Astellas Pharma Inc.

Financial Results for the Q1 of FY2025

July 30, 2025

Event Summary

[Company Name]	Astellas Pharma Inc.	
[Company ID]	4503-QCODE	
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[Event Type]	Earnings Announcement	
[Event Name]	Financial Results for the Q1 of FY2025	
[Fiscal Period]	Q1 of FY2025	
[Date]	July 30, 2025	
[Time]	16:00 – 17:30 (Total: 90 minutes, Presentation: 29 minutes, Q&A: 61 minutes)	
[Venue]	Webcast	
[Number of Speakers]	4	
	Atsushi Kitamura	Chief Financial Officer (CFO)
	Tadaaki Taniguchi	Chief Research & Development Office (CRDO)
	Claus Zieler	Chief Commercial & Medical Affairs Officer (CCMAO)
	Hiromitsu Ikeda	Chief Communications & IR Officer (CCIRO)
[Questioner]	Hidemaru Yamaguchi	Citigroup Global Markets
	Seiji Wakao	JPMorgan Securities
	Akinori Ueda	Goldman Sachs
	Koichi Mamegano	BofA Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Miki Sogi	Sanford C. Bernstein
	Hiroyuki Matsubara	Nomura Securities
	Fumiyoshi Sakai	UBS Securities

Presentation

Ikeda: Thank you very much for joining FY2025 Q1 financial results announcement meeting organized by Astellas Pharma Inc. out of your very busy schedule today. I'm serving as a facilitator today. I'm Chief Communications and IR Officer, Ikeda. Thank you for your time.

After our presentation, we will move on to the Q&A session. We will present based on the presentation material posted on the website under IR meetings. Including the Q&A session, we have simultaneous translation between Japanese and English. We can't guarantee the accuracy of the simultaneous translation. Thank you for understanding. You can choose the language from the Zoom webinar screen menu. If you select the original sound, you can listen to the original without going through the simultaneous translation.

This is a disclaimer today. This material or presentation by representatives for the Company and answers and statements by representatives for the Company in the Q&A session include forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Actual financial results may differ materially depending on a number of factors. They contain information on pharmaceuticals, including compounds under development, but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations, promote unapproved uses in any fashion, or provide medical advice of any kind.

Today's participants, Chief Financial Officer, Atsushi Kitamura; Chief Research and Development Officer, Tadaaki Taniguchi; Chief Commercial and Medical Affairs Officer, Claus Zieler. We have three members from our company so we'd like to go into a presentation. Kitamura-san, please.

Kitamura: Hello, everyone. I'm Atsushi Kitamura from Astellas Pharma. Thank you very much for joining our FY2025 Q1 financial results announcement meeting out of your very busy schedule today.

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

Q1 YTD/FY2025 Overview
- Exceptional Q1 Progress Outperforming Expectations -

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Q1 YTD/FY2025 Consolidated Financial Results

Revenue

- ✓ Robust growth YoY (underlying growth excluding FX impact: +12%)
- ✓ Strategic Brands: Significantly driving overall revenue growth (underlying growth excluding FX impact: +57%)

SG&A expenses*

- ✓ SG&A ratio improved significantly driven by robust progress of SMT (-4.2ppt YoY)

Core operating profit

- ✓ Robust growth YoY (underlying growth excluding FX impact: +69%)
- ✓ Core OP margin increased to 28.1% (+9.5ppt YoY)

Pipeline Progress

- ✓ ASP3082: PoC achieved in non-small cell lung cancer
- ✓ Exclusive license agreement with Evopoint to enhance leading position in Claudin 18.2

*Excl. US XTANDI co-pro fee
Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA
SMT (Sustainable Margin Transformation): See slide 26 for overview

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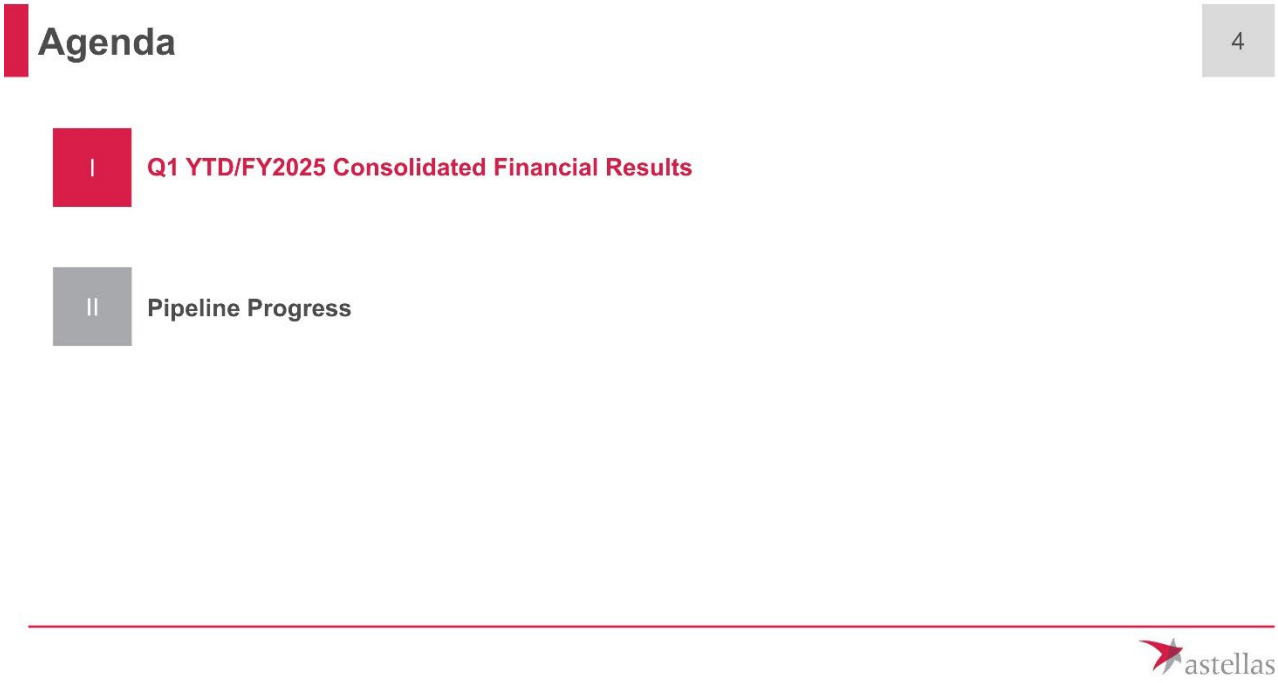
On page three, I will give you highlights of FY2025 Q1 financial results.

Q1 made an exceptional progress outperforming expectations off to a good start. In Q1, revenue increased substantially YoY with underlying growth of 12%, excluding FX impact. Strategic brands significantly drove overall revenue growth with an underlying growth of 57%, excluding FX impact.

As for SG&A expenses, thanks to the steady progress of SMT, sustainable margin transformation, our company-wide cost optimization initiative, SG&A ratio improved by 4.2 percentage points YoY. As a result, core operating profit increased substantially YoY with underlying growth rate of 69%, excluding FX impact.

Core operating profit margin rose by 9.5 percentage points YoY to reach 28.1%.

As for pipeline progress, ASP3082, a flagship program in primary focused targeted protein degradation achieved PoC also in NSCLC following PoC in pancreatic duct adenocarcinoma, PDAC. Furthermore, in order to enhance leading position, including 18.2, we concluded an exclusive license agreement with Evopoint.



Page four is the agenda for today. From the next page, I will explain these topics.

Q1 YTD/FY2025 Financial Results

(billion yen)	Q1 YTD FY2024	Q1 YTD FY2025	Change	Change (%)	FY2025 FCST*	FX impact (YoY)	Underlying Growth (Excl. FX Impact)
Revenue	**473.1**	**505.8**	**+32.7**	**+6.9%**	**1,930.0**	-26.1	**+12%**
Cost of sales	91.1	94.8	+3.7	+4.1%	373.0	-2.9	
SG&A expenses	206.9	197.0	-9.9	-4.8%	805.0	-12.4	
US XTANDI co-pro fee	61.6	62.9	+1.3	+2.1%	229.0	-4.9	
SG&A excl. the above	145.3	134.1	-11.2	-7.7%	576.0	-7.5	
(SG&A ratio**)	30.7%	26.5%	-4.2ppt		29.8%		
R&D expenses	86.8	71.7	-15.1	-17.4%	342.0	-3.6	
(R&D ratio)	18.4%	14.2%	-4.2ppt		17.7%		
Core operating profit	**88.3**	**142.3**	**+54.0**	**+61.1%**	**410.0**	-7.1	**+69%**
(Core OP margin)	18.7%	28.1%	+9.5ppt		21.2%		
<Full basis>							
Amortisation of intangible assets	35.0	32.8	-2.2	-6.4%			
Other income	4.9	4.4	-0.5	-10.8%			
Other expenses	10.4	21.3	+11.0	+105.5%			
Operating profit	**50.7**	**94.6**	**+44.0**	**+86.8%**	**160.0**		
Profit before tax	50.5	90.4	+39.9	+79.1%	150.0		
Profit	**37.6**	**68.4**	**+30.8**	**+82.0%**	**130.0**		

Other expenses (Main items)
- Impairment loss related to certain Xyphos-related programs: 11.5

*Disclosed in Apr 2025, **Excl. US XTANDI co-pro fee
FX rate assumption for FY2025: 140 yen/USD, 160 yen/EUR
Actual FX rates for Q1/FY2025: 145 yen/USD, 164 yen/EUR (Actual exchange rates of Q1/FY2024: 156 yen/USD, 168 yen/EUR)

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On page five, I will give you an overview of the FY2025 Q1 financial results. Revenue reached JPY505.8 billion, up by 6.9% YoY.

Core operating profit rose to JPY142.3 billion, up by 61.1% YoY.

The FX impact is shown on the right-hand side of the table. FX had a negative impact on both revenue and core operating profit. Underlying growth rate, excluding this impact, was 12% for revenue and 69% for core operating profit, demonstrating a stronger growth.

The bottom half of this page shows our full basis results. In the bottom right of the table, we included other expenses booked in Q1.

In response to the termination of certain Xyphos-related programs, we reviewed asset value and booked impairment loss of JPY11.5 billion accordingly. In the end, operating profit was JPY94.6 billion, up by 86.8% YoY. Profit increased to JPY68.4 billion, up by 82% YoY.

Q1 YTD/FY2025 Financial Results: Main Brands

*Strategic Brands expanded to **over 110.0 bil. yen** in just three months, driving overall revenue and profit growth*

(billion yen)	Q1 YTD/FY2025	YoY (Incl. FX Impact)	Underlying Growth (Excl. FX Impact)	
Strategic Brands Total	112.0	+36.7 (+49%)	+57%	✓ Continued strong growth, with notable contribution from **VYLOY** ✓ Expect continued positive momentum throughout FY2025
PADCEV	55.5	+17.1 (+45%)	+52%	✓ Continued robust growth momentum driven by 1L mUC across all regions ✓ Overall progress in line with expectations
izervay	15.9	+3.2 (+25%)	+35%	✓ Record-high quarterly sales ✓ Retuned to growth trajectory, with a +22% QoQ growth (vs. Q4/FY2024)
VEOZAH	9.6	+3.0 (+46%)	+56%	✓ Solid global sales growth, in line with expectations ✓ Expect steady growth moving forward
VYLOY	14.0	+13.7 (>+100%)	>+100%	✓ Exceptional start exceeding expectations; raising prospects for potential upside ✓ Driven by above benchmark Claudin 18 testing rates and lower discontinuations
XOSPATA	17.0	-0.3 (-2%)	+3%	✓ Steady global performance and on track overall
Xtandi	233.0	+8.7 (+4%)	+10%	✓ Solid performance across all regions

Actual exchange rates of Q1/FY2025: 145 yen/USD, 164 yen/EUR (Actual exchange rates of Q1/FY2024: 156 yen/USD, 168 yen/EUR)
1L: First line, mUC: Metastatic urothelial cancer
VEOZAH: Approved as "VEOZA" in ex-US

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On page six, I will explain the FY2025 Q1 results of our main products.

Sales of strategic brands driving our growth, namely, PADCEV, IZERVAY, VEOZAH, VYLOY, and XOSPATA exceeded JPY110 billion in just three months, substantially up by JPY36.7 billion or 49% YoY.

Underlying growth rate, excluding FX impact, was 57%, showing a strong growth. Due to high profitability of these brands, they not just contributed to revenues, but also made a great contribution to profit growth on a consolidated basis as a whole. We're expecting this positive growth momentum to continue throughout FY2025.

Let me also explain individual strategic brands. I will explain the details of PADCEV, IZERVAY, and VYLOY in the later slides.

Global sales of PADCEV increased to JPY55.5 billion, up by JPY17.1 billion or 45% YoY. Robust growth momentum was achieved across all regions with overall progress in line with our expectations.

As for IZERVAY, sales were JPY15.9 billion, up by JPY3.2 billion or 25% YoY, achieving record high quarterly sales. IZERVAY has returned to a growth trajectory after temporary growth slowdown in H2 of last fiscal year.

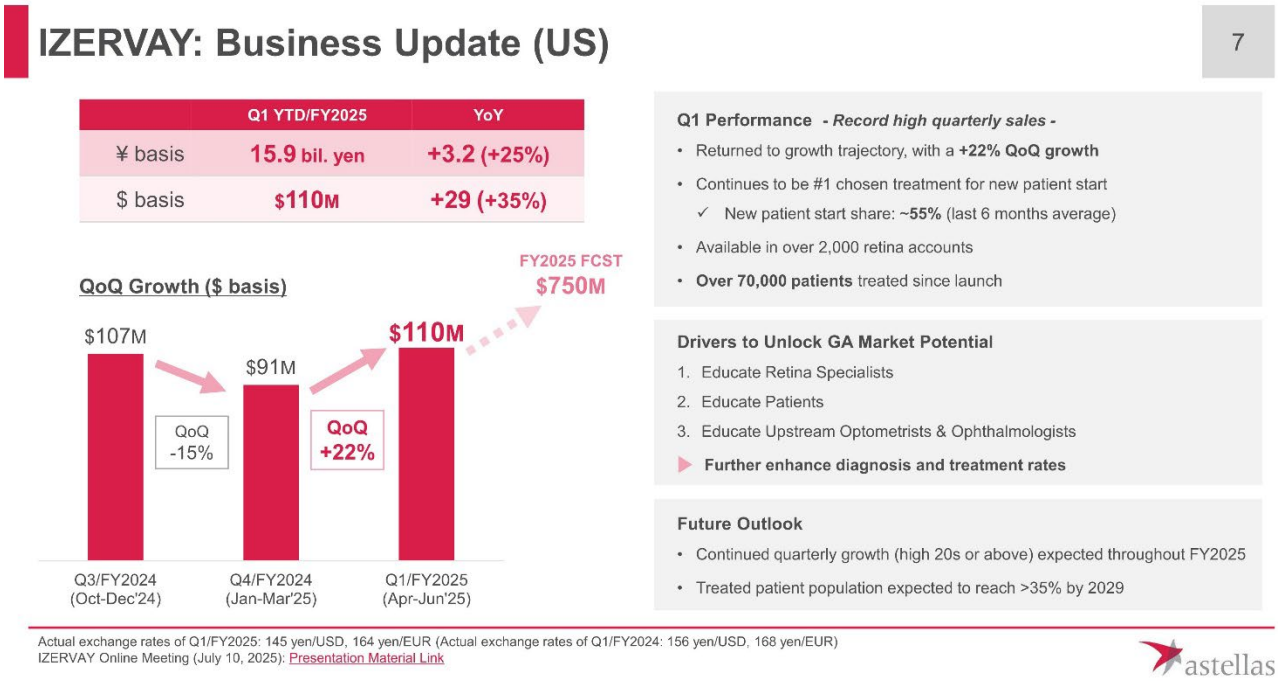
Global sales of VEOZAH expanded in line with expectations to reach JPY9.6 billion, up by JPY3 billion or 46% YoY. We're expecting steady growth moving forward as well.

With regards to VYLOY, global sales reached JPY14 billion. It has made an exceptional start, exceeding expectations, raising prospects for potential upside.

Regarding XOSPATA, global sales reached JPY17 billion. Underlying growth, excluding FX impact, was 3%, making steady progress overall.

As for XTANDI, global sales increased to JPY233 billion, up by JPY8.7 billion or 4% YoY with solid performance across all regions.

With regards to IZERVAY, we organized an online meeting for investors and analysts on July 10, Japan time.



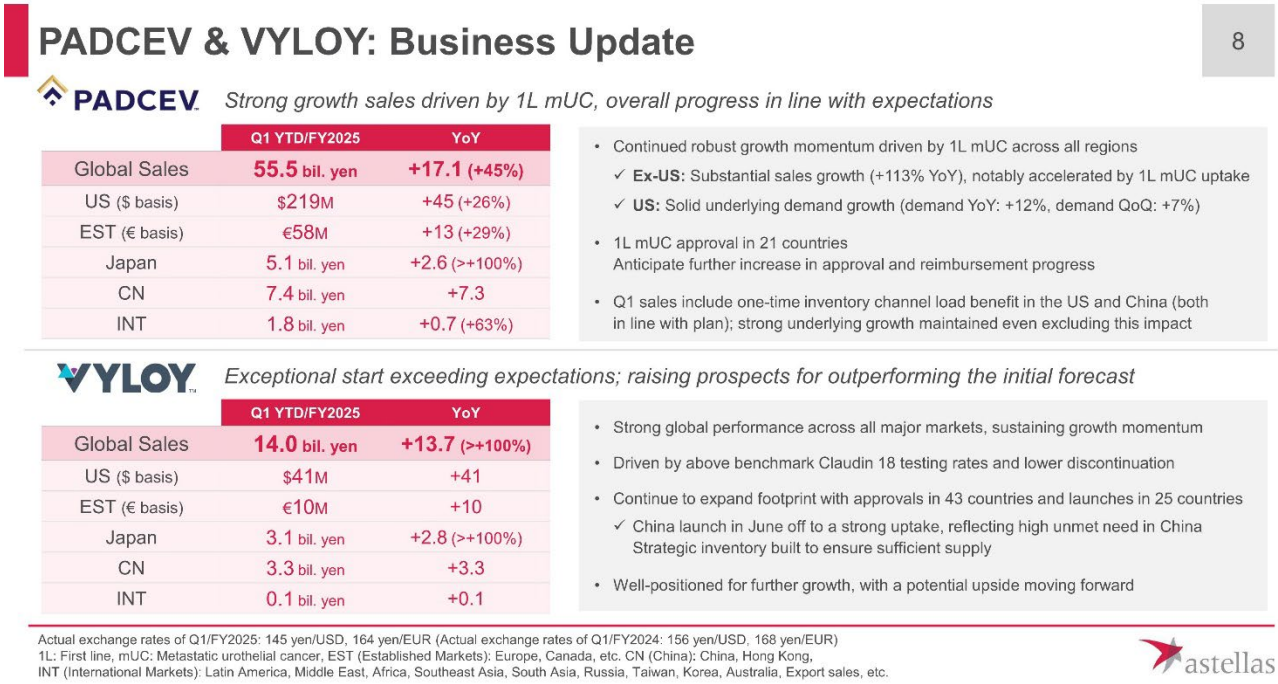
I'd like to explain IZERVAY's Q1 progress in the United States once again on page seven.

Sales of IZERVAY rose to USD110 million, up by USD29 million or 35% YoY. After a temporary growth slowdown seen in H2 of the previous fiscal year, Q1 sales increased by 22% from the previous quarter with a return to growth trajectory. IZERVAY has continued to establish its position as the number one chosen treatment for new patient starts with GA, geographic atrophy. New patient start share is estimated at about 55% of the last six months average.

This figure is calculated based on the insurance claims data, which represents patients actually administered with IZERVAY, so we believe this reflects the real situation. IZERVAY is now available in over 2,000 retina accounts. Over 70,000 patients have been treated since launch.

As we explained during the online meeting, in order to unlock GA market potential, we are promoting three drivers: educate retina specialists, educate patients, and educate upstream optometrists and ophthalmologists. Through these initiatives, we will further enhance GA diagnosis and treatment rates.

We have been able to confirm that the solid growth trend is also continuing in July. We are expecting continued high growth in each quarter ahead. Also, treated target patient population is expected to rise from the current 15% to over 35% by FY2029.



On page eight, I will explain business update for PADCEV and VYLOY.

First, about PADCEV. First-line metastatic urothelial cancer, MUC is driving growth across all regions and robust growth momentum has continued since last fiscal year, particularly in ex-US region, first-line MUC uptake is progressing well. Sales rose substantially by 113% YoY.

Also in the United States, underlying demand increased solidly by 12% YoY and by 7% QoQ. The NCCN guidelines, which many physicians are referring to when they determine their prescription were updated in March this year to position the combination therapy of PADCEV and pembrolizumab as the only category 1 therapy in MUC as the first-line therapy with the highest recommendation level, which is also supporting the solid growth.

Q1 sales include one-time inventory channel load benefit in the United States and China, both of which are in line with our plan. We are maintaining strong underlying growth, even excluding this impact. Overall, we are making progress as expected.

Next about VYLOY. Overall, we have made an exceptional start exceeding our expectations, raising prospects for outperforming the initial forecast. Thanks to our activities to proactively raise awareness and disseminate Claudin 18 testing, the testing rates are above benchmark for other biomarker tests.

In addition, through appropriate information provision about potential AE management, the discontinuation rate is also lower than our assumptions. These factors are contributing to the overall positive progress.

We are also continuing to expand footprint steadily with launches in 25 countries by now. Particularly among them, VYLOY was launched in June in China with a big gastric cancer market. The China launch was off to a strong uptake, reflecting high unmet medical needs there. Aiming to ensure stable sufficient supply, we made strategic inventory build in Q1.

VYLOY is still in its initial stage after launch, but its progress to date is substantially exceeding our assumptions. We have high expectations for its further growth potential in the future.

Q1 YTD/FY2025 Financial Results: Cost Items

- *Overall progress in costs on track. Cost optimization through SMT progressing well (total approx. -6.0 bil. yen)*
- *SG&A*: Ratio improved by 4.2 ppt YoY. While driving SMT, continue investments in SBs to maximize potential*
- *R&D: Expand investments from Q2 onwards aligned with further expected PoC achievements in Primary Focus*

(billion yen)

Cost Items	YoY change	Ratio to Revenue	
SG&A expenses*	-7.7% (-2.6% excl. FX impact)	SG&A ratio: 26.5% (Ratio improved by 4.2ppt YoY)	YoY decrease excl. FX impact: approx. -4.0 ✓ SMT cost optimization (approx. -3.0) (Organizational restructuring, reduction of mature products-related expenses, streamlining IT Infrastructure etc.) Continue investments in SBs to maximize potential and SMT investments for further optimization
R&D expenses	-17.4% (-13.2% excl. FX impact)	R&D ratio: 14.2%	YoY decrease excl. FX impact: approx. -12.0 ✓ SMT cost optimization (approx. -3.0) (Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials etc.) ✓ Decrease in clinical development costs in SBs (approx. -3.0) ✓ One-time co-development cost payments in Q1/FY2024 Expand investments aligned with further expected PF PoC achievements and enhance in-house capability

*Excl. US XTANDI co-pro fee
SMT: Sustainable Margin Transformation, SBs：Strategic Brands, PF: Primary Focus, PoC: Proof of concept

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On page nine, I will explain cost items. Overall progress in cost as a whole was on track. Cost optimization through SMT has made steady progress. We realized cost optimization of about JPY6 billion in total for SG&A expenses and R&D expenditure combined.

Excluding US XTANDI co-promotion fees, SG&A expenses decreased by 7.7% YoY. Excluding FX, SG&A costs fell by 2.6% from the previous year. SG&A ratio was 26.5%, improving by 4.2 percentage points YoY.

As SMT progresses, we realized cost optimization of about JPY3 billion through continuous global organizational restructuring, reduction of mature product-related expenses, and streamlining of IT infrastructure.

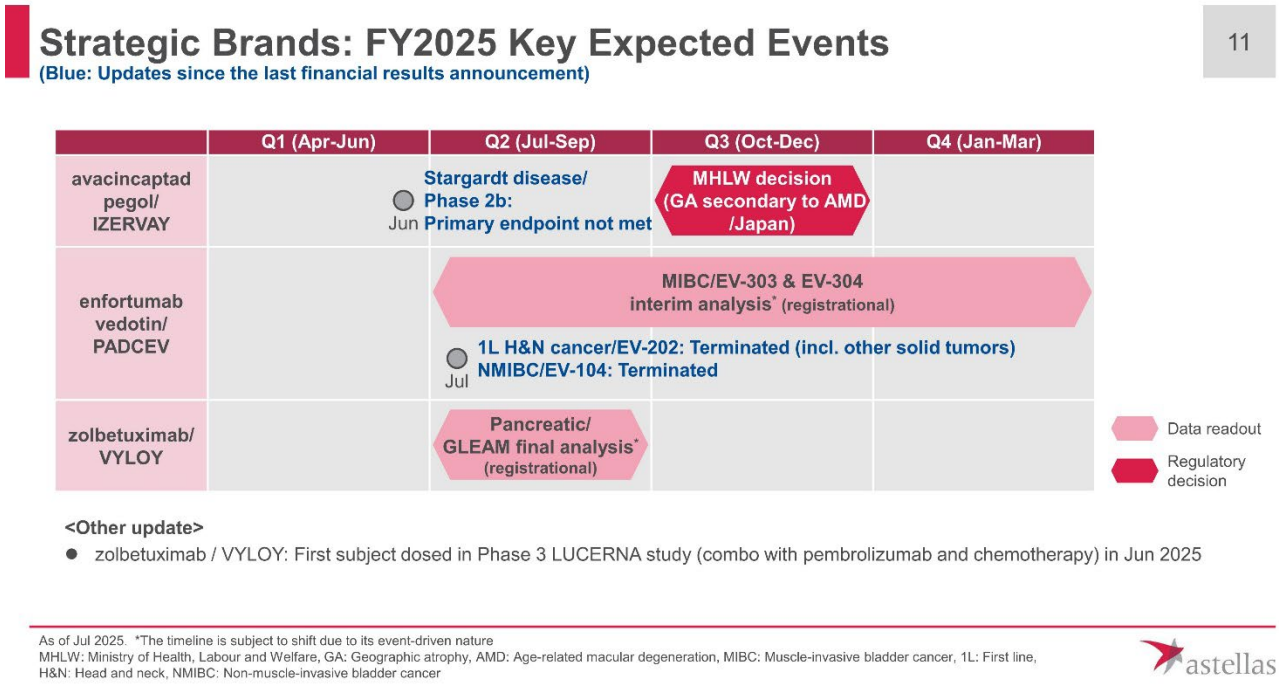
In addition to investments to maximize the potential of strategic brands, we will continue to make investments needed for SMT execution in order to realize further cost optimization.

R&D expenditure decreased by 17.4% YoY. Excluding FX impact, it was down by 13.2%. As the main factor, we made progress in outsourcing cost reduction through in-sourcing development capabilities, including clinical trials, under SMT, which led to cost optimization of about JPY3 billion.

Furthermore, due to the completion of large clinical studies, clinical development costs for strategic brands decreased by about JPY3 billion. In addition, one-time co-development cost payment booked in Q1 of FY2024 was another factor for cost decrease YoY.

In Q2 onwards, we will expand investments aligned with further expected primary focus PoC achievements and enhance our in-house capabilities. We are expecting a cost increase.

From here, I will explain our pipeline progress.



On page 11, I will explain the progress of strategic plans and key events expected in FY2025. Updates since the last financial results announcement are shown in blue.

Regarding IZERVAY, we had Phase II study top-line results data readout in Stargardt disease, where the primary endpoint was not met. We will analyze the data in detail and determine our future direction. As for PADCEV, we comprehensively reviewed the data obtained so far from Phase II EV-202 study in head and neck cancer and other solid tumors, except for urothelial cancer, and Phase I EV-104 study in NMIBC, non-muscle invasive bladder cancer. As a result, we decided to terminate our development for additional indications.

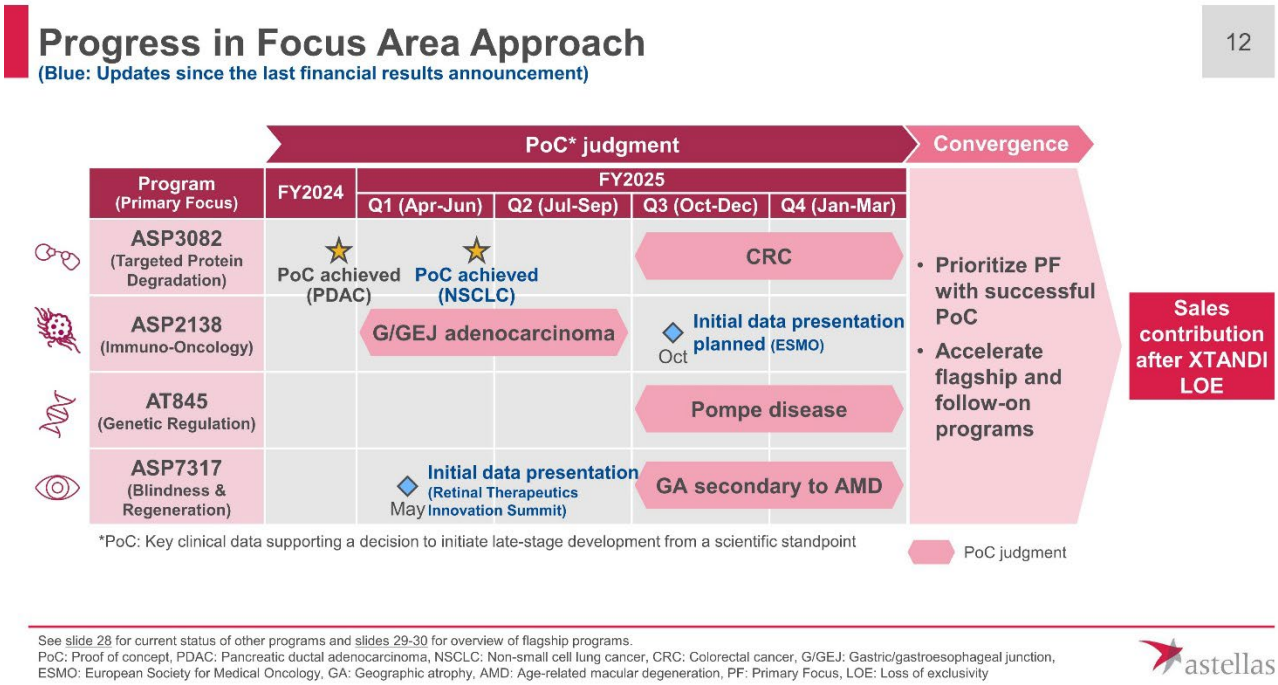
Please note that the current peak sales forecast for IZERVAY and PADCEV do not include contributions from these indications. Therefore, we would like to emphasize that the results of this study are not expected to have an impact on the mid- to long-term sales outlook for either product.

As for future events, IZERVAY is awaiting regulatory decisions on its JNDA expected in Q3 of [inaudible].

PADCEV is expected to have a readout of the interim analysis for both the Phase III EV-303 and EV-304 trials targeting MRBC in Q2 to Q4.

VYLOY is expected to have a readout of the final analysis from the Phase II GLEAM trial for pancreatic ductal adenocarcinoma or PDAC in Q2. We'll notify you of any future updates when necessary.

Other updates include the initiation of the Phase III LUCERNA study evaluating the efficacy and safety of VYLOY in combination with pembrolizumab and chemotherapy with the first subject dose in June.

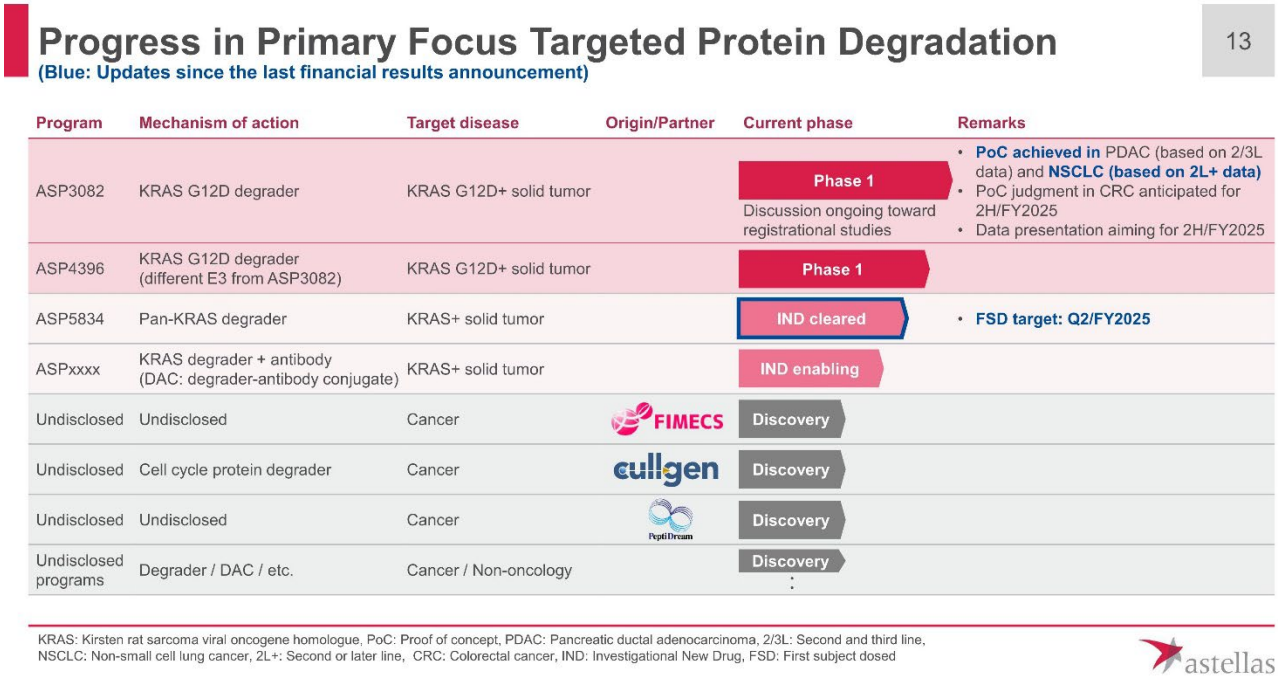


Page 12 provides an update on progress in the focus area approach. For each primary focus, progress made since the previous financial results announcement is highlighted in blue.

ASP3082 in the targeted protein degradation has achieved proof of concept in non-small cell lung cancer. This marks the second PoC achievement following the PDAC. The next slide will provide an overview of the overall progress of the primary focus.

As for ASP2138 in cancer immunotherapy, Phase I trials PoC judgment in FY2025 is ongoing with initial clinical data expected to be presented at ESMO in October.

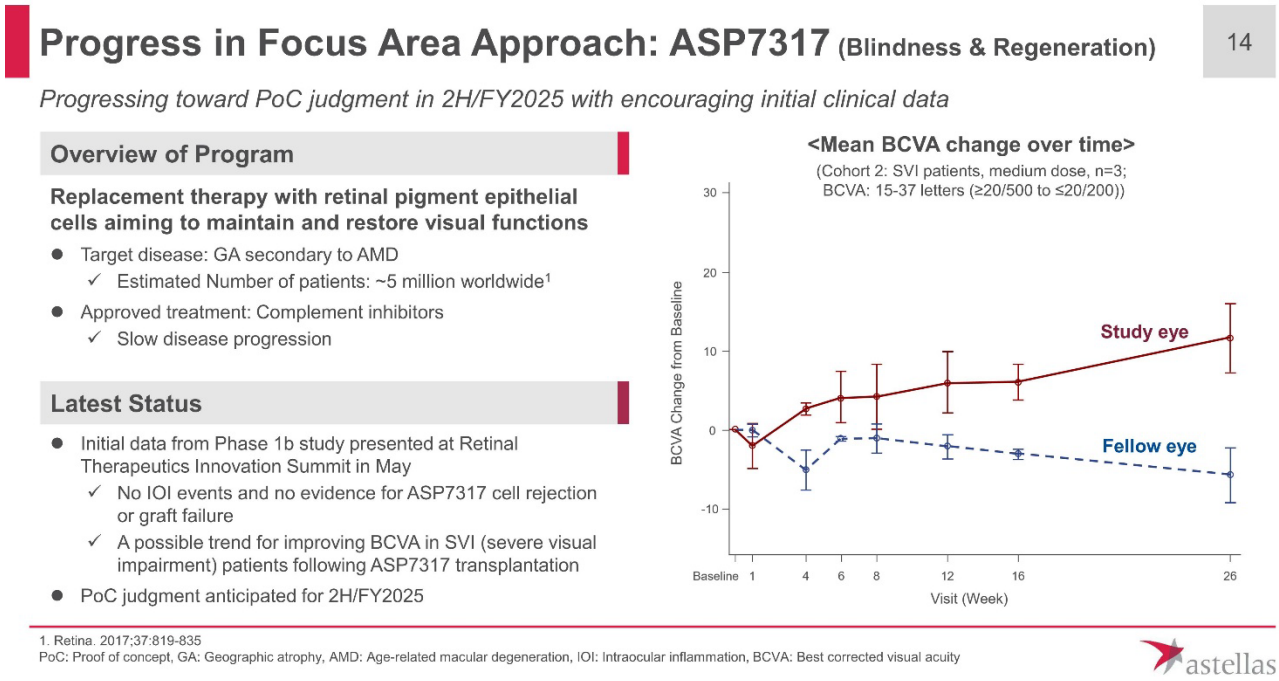
ASP7317 for blindness and regeneration has published initial clinical data in May. Further details will be provided later. The current status of other programs is summarized in slide 28 of the appendix.



Page 13 provides an overview of the progress in the primary focus of targeted protein degradation. The flagship program, ASP3082, has successfully achieved its second PoC based on data from a Phase I trial in non-small cell lung cancer, second line and after. In conjunction with PDAC, discussions are ongoing toward the early registration studies. The timeline for PoC judgment for colorectal cancer remains unchanged with H2 targeted. We aim to present clinical trial data by H2.

Following the PoC achievement of ASP3082, we are actively advancing research and development of the subsequent programs.

ASP5834, the third line from the top was developed as a pan-KRAS degrader targeting various KRAS variants. In July, we obtained IND approval, enabling us to begin trials aiming the first patient dose in Q2. We will provide further updates as they become available, including other programs.



Page 14 describes the progress of ASP7317. ASP7317 is being developed as a replacement therapy for retinal epithelial pigment cells targeting the same indication as IZERVAY, GA secondary to AMD. The estimated number of GA patients worldwide is reported to be about 5 million. Currently, approved drugs are limited to complement inhibitors, and slowing disease progression of GA has been reported.

ASP7317 is a direct replacement of retinal epithelial pigment cells to damaged areas from outside of the body, potentially maintaining or restoring visual function. Currently, a Phase Ib clinical trial for patients with GA patient is underway. The initial data from this trial was presented in Congress in May.

Regarding safety to date, no intraocular inflammation has been reported in patients dosed with ASP7317. No signs of cell rejection or graft failure have been observed.

Regarding efficacy, the graph on the right shows the change in best corrected visual acuity or BCVA over time for patients with a severe visual impairment following a single dose of ASP7317 at an intermediate dose. Red indicates the study eye, the eye that received the transplantation. Blue indicates the fellow eye, the other eye that did not receive the drug.

During the 26-week observation period, the study eye showed a trend toward improved BCVA compared to fellow eye. Although the current data are limited to only three cases, we are proceeding with the planned enrollment of additional cases and remain on track to judge a PoC in H2.

Exclusive License Agreement with Evopoint

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A promising new asset to enhance Astellas' leading position in Claudin 18.2-targeted therapies

Overview of Agreement

- Worldwide (excluding China's mainland, Hong Kong, Macao and Taiwan region) exclusive license to develop and commercialize XNW27011*
  *Astellas' development compound number: ASP546C
- Upfront payment: $130M, near-term payments: up to $70M, and additional milestone payments and royalties (if approved)

ASP546C (XNW27011)

Antibody-drug conjugate (ADC) targeting CLDN18.2

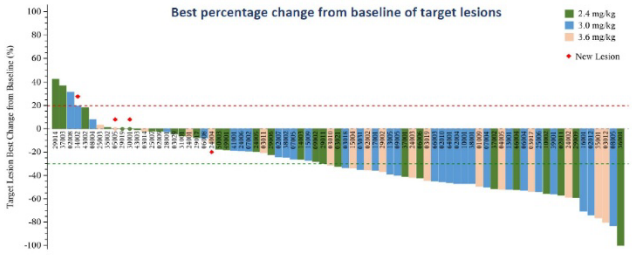
- Payload: Proprietary topoisomerase I inhibitor, Drug-to-antibody ratio: 8
- Linker: MediLink's TMALIN (Tumor Microenvironment Activable LINker) technology
- Fast Track designation by FDA granted (gastric cancer)
- Phase 3 study initiated in China in G/GEJ cancer, Global Phase 1b/2 study under planning

EVOPOINT Biosciences

<Preliminary efficacy in CLDN18.2+ G/GEJ adenocarcinoma>[1]

(CLDN18.2+: CLDN18.2 expression ≥5%, IHC ≥2+)

	2.4 mg/kg (n=29)	3.0 mg/kg (n=31)	3.6 mg/kg (n=18)
BOR	31.0%	61.3%	66.7%
DCR	82.8%	87.1%	88.9%



- Common TRAEs (≥20% patients): Hematologic disorders and gastrointestinal disorders

1. ASCO (American Society of Clinical Oncology) 2025
CLDN18.2: Claudin 18.2, FDA: Food and Drug Administration, G/GEJ: Gastric/gastroesophageal junction, IHC: Immunohistochemistry, BOR: Best overall response, DCR: Disease control rate, TRAE: Treatment-related adverse event

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Page 15 explains the exclusive license agreement with Evopoint, which we announced in the press release in May. Under this agreement, Astellas has obtained an exclusive license for the development and commercialization of XNW27011 worldwide, excluding Mainland China, Hong Kong, Macau, and Taiwan.

Astellas has assigned the development compound number, ASP546C to this asset. This number will be used in future descriptions. The upfront payment under this agreement is USD130 million, and the development milestones to be paid in the near term may be up to USD70 million. Depending on the progress of the program, there may be additional milestone payments or royalty.

ASP546C is an antibody drug conjugate or ADC targeting a Claudin 18.2. The payload is a proprietary topoisomerase 1 inhibitor with an average drug-to-antibody ratio of 8. The linker that connects antibodies and drugs is MediLink's proprietary technology and is designed to be specifically clipped within a tumor tissue.

The FDA has granted fast-track designation for gastric cancer, and a Phase III trial has recently commenced in China under the leadership of Evopoint. Astellas is currently planning to initiate a global Phase Ib/II clinical trial.

The figure on the right shows preliminary efficacy data from the Phase I/II trial currently underway in China in patients with gastric GEJ adenocarcinoma.

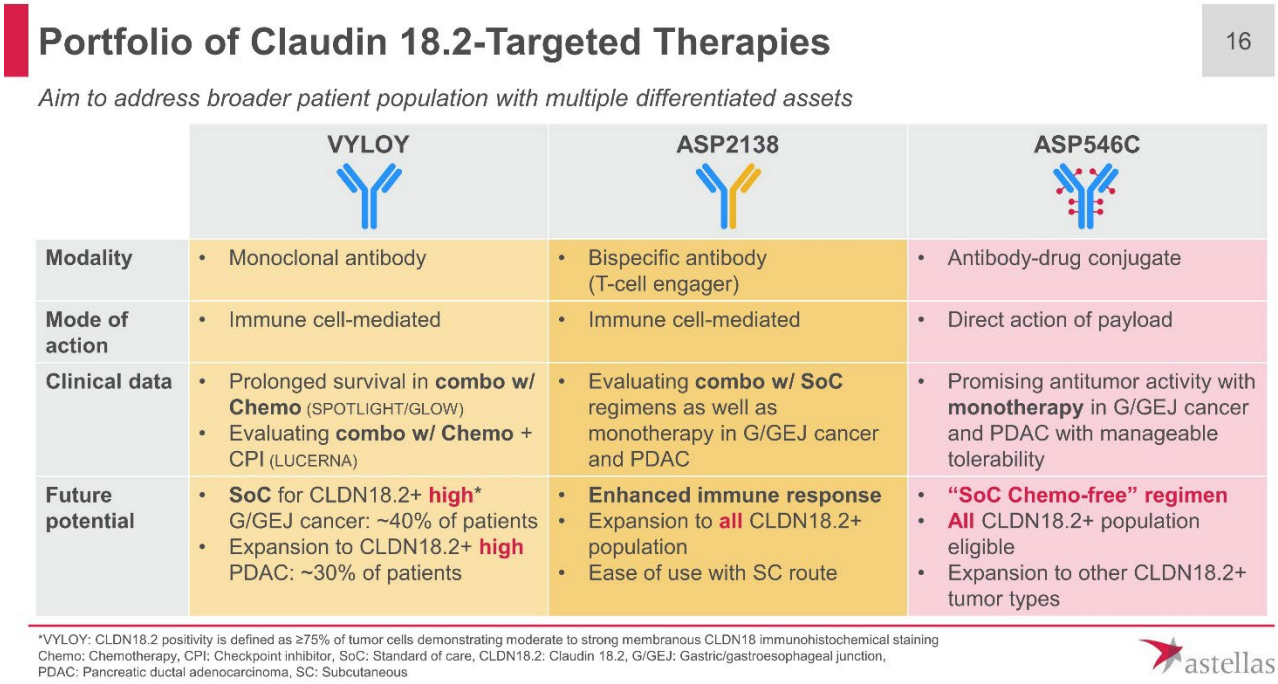
In this study, cases where 5% or more of tumor cells were stained by immunohistochemistry were classified as Claudin 18.2 positive. Compared to the reference value of 75% for VYLOY, patients with lower expression levels are also included for the study.

As shown in the table, doses exceeding 3 milligrams per kilo response rates exceeding 60% and disease control rates approaching 90% were observed.

As shown in the figure, tumor regression was observed in most patients.

The common treatment-related adverse events were hematologic and gastrointestinal disorders.

Astellas has established a leading position, including 18.2 targeted therapy with VYLOY and ASP2138. Through this collaboration, we have acquired a promising asset that further enhances this position. Going forward, we will validate the efficacy of ASP546C in global clinical trials.



Portfolio of Claudin 18.2-Targeted Therapies

16

Aim to address broader patient population with multiple differentiated assets

	VYLOY	ASP2138	ASP546C
Modality	• Monoclonal antibody	• Bispecific antibody (T-cell engager)	• Antibody-drug conjugate
Mode of action	• Immune cell-mediated	• Immune cell-mediated	• Direct action of payload
Clinical data	• Prolonged survival in **combo w/ Chemo** (SPOTLIGHT/GLOW) • Evaluating **combo w/ Chemo** + CPI (LUCERNA)	• Evaluating **combo w/ SoC** regimens as well as monotherapy in G/GEJ cancer and PDAC	• Promising antitumor activity with **monotherapy** in G/GEJ cancer and PDAC with manageable tolerability
Future potential	• **SoC** for CLDN18.2+ **high*** G/GEJ cancer: ~40% of patients • Expansion to CLDN18.2+ **high** PDAC: ~30% of patients	• **Enhanced immune response** • Expansion to **all** CLDN18.2+ population • Ease of use with SC route	• **"SoC Chemo-free" regimen** • **All** CLDN18.2+ population eligible • Expansion to other CLDN18.2+ tumor types

*VYLOY: CLDN18.2 positivity is defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining
Chemo: Chemotherapy, CPI: Checkpoint inhibitor, SoC: Standard of care, CLDN18.2: Claudin 18.2, G/GEJ: Gastric/gastroesophageal junction, PDAC: Pancreatic ductal adenocarcinoma, SC: Subcutaneous

astellas

Page 16 will explain the characteristics of each asset targeting Claudin 18.2, including ASP546C, which was explained earlier. VYLOY is a monoclonal antibody that binds to Claudin 18.2 on the surface of cancer cells, exerting an antitumor effect by activating immune cells that attack cancer. Clinical trials have demonstrated prolonged survival when used in combination with chemotherapy.

For VYLOY as a first-in-class drug, activities promoting awareness of Claudin 18 testing have been executed, and it is aimed to become the standard of care for Claudin 18.2 positive gastric cancer. However, treatment is currently limited to patients with high expression accounting for approximately 40% of gastric cancer patients.

ASP2138 is a bispecific antibody that binds to Claudin 18.2 and CD3 on the surface of T-cells. Like VYLOY, its antitumor effects depend on immune cells. By binding to CD3, it is expected to enhance the immune response by bringing T-cells and the Claudin 18.2 expressing cancer cells into close proximity.

Based on this MOA, if high efficacy is demonstrated in future clinical trials, it may be possible to expand the target population to include all Claudin 18.2 positive patients, including those with low expression.

Additionally, subcutaneous administration is currently being evaluated in clinical trials. If its usefulness is confirmed, it could provide more convenience for patients and healthcare institutions compared to IV.

ASP546C is an ADC that serves its antitumor effects through the direct action of the payload it carries. As shown in the previous slide, preliminary clinical data indicate a promising antitumor activity as a monotherapy.

If further clinical trials are conducted globally and favorable data are obtained, we anticipate that chemo-free enrichment may become possible.

Furthermore, preliminary clinical data suggests that Claudin 18.2 positive patients, including those with low expression, may be eligible for this treatment. We also believe there is potential to expand the indication to other tumor types beyond gastric and pancreatic ductal adenocarcinoma.

As a frontrunner in Claudin 18.2 targeted therapy, we aim to maximize the value of VYLOY. Through advancing the development of ASP2138 and ASP546C, we aim to provide multiple treatment options for a broader patient population.

Page 17, summary of today's presentation. Q1 showed exceptional progress, outperforming our expectations. We expect the positive momentum to continue throughout FY2025. We expect our key strategic products to have continued strong momentum to drive overall revenue and profit growth.

For the focus area approach, we will advance further PoC judgment and flagship programs. We will accelerate research and development of the primary focus, including for programs in line with PoC achievements.

As for SMT, we will continue to pursue further cost optimization to generate growth investment and improve profit margin.

Through these initiatives, we aim to achieve further profit growth throughout FY2025 and enhance the value of our pipeline serving as a foundation for sustainable growth.

While we have now revised our full-year forecast in this earnings report, we plan to review our full-year forecast in our Q2 earnings report, taking into account the strong performance through Q1 and the progress for the future.

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

Question & Answer

Ikeda [M]: That's all as for our presentation today. We now would like to entertain questions from the audience. If you have a question, please press the raise-hand button. You can find it at the bottom of your Zoom screen. If you're joining from your smartphone, if you tap details, raise-hand function will be shown, so please press that. I'm going to name you one by one. If you are named, please unmute yourself on the screen and mention your name and affiliation, and then ask your question. Anyone with a question?

Thank you for waiting. First, Mr. Yamaguchi from Citigroup Securities please.

Yamaguchi [M]: Mr. Yamaguchi from Citigroup Securities. Can you hear me?

Ikeda [M]: Now we can hear you. Sorry.

Yamaguchi [Q]: I'm Yamaguchi from Citigroup Securities. I have a few questions. Mr. Kitamura, you had a summary at the beginning and at the end, Q1 progressed very well. As for the cost, you said the cost was in line with the expectation. As for revenue, it was also in line with the expectations. There is some inventory build for some areas. Even excluding those factors, Q1 progress was very good as it seems. Is my understanding correct? Excluding special factors, is that in line with your assumptions or not? You also talked about Q2. Could you explain once again?

Kitamura [A]: Yamaguchi-san, thank you very much. First of all, Q1 was very strong. At the same time, overall, this was in line with expectations, but there are areas that were better than expected, VYLOY global performance and the speed of uptake. XTANDI was also very strong in its growth.

On the cost side, in reality, SMT worked on certain measures. We are harvesting its effectiveness ahead of the original schedule. Compared to our original forecast, this is working positively and better than expected according to analysis.

Yamaguchi [Q]: Thank you very much. As for XTANDI, Medicare policy change could be affecting the product. Since Q4, there was a numerical guidance. Including such impact, you're still growing the actual volume. As for the impact compared to the full-year forecast, you are progressing well. Including the change of the policy, what about XTANDI's progress?

Kitamura [A]: First, I'd like to briefly give you a whole picture of XTANDI. If there's anything additional, Claus could mention. XTANDI is performing well, not just in the United States with the impact of Medicare Part D, but also globally as well. Our business is expanding with XTANDI so that's the basis. Of course, in the United States, the impact of Medicare Part D exists. What's going to happen to the price is one question. For patient affordability issue, the demand is very robust. In combination of these factors, we are maintaining the good performance. Claus, if you have any addition, please go ahead.

Zieler [A]*: Yes. Thank you, Atsushi. To your question, Yamaguchi-san, we are seeing a very strong performance of XTANDI across all geographies. That continues to be driven, we believe, by our EMBARK data that we published about two years ago. The positioning of XTANDI is most probably the most effective molecule in this disease area and certainly the one where we can claim to say that it has the broadest indications. That is just driving acceptance of XTANDI.

Now as Atsushi just said, in the United States, of course, we have a special situation with Medicare Part D, where since January 1, 2025, we have to give a higher discount to the Medicare system, right? Our gross to net is impacted by that reform of the Medicare Part D design.

However, what we are seeing is almost an acceleration of the volume growth, which has been strong, as you know, over the last two years already on the back of the EMBARK data, also in the United States.

Medicare Part D is doing what it was designed to do. It is lowering the co-pay that patients have to afford out of pocket, and it is allowing patients to take that co-pay and spread it over 12 months rather than having to pay it at once. That means more patients are able to access XTANDI from an affordability point of view that were not really able to access XTANDI before. They probably went into generic options or a PAP program before. That is why we're seeing paid demand on XTANDI growing so significantly in the United States.

Just as a number, the Q1 growth of paid demand for XTANDI was 33% versus the same quarter of the previous year. That's a very, very high growth rate of pay demand that we've always been in the 20s in the last quarters, but this is the highest we've seen recently.

Yamaguchi [Q]: Thank you very much. The tariff factor is factored in to a certain extent. That's my understanding, as manufacturing is expected to increase, and that trend is likely to continue. Now, new initiative in order to increase the production in the United States, what are the other things that they are trying to do? As Astellas has said, is there anything you are trying to do?

Kitamura [A]: Thank you very much for pointing out that question. Including the US, there are a lot of discussions that are ongoing. Currently, internally, we have tasked teams to collect information, analyze it, and come up with several potential scenarios so that we can discuss those scenarios and the potential situations. I cannot tell you any specific numbers, but for our United States business, it's extremely important. To a certain extent, we are producing products in the United States. For the future, new products, where they are going to be produced, when you think about it, you have to think about the situation in the United States. At this moment, nothing is fixed, so we are not sure what kind of scenario is actually happening. I'd rather refrain from making a specific comment. Of course, we are discussing about it internally.

Yamaguchi [M]: That's all, thank you.

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

Wakao [M]: JPMorgan, Wakao is my name. Can you hear me?

Ikeda [M]: Yes.

Wakao [Q]: Thank you. This might be a follow-up question of Yamaguchi-san. First of all, in Q2, you are going to collect more information. Top-line, I think you made a detailed explanation. When you are answering Yamaguchi-san's question about the cost from earlier phase, you said are going to harvest. More specifically, R&D, SG&A, what is it against the full-year plan? Against the full-year plan, what is it likely to be if you go in this phase?

As for the tariff in EU for the pharmaceutical products, it is 15%. You produce products in Ireland, so that percentage is lower than the conventionally expected. Could you make some comments about this? If it is possible, please answer how you are going to incorporate this factor in the revised plan.

Kitamura [A]: Wakao-san, thank you very much. We didn't say the upward revision at all. For the SG&A, we are harvesting the outcome from SMT. To what extent it is reflected in the revenue, we use that as a fund for either the Q2 or Q3 or Q4 business for further investment. That kind of discussion is currently ongoing internally. There are things that we have to push further or things that we have to reduce further. Internally, we are very active discussing those matters.

For R&D, our initial plan includes the PoC judgment that is coming in the middle to later phase of the fiscal year. Depending on the timing, we need to think about the acceleration if it is necessary. After SMT, what we learned is that the areas that we can harvest as early as possible, we would do that, and that is the positive factor for us.

Just like having a discussion with Taniguchi. For example, ASP3082, we were able to get a PoC, even the second PoC. How can we excel this further? It's not something like we are going to cut everything through effort. We come up with certain savings that are going to be used to invest for further acceleration, or it's going to be reflected in the bottom line. That is under discussion these days. That is the response to your first question.

As for the tariff matter, 15% in EU, that is the story that came up only recently. Is it really true? What would happen in the case of Japan? We have to be cautious about such kind of information. If information is collected in Q2, we are going to reflect whatever needs to be reflected.

It will be decided only after things are all decided clearly. Until then, internally, we have a downside. The downside is included in making the forecast. At against the buffer we have, the impact will be plus or positive or negative. That is continuously monitored internally. If we see a clear picture, then we will incorporate that so that we can report it to you.

Wakao [Q]: As a follow-up, fixed costs compared to your internal plan are lower for SG&A costs and R&D costs. As for the tariff, according to a recent media report, compared to your assumptions, it's not going to be higher than that. Is my understanding correct?

Kitamura [A]: For the latter part of your question, it's not very much different from what you think because we are factoring in a certain level of risk, but not so much.

Wakao [Q]: Okay. Fixed costs compared to your internal plan, lower in Q1?

Kitamura [A]: We are able to achieve reductions earlier than scheduled.

Wakao [Q]: Okay. Second, IZERVAY numbers have been shared, and I was able to understand. What about the monthly trends? That's something I'd like to know. Gross sales on a monthly basis, there is something we can see in July or June compared to May, more than a 10% growth, particularly growth was seen in the month of in June. In June, gross sales and net sales compared to usual, any gap? That's something I'd like to know. The gross sales results we are monitoring, if you know, that trend is continuing also in July. Since July and onwards, based on the trend, net sales are also going to increase. Could you share anything?

Kitamura [A]: Thank you for the question. The numbers Wakao-san is seeing, what are you referring to? What's the difference compared to our numbers is the question. As for the details, it's difficult to respond. On our end, also in July, we still see growth. That's what we can say. Claus-san, do you have any further comment? Could you please?

Zieler [A]*: Yes. Thank you for your question. I think there are a few things to note. First of all, this quarter was the strongest quarter for IZERVAY since launch. The expectation that we set out in our last earnings call, that with the label update, that was accepted by the FDA in February. We would return to the growth curve that we had before the CRL. That is starting to bear out. This quarter is the first positive data point that we're returning to growth. As you can see, it's a very substantial growth with a 22% QoQ evolution.

I think the overall trend picture that we had imagined is intact in terms of returning to growth. As Atsushi said, the preliminary data from July further underlines that this trend is continuing and is in line with our expectations.

Now, when we look at demand, we actually had expected a slightly stronger picture this quarter, which is why we said in the previous IR call in early July that this quarter was slightly behind our expectations. That's mostly due to inventory fluctuations, so inventory was a little bit lower. We had changed the distribution system, and we had gotten some returns because of that. That's why this number is slightly lower than we had expected. But what's important is that the underlying demand trend is recovering from that CRL period where it had stagnated and is returning to the growth phase exactly as we had imagined.

Wakao [Q]: Okay. Understood. Lastly, one more question about most favored nation status. I have a question on that. In reality, for the target price, I don't know if it's the US government or any other organization, but any contact with them about the target price? How do you see the most favored nation status in terms of the feasibility? Any comment from your side? That's all from me.

Kitamura [A]: Thank you for your question. Regarding MFN, most favored nation status, based on the facts from May 12, an executive order was signed. Within 30 days, the targets or goals are going to be communicated according to the announcement. As of today, we haven't received any notice or notification from the US government. We haven't started any discussions with the US government as of now. That's the current status.

What is going to happen in the future? As soon as we receive the notice, we will examine the contents and consider what to do. As of now, we haven't received any notice, and we haven't started the discussions with the government yet.

Wakao [Q]: What about the feasibility? Is that going to be realized or not? What's your view?

Kitamura [A]: As of now, in the current stage, there's nothing I can comment. Please allow me to refrain from commenting.

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

Ikeda [M]: Thank you, Mr. Wakao. BofA, Mr. Mamegano, please. Mr. Mamegano, please unmute yourself. Mr. Mamegano, can you hear us? There might be a system problem.

In that case, we would like to move on to Goldman Sachs Securities, Mr. Ueda, please.

Ueda [M]: Goldman Sachs, Ueda is my name. Thank you very much.

Ikeda [M]: Thank you very much.

Ueda [Q]: My first question is also related to the tariff. This might be a follow-up question. Currently at Astellas, what kind of countermeasures are you doing? For example, for the United States, you are now building up the inventory. Also, you mentioned that for the future, you are considering a lot of things. For example, making changes in the manufacturing site or making further investments to the United States, what kind of items are on your list for further consideration regarding tariff?

Kitamura [A]: Thank you for your question. Of course, we are not just waiting without doing anything. For a short-term perspective, what can we do, including the buildup of the inventory, what should be done at what point in time? In the ordinary S&OP process, we are working on it.

The investment in the United States. Again, the United States is the biggest market for us. R&D, supply chain, including those, we have a lot of business in the United States. For those, what we can say is that conventionally, we are working on that.

Furthermore, what kind of leverage are we going to now make use of? what should be pushed at what point of time? For decision-making, there are still a lot of uncertainties. Unlike other industries, we cannot change supply chain so easily or quickly. Including that, we still are having the discussions internally.

Ueda [Q]: Thank you very much. Second question, that is about R&D expenses. In April, the management system was changed. That is also impacting for R&D costs. What kind of impact have you experienced? R&D expenses progress level is quite low. As you mentioned, if the PoC of several projects is achieved, then it will be further accelerated. Is it in line, or it is still underperforming compared to your plan? That's what I want to know. In April, for the R&D primary focus lead, those are going to be integrated to have a new management system. With this kind of organizational change, what kind of impact have you experienced? If this new management is going to be in a steady state, then the cost or expenses status is going to be further accelerated for a better situation.

Kitamura [A]: Thank you for your question. Briefly, first, I'd like to talk about the cost or expenses. After that, Taniguchi is going to make a detailed answer.

As for costs or expenses, as has been pointed out, the foundation, what we have is the reduction, which is better than we've expected or we've planned, so it's accelerated. That's a positive factor for us. On the other hand, we are going to accelerate R&D. PoC were gained or achieved. Therefore, we are going to accelerate this further, we are going to save money for that. For the new organization, about what has changed further, Taniguchi is going to make a comment.

Taniguchi [A]: Now, I'll talk about the cost-related matters, including the current R&D organization. For the change in the organization this fiscal year, from April 1, this new organizational system was launched or started. With that, as has been mentioned, primary focus lead research as well as development, they have become one organization. With that, needless to say, certain synergy, including cost reduction, was achieved marginally. This cost in Q1 is low, just like Kitamura explained.

Since last year, the internalization of clinical trials has been ongoing. With that, we were able to reduce the outsourcing cost, and that is more than what we expected. I think that this is the biggest factor. We have this much cost reduction effect.

For ASP546C from Evopoint, we will develop a new development plan. As has been said, ASP3082 in PDAC and lung cancer, we're going to accelerate such clinical studies as well. Towards the latter half of the current fiscal year, we would promote and accelerate development, which we'd like to focus on. We'd like to allocate our costs in those areas under this structure.

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

Ikeda [M]: Ueda-san, thank you very much. Next, Mamegano-san from BofA Securities.

Mamegano [M]: Can you hear me?

Ikeda [M]: Yes.

Mamegano [Q]: Mamegano from BofA. I wanted to ask a question about R&D. ASP3082 achieved PoC in lung cancer following PDAC as well. How are you going to proceed after PoC achievement, and around when can you talk about the next stage? That's my first question.

Also, I have another question. PADCEV's NMIBC study is terminated. What's the reason? You might have explained earlier. If that's the case, sorry, but I'd like to confirm.

Taniguchi [A]: Thank you very much. I would respond. First, ASP3082, as you said, in PDAC and NSCLC, the PoC was achieved in both indications, so we will publish the data from them. The abstracts should be accepted first and then see when to publish and which data can be shared. Phase III regeneration trial would be considered. Needless to say, we have to accelerate when, at what timing, what kind of studies should be initiated into the future. Once we determine our plan, we hope we can explain. We are accelerating so that we can start early. We are making such efforts internally. Once such a time comes, we'd like to explain.

As for PADCEV, you're talking about non-muscle invasive bladder cancer, right? Regarding the study, we are working with Pfizer to implement the study. The data are being finalized, and we had a variety of discussions about the safety and efficacy as well as the data. We have also adjusted the competitive situation right now comprehensively and decided not to proceed with the development. That's the decision by Pfizer and Astellas.

Mamegano [Q]: Thank you very much. Additionally, in Q2 onwards, the MIBC interim analysis results will be announced. Is there going to be no impact on that part?

Taniguchi [A]: MIBC is already in Phase III. Enrollment is over, and final events are being collected. We are waiting for analysis results. Of course, regarding MIBC, it's not PADCEV monotherapy but a combination with pembrolizumab mainly as a regimen. Regarding NMIBC, our termination decision in NMIBC will not affect MIBC indication.

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

Ikeda [M]: Mamegano-san, thank you very much. Next, Morgan Stanley MUFG Securities, Mr. Muraoka, please.

Muraoka [Q]: Thank you very much. Muraoka from Morgan Stanley speaking. First, I have a question to Kitamura-san. You said that you may not necessarily make an upward revision in Q2, but I believe that it can be an upward revision. I think I felt such a nuance because of the good results. I have a question. If the profit figures are going to increase, the dividend payout currently is JPY74 up by JPY4, is there any plans to increase this? Or you may slow down the dividend payment moving forward, but what's your plan? I'd like to hear your view on your thinking behind the dividend.

Kitamura [A]: Regarding the dividend, according to our principles of capital allocation, needless to say to you, for growth, we should make investments for growth. Expenses or investments can be a question. Finally, as Taniguchi said, we have good signs of science, so we'd like to invest in those areas for sure. Stable return to shareholders as part of those measures, we have a dividend. It's not the decision in a single year. We have to look at the situation in multiple years. In order to strengthen the balance sheet, we would repay the debt. We're doing those things a lot. Because of the good results in Q4, are we going to increase the dividend payment and increase the pace of dividend payout? Not necessarily. Overall, we have to judge.

Muraoka [M]: Understand. Profit momentum is really good. The guidance for this year, you might think that the guidance, the dividend is too low.

Kitamura [A]: It's not like that. It's just like last year, a JPY4 increase of dividend, so there is no change since last year. The performance is good. That's why there is an increase or decrease. It's not something like that for a certain period of time. We observe the cash flow to make a decision. Also, this is related to stock prices. The current yield of the dividend is to a certain extent. That's why for the decision-making factors, a JPY4 increase is not changed. There is a consistency here. Of course, a lot of factors incorporated, capital allocation, principles, and balance sheet enhancement, those are considered in a comprehensive manner, and the discussion is always ongoing.

Muraoka [Q]: Thank you very much. For the data book (supplement document), the country-wide sales are what I am referring to. In China, JPY29.4 billion YoY plus JPY10.8 billion, and the strategic buildup of the inventory, that is what you're trying to do. My question is, out of the plus JPY10.8 billion how much was from the buildup of the inventory? It doesn't have to be necessarily the number. Could you tell us about that situation?

Kitamura [A]: I cannot tell you the overall amount, but a third, for example, I think it's the same thing. Basically, China is a big market, and PADCEV was launched last year in China. This June, VYLOY was launched. In that perspective, our Strategic Brands, the setting for selling them was well prepared. Claus, do you have any comments?

Zieler [A]*: Yes. You have to differentiate between the established portfolio, so tacrolimus, XTANDI, XOSPATA, and the launch products, right? When you launch products into a large market like China, you need to build a certain inventory because you just don't know how quickly the uptake will be, so that's what we did. We've made sure that we imported into China, both for PADCEV and for VYLOY, which are the two launch brands with a sufficient amount of goods. Those are then registered as sales upon import, and that's what you see. Over time, we will then, of course, be able to judge more clearly what the in-market demand is, and we'll update you when we have those numbers.

Muraoka [Q]: Thank you very much. One last question for me. IZERVAY, in the United States, if the sales is low, it might end up with an impairment loss. That's what I often talk about with the investors. If slow momentum of growth continues, a USD4 billion impairment loss risk is not necessary for us to discuss. We don't need to worry about that kind of impairment loss. Could you make a comment about this?

Kitamura [A]: Thank you very much. The IZERVAY sales in the United States, the intangible asset in sales, right? Amortization has already started, so the remaining intangible asset is now decreasing. Just like Claus mentioned, the growth momentum returned, and the treatment rate is 15%. For that, we would like to increase it to over 35%. If that happens, we don't need to worry about impairment loss.

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

Ikeda [M]: Muraoka-san, thank you very much. Next, Sanford C. Bernstein, Sogi-san, please.

Sogi [Q]: Thank you very much. First of all, the question is about PADCEV. Last fiscal year, QoQ PADCEV, your sales was quite flat. That is my understanding. This year, demand basis, the growth is about 12%. For Q4, consecutively, it's been flat, but now, it is 12%. That means that there are some changes that happened. NCCN guideline has been updated. Has it contributed to the increase of new patients? Could you explain the background of this situation?

Kitamura [A]: As for PADCEV, demand in the previous fiscal year, in reality, there was a change in the distributor to have some inventory build. Excluding that, 7% growth has been recorded in reality. As you pointed out, NCCN updated guidelines is one factor to contribute. There is a very strong momentum by taking a high market share to be maintained and also to be expanded. Claus-san, do you have any further comment? Please go ahead.

Zieler [A]*: Yes, Sogi-san, thank you for your question. I would like to go back to the uptake curve that we've been discussing with you on several occasions, where PADCEV is quite particular. It ramps up very, very quickly. Within six months, we come to a shoulder where the progression of the brand in the market starts flattening off. That's exactly what we've seen. We've always said after that shoulder, we would be in the mid-single digits in terms of growth rate, and that's exactly what we've seen. We believe that in the United States, in the first-line indication for urothelial cancer, we're now starting to be pretty much at the peak market share that we can imagine.

Outside the United States, that's where we're still in that steep take-up curve, so that's where we see much higher growth rates because we haven't hit that shoulder yet. Because the United States launched first, we're just more progressed in terms of the uptake curve, and we are in that more single-digit growth phase, which I believe will continue in the future. I don't think we're going to see double-digit growth in this indication in the future in the United States.

Sogi [Q]: Thank you for the clarification. Thank you. Next, regarding the pipeline products, KRAS targeting protein degraders, I have a question. For KRAS targeting degraders, two G12D, IND was approved for pan-KRAS, and the first patient trial is going to start. To begin with G12D, you have two similar products. In the future, in the end, you're going to converge into either of the two programs or pan-KRAS compared to the G12D products ahead of you. What kind of development are you considering to differentiate from the existing or the degraders ahead of you?

Taniguchi [A]: I'd like to respond. First of all, for KRAS G12D, we have two assets, ASP3082 and ASP4396. Regarding the two, E3 ligase and ASP4396, ligase is a different type. That's the difference between the two. The physical properties are also different, so these two molecules are under development in Phase II. ASP3082 has already been discussed before. In two tumor types, we achieved PoC. For the registration study, we are going to proceed.

As for ASP4396, what are we going to do with this? Physical properties are slightly different. Right now, PDAC, lung cancer, and CRC are the indications right now, but we will see the results and the data to proceed in parallel. Are we going to decide whether to discontinue this product? We will discuss. We are collecting data right now. Once we are able to collect the data, once we make a final decision, we'd like to communicate to you.

Pan-KRAS 5834, pan-KRAS covers not just K12D, but other KRAS to be degraded. They are broader indications, which could be possible. For example, in PDAC, in about 90% of pancreatic cancers, a certain KRAS mutation is being seen according to the publication. More broad pancreatic cancer or PDAC coverage could be possible. As for lung cancer, 25% to 30% of lung cancers have a certain KRAS mutation according to my memory. G12D in lung cancer, it's about 5%. More broad lung cancer indication can be targeted by us.

ASP5834, just at the time of the IND that was accepted, so clinical trial is going to start. In that way, we would like to prepare the situation to get more data.

Sogi [Q]: G12D mutation target, that's the start point to move to the pan-KRAS as well. Is that because you've changed the way of thinking, or G12D degrader development itself is easier? What's the background of this?

Taniguchi [A]: As a product, if it is easy or not, that's one thing. Of course, if the target is wider, the efficacy on the tumors, and the safety is also different. Frankly, we know that based upon the preclinical data, so using such kind of information as a reference, we are working toward the development of both. Also, we get opinions from the experts for this field, and targeted products are better to be developed fast. That is one opinion that we have received.

From the perspective of the patients, a wider indication is better for ease of use for patients and doctors. That's why we are working on the development for both.

Sogi [M]: Thank you very much.

Ikeda [M]: Thank you very much, Sogi-san. Next, Nomura Securities, Matsubara-san, please.

Matsubara [M]: Matsubara from Nomura Securities. Can you hear me?

Ikeda [M]: Yes.

Matsubara [Q]: Thank you. First question is about MFN. In a previous comment, you said that you don't have any particular discussions currently with the United States. However, looking at the other overseas pharmaceutical companies, in order for the negotiation with the US government, they are thinking about the direct sales to the US market. Are you thinking about the direct sales in the US market?

Kitamura [A]: As has been mentioned, we don't have the specific information yet. Therefore, it's very difficult to make a comment. That is not so meaningful.

Matsubara [Q]: The next question is about the VEOZAH. Bayer came up with elinzanetant. The approval was delayed by three months. That is a positive situation for you. However, in other markets, the competitor's product is already launched. Also, the blood test requirements are lower than VEOZAH. What is this situation impacting on your performance? What's your view?

Kitamura [A]: Just like you mentioned, the PDUFA was postponed. We were thinking about the decision-making depending on the label that they are granted. It is likely that it is going to be delayed. In some countries, the competitors' products have been approved. That's what we know. That is not impacting onto the discussion about changing the direction because the US market is too big for us.

Zieler [A]*: Thank you for the question. I want to emphasize that the label that we've seen for elinzanetant in the UK is very, very, very similar to the label that we had at launch. Remember that the liver side effects is a very rare side effect that has not been seen in clinical studies, neither in the Bayer compound nor in our own compound. What you're seeing today in the label that Bayer has obtained in the UK is really almost identical to the label that we had when we launched because the liver side effects simply have not been observed yet in real practice.

The question then becomes what happens over time? Will elinzanetant over time accumulate the same AEs that we saw as we started building a patient base, or will they not? The real question is, is it a class effect, or is it not a class effect? We will not know that for a number of months, if not maybe six months, nine months, something like that. I think this will be something where you can't expect us to say, "Oh, now the label has been published. Now we know exactly what the impact of elinzanetant will be in the competitive behavior with VEOZAH." It's a picture that will become clearer over a fairly medium-term time frame as more data are gathered.

The other thing I would like to say is, actually, I welcome the entry of Bayer with another NK antagonist. It's not exactly the same target that their molecule has versus the NK3 that we target very, very specifically. It is also a non-hormonal treatment for vasomotor symptoms. We know that that market is very large. We also know that that market takes time to develop. With two companies communicating and educating in this marketplace, I think this market will grow more quickly than if one company does it alone. You have to see, in my mind, the entry of Bayer both as a competition to our position with VEOZAH but also as a benefit for the development of the market as a whole.

Matsubara [Q]: Thank you very much. Additionally, your VEOZAH, when it was approved in the United States, there was a delay by three months. What kind of discussions did you have with FDA? Why was there a delay? As far as you can share, could you talk about it, if possible?

Zieler [A]*: Yes. It's really impossible to answer that question because it's a decision of the agency. In their internal processes, we don't have insight into why they decide to ask for an additional 90 days. Maybe the reviewer felt sick and had to come back. We don't know all these things. Please accept that that's not something that a company that is making the application would ever understand. It's the decision of the

agency to ask for more time. It is based on their own internal processes, the time they need to make an assessment. We're not privy to that information.

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

Ikeda [M]: Matsubara-san, thank you very much. Next, UBS Securities, Mr. Sakai, please.

Sakai [Q]: Sakai from UBS speaking. I have two questions. First, your forecast revision was mentioned. In Q1, listening to your explanation, Strategic Brands are growing, and the profit has more impact on mirabegron and PROGRAF legacy products. The profit is almost 100% for these products. On the other hand, for Strategic Brands, there are still promotion costs needed. The profit upside in the results could be seen with PROGRAF and mirabegron, which we need to watch closely. There are no mirabegron generics, but if there are generics in Q2 and beyond, what would be the impact? If I can calculate, I can tell, what kind of risks should we assume? That's my first question for you.

Kitamura [A]: Sakai-san, thank you very much for your question. First, we'd like to sell Strategic Brands for sure, that's the most important thing, so we are working on this. To do so, with SMT, we have additional funding so that we can invest to continue a good cycle, which we think is very important. If you look at the YoY progress, what is the biggest profit driver? Like last year, the growth of Strategic Brands, I should say that that's our first priority.

At the same time, for XTANDI, as there was a question and Claus responded, it's doing very well. We are discussing LOE, but we are doing whatever we can right now. Because of the big business, there is a positive impact. As for mature products, how to maintain or how to protect those products is a question. Myrbetriq in the United States, for example, there are generic versions, so what kind of action are we going to take to protect our products? This is a strategy for defense which is working very well right now.

Last year, to a certain degree, we factored in some level of risk. Against the initial forecast, we are able to achieve a lot of upsides, and we're continuing a similar defense strategy. At some point, we will have LOE, of course. As Sakai-san pointed out, if you calculate, you may be able to tell to a certain degree, but we'd watch that. Based on the assumption that is going to happen, we'd like to grow our Strategic Brands to build a foundation for growth. That's our first priority. We will continue this into the future as well.

Sakai [Q]: Mirabegron generics. There are two generics by two companies. You can prevent the further entry of generics.

Kitamura [A]: Other than the two, the formula or formulation patents, we have a litigation action we are taking, so there is a favorable decision for us right now. Of course, generics companies may appeal additionally. For the time being, there is a favorable decision for us. When? Actually, it's going to be in February next year or beyond.

Sakai [Q]: In February and beyond, you will see the outcome of the litigation?

Ikeda [A]: The litigation will start in February, and then we will see the results after that. February 9, that's the start of the litigation or trial.

Sakai [Q]: One more point. I have a question for Taniguchi-san. Claudin 18.2 as a new biomarker, it may not be new, but as a biomarker, it can be very useful. According to the rising assessment of this, your products, which page was it? You have three modalities right now, monoclonal antibody, bispecific antibody, and ADC this time. In the future strategy, modality would be expanded. Is that going to be the direction, or would three modalities have a deep dive? What's your view? Expansion of tumor types, Claudin 18.2 expressing cancers,

including lung adenocarcinoma and bladder cancer, which have been seen as promising. Are you going to address those with your ADC?

One more question. This deal with Evopoint, US pharmaceutical companies acquire the Chinese biological companies. They are trying to acquire smaller companies in the earlier phase. I believe that this is the very first time for you to make the deal with the company in that sense. Taniguchi-san, for the Chinese biological companies, do you think this kind of trend is going to be further accelerated, especially from Japan as well? As Astellas, are you going to enrich further this kind of approach in the Chinese market or Chinese companies?

Taniguchi [A]: Thank you for your question. The modality of Claudin 18.2, just like you mentioned, VYLOY, ASP2138, and Evopoint ASP546C. We have those three. Are we going to increase the modalities more? So far, using these three different modalities, we are thinking about establishing strategies for Claudin 18.2. VYLOY was already launched, and Claudin 18.2 is here. Claudin 18.2 highly expressed tumor types. We believe we can expect this business a lot, so the clinical trial has started. The gastric cancer checkpoint inhibitor chemotherapy combination study has proceeded so that the more useful and more efficacious drug is what we can realize.

For ASP2138, this is a bispecific antibody. CD3 is added as a T-cell engager. The CD3 is compared to VYLOY, for example, how efficacious it will be. In order to learn that, Phase I study is ongoing. That data is going to be available soon. Based upon that result, what kind of patients will be targeted so that this ASP2138 could be active enough within our portfolio targeting Claudin 18.2? When the result becomes available, we would like to talk more about this.

For ASP546C, which is in China already, Evopoint is going to start the Phase III study. It has very robust data for gastric cancer and also the pancreatic cancer for the second line and afterwards, so we would like to promote the development in other countries than China. That is under consideration currently.

The second question is about the pancreatic cancer or gastric cancer. Other than those, what would be the strategies? We are going to have more considerations, especially to what level of Claudin expression level would be required, what kind of modalities or what kind of combinations. Those are all related. Depending on the discussions in the future, wider indications on top of gastric cancer and PDAC will be a conceivable scenario. Once the data become available, how we are going to horizontally expand this could be explained to you.

The third question, that is a biological company in China. This time, we have a license agreement with Evopoint. While we are working day-to-day with a biologic company in China or a tech company in China, they come up with new modalities or new drugs, especially for the Chinese market. We see more and more companies emerge, but this time, we came to an agreement with Evopoint, the US biotech company. On top of that, as Astellas, throughout the world, such biotech start-up companies are candidates for collaboration, if there is any opportunity. In China, such a biotech industry is quite matured. It is the impression that we have. In the future, further collaboration with Chinese companies will take place if there's any opportunity.

Sakai [M]: Thank you very much.

Ikeda [M]: Thank you, Mr. Sakai. I'm sure that you still have many questions, but the time is up. With this, we would like to close this earnings call. Everyone, thank you very much for your participation.

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