	+23.2 (+152%)	151.2	<ul style="list-style-type: none"> ✓ Significant growth YoY, driven by the penetration of 1L mUC in the US and strong demand growth of 2L+ mUC in EST ✓ Continued quarterly growth expected from Q2 onwards
 izervay	12.7	+12.7	46.4	<ul style="list-style-type: none"> ✓ Demand growth stronger-than-expected following the effective J-Code in April ✓ Safety profile remains consistent with clinical trial results ✓ Q1 results exceeded expectations; raising prospects for outperforming the initial forecast
 VEOZAH	6.6	+6.0 (+972%)	28.3	<ul style="list-style-type: none"> ✓ Steady growth in line with initial forecast ✓ Overall initiatives progressing as planned, such as payer coverage and DTC
 VYLOY	0.3	+0.3	3.7	<ul style="list-style-type: none"> ✓ Successful Japan launch (June), accessed vast majority of target physicians ✓ Solid progress in available accounts for VYLOY and CLDN18.2 testing penetration
 XOSPATA	17.3	+4.3 (+33%)	60.0	<ul style="list-style-type: none"> ✓ Sales expanded in all regions ✓ Continued steady growth expected from Q2 onwards

*Announced in Apr 2024, exchange rates of initial FY2024 FCST: 145 yen/USD, 155 yen/EUR. Actual exchange rates of Q1/FY2024: 156 yen/USD, 168 yen/EUR
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, 1L: First line, mUC: Metastatic urothelial cancer, 2L+: Second or later line, DTC: Direct-to-consumer, CLDN18.2: Claudin 18.2, VEOZAH: Approved as "VEOZA" in ex-US, EST (Established Markets): Europe, Canada, etc.



On page six, I will explain FY2024 Q1 results of XTANDI and Strategic Brands.

First, about XTANDI. Global sales increased to JPY224.2 billion, up by JPY50.2 billion or 29% YoY. Even excluding ForEx impact, XTANDI achieved about 16% growth. Global sales were off to a strong start driven by higher-than-expected US performance, in particular.

In the US, which has contributed the most to the overall sales expansion, in addition to the growth of the market as a whole, the penetration of the additional indication of M0 CSPC approved in November last year, based on EMBARK study and its ripple effects on other indications have made great contributions, so demand exceeded expectations. In ex-US regions, demand was as expected or exceeded expectations.

Sales of Strategic Brands supporting our future growth, namely PADCEV, IZERVAY, VEOZAH, VYLOY, and XOSPATA expanded to JPY75 billion in total, increasing three times YoY with a robust growth of additional JPY50 billion approximately.

PADCEV global sales increased to JPY38.4 billion, up by JPY23.2 billion, expanding substantially with a growth of 152%.

As for IZERVAY, Q1 sales were JPY12.7 billion, exceeding expectations. Demand growth was stronger than expected. Following J-Code in April, in particular. Increased confidence in the safety profile has also contributed to sales expansion.

Global sales of VEOZAH reached JPY6.6 billion, making a steady growth in line with the initial forecast. Overall initiatives have progressed as planned, such as payer coverage and DTC efforts.

PADCEV, IZERVAY, and VEOZAH will be explained later in detail.

VYLOY was launched successfully in Japan in June. In just two weeks after its launch, we accessed vast majority of target physicians. Information provision to physicians is making steady progress. There is a solid progress in available accounts for VYLOY, including 18.2 testing penetration. We will focus on the penetration also in

Support

Japan	050.5212.7790	North America	1.800.674.8375
Tollfree	0120.966.744	Email Support	support@scriptsasias.com



Q2 and beyond. In the US, Established Markets, international market, and China, we are anticipating approval sequentially from Q2 onwards. We are expecting sales contribution after approval.

Regarding XOSPATA, global sales increased to JPY17.3 billion, up by 33% YoY. Sales expanded in all regions. Continued steady growth is expected from Q2 onwards as well.

PADCEV & VEOZAH: BUSINESS UPDATE

7

PADCEV Robust sales growth driven by the US and EST. Expect further sales contribution going forward

	Q1/FY2024 Act	YoY
Global sales	38.4 bil. yen	+23.2 (+152%)
US (\$ basis)	\$174M	+98 (+128%)
EST (€ basis)	€45M	+29 (+178%)
Japan·China·INT	3.7 bil.yen	+1.4 (+60%)

QoQ (vs. Q4/FY2023): **+8.6 bil. yen (+29%)**

<US>

- ✓ Significant contribution from 1L mUC share expansion
New patient share of over 50%

<ex-US>

- ✓ Strong demand growth in 2L+ mUC, especially in EST
- ✓ Launched countries increased to 38, with reimbursement initiated in 17 countries
- ✓ Anticipate potential approval for 1L mUC sequentially from Q2 onwards, expect sales contribution after approval

VEOZAH Steady sales growth as expected. Expect continued linear growth from Q2 onwards

	Q1/FY2024 Act	YoY
Global Sales	6.6 bil. yen	+6.0 (+97%)
US (\$ basis)	\$39M	+35 (+77%)
EST (€ basis)	€3M	+3

QoQ (vs. Q4/FY2023): **+2.9 bil. yen (+77%)**

<US>

- ✓ Commercial lives covered (payer coverage) expanded to over 60% as planned
- ✓ Implementing DTC with a focus on ROI, steady increase in patient activation

<ex-US>

- ✓ Launched countries increased to 13 (+5 countries from previous quarter)

1L: First line, mUC: Metastatic urothelial cancer, 2L+: Second or later line, DTC: Direct-to-consumer, ROI: Return On Investment
VEOZAH: Approved as "VEOZA" in ex-US, EST (Established Markets): Europe, Canada, etc., China: China, Hong Kong
INT (International Markets): Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Korea, Taiwan, Australia, Export sales, etc.



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

PADCEV achieved robust sales growth in all regions, driven by the US and Established Markets, in particular. Sales grew by JPY8.6 billion, just in three months from the previous quarter. Quarterly growth rate is also making a solid progress.

In the US, sales increased by about USD100 million YoY on a local currency basis, growing at 128%. Thanks to the penetration of EV-302 study data with extremely favorable results presented at ESMO last year, first-line share expanded and contributed to sales growth. New patient share in the first-line settings is over 50%. We believe it's establishing its position as standard of care.

In ex-US regions, demand grew strongly in the second-line settings and beyond. Especially Established Markets had a strong growth rate of 178% on a local currency basis. Outside of the US, launched countries increased to 38 with reimbursement initiated in 17 countries.

Regarding the additional first-line indication in Europe, CHMP adopted the positive opinion in July and approval is expected by October.

Also in Japan, we are anticipating approval within Q3. We are expecting contribution to sales after the respective approval.

In addition, in China, approval of the indication in [inaudible] is anticipated by the end of Q2. If approved, it's going to be a new launch in China.

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



For PADCEV, as countries with first-line approval, our new launched countries are increasing outside of the US. In addition to the growth in the US, we're expecting further sales expansion.

With regards to VEOZAH, global sales grew steadily, mainly in the US. In the three months from the previous quarter, global sales increased by JPY2.9 billion with a linear growth in line with the initial forecast.

In the US, payor coverage expanded as expected from 50% as of the end of March to over 60% as of the end of June. HCP's perception of VEOZAH market access is gradually improving, thanks to the promotion of education activities with direct information provision by field sales force and digital channels.

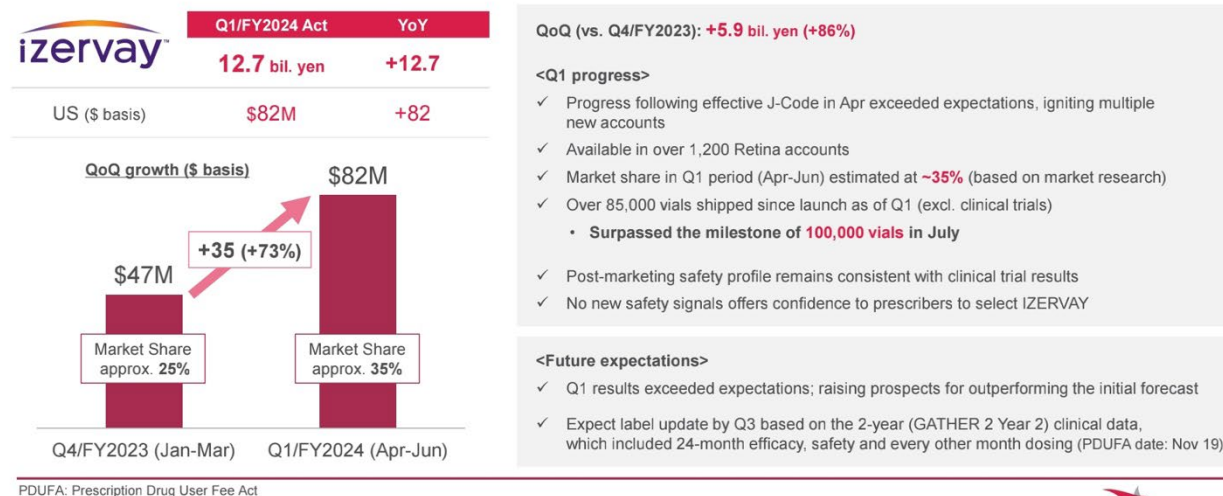
As for DTC efforts, as was shown at the beginning of the year, initiatives with low ROI are being reduced to stock so that we can invest with a focus on high ROI initiatives. We are trying to optimize DTC at any time. We believe we can aim to achieve profit early by continuing to promote initiatives with a focus on ROI. Partly due to the effectiveness of our DTC efforts, we are observing enhanced patient activation as well. According to market research results, we were able to confirm that the proportion of women who reported high intent to ask HCPs about VEOZAH has risen.

Outside the US, launched countries increased to 13, and we are expecting contribution to sales growth going forward. For VEOZAH, we are anticipating continued linear growth from Q2 onwards by promoting payor coverage and DTC steadily, mainly in the US.

IZERVAY: BUSINESS UPDATE (US)

8

*Performance exceeded expectations, particularly driven by stronger-than-expected demand following J-Code
Prescriber perception of safety profile is favorable*



On page eight, I will explain the business update for IZERVAY in the US.

IZERVAY performance exceeded expectations with sales expansion, particularly driven by the J-Code and its safety profile. Sales increased to USD82 million, up by USD35 million or 73% in just three months from the previous quarter. It's growing at the speed higher than expected. Demand following effective J-Code in April exceeded expectations, igniting multiple new accounts. As of the end of June, IZERVAY is available in the 1,200 Retina accounts. Market share in the previous quarter was about 25%, but based on market research, market share is estimated to have expanded to about 35% in Q1, between April and June. Given the fact that the

Support

Japan	050.5212.7790	North America	1.800.674.8375
Tollfree	0120.966.744	Email Support	support@scriptasia.com



competitor product was launched about six months earlier, we think that the number of new patients is increasing steadily.

As for ASRS or the American Society of Retina Specialists, it's the world's largest academic society organization for retina specialists. Its annual meeting was held last month in Stockholm. The society surveyed more than 1,000 specialists on their selection of treatment. The survey results that were made public showed a higher utilization of IZERVAY-only over the competitor product only in clinical practice. Achieving these results in a third-party survey is further deepening our confidence in the competitiveness of IZERVAY.

By the end of June, over 85,000 vials have been shipped since launch. Furthermore, in July, the number of vials increased steadily and surpassed the milestone of 100,000 vials last week.

Post-marketing safety profile remains consistent with clinical trial results. No new safety signals were observed. This offers higher confidence to prescribers to select IZERVAY according to market research results.

As for future expectations, Q1 made good progress raising prospects for outperforming the initial forecast. On the other hand, we need to recognize that this is just the progress in the three months. We will consider reviewing our forecast based on the future progress and the latest outlook.

We are expecting label update by Q3 based on the two-year clinical study data, which includes 24 months efficacy, safety, and every other month dosing data. IZERVAY has continued to make good progress since launch in the US in September last year. We're expecting further sales expansion as a growth driver going forward as well.

Q1/FY2024 FINANCIAL RESULTS: COST ITEMS

9

- SG&A and R&D expenses: Invested as planned for future growth
- Timely cost management with a focus on ROI (mainly VEOZAH)

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

Cost Items	YoY change	Ratio to Revenue	(billion yen)
Cost of sales	+32.2%	19.3% (+0.9 ppt YoY)	YoY increase due to one-off factors including provision for US mirabegron inventory disposal and royalty payment adjustment
SG&A expenses excl. US XTANDI co-pro fee	+17.5% (+6.6% excl. FX impact)	30.7% (-2.3 ppt YoY)	YoY increase excl. FX impact: approx. +8.0 ✓ Strategic Brands-related expenses (mainly IZERVAY and VEOZAH) (approx. +12.0 YoY) ✓ Reduction of mature products-related expenses (approx. -4.0 YoY) ✓ Global organizational restructuring in FY2023 (approx. -2.0 YoY)
R&D expenses	+34.4% (+23.6% excl. FX impact)	18.4% (+1.1 ppt YoY)	YoY increase excl. FX impact: approx. +15.0 ✓ Primary Focus and enhanced R&D functions (approx. +7.0 YoY) ✓ One-time co-development cost payments

VEOZAH: Approved as "VEOZA" in ex-US
ROI: Return On Investment



On page nine, I will explain the cost items.

As shown at the top row of the table, the cost of sales ratio to revenue is 19.3%. This is 0.9 percentage points increase YoY because of one-off factors, including provision for US mirabegron inventory disposal due to generic entry and the royalty payment adjustment.

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



The SG&A expenses, excluding US XTANDI co-promotion fee increased 17.5% YoY. Excluding the ForEx impact, it increased to 6.6% or about JPY8 billion. This is mainly due to a YoY increase of about JPY12 billion in promotional expenses for Strategic Brands, mainly IZERVAY and VEOZAH. The acquisition of Iveric Bio had not been completed at the YoY time point, and therefore, the costs related to IZERVAY had not been booked, which leads to this increase.

On the other hand, mature products-related expenses such as mirabegron, decreased by about JPY4 billion YoY. And the global organizational restructuring in 2023 resulted in a decrease of SG&A expenses about JPY2 billion year.

While investing as planned for future growth, we also revisited investments with a focus on ROI and managed expenses in a timely manner. As a result, the shift to the growth phase, the SG&A to revenue ratio decreased by 2.3 percentage points YoY.

R&D expenses increased 34.4% YoY. Excluding the ForEx impact, it increased by 23.6% or about JPY15 billion. Also, mainly due to investments to strengthen the primary focus and R&D functions, it increased about JPY7 billion YoY. The booking of onetime co-development cost payments is another factor of this increase. This impact has already been factored in our initial forecast and our R&D expenses have been expected.

I'll now explain the new initiatives for sustainable growth.

XTANDI AND STRATEGIC BRANDS: FY2024 KEY EXPECTED EVENTS

(Blue: Updates since the last financial results announcement)

11

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)
enzalutamide/ XTANDI		★ Jun Approval (M1 CSPC; China)		
enfortumab vedotin/ PADCEV		★ Jul CHMP positive opinion (1L mUC; Europe) NMPA Decision (2L+ mUC; China)	MHLW Decision (1L mUC; Japan)	
zolbetuximab/ VYLOY	★ May Resubmission acknowledgment (US)	★ Jul CHMP positive opinion (Europe)	PDUFA date (US) Nov	NMPA Decision (China) TLR* (Pancreatic)
avacincaptad pegol/ IZERVAY			PDUFA date (Label update; US) Nov EC Decision (Europe)	

▶ Regulatory decision
▶ Regulatory submission
▶ Data readout

<Other updates>
 ● zolbetuximab / VYLOY: Phase 3 study in combination with checkpoint inhibitor and chemotherapy to start in 1H/CY2025

As of Jul 2024. *The timeline of TLR is subject to shift due to its event-driven nature. M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CHMP: Committee for Medicinal Products for Human Use, 1L: First line, mUC: Metastatic urothelial cancer, NMPA: National Medical Products Administration, 2L+: Second or later line, MHLW: Ministry of Health, Labour and Welfare, PDUFA: Prescription Drug User Fee Act, TLR: Topline results, EC: European Commission



The progress of key expected events in FY2024 with respect to XTANDI and the Strategic Brands are described here on page 11.

The update since the last financial results announcement is indicated in blue. XTANDI was approved in China in June for the additional indication of M1 CSPC, metastatic castration-sensitive prostate cancer, based on the China ARCHES study.

As for PADCEV, for the additional indication of first-line locally advanced or metastatic urothelial carcinoma, the CHMP adopted the positive payment based on the EV-302 study, that is, in July.

Support

Japan	050.5212.7790	North America	1.800.674.8375
Tollfree	0120.966.744	Email Support	support@scriptasia.com



VYLOY will be explained on the next slide.

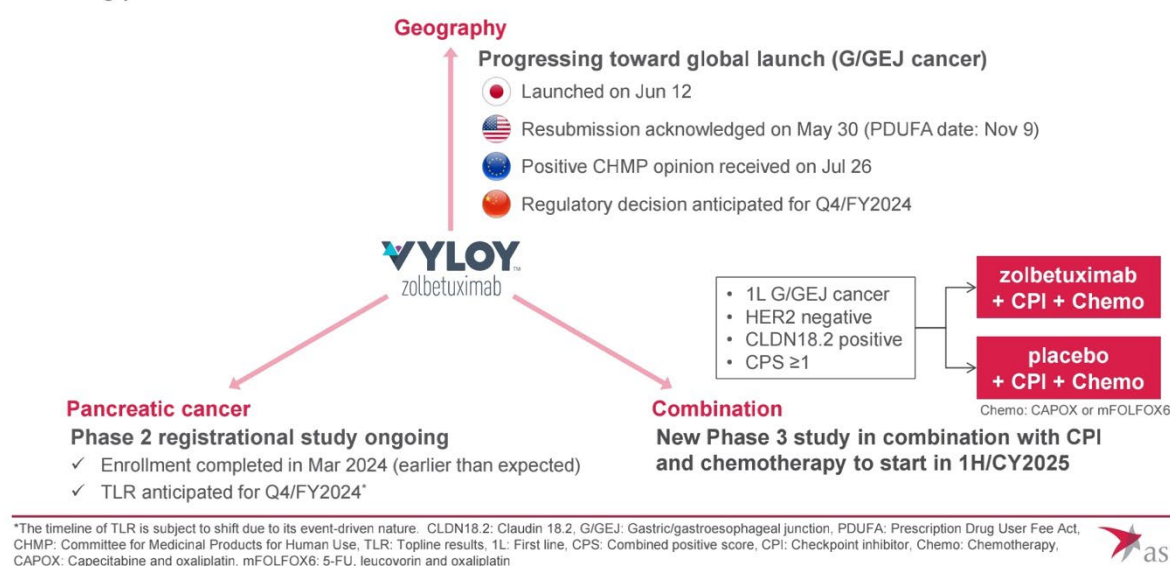
Now, there are no major updates on IZERVAY in the past three months and the regulatory review of the US label update and the application in EU is still ongoing.

For the EU regulatory submission, we received a Day 180 list of questions from the CHMP in Q1 following the standard timeline. We will continue to communicate with the authorities for the approval and will update you with the results when we receive the CHMP's opinion.

ZOLBETUXIMAB / VYLOY: LATEST STATUS

12

Pursuing product value maximization as the first-in-class anti-CLDN18.2 treatment



On page 12, I will explain the latest status of VYLOY.

We are actively pursuing life cycle management initiatives to maximize the value of VYLOY as a first-in-class anti-Claudin 18.2 antibody. First, we are progressing toward the global launch of VYLOY for geographic expansion.

In Japan, VYLOY was launched on June 12.

In the US, we resubmitted the application after receiving the complete response letter from the FDA in January. The submission was acknowledged on May 30 and the PDUFA date was set as November 9.

Regarding EU, the positive CHMP opinion was adopted on July 26, and the approval is expected by October.

In China, the review of the dossier is still ongoing, and the regulatory decision is anticipated in Q4.

Left bottom of the slide, the Phase II registrational study for the pancreatic adenocarcinoma is ongoing. The patient enrollment was completed in March, earlier than expected. And the top-line result is anticipated in Q4.

As shown in the lower righthand corner of the slide, we have also decided to conduct a new Phase III trial in combination with the CPI or immune checkpoint inhibitors and chemotherapy. In the study for the first-line treatment of gastric cancer in patients with HER2-negative Claudin 18.2 positive, CPS 1 or higher, the efficacy

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com

 **SCRIPTS**
Asia's Meetings, Globally

and safety of zolbetuximab or placebo in combination with immune checkpoint inhibitors and chemotherapy will be evaluated. The study is scheduled to start in H1 of calendar year 2025.

VYLOY is currently approved for the combination with chemotherapy in Claudin 18.2 positive gastric cancer. In addition to this, we expect to make further contributions to the treatment of gastric cancer with high unmet medical needs by referring combination with an immune checkpoint inhibitor as a new treatment option for patients with a high CPS.

PROGRESS IN FOCUS AREA APPROACH: CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

(Blue: Updates since the last financial results announcement)

13

Primary Focus	Biology/Modality/Technology	Project	Mechanism of Action	Current status
Immuno-Oncology	Checkpoint	ASP1570	DGK ζ inhibitor	Phase 1 study ongoing. Initial data to be presented at ESMO in Sep 2024
	Bispecific immune cell engager	ASP2138	Anti-Claudin 18.2 and anti-CD3	Phase 1 study ongoing. Orphan drug designation granted by FDA in Jun 2024 (pancreatic cancer)
		ASP1002	Anti-Claudin 4 and anti-CD137	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	FSFT in Phase 1 study in May 2024
	Cancer cell therapy	ASP2802	CD20 convertible CAR-T (autologous)	Phase 1 study under preparation to start in Q2/FY2024
Targeted Protein Degradation	Protein degradation	ASP3082	KRAS G12D degrader	Phase 1 study ongoing. dose expansion initiated. Initial data to be presented at ESMO in Sep 2024
		ASP4396	KRAS G12D degrader	Phase 1 study ongoing
Genetic Regulation	Gene replacement (AAV)	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	GAA gene	Phase 1 study ongoing
		ASP2016	FXN gene	Phase 1 study under preparation to start in Q3/FY2024
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells	Phase 1b study ongoing
Immune Homeostasis (PF Candidate)	Immune modulation	ASP5502	STING inhibitor	Phase 1 study under preparation to start in Q2/FY2024
Others (Non-PF)	Long-acting abiraterone prodrug	PRL-02	CYP17 lyase inhibitor	Phase 1 study ongoing

DGK: Diacylglycerol kinase, ESMO: European Society for Medical Oncology, FDA: Food and Drug Administration, IL-2: Interleukin-2, FSFT: First subject first treatment, CAR: Chimeric antigen receptor, KRAS: Kirsten rat sarcoma viral oncogene homologue, AAV: Adeno-associated virus, MTM1: Myotubularin 1, GAA: Acid alpha-glucosidase, FXN: Frataxin, RPE: Retinal pigment epithelium, PF: Primary Focus, STING: Stimulator of interferon genes



Please refer to page 13. Next is progress in Focus Area Approach. Projects in the clinical trial stage with updates since the last financial announcement are shown in blue.

First, ASP1570 immuno-oncology in the primary focus. An application of the poster presentation in September was accepted by ESMO for the poster presentation with all new data, including part of the ongoing Phase I study.

ASP2138 was granted with orphan drug designation for pancreatic cancer from the FDA in June.

For ASP1002, we published the information that this is a bispecific antibody targeting Claudin 4 and CD137. Claudin 4 is known to be highly expressed in various types of cancer. CD137 is expressed on the surface of activated T cells. We hypothesized that ASP1002 will enhance the antitumor response of T cells by binding CD137 positive T cells to Claudin 4 positive cancer cells.

The first patient dose of ASP1012 was achieved in May.

ASP3082 is a targeted protein degradation. Based on data update and a monotherapy dose escalation cohort of the Phase I study, a dose expansion cohort was started. A presentation on the initial data from the Phase I study was accepted for oral presentation at ESMO. We are considering holding a briefing session on the presented data after the conference. We will inform you of the details as soon as they are finalized.

ASP5502, our primary focused candidate for immune homeostasis has entered a clinical development phase. ASP5502 is a low molecule weight STING inhibitor that is expected to improve the symptoms of chronic

Support

Japan	050.5212.7790	North America	1.800.674.8375
Tollfree	0120.966.744	Email Support	support@scriptasia.com

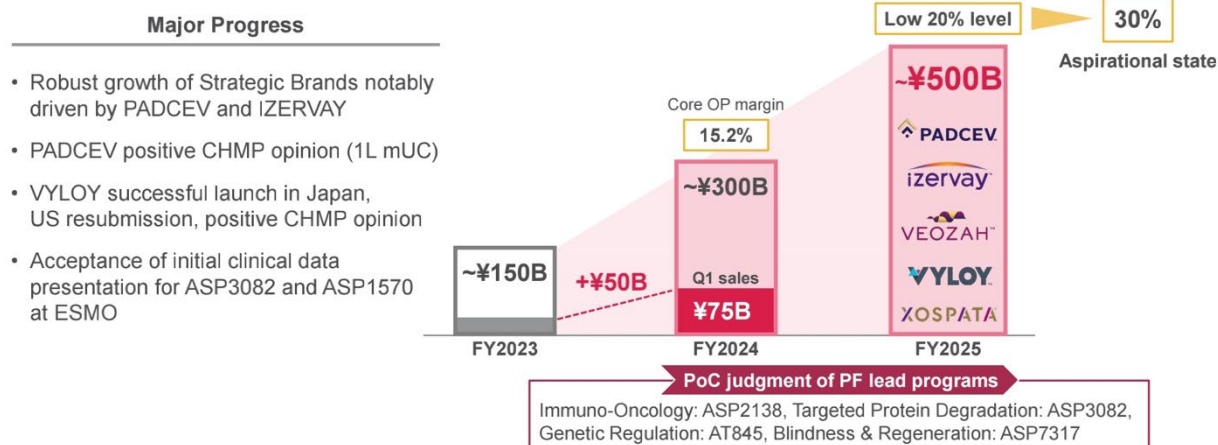


autoimmune diseases by modulating the immune response pathway involving STING. We plan to conduct clinical trials first, for primary Sjogren syndrome.

Q1/FY2024 PROGRESS

14

Solid start toward achieving the FY2024 initial forecast



CHMP: Committee for Medicinal Products for Human Use, 1L: First line, mUC: Metastatic urothelial cancer, ESMO: European Society for Medical Oncology, PoC: Proof of concept, PF: Primary Focus



The last slide on page 14 summarizes our progress in Q1 FY2024.

As shown on the left side of the slide, our Strategic Brands grew strongly, notably driven by PADCEV and IZERVAY. We also achieved several regulatory milestones for PADCEV and VYLOY. The Focus Area Approach program also progressed with early clinical data from ASP3082 and ASP1570 accepted for presentation at ESMO. We will continue to accumulate data to judge POCs and build a pipeline that will allow us for sustainable growth.

As shown in the figure on the right, we expect total sales of Strategic Brands to grow to approximately JPY300 billion in FY2024 and JPY500 billion in FY2025. In Q1, total sales increased by about JPY50 billion YoY to JPY75 billion, and we are making steady progress while achieving this goal.

Overall, Q1 FY2024 was a quarter in which Strategic Brands moved into a growth phase and the Focus Area program made progress toward the judgment of POC.

We are off to a solid start toward achieving our full-year focus set at the beginning of the fiscal year. We will continue to make steady progress in Q2 and beyond, with a focus on achieving our goals.

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

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Question & Answer

Ikeda [M]: That's all for our presentation. We're going to entertain your questions. Anyone with questions? Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [Q]: Yamaguchi from Citigroup. First, the results. The revenue in Q1, XTANDI, IZERVAY, as of now, exceeded the forecast. Regarding these two products, there can be an upside exceeding the expectations. Is my understanding correct for these products?

Ikeda [M]: Yamaguchi-san, thank you very much. Kitamura would like to respond.

Kitamura [A]: First of all, if you look at the results of Q1, XTANDI and IZERVAY progressed very strongly, higher than expected. Yes, that's true.

Yamaguchi [Q]: And going forward, listening to your presentation, there's going to be no element for the sales to decline, but IRA may affect XTANDI?

Kitamura [A]: Regarding XTANDI, Medicare Part D could have an impact from Q4. We are expecting some decline. According to original assumption, that is already factored into our plan.

Yamaguchi [Q]: IZERVAY does not have any factors for decline, right?

Kitamura [A]: It's growing very strongly right now. How far can it go? In Q2 and beyond, we'd like to examine the details so that we can report to you.

Yamaguchi [Q]: Understood. My second question is about IZERVAY. I understand it may be difficult for you to comment, but this is a great opportunity. In Europe, Day 180 list of questions was sent to you. After you respond, then there's going to be the remaining 30 days to be addressed. But on your side, whether you have submitted your questions or responses or not, so it's just the timing to wait for the response to the European authorities. What's the current situation or the potential news?

Kitamura [A]: Regarding the IZERVAY approval in Europe, of course, we can share some and there is something we cannot share, but CMO can comment.

Taniguchi [A]: I'd like to talk about the current status of our submission in Europe. Based on the standard timeline, in Q1 from CHMP, we received a list of Day 180 questions. Currently, at the Company, our team is addressing this towards an early approval. We are making utmost efforts towards that goal. Right now, there is no change from before. In Europe, the final decision would be in H2 this year. We will do our best. We are doing our best to promote or development.

Yamaguchi [Q]: Later this year, okay. It may be difficult for you to comment whether you have submitted your responses or not.

Taniguchi [A]: Today, we'd like to refrain from commenting on that today.

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

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

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Wakao [Q]: Thank you very much. Wakao speaking. Thank you very much for the presentation. I also would like to ask you questions about IZERVAY. It's doing very well, USD400 million or more on a full-year basis, so it can be great according to my impression. Feedback from physicians was explained, but I'd like to know more details. The key is that there's no new safety signals. Confidence has been enhanced resulting in the selection of IZERVAY, not SYFOVRE. No new safety signals being observed, and they are selecting IZERVAY because SYFOVRE had issues initially. There is a negative impression on SYFOVRE, but for IZERVAY, there's almost no issue or problem. That is leading to their confidence. Is my understanding correct? I'd like to know the meaning here more deeply.

Kitamura [A]: Thank you for the question. That is about the safety profile of IZERVAY, I believe. I'm going to make an answer for that and if it is necessary, Claus or Taniguchi are going to follow up.

First of all, towards the end of June 85,000 vials and at the end of July, 100,000 vials that we've already achieved for the shipment. The new information about the safety profile, that is now taking place, retina inflammation, for example. Well, there is one report on off label usage of the drug that we've recognized, but that is the only one. There was no new safety-related information that came up. The data we gained from the clinical trial is also possible to be clearly applied to the real world as well according to the kind of situation. The specialists also recognize the benefit of this drug. That's why they make such a favorable comment of this product in the Society Congress. Is there any supplement additional comment, Claus?

Zieler [A]*: Thank you, Atsushi, and thank you for your question. There are really two factors driving IZERVAY growth. One, as you're aware, we got the J-Code, the permanent J-Code in April. And we clearly see a drop as a result of essentially that reimbursement modality coming into place. But the other factor is exactly as you and Atsushi said. It's the confidence in the medication based on the volume that has now been used in the market. With 100,000 vials shipped as of the end of July and a consistent safety profile with label, the confidence of the retina specialist community is quite strong. And we see that in the survey results that Atsushi mentioned. But I also see that anecdotally when I talk to doctors. There's a very clear signal from the retina community saying, "You have had no additional safety signals. Your volume is now at a level where we think this is a relevant data point that we take into consideration when we make our choice of drug."

Wakao [Q]: Compared to SYFOVRE, the confidence or trust of this drug is enhanced. Is that what you mean? Because there are only two drugs available for this class. Are you talking about IZERVAY alone or are you comparing IZERVAY with SYFOVRE when you talk about the increase of the trust?

Zieler [A]*: Yes. I usually don't want to talk about my competitors, so I'll leave that to others to do that for them. I can only tell you that when we ask doctors, of course, doctors compare. And we have several data points. We have data points from chart reviews. We have data points from the survey that Atsushi mentioned, which indicate to us that when we asked the question in new patients, "Which drug do you choose?", when we ask doctors that, we believe the data points show that we have a majority of patients being put on IZERVAY. I think that's a very strong statement of confidence in our product.

Wakao [Q]: Target share is already close to 40% of the target as of the end of this fiscal year. But considering this trend, to what extent is this market share going up that you expect?

Kitamura [A]: Thank you for the question. Yes, we see the strong growth of IZERVAY, which is a fact. To what extent can we grow? That is what we can learn in Q2 and afterwards, and we would like to update you around that time.

Wakao [Q]: Understood. Thank you. Another one, mirabegron. Looking at your number and looking at the prescription trend, the generic is not really increased in prescription. Q1 sales so far is better than you've expected, basically, I believe. What is the current status of mirabegron sales? Why is the generic not so much increased for the usage? Thank you.

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Kitamura [A]: Mirabegron generics and their impact regionally, compared to our assumptions, the decline is larger. That's a fact. If there were litigations, including suspension, we took a variety of action. And as of now, generic manufacturers, two of them just entered the market. In that sense, we were expecting a decline, and there is some impact already, but the decline, compared to our initial assumptions, is larger. That's a fact.

Wakao [Q]: Growth, any additional comment from your side?

Zieler [A]*: Yes. Thank you, Atsushi. You have to imagine the entry of generics in two stages. One, as Atsushi said, we have two generics on the market right now. That creates a certain level of competition. But we also know that a number of additional generics have filed with the FDA. And when they get approval—and you know approval times for generics are usually 90 days. Right? So, when they get approval, you have a number of additional competitors entering the market, and that really affects the dynamics of the market. We are expecting that to happen in the next quarter.

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

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

Ueda [Q]: Ueda from Goldman Sachs Securities. My first question is about XTANDI. I have a question on the XTANDI trend. Just looking at the numbers, there seems to be an acceleration once again. Now, there is an additional indication. Is that the only factor, the additional indication or the inventory level? And the price, is there any special factors behind?

Kitamura [A]: Mr. Ueda, thank you for your question. Why is XTANDI performing well? As you pointed out, there are two major factors behind. First, the entire market is growing, that's one thing. And also, in addition, because of EMBARK study, last year, in November, we got the indication and XTANDI grew a lot since. For other cases, there can be halo effects to other indications. And overall, it's increasing. It's not about a onetime inventory adjustment, but rather, this is a trend which is happening right now.

Do you have any additional comment, please?

Zieler [A]*: Thank you for the question. Exactly right, as Atsushi said, there are two major factors. I think I told you in the Q4 call, last quarter, I told you that the volume growth of this market is quite significant. We're seeing a 16% volume growth in the market as a whole, which, given the maturity of the market, it's quite exceptional to have a market growing at that clip with the class of products being more than 10 years on the market. That's one factor. We have a strong underlying growth rate in the market.

But XTANDI with the EMBARK data is really keeping its share, which again, we've been—we launched 2012, and there are generic options for abiraterone available on this market. Again, this is quite a remarkable performance of XTANDI within this market to be so competitive. And that is due to the EMARK data. Those are the two factors driving the XTANDI performance.

Ueda [Q]: Thank you very much. My second question is about VEOZAH trend. In particular, doctors who have used VEOZAH as well as the feedback from patients, I'd like to hear safety, efficacy, and the onset of efficacy, and the convenience. What kind of feedback have you received? I'm sure you have accumulated such feedback from physicians. Insurance payor coverage is not sufficient according to physicians before. The coverage is expanding and increasing, so is the assessment or perception changing?

Kitamura [M]: Thank you very much. VEOZAH and the actual feedback from HCPs. Right? We'd like to ask Claus to explain. Claus, please?

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Zieler [A]*: Yes. The feedback from doctors and from patients is very positive because the drug works according to this feedback and the drug works quickly, and it does alleviate the symptoms it is designed to treat. In that context, we have very good feedback from both the patient side and the HCP side on VEOZAH.

As we described before, the major hurdle that HCPs have told us in market research has been their struggle with the coverage. Now, as you know, the coverage is improving, from 50% end of last quarter to more than 60%, which is very much in line with our projections. And HCP feedback is also starting to improve. It's not a category jump, that's not dramatic, but we can see in the market that HCPs are starting to recognize that, oh, yes, coverage is improving. And we do get more writers and we do get more pull-through when our sales force sits down with the physicians and especially with the physician staff to explain which payor now has coverage and how to fill out the forms and go about that.

I think we're making good progress there, and we are on track to achieve the 80% coverage and then getting to that recognition in the market at the end of the year.

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

Ikeda [M]: Next UBS, Ms. Haruta, please.

Haruta [Q]: Haruta from UBS. First question is about VEOZAH. When do you think or when are you targeting to achieve breakeven? According to the past example, JPY50 billion sales timing is what you suggested about the time of the breakeven. But still, in the face of the expansion of the recognition of this drug and still in the timing of investment, that you've focused on ROI, you mentioned, but with this point, what kind of view do you have? Would you please share your focus within these one or two years?

Kitamura [A]: Ms. Haruta, thank you very much. First, it's about VEOZAH. We have strong confidence in it. The end of last year, we did some revision and revised the peak sales, that is what we are aiming to achieve. And we do our best for that. The purpose is not shrinking investment. Cost benefit is also what we are aiming at. When we can achieve breakeven, please wait a little bit more. Currently, ROI analysis is ongoing based upon our new approaches. And based upon that, we will look at H2 plan.

PDCA is always ongoing for us. A little later, we can show you probably the timing of the breakeven as well. We need to do a little—we need to have a little more time for the further analysis. This might be the repetition. Our purpose is not reducing the spend of our investment VEOZAH peak sales. In order to achieve that as early as possible, we are going to wisely use our money. We need a little more time to evaluate this.

Haruta [Q]: Thank you. And that cost/benefit, for example, what kind of indicators are you referring to?

Kitamura [A]: Well, VEOZAH's sales looking to the details, what would be the key parameters? For that purpose, we set up various parameters, and we are having the DTC activities and which activities lead to the increase of KPI. That kind of approaches, which is quite standardized, I believe, are currently what we are doing.

Haruta [Q]: Understood. Thank you very much. Second question is about IZERVAY. The number of vials and also the sales, with a simple calculation if I do, then gross to net is not so much discounted I feel, but appropriate price maintenance is important. But since the launch, how do you view about the gross to net changes? What's the trend of that? And for further increase of the market share, this growth to net focus, do you have any?

Kitamura [A]: Thank you very much for your question. First of all, IZERVAY pricing strategy, that is not going to be disclosed. That's a principle for us. I rather would like to refrain myself from talking about the details. It's not something like that we are selling it with a large amount of the discount. I sustain.

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



As mentioned by Claus, the current expansion is the effectiveness of J-Code and the safety profile data and also because this is a new treatment, so the educational activities, that is also the fact as well this growth.

Haruta [Q]: So, we can assume the appropriate pricing?

Kitamura [A]: Yes.

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

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

Muraoka [Q]: Muraoka from Morgan Stanley. Thank you very much. Almost all questions I wanted to ask were already asked. Regarding XTANDI, the growth, it was not growing much. The volume was growing, but the unit price is a tough element according to my memory before. But—so the growth mode switch is turned on by now?

Kitamura [A]: Muraoka-san, thank you very much. Basically, yes. As we mentioned and explained from before, the entire market is growing, and also, there is a new indication, and there is the halo effect to other indications according to what we are seeing. Claus, any additional comments in detail? Do you have any other comment, including some detail?

Zieler [A]*: Yes. Thanks, Atsushi. I think we've talked about this before, that the volume evolution is extremely strong and extremely positive for us. That was true in Q4 of last fiscal year, and it continues to be true in Q1 of this year.

Where we do see pricing effects coming is in Q4. With the Medicare revisions that kick in on the first of January 2025, then we will see pricing impacts. And those have been factored into our forecast. There's going to be, hopefully, no surprises there.

The volume is slightly stronger than what we anticipated. We are benefiting in the good phase now, as you say, the growth phase is turned on. And the pricing impacts that we talked about are not relevant yet because they are coming in the future.

Muraoka [Q]: Thank you very much. And also, this may be a question too early to be asked, but regarding this performance momentum, if that is going to continue, there can be a variety of revisions or review in Q2. Regarding the dividend, you were increasing by JPY10 every year before, but this year, it was just a JPY4 increase because of the situation you're facing, according to my understanding. But JPY10 increase every year for the dividend, is that beginning to be in your sight? Or am I jumping too much to the future.

Kitamura [A]: Thank you very much for your question. Shareholder return is a very important element. It's one of the important elements in the capital allocations. And short-term profit, increase or decrease is not a determinant. Within the CSP, in the longer range of timeline, we want to give a stable dividend payment. Because of the good performance in Q1, so quickly, an increase in dividend, no, that is not going to happen in principle. We'd like to have a good performance in the current fiscal year, and we'd like to sustain our growth beyond the current fiscal year. We'd like to create such a mechanism, and we need to discuss the shareholder return.

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

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

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Hashiguchi [Q]: Hashiguchi speaking. Thank you very much. I have a question about Focus Area Approach. ASP3082 and 1570, you are going to present data at ESMO. POC judgment has been made. Do you have such data to enable the POC judgment? Or will it take some more time until POC judgment? But as of now, do you have some data in your hand to be presented?

Kitamura [A]: Hashiguchi-san, thank you very much for your question. We are going to present the data. Phase I clinical study data is partly included in the presentation. But is that equivalent to PoC? The timeline is slightly different. We are going to explain just briefly.

Taniguchi [A]: Thank you. At ESMO, ESMO is going to take place in September. And there, 3082, that is KRAS G12D degrader and also 1570 DGK ζ inhibitor. These two study results will be presented. The study results, well, in other words, this is the very first occasion to announce the clinical data. What's going to be announced? Well, first of all, Phase I dose escalating study results will be the center of the presentation and other collected data will be also shared as well.

Needless to say, in a parallel manner, expansion cohort study will be conducted with aiming at POC. The plan that we shared with you last time is what we are currently following, and things are going without any bumps.

Hashiguchi [Q]: Thank you very much. In my understanding, the original concept of focus area is that with the lead product, positive sign is observed. Then, within the same primary focus, the following pipeline will be further accelerated for the development of activities. But including the dose expansion cohort, do you need to gain more information to do that? And also, the protein degrader, about two years ago, there was an R&D briefing session that took place, and you mentioned there are some follow-ups. ASP1570, do you have the multiple candidates waiting after this ASP1570?

Taniguchi [A]: Let me answer to that as well. Regarding the Focus Area Approach, just like you mentioned, we first have one product, that is the first product. And if we see some potential of the efficacy, then same class drugs will be continuously developed. That is our strategy.

For the protein degrader or, in other words, ASP3082, as you see it here, ASP4396, the next generation is continuously worked for the development. And there are many in the clinical phase. Within a couple of years, they are expected to get into clinical development phase.

For DGK inhibitor, this is the general type of small molecule drug and [for this], currently, because this is low molecule weight compounds and we do not have followings, so first, we focus on ASP1570 to identify the efficacy level, managed multiple cancer types, so some cancer types, and we will think about the future based upon that.

Hashiguchi [M]: I understood it clearly. Thank you very much. That's all for me.

Ikeda [M]: Thank you. Next, Mitsubishi UFJ, Mr. Hyogo, please.

Hyogo [Q]: Mitsubishi UFJ Trust. Shinichiro, thank you very much for this presentation today. Kitamura-san, you talked about ROI. Now you assume it as the CFO of this company and for their budgeting and cost management. Do you identify any challenges within this period of time? Did you realize something? And for the ROI, how is it managed? It's okay that you can mention only the possible comment, but would you please share your thinking?

Kitamura [A]: Thank you very much, Mr. Hyogo. As CFO, how the cost is managed, how ROI is followed, I think that's basically your question. It's not something that we didn't have such kind of approach from the beginning in our company. We've been working on that. However, there are some points that we need to improve.

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Of course, in this industry, there is always uncertainty. Coming up with a different scenario, what happened, what would we do with what happened? Those kinds of scenarios are prepared. It's not something that this is the thing, so we budget in this way or that. Rather, we come up with several slides, and we expand that kind of options of the scenario so that we can think with a wide scope second.

If we talk about disciplines, we are reducing cost. And instead of coming to the bottom line, it may be used somewhere else to be even in the end. There were such cases. We'd like to ensure good management. That's one improvement.

And as was mentioned for VEOZAH, we will monitor KPIs. And based on the progress, we run the PDCA cycle, so we want to enhance visibility as well as the attention of management. This is something everybody takes for granted, but we are reinforcing such areas.

Cost reduction, not just spending for VEOZAH, but cost-reduction programs do exist and whether we did a good job or not, if we did, is that reflected on to the bottom line? From the budgeting phase, we create a mechanism, and we are implementing this right now.

Hyogo [Q]: Then PDCA cycle for VEOZAH is—PDCA cycle is accelerated and managed well?

Kitamura [A]: Yes.

Hyogo [M]: You are reducing cost and I'm expecting that you would achieve great results. Thank you very much.

Ikeda [M]: Next, Sanford C. Bernstein, Ms. Sogi, please?

Sogi [Q]: Thank you very much. I have a few questions. First, about XTANDI. As you mentioned, it's a mature market, but the entire market is growing right now. What's the reason behind? And the market growth will continue into the future, is that what you can expect? And XTANDI, 16% growth, based on the growth, is it driven by the market growth? And also, XTANDI's share, progress continuation because of EMBARK data. 16%, what's the breakdown of the 16% based on the idea?

Kitamura [M]: Sogi-san, thank you very much. Rather than my feeling, I think it's better to ask Claus. First, we'd like to ask Claus to comment.

Zieler [A]*: Thank you, Sogi-san. Yes, the market growth is strong. It's actually been strong for some time on a volume basis. What we are now seeing is a combination of the strong market growth and our EMBARK data really making a difference in the market.

I'll give you an example. We see in the US 5% more HCPs writing for XTANDI than before. we're getting traction with that scientific data that we published last year, with the approval of this additional indication that we got at the end of last calendar year. And it is making a difference in the market. We hear that anecdotally and I think it is contributing to the fact that not only the market is growing, but externally can grow with the market.

We have a very strong positioning in spite, as I said before, of other generic molecules being available in this market. It's a fight between do you want to give the most affordable molecule to a patient, or you want to give what a doctor perceives to be the molecule with the most extensive data sets and convincing science to a patient? And that's where we are really making a difference with the EMBARK data set.

Sogi [Q]*: That's clear. Thank you very much. I'm actually curious to see, I'm sorry, if I am asking a repetitive question, but what is really driving the overall market expansion? Is it something you were saying that this is happening over time? Is it because there are some patients that were not underdiagnosed during COVID-19

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



and some of those people are coming out? Or is there anything that can explain the underlying marketing expansion?

Zieler [A]*: Yes. Thank you, Sogi-san. Maybe COVID-19 has some implications. I would have to go back. But COVID-19 is more a blip and now we're back to normal. The underlying market dynamics is that you still have a lot of doctors treating with traditional ADT, right? If you look at the part of the market that uses ADT versus ADT plus the NHT class, there is still room for growth. I mean, and there's still tremendous room for growth, and that is what's happening.

It's the NHT class that is just becoming relevant into doctors' minds as a meaningful addition, a treatment addition to therapy. And because the ADT mono is still such a large part of scripts today, that's where the NHT growth is coming from. And as I said, it is the NHT class growth, that's what we refer to as market growth. Does that help?

Sogi [M]*: Yes, yes. No, actually, I'm just really impressed that because of the maturity of the drug, that kind of shift has already happened, but it's still continuing. It's great.

Zieler [M]*: It's still continuing. Exactly.

Sogi [Q]*: Yes. That's great. And then I have some additional question around the PADCEV. I was really impressed by the strong growth in Europe, and especially in Europe, the first line of the indication has not been approved yet. Can we expect even further acceleration of growth in Europe with the first-line approval?

Zieler [A]*: We continue to be very, very optimistic on the growth of PADCEV. And I think you've captured the situation well. We are on the verge of the first line now driving demand in the European and then in other ex-US geographies. We've been benefiting from that, of course, in the US. But I do want to manage expectations a little bit in the sense that what we've consistently seen in PADCEV is a very steep ramp up because the data is so convincing, a very, very steep penetration curve. But then when you get to the sort of the peak share that is realistic in the market, you have a very sharp leveling off. We expect that to happen in the US. We don't know exactly when. But in the next six months, that will happen, yes?

While Europe will continue to drive growth and then other geographies will continue to drive very strong growth with the second line and second-line reimbursements and then first-line launches, the US world can have a tendency to now level off in the next six months.

Sogi [M]*: Thank you.

Zieler [A]*: We're very optimistic about this. And Sogi-san, you will remember last quarter, I told you that. Yes, I told you that we have very strong growth in PADCEV, and I think maybe we've not been—we feel we've not been recognized yet for that very strong growth of this fantastic treatment option.

Sogi [Q]*: No, it's amazing how it's growing and also definitely the first-line data is amazingly good. I definitely think so.

At the end, now it's about the IZERVAY regulatory question in Europe. SYFOVRE did not have clinical efficacy data. That's why it's not approved in that market. I think that is something common with IZERVAY's data set as well. From this perspective, what's the current status of [EMA] negotiation? Or what kind of scenario are you considering currently?

Taniguchi [A]*: Thank you for the question. IZERVAY European market status, I believe I've touched upon this a little bit. But as you know, needless to say, the European authority, they always look at efficacy, safety, and

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



also risk/benefit balance. They consider these factors and ultimately decide about the approval of this drug. That's what we think.

Then about our IZERVAY, with the two Phase III, we confirm the positive for both, and as has been discussed. In the case of the US, GATHER1, GATHER2 study result, safety data, equivalent or [consistent] standard data is available now. Considering those information and data and based upon that, European authority would make the decision about the approval. In order to support that, we are going to submit the available data so that earlier approval is achieved.

Sogi [M]: Thank you very much.

Ikeda [M]: Thank you. Macquarie Capital, Mr. Tony Ren, please.

Ren [Q]*: Yes, Tony Ren from Macquarie. Thank you very much for the chance to ask my questions. One is, again, going back to IZERVAY European application. Is the EMA asking for an oral explanation, an oral meeting? I believe that typically happens at day 210. I just want to see if that is happening.

And then just also going back to PADCEV, very strong sales revenue. I think your first question is about the clinical profile. When I was at ESMO in Barcelona, there was some concern about peripheral neuropathy and the skin toxicity. Now you've got a lot more experience with this EV-302 regimen, just want to see how that is playing out in the GU oncology setting?

And then the second question is probably for Claus. It's about the Medicare Part B inflation rebate. How is that affecting PADCEV?

Kitamura [M]*: Thank you, Tony. Your question is maybe three. Actually, the IZERVAY and the European status; also, the PADCEV, the EV-302; and also skin irritation questions, right?

Ren [M]*: Correct. And then—

Kitamura [M]*: Yes. As two questions will be covered by our key medical officers. Last one would be [Claus].

Taniguchi [A]: First, IZERVAY status in Europe. Once again, as there was another question, I would like to respond. As I explained earlier, IZERVAY submission in Europe, needless to say, we are submitting a document in writing in principle. Where necessary from the regulatory authorities, they may request for a meeting in person. We'd like to use both ways so that IZERVAY safety and efficacy data can be fully communicated to them. That's how we are proceeding.

About PADCEV and skin adverse events and peripheral neuropathy, there was such a question. Needless, the so-called GU bladder cancer treaters, regarding these symptoms, they have never handled these adverse events before in reality. But second-line monotherapy is already approved and marketed. Medical affairs and commercial are providing information to the physicians to promote appropriate use.

In case of adverse event, what they should do, they are communicating how to manage adverse events so that the situation can be addressed appropriately. We have such education programs and providing necessary information. We are doing our best in these activities.

For the time being, doctors are very interested in prescribing this drug as we have heard. And safety management into the future will be important in continuing to use this drug. We will continue to make our utmost efforts to provide information to them.

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Zieler [A]*: Yes, let me add maybe to the PADCEV question. Of course, both the skin toxicity and the neuropathy are unknown adverse events. This is nothing new. And the question of educating doctors on how to deal with them has been with us from the very, very start of the launch of PADCEV.

In that sense, this is not an unexpected discussion that you're witnessing at ESMO, Tony. It's the grappling with how we do the best for patients because the efficacy of the treatment has been published and has been demonstrated and is recognized. And people are trying to understand how do we best grapple with the AEs. And that's a normal discussion. We don't see that affecting market penetration.

I think I told you at the last quarter that we had almost 50% of new patient share. We're now up to 54% to 56%, somewhere in that range of new patient share for PADCEV in the US in first line. We're continuing to make fair progress, which speaks for an understanding in the community of how to handle this balance of efficacy and adverse events. I don't think you should take the ESMO discussion as anything that affects the market performance of PADCEV and the acceptance of PADCEV to appropriate patients in the market.

I think your last question, if you could just repeat it?

Ren [Q]*: Yes, it is about the Medicare Part B, the inflation rebate.

Zieler [A]*: Correct. Yes. Our last price increase on PADCEV was in March, and we factored the Part B legislation into that. I don't anticipate major deviations and major corrections in terms of Part B for PADCEV in the future.

Ren [Q]*: Okay, yes. If I may just very quickly, Claus. You said that the market share in frontline urothelial carcinoma in the US is already 56%. Right?

Zieler [A]*: Between 54% and 56%, yes. Between 54% and 56%, yes.

Ren [Q]*: Yes, that's a pretty narrow range. And you said that it's going to peak out in the next six months. When do you think the peak will be? 65% or some—

Zieler [A]*: That's the million-dollar question, Tony. I wish I knew the answer to that. We've been surprised by PADCEV in the past, and I don't want to fall into the trap of getting into a linear extrapolation. We honestly don't have a very clear view of where the peak will be. We're essentially already where we thought we would be six months from now and we're already there. The upside is there. Whether that will continue, I don't know.

Ren [M]*: Thank you very much.

Ikeda [M]*: Thank you very much. I'm sure that you are waiting for the opportunities of asking questions, but with the time [stop], so with this, we would like to close today's announcement. Thank you very much for your participation.

Everyone, thank you so much for your participation. I would like to close at announcement. Thank you very much for your participation.

[END]

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptasia.com



Document Notes

1. *Portions of the document where the audio is obscured by technical difficulty are marked with [TD].*
2. *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.*
3. *This document has been transcribed based on interpreted audio provided by the Company.*

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptsasia.com



Disclaimer

SCRIPTS Asia reserves the right to edit or modify, at its sole discretion and at any time, the contents of this document and any related materials, and in such case SCRIPTS Asia shall have no obligation to provide notification of such edits or modifications to any party. This event transcript is based on sources SCRIPTS Asia believes to be reliable, but the accuracy of this transcript is not guaranteed by us and this transcript does not purport to be a complete or error-free statement or summary of the available data. Accordingly, SCRIPTS Asia does not warrant, endorse or guarantee the completeness, accuracy, integrity, or timeliness of the information contained in this event transcript. This event transcript is published solely for information purposes, and is not to be construed as financial or other advice or as an offer to sell or the solicitation of an offer to buy any security in any jurisdiction where such an offer or solicitation would be illegal.

In the public meetings and conference calls upon which SCRIPTS Asia's event transcripts are based, companies may make projections or other forward-looking statements regarding a variety of matters. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the applicable company's most recent public securities filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are accurate and reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the anticipated outcome described in any forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE PUBLIC MEETING OR CONFERENCE CALL. ALTHOUGH SCRIPTS ASIA ENDEAVORS TO PROVIDE ACCURATE TRANSCRIPTIONS, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE TRANSCRIPTIONS. IN NO WAY DOES SCRIPTS ASIA OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BY ANY PARTY BASED UPON ANY EVENT TRANSCRIPT OR OTHER CONTENT PROVIDED BY SCRIPTS ASIA. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S PUBLIC SECURITIES FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS. THIS EVENT TRANSCRIPT IS PROVIDED ON AN "AS IS" BASIS. SCRIPTS ASIA DISCLAIMS ANY AND ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, FREEDOM FROM BUGS, SOFTWARE ERRORS OR DEFECTS, AND ACCURACY, COMPLETENESS, AND NON-INFRINGEMENT.

None of SCRIPTS Asia's content (including event transcript content) or any part thereof may be modified, reproduced or distributed in any form by any means, or stored in a database or retrieval system, without the prior written permission of SCRIPTS Asia. SCRIPTS Asia's content may not be used for any unlawful or unauthorized purposes.

The content of this document may be edited or revised by SCRIPTS Asia at any time without notice.

Copyright © 2024 SCRIPTS Asia K.K. ("SCRIPTS Asia"), except where explicitly indicated otherwise. All rights reserved.

Support

Japan 050.5212.7790
Tollfree 0120.966.744

North America 1.800.674.8375
Email Support support@scriptsasias.com

