



Astellas Pharma Inc.

Earnings Call for the Q1 of FY2026

August 5, 2026

Event Summary

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[Participants]		
[Number of Speakers]	4	
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	Tadaaki Taniguchi	Chief Research and Development Officer (CDRO)
	Claus Zieler	Chief Commercial & Medical Affairs Officer (CCMAO)
	Nobuko Kato	Chief Communications & IR Officer
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	Seiji Wakao	JPMorgan Securities
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	Hiroyuki Matsubara	Nomura Securities
	Hiroshi Wada	SMBC Nikko Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Miki Sogi	Sanford C. Bernstein

Presentation

Kato: Thank you very much for joining Astellas Pharma's FY2026 Q1 year-to-date financial results announcement meeting despite your busy schedule today.

I'm delighted to serve as the emcee today. I'm Kato, Chief Communications and IR Officer. Thank you very much for your time.

Today, after our presentation, we will move on to a Q&A session. We will explain based on the meeting material posted on our website. Including Q&A, simultaneous interpretation is available in Japanese and English. We cannot guarantee the accuracy of simultaneous translation so thank you for your understanding. You can select the language from your Zoom webinar screen menu. If you select the original sound, you can listen to the original sound without going through simultaneous translation.

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Let me introduce the participants from our company. CFO, Atsushi Kitamura; Chief Research and Development Officer, Tadaaki Taniguchi; and Chief Commercial and Medical Affairs Officer, Claus Zieler. We have three executives attending today.

We now like to go into presentation. Kitamura-san, please.

Kitamura: Hello, everyone. I'm Atsushi Kitamura from Astellas Pharma.

Thank you very much for joining our FY2026 Q1 year-to-date financial results announcement meeting after a very busy schedule today.

Cautionary Statement Regarding Forward-Looking Information

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

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

Q1 YTD/FY2026 Overview

- Strong Q1 progress toward record-high full-year Revenue and Core OP -

Financial Results

- ✓ Robust growth in Revenue (+27% YoY) and Core OP (+56% YoY)
- ✓ Core OP margin increased to **34.5%** (+6.4ppt YoY)
- ✓ Driven by strong Strategic Brands growth and disciplined cost optimization, with favorable FX impacts

Pipeline Progress

- ✓ PADCEV (MIBC): Approval (Europe, US) and filing (Japan, China), Phase 3 study initiated for bladder-sparing (EV-309)
- ✓ VYLOY (combo with pembro and chemo): Target enrollment achieved ahead of schedule in Phase 3 LUCERNA study
- ✓ Two new Phase 3 studies opened for recruitment (setidegrasib NSCLC, ASP2138 G/GEJ)
- ✓ New clinical data presented (setidegrasib BTC and GYN, ASP546C G/GEJ and PDAC)

Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA. See slide 23 for overview of cost optimization.
BTC: Biliary tract cancer, chemo: Chemotherapy, G/GEJ: Gastric/gastroesophageal junction, GYN: Gynecologic cancers, MIBC: Muscle-invasive bladder cancer, NSCLC: Non-small cell lung cancer, PDAC: Pancreatic ductal adenocarcinoma, pembro: Pembrolizumab

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On page three, I will give you an overview of FY2026 Q1 year-to-date financial results.

Towards record high full-year revenue and core operating profit, we made a strong Q1 progress. Revenue increased by 27% and core operating profit rose by 56% YoY. Both made a robust growth. Core operating profit margin increased by 6.4 percentage points YoY to 34.5%, exceeding 30%. Overall growth was driven by continuous strong strategic brands growth and by ensuring disciplined cost optimization.

There were favorable FX impacts due to the yen's depreciation, but even excluding ForEx impact, revenue and core operating profit grew substantially by 15% and 38%, respectively.

Our pipeline also made a solid progress. PADCEV in its development for MIBC, muscle-invasive bladder cancer, was approved in Europe and the United States. Filing was made in Japan and China. Furthermore, Phase III study was initiated for bladder-sparing MIBC. PADCEV achieved multiple significant milestones.

As for VYLOY, in Phase III LUCERNA study, to evaluate combination with pembrolizumab and chemotherapy, target enrollment was achieved well ahead of schedule. Two Phase III studies were opened for recruitment for setidegrasib NSCLC and ASP2138 for gastric cancer. Development made steady progress. Also, new clinical data was presented for setidegrasib in BTC, biliary tract cancer, and gynecologic cancer as well as for ASP546C in gastric cancer.

Agenda



Q1 YTD/FY2026 Consolidated Financial Results



Pipeline Progress

Page four is the agenda for today.

From the next page, I will explain these topics.

Q1 YTD/FY2026 Financial Results

Great start to FY2026, delivering robust revenue and Core/Full OP growth fueled by favorable FX impacts

(billion yen)	Q1 YTD FY2025	Q1 YTD FY2026	Change	Change (%)	FX impact (YoY)	FY2026 FCST*
Revenue	505.8	640.9	+135.1	+26.7%	+60.0	2,220.0
Cost of sales	94.8	122.7	+27.9	+29.4%	+9.0	445.0
SG&A expenses	197.0	215.1	+18.1	+9.2%	+19.6	800.0
US XTANDI co-promote fee	62.9	67.5	+4.6	+7.2%	+6.3	216.0
SG&A excl. the above	134.1	147.6	+13.5	+10.1%	+13.3	584.0
(SG&A ratio**)	26.5%	23.0%	-3.5ppt			26.3%
R&D expenses	71.7	81.7	+10.0	+14.0%	+5.8	355.0
(R&D ratio)	14.2%	12.8%	-1.4ppt			16.0%
Core operating profit	142.3	221.4	+79.1	+55.6%	+25.5	620.0
(Core OP margin)	28.1%	34.5%	+6.4ppt			27.9%
< Full basis >						
Amortisation of intangible assets	32.8	35.7	+2.9	+8.9%		
Other income	4.4	3.9	-0.5	-10.4%		
Other expenses	21.3	4.3	-17.0	-79.8%		
Operating profit	94.6	184.5	+89.9	+94.9%		395.0
Profit before tax	90.4	186.5	+96.1	+106.3%		385.0
Profit	68.4	141.8	+73.3	+107.2%		300.0

*Disclosed in Apr 2026, **Excl. US XTANDI co-promote fee
Actual exchange rates of Q1/FY2026: 159 yen/USD, 185 yen/EUR (Actual exchange rates of Q1/FY2025: 145 yen/USD, 164 yen/EUR)
Exchange rate assumption of FY2026 FCST: 150 yen/USD, 180 yen/EUR

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On page five, I will explain FY2026 Q1 year-to-date financial results.

Following last fiscal year, we were able to make a great start to FY2026 again. In addition to solid growth of strategic brands, fueled by favorable ForEx impact, revenue, core operating profit, and full operating profit all grew substantially. As a result, quarterly results hit a record high since the establishment of Astellas.

Let me explain main items. Revenue reached JPY640.9 billion, substantially up by 26.7% YoY. Core operating profit significantly increased to JPY221.4 billion by 55.6% YoY. While continuing to steadily make investments necessary for future growth, we ensured disciplined cost management, which enabled us to expand our profits substantially.

The bottom half of this page shows our full basis results. Operating profit was JPY184.5 billion, and profit was JPY141.8 billion, both increased by about twofold compared to the previous year.

Q1 YTD/FY2026 Financial Results: Main Brands

Continued strong momentum of Strategic Brands, driving overall revenue and profit growth

(billion yen)	Q1 YTD/FY2026	YoY Growth	Strong momentum expected to continue throughout FY2026
Strategic Brands Total	160.3	+48.3 (+43%)	PADCEV - Progress exceeding expectations, driven by strong penetration in global 1L mUC and US MIBC IZERVAY - Strong growth momentum driven by increased new patient starts, achieving market leadership in geographic atrophy VYLOY - Solid sales growth driven by continued increases in Claudin 18 testing rates VEOZAH - Continued growth, whilst holding a strong share position versus new competition in the US
 PADCEV	75.5	+20.0 (+36%)	
 IZERVAY	27.2	+11.2 (+70%)	
 VYLOY	21.1	+7.1 (+51%)	
 VEOZAH	14.9	+5.3 (+55%)	
 XOSPATA	21.6	+4.6 (+27%)	
 Xtandi	276.6	+43.6 (+19%)	Progress in line with expectations, supported by favorable FX impact

VEOZAH: Approved as "VEOZA" in ex-US.
1L: First line, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer

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Page six shows FY2026 Q1 year-to-date results of our main brands.

Strategic Brands continue to maintain strong momentum, driving overall revenue and profit growth for Astellas.

First, sales of five Strategic Brands, namely PADCEV, IZERVAY, VYLOY, VEOZAH, and XOSPATA exceeded JPY160 billion in total, substantially up by JPY48.3 billion or 43% YoY. All strategic brands achieved robust growth. PADCEV in particular, exceeded the initial expectations. Other Strategic Brands are progressing as expected. The strong growth momentum of Strategic Brands is expected to continue throughout FY2026.

Next, I will explain individual Strategic Brands and XTANDI. As for PADCEV, sales increased to JPY75.5 billion, up by JPY20 billion or 36% YoY. Overall, global progress is exceeding our expectations, driven by strong penetration in global first-line metastatic urothelial cancer. In particular, penetration is accelerating in markets outside of the United States. In Europe, progress in reimbursement in many countries also led to sales expansion as well. Also, penetration of cis-ineligible MIBC in the United States also contributed to sales growth.

In addition, recently, we had important progress as well. Approval was granted for cis-ineligible MIBC in Europe in June and for cis-eligible MIBC in the United States in July. We are expecting a future sales contribution from these additional indications.

On the other hand, market penetration is making rapid progress, particularly in the United States so we are not assuming that the recent high growth rate will continue as is. In the future, along with expansion of penetration, the growth rate is expected to be milder gradually over time. Still, there is no change in our perception of growth potential of PADCEV as an important product to continue to drive Astellas' growth. Mid-to long-term growth is expected.

As for IZERVAY, sales rose to JPY27.2 billion, up by JPY11.2 billion or 70% YoY. In addition to a steady increase in new patient starts, adoption across the retina community is also making good progress. IZERVAY is achieving market leadership in GA, geographic atrophy. Also, we are strengthening awareness activities for both

physicians and patients. We are continuing to work to drive awareness of the importance of early diagnosis and early treatment of GA.

Furthermore, through DTC campaigns using insights from patients, we are trying to increase the diagnosis rate and the treatment rate as well. These initiatives are steadily resulting in achievements. Through market expansion and the progress of treatment penetration, growth momentum IZERVAY is expected to continue into the future.

With regards to VYLOY, sales reached JPY21.1 billion, up by JPY7.1 billion or 51% YoY. Penetration of Claudin 18 testing is continuing steadily. Based on that progress as a background, sales grew solidly in all regions. The current testing rate is over 90% in Japan. Also in the United States and Germany, penetration is rising to the 70% to 80% level. Due to the increase in testing rates, prescription to appropriate patients is making steady progress. We're expecting solid growth of VYLOY sales into the future.

Sales of VEOZAH increased to JPY14.9 billion, up by JPY5.3 billion or 55% YoY. Since last fiscal year, competitor product has entered the market, but the launch impact is just in line with assumptions. VEOZAH is continuing to grow steadily while holding the strong share position versus new competition in the United States.

Regarding XOSPATA, sales reached JPY21.6 billion, up by JPY4.6 billion or 27% YoY. Globally, steady growth is continuing.

XTANDI sales increased to JPY276.6 billion, up by JPY43.6 billion or 19% YoY. For XTANDI, favorable ForEx impact from the yen's depreciation, in particular, is contributing greatly to its sales increase. Excluding the ForEx impact, the growth rate is about 7%. This is a high progress rate vis-a-vis our full-year forecast. As we said at the beginning of the year, towards H2 of FY2026, we're expecting a decrease in sales due to price reduction in the United States and the impact of patent expiry in some of the countries. The Q1 progress is in line with our full-year forecast expectations.

From Q2 onwards, Strategic Brands are expected to have a higher presence as growth pillars and further drive Astellas' revenue and profit growth strongly.

Q1 YTD/FY2026 Financial Results: Cost Items

- **SG&A expenses* held flat YoY through disciplined management, ratio improved by 3.5ppt YoY**
- **Cost optimization (SMT): Approx. -8 billion Yen YoY (Total of SG&A expenses, R&D expenses, cost of sales)**

Cost Items	YoY change	Ratio to Revenue	(yen)
SG&A expenses (excl. US XTANDI co-promote fee)	+10.1% (+0.1% excl. FX impact)	SG&A ratio: 23.0%	Held flat YoY excl. FX impact ✓ Increase in Strategic Brands-related investments for further growth ✓ SMT cost optimization: approx. -3 bil. (Efficiency benefits from Global Capability Center establishment, AI and digital capabilities, etc.)
R&D expenses	+14.0% (+5.9% excl. FX impact)	R&D ratio: 12.8%	YoY increase excl. FX impact: approx. +4 bil. ✓ Increase in pipeline clinical development costs: approx. +4 bil. (mainly setidegrasib, ASP2138 and ASP546C) ✓ Increase in Strategic Brands LCM clinical development costs: approx. +2 bil. (PADCEV and VYLOY) ✓ SMT cost optimization: approx. -3 bil. (Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials, etc.) Expect increased investments from Q2 onward, aligned with Phase 3 initiation and patient enrollment progress

*Excl. US XTANDI co-promote fee and FX impact
SMT: Sustainable Margin Transformation, LCM: Lifecycle Management

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Page seven is about cost items.

While we steadily executed investments necessary for our future growth, we were able to manage SG&A expenses, excluding US XTANDI co-promotion fees and ForEx impact, at a level similar to the previous year. As a result, also due to revenue increase, SG&A expense ratio improved by 3.5 percentage points YoY.

Thanks to what we call SMT, Sustainable Margin Transformation, our company-wide cost optimization initiative, we realized cost optimization of about JPY8 billion YoY for SG&A, R&D expenditure, and cost of sales combined.

Next, let me explain a specific breakdown of SG&A costs and R&D expenditure. SG&A expenses, excluding ForEx impact, almost remained flat, up by 0.1% YoY. While we increased the revenue substantially, we were able to hold SG&A expenses flat at a level similar to the previous year. While we increased investments for future growth, further growth of Strategic Brands, as an SMT initiative, we realized cost optimization of about JPY3 billion through efficiency benefits from Global Capability Center establishment, AI and digital capabilities, etc. As a result, while fully executing investments for Strategic Brands, we were able to offset the increase through SMT cost optimization according to assessment.

Excluding the ForEx impact, R&D expenses increased by 5.9% YoY. In line with the steady progress and development, clinical development costs for our pipeline, primarily for setidegrasib, ASP2138 and ASP546C increased by approximately JPY4 billion. In addition, life cycle management for PADCEV and VYLOY is progressing smoothly, and clinical development cost for these increased by approximately JPY2 billion. On the other hand, outsourcing cost reduction through in-sourcing development capabilities, including clinical studies and so on as part of our SMT initiative, continue to progress smoothly, resulting in a cost optimization of about JPY3 billion. This helped offset part of the cost increase.

Looking ahead with the Phase III initiation and the patient enrollment progress as clinical trials advance, we expect a further increase of investment from Q2 onwards. By steadily advancing disciplined cost optimization, we are making steady progress in building a robust financial foundation that allows us to make sufficient

growth investments in our Strategic Brands and pipeline while maintaining high profitability. We will continue to balance profitability improvements with growth investments to drive sustainable growth.

I will now explain our pipeline progress.

Strategic Brands: Progress of Lifecycle Management

(Blue: Updates since the last financial results announcement)

Significant milestones achieved, notably **PADCEV MIBC** and **VYLOY Phase 3 study**

Brand	Indication	FY2026				FY2027
		Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
	Cis-ineligible (EV-303 study)	Europe: Approved (Jun)	China: Filed (Jul)	Japan: Regulatory decision		
	Cis-eligible (EV-304 study)	Japan: Filed (May)	US: Approved (Jul)	Europe: Regulatory decision		
	Bladder-sparing	Phase 3 EV-309 study initiated (Jun)				
	GA secondary to AMD	China: Filed (May)				
	Gastric and GEJ cancer (combo with pembro and chemo)		Target enrollment achieved (Jul)			Phase 3 LUCERNA study data readout
	VMS associated with menopause	STARLIGHT 3: Primary endpoint met (Apr)	Japan: Filing	China: Filing		
	VMS in breast cancer women					Phase 3 HIGHLIGHT 1 study data readout

VEOZAH: Approved as "VEOZA" in ex-US

AMD: Age-related macular degeneration, chemo: Chemotherapy, Cis: Cisplatin, GA: Geographic atrophy, GEJ: Gastroesophageal junction, pembro: Pembrolizumab, VMS: Vasomotor symptoms

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On page nine, I will discuss progress of the life cycle management of our strategic brands. We have achieved significant milestones, notably the Phase III trials for PADCEV in MIBC and VYLOY.

Regarding PADCEV, for cisplatin-ineligible MIBC, we obtained approval in Europe in June based on the EV-303 trial. Next, for cis-eligible MIBC, we filed in Japan in May based on the EV-304 study. In the US, we received approval in July, one month ahead of the PDUFA date. Furthermore, in China, based on both the EV-303 and EV-304 studies, filing was accepted in July. We also initiated the Phase III EV-309 trial in June for bladder-sparing MIBC.

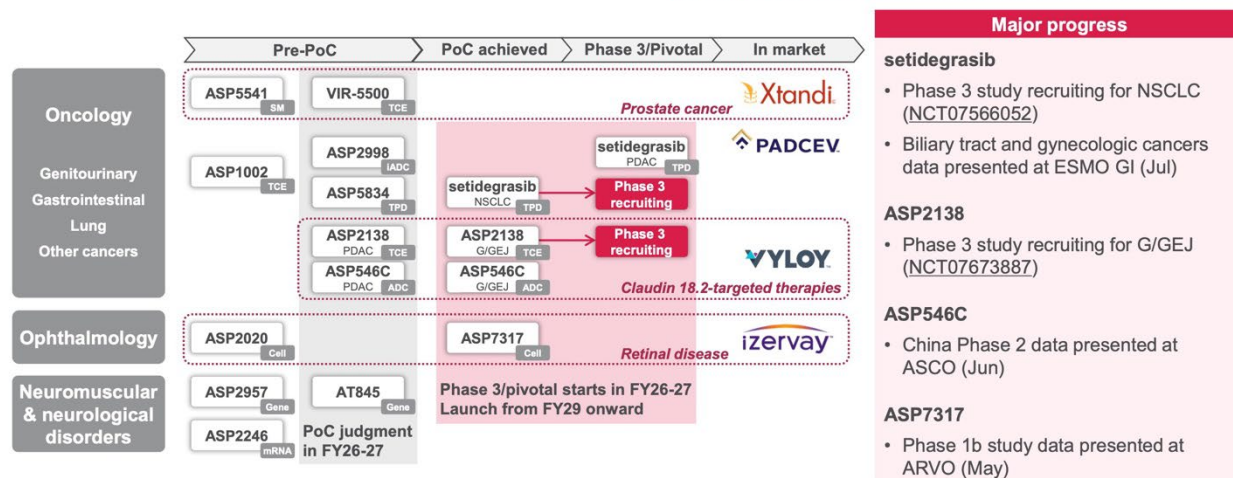
For IZERVAY, the filing in China based on overseas clinical trial data was accepted in May.

Regarding VYLOY, the Phase III LUCERNA trial, which is evaluating the efficacy and safety of combination with pembrolizumab and chemotherapy, is currently underway. In July, we reached the target enrollment of 500 patients in approximately one year, 20 months ahead of the initial schedule. We believe this achievement is due not only to the high level of interest in a new treatment option for Claudin 18.2-positive gastric cancer, but also to concerted efforts of Astellas' multidisciplinary team, which worked together to accelerate enrollment. Given the smooth progress of patient enrollment, we expect the data readout from the interim analysis during FY2027.

In April, VEOZAH met its primary endpoint in the STARLIGHT 3 trial, which is evaluating long-term safety in Japanese women. We plan to do filing in Japan based on the results of this study in Q2.

Pipeline Progress

Pipeline progressing steadily in line with CSP2026, with two new Phase 3 studies opened for recruitment



As of Jul 2026. Not exhaustively listed. (I)ADC: (immunostimulatory) Antibody-drug conjugate, ARVO: Association for Research in Vision and Ophthalmology, ASCO: American Society of Clinical Oncology, CSP: Corporate Strategic Plan, ESMO GI: European Society for Medical Oncology Gastrointestinal Cancers, G/GEJ: Gastric/gastroesophageal junction, mRNA: messenger RNA, NSCLC: Non-small cell lung cancer, PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept, SM: Small molecule, TCE: T-cell engager, TPD: Targeted protein degrader

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Page 10. I will discuss progress in our pipeline.

In our CSP2026, to accelerate the pipeline growth, we set key derivables to invest more aggressively in R&D and aim to initiate more than 10 Phase III or pivotal trials by FY2030. Focusing particularly on those which have already achieved POC, highlighted in pink, we expect to initiate more than five Phase III or pivotal trials by FY2027. We have recently begun patient enrollment in Phase III for setidegrasib as second-line or later treatment for NSCLC and for ASP2138 as first-line treatment for gastric cancer, making steady progress in line with the CSP2026. Please refer to page 33 and 34 of the appendix for details on the design of each study.

We also announced new clinical trial data for several programs. We presented clinical trial data for setidegrasib in BTC and GYN at the ESMO GI meeting in July. Additionally, we presented data from the Phase II study of ASP546C in China at the ASCO meeting in June. Details are provided on the next two pages.

We presented additional data from the Phase Ib trial of ASP7317 at the ARVO meeting in May. Please refer to page 36 of the appendix for details on the data.

Progress in ASP546C

China Phase 2 study demonstrated anti-tumor activities in G/GEJA and PDAC

Overview

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)
- Exclusive license to develop and commercialize worldwide, excluding China's mainland, Hong Kong, Macao and Taiwan region



Current status

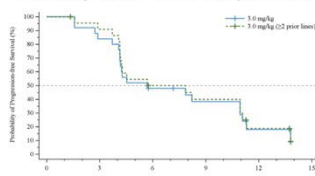
- Global Phase 1b/2 study ongoing (NCT07488676, sponsored by Astellas)
- Phase 3 study in China in G/GEJA ongoing (sponsored by Evopoint)

*Unconfirmed, ASCO: American Society of Clinical Oncology, 2L+: Second or later line, CLDN18.2: Claudin 18.2, DCR: Disease control rate, FDA: Food and Drug Administration, G/GEJA: Gastric/gastroesophageal junction adenocarcinoma, Mono: Monotherapy, ORR: Objective response rate, mOS: Median overall survival, PDAC: Pancreatic ductal adenocarcinoma, mPFS: Median progression-free survival, TOP1i: Topoisomerase I inhibitor

Latest data

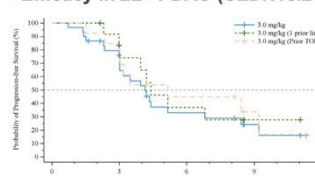
- Clinical data from China Phase 2 study presented at ASCO 2026

<Efficacy in 2L+ G/GEJA (CLDN18.2 ≥20%) @ 3mg/kg, mono>



	ALL (n=26)	≥2 prior lines therapy (n=23)
ORR	65.4%	73.9%
DCR	84.6%	87.0%
mPFS	5.7m	6.8m
mOS	11.7m	11.9m

<Efficacy in 2L+ PDAC (CLDN18.2 ≥5%) @ 3mg/kg, mono>



	ALL (n=30)	1 prior line therapy (n=13)	Prior TOP1i therapy (n=13)
ORR*	26.7%	46.2%	30.8%
DCR*	83.3%	100.0%	84.6%
mPFS	4.1m	4.4m	5.2m
mOS	10.0m	10.1m	10.0m

Page 11 provides an update on the development of ASP546C.

ASP546C is an antibody drug conjugate or ADC that targets Claudin 18.2. Under an exclusive license agreement with Evopoint, Astellas holds the rights to develop and commercialize the compound worldwide, excluding Mainland China, Hong Kong, Macau and Taiwan. Currently, a global Phase Ib/II study led by Astellas is underway. Additionally, a Phase III trial led by Evopoint for gastric cancer is ongoing in China.

The figure on the right shows efficacy data from the Phase II trial in China led by Evopoint, which was presented at ASCO in June. This study evaluated the efficacy and safety of ASP546C as a monotherapy in patients with gastric or GEJA or pancreatic ducts adenocarcinoma or PDAC receiving second-line or later treatment.

For gastric cancer, the objective response rate or ORR, measure of efficacy, was 65.4%, demonstrating a very high response rate that exceeded previously reported figures. Furthermore, the median progression-free survival or PFS was 5.7 months overall, and the median overall survival or OS was 11.7 months.

Furthermore, in PDAC, the overall ORR was 26.7%. The median PFS was 4.1 months, and the median OS was 10.0 months. These results confirm that drugs targeting Claudin 18.2 demonstrate anti-tumor activity also in PDAC.

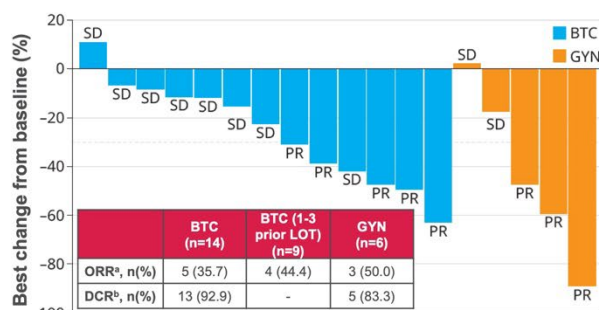
Leveraging our leading position in Claudin 18.2-targeted therapy established by VYLOY and ASP2138, we will continue to accelerate the development of ASP546C.

Progress in setidegrasib

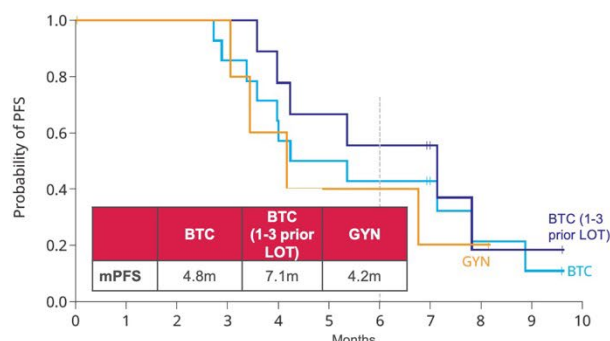
Anti-tumor activities observed in biliary tract and gynecologic cancers

Latest data

- Clinical data in patients with biliary tract (BTC) and gynecologic cancers (GYN) from Phase 1 study presented at ESMO GI 2026
 - ✓ Anti-tumor activities observed; which was most notable in patients with 2-4L BTC
 - ✓ KRAS G12D mutations occur in ~9% of patients with BTC and ~5% with GYN^{1,2}



Patients whose response was not determined are excluded from the plot (n = 1 each for BTC and GYN).
^a Defined as patients with BOR of CR/PR with confirmation; ^b Defined as patients with BOR of CR, PR, or SD, or non-CR/non-PD for patients with no measurable disease at baseline per RECIST v1.1.



1. Iida K et al. ESMO Open. 2025;10(6):105306. 2. Son J et al. Clin Cancer Res. 2024;30(14): 2986-95. ESMO GI: European Society for Medical Oncology Gastrointestinal Cancers; 2L: Second line, 4L: Fourth line, BOR: Best overall response, CR: Complete response, DCR: Disease control rate, KRAS: Kirsten rat sarcoma viral oncogene homologue, LOT: Line of treatment, ORR: Objective response rate, PD: Progressive disease, mPFS: Median progression-free survival, PR: Partial response, SD: Stable disease

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On page 12, I will explain the update of setidegrasib's development. We presented preliminary clinical data from Phase I trials in BTC and gynecological cancers at ESMO GI. Promising early anti-tumor activity was observed, and this was most pronounced in patients with BTC receiving second to fourth-line treatment.

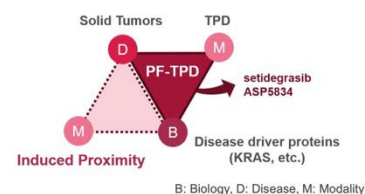
As shown in the figure on the left, the ORR, a measure of efficacy, was 35.7% for all BTC patients, 44.4% for those receiving second to fourth-line treatment, and 50% for all gynecologic cancer patients.

Furthermore, as shown in the figure on the right, the median PFS was 4.8 months for BTC patients, 7.1 months for those receiving second to fourth-line treatment, and 4.2 months for gynecologic cancer patients. We will announce our future development plans for KRAS G12D mutation-positive cancers, including BTC and gynecologic cancers, at the appropriate time once they are finalized.

Expanding Primary Focus: From “Targeted Protein Degradation” to a Broader “Induced Proximity” Platform

Induced Proximity unlocks differentiated pipeline potential in hard-to-treat cancers with long-term growth opportunity

- Many disease-driving proteins remain difficult to target with conventional approaches, creating significant room for innovation
- Induced Proximity modalities are designed to overcome barriers of traditional treatments by creating new connections inside the cell that help remove harmful proteins and regulate disease processes



Primary Focus	Targeted Protein Degradation	Induced Proximity
Biology	Inhibit signal transduction with target protein degradation	Regulation of protein function with induced proximity
Modality	Protein of interest (POI) E3 ligase Protein degraders	Protein degraders Effector protein (EP) RIPTACs Molecular Glues
Disease	Solid tumors (KRAS mutation)	Potential to extend beyond solid tumors

KRAS: Kirsten rat sarcoma viral oncogene homologue, RIPTACs: Regulated induced proximity targeting chimeras, TPD: Targeted protein degradation, Ub: Ubiquitin

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Page 13. I will now explain the expansion of Primary Focus.

We have expanded the scope of Primary Focus, Targeted Protein Degradation or TPD, into broader Primary Focus, Induced Proximity platform. To date, through the induction of TPD, we have been engaged in drug discovery targeting causative proteins of disease that cannot be adequately addressed by conventional drug discovery approaches. However, there are still many disease-driving proteins who remain difficult to target with conventional approaches, creating significant room for innovation.

In Induced Proximity, in addition to the Target Protein Degradation we have been developing, we utilize modalities such as RIPTAC and Molecular Glue to intentionally bring two intracellular molecules, which would not normally interact closer together. By creating new connections inside the cell, we are able to overcome barriers of traditional treatments, that is to remove harmful proteins and regulate disease processes. Building on the insights and competitive advantages cultivated through TPD, we aim to unlock differentiated pipeline potential in hard-to-treat cancers with long-term growth.

Key Takeaways

Great start to FY2026, building strong momentum toward CSP2026



Robust Q1 Revenue and Profit Growth

- **Strong Strategic Brands growth**
Driving robust revenue and profit growth, strong momentum expected to continue throughout FY2026
- **Solid progress of disciplined cost optimization**
SG&A expenses held flat YoY* through disciplined management



Solid Pipeline Progress

- **Significant milestones achieved in LCM**
PADCEV (MIBC): Multiple approvals and filings, Phase 3 EV-309 study initiated for bladder-sparing
VYLOY: Target enrollment achieved in Phase 3 LUCERNA study
- **Phase 3 studies opened for recruitment**
setidegrasib NSCLC, ASP2138 G/GEJ

*Excl. US XTANDI co-promote fee and FX impact

CSP: Corporate Strategic Plan, G/GEJ: Gastric/gastroesophageal junction, LCM: Lifecycle management, MIBC: Muscle-invasive bladder cancer, NSCLC: Non-small cell lung cancer [LINK to CSP2026 presentation material](#)

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Page 14, key takeaways of today's presentation.

Following last fiscal year, we were able to get off to a great start this fiscal year as well. Revenue and profits grew significantly. Our Strategic Brands grew strongly and drove the growth of overall revenue and profits. We expect the strong growth momentum to continue throughout FY2026. Furthermore, through rigorous disciplined cost optimization, we managed SG&A flat YoY. We believe we have successfully achieved both revenue and profitability growth.

Our pipeline also made solid progress. We achieved several key milestones in life cycle management of Strategic Brands. In PADCEV's MIBC development, in addition to obtaining multiple approvals and filings, we have initiated Phase III EV-309 study for bladder-sparing MIBC. VYLOY has achieved enrollment of the target number of patients in the Phase III LUCERNA study evaluating pembrolizumab in combination with chemotherapy at a rate significantly faster than planned. We also made steady progress towards the pipeline-driven growth strategy outlined in CSP2026. We have begun patient enrollment in new Phase III studies for setidegrasib in NSCLC and for ASP2138 in gastric cancer. At Q1 of the CSP2026, we believe we have built strong momentum toward achieving our targets.

That concludes my presentation. Thank you for your attention.

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

Question & Answer

Kato [M]: We'd now like to take questions from the audience. If you have a question, please press the raise hand button at the bottom of your Zoom screen. If you're joining from your smartphone, please tap details. Then raise hand will be shown, so please press it. I'm going to name you one by one. If your name is called, please unmute yourself on your screen, mention your name and affiliation and ask us your questions.

Now, we'd like to open the floor for questions. First, Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [M]: Yamaguchi from Citigroup Securities.

First, slide six shows the progress of your main brands and also on the previous page as well. There was the ForEx impact. PADCEV exceeded the impact. XTANDI had an initial good start, so it's going to come down. Zolbetuximab is in line with your assumptions, as I heard. But profit progress is very good, it seems, in the end. What about the difference compared to your initial assumptions or expectations? The progress rate seems to be very strong. Is my understanding correct, excluding ForEx impact? Please comment.

Kitamura [M]: Yamaguchi-san, thank you very much.

Your question is about the sales, not just the sales of Strategic Brands, but the progress of the business as a whole. What about the progress compared to the initial plan? Is that your question?

Yamaguchi [M]: Yes.

Kitamura [A]: FY2026 is the first year in the CSP2026. Following last year, a record-high revenue and record-high profit is what we'd like to achieve in the current fiscal year. Q1 made a very strong progress, as you said, particularly in terms of revenue and sales. PADCEV had very good sales. We had the cost management in line with the plan. For us, Q1 was very strong in our view.

The progress rate, it's not just the 1/4 of the annual plan, but we still think that Q1 is very strong. In Q2 and beyond, we'd like to accelerate science from now on. The R&D expenditure is going to be used later this fiscal year more, and we developed a full-year plan based on that. Looking at Q1 only, it was very strong.

Yamaguchi [Q]: Thank you very much.

Secondly, new Primary Focus is going to be Induced Proximity. As explained, there is no specific pipeline yet. I haven't checked the details myself yet. TPD has an output for anti-cancer agents. Regarding the Induced Proximity, what about its therapeutic areas? What are you aiming for in this field?

Kitamura [A]: As an applied therapeutic area, we are very excited. Primary Focus is going to be expanded. We can identify opportunities to create drugs so this is very exciting.

Rather than me talking about exciting topics, I'd like to hand over to Taniguchi to explain further.

Taniguchi [A]: Thank you very much.

Targeted Protein Degradation is going to be expanded to Induced Proximity. We had proteins – we have binders bound to proteins, and that is making a lot of progress. Recently, Target Protein Degradation or

RIPTAC and molecular glue in these fields, research is progressing. Various target proteins can be used with the various modalities to pursue new treatments. That is going to be a focus.

As for the Induced Proximity, it's going to be focused on the oncology field. Induced Proximity technologies can be utilized first to determine a pathway. As a new target for cancer using the new technologies, more pathways and more tumor types can be addressed so that we can expand the therapies. Other than oncology field, how this can be applied? Including that point, currently in R&D, we've been working for the wide scope of consideration. First start is oncology, and afterwards, we are thinking about expanding it to other fields as well. That's the current strategy.

Yamaguchi [M]: Thank you very much.

Kato [M]: Thank you for the question. Next, JPMorgan Securities, Mr. Wakao, please.

Wakao [M]: Thank you. JPMorgan, Wakao is my name. Thank you for this opportunity.

Q1 SG&A XTANDI co-promotion fee, excluding others, the progress of that, how should we look at it in Q2 afterwards full-year core OP margin? I would like to hear how you think about it. Q1, the cost control is good. Excluding ForEx impact, it is almost the same level as the previous term. That is great. But this JPY584 billion, that is the plan for this fiscal year. Excluding XTANDI co-promotion fee, the progress level currently is around 25%. This others, the e portion of the others, is likely to move in Q2 and afterwards. For Q1, top line is rigorous and cost is well controlled. The profit margin is really good. If you control the cost well and top line is good, then OP margin 30% is likely to be achievable. I would like to hear how you think about it.

Kitamura [A]: Thank you very much for your question.

First of all, SG&A prospect. Basically, it's not something we'll think about in the short term. Rather, mid- to long-term perspective, we are working for the SMT. We wouldn't expect some trend will be changed in later on. Rather, we continue SMT. JPY40 billion is something we would like to realize in this fiscal year. Q1, JPY8 billion, and Q2 afterwards, we have to accelerate it, not only for SG&A, but we have to just keep the plan. SG&A, we wouldn't expect it to be greatly changed later on. We just try to achieve the target. That is our base plan.

The Q1 34.5% core profit, that is about just three months or one quarter matter. This is the first time that we achieved more than 30%. In that sense, as you pointed out, the sales, revenue increases and if cost is well controlled, then 30% is not an impossible number. We've been always saying 30%. This is always the target, and we would like to realize that. However, the result is only from this Q1 and we have remaining three quarters, so as has been mentioned, in these five years, we would like to create the pipeline that is leading to the future growth. Currently, the seeds are available. As Taniguchi is sitting here, he has strong intention to accelerate the development. With taking balance, we are going to operate what we need to do. I don't know if this is answering your question, but that is the very initial feeling that we have.

Wakao [Q]: Thank you very much.

Second is about PADCEV. The Q1 US dollar-based progress, that is quite strong, which is quite surprising for me. This is more than your expectation. What has exceeded your expectation? I thought you are a bit conservative to looking at the market penetration. Is the market penetration better than you expected? What is that the cause? I think the patients' sales for the product is booked in an earlier phase and MIBC peak achieved earlier, or MIBC potential itself is likely to be bigger than you expected. Would you please make a comment about this point?

Kitamura [A]: Q1 PADCEV sales were good, as you said. I would briefly respond and then Claus will add later.

As for PADCEV, very strong growth was achieved in Q1. There are two factors behind. Outside of the United States, first-line indication expanded partly due to reimbursement. There is a steady growth in the United States. First line plus MIBC. MIBC catch-up, initially, there is a faster trend compared to the initial outlook. The same phenomenon occurred for the first-line indication in the United States. This is a very exceptional and effective drug so the drug can be used earlier. That happened for MIBC.

Claus, anything to add from you?

Zieler [A]*: Yes. I think you've outlined the two main factors. The reimbursement for the first line, particularly in Europe and some of the international markets, was very strong. The take-up was very strong. But the other factor is the MIBC take-up in the US and let me put a little bit more color on to that. As you know, in the last quarter, we only had the approval for the EV-303 study for the cis-ineligible patients in MIBC. The approval for the EV-304 study for the cis-eligible patients, we only got recently.

But when I talk to doctors, for instance, when I went to ASCO, doctors in the academic centers are no longer distinguishing between cis-ineligible and cis-eligible. They're putting everyone on PADCEV who can tolerate the drug. We're getting a much faster pick-up in the United States in MIBC than we expected because essentially, there is a non-promotional part that is being used where this drug is already being used, which we didn't expect because we didn't have the label.

Now, let me also temper your expectations a little bit going forward because what that essentially does is it draws forward sales of PADCEV or growth of PADCEV that we would have expected with the approval of the EV-304 study in the United States. We're getting a much earlier adoption of PADCEV in both cis-eligible and in cis-ineligible patients almost at the same time. We also know that from our past indication expansions, we know that the first six months after the labeling of the drug, we get very fast uptake, and then we get a flattening of the growth curve into the single-digit growth trajectory. We very much expect that to happen in the United States now because we've seen the strong pick-up in MIBC essentially with the labeling of the EV-303 study in November. The six months are now over. We are now expecting that leveling off into a single-digit growth rate.

So, yes, very strong quarter with MIBC in the US, much more so than we expected because doctors are really not distinguishing, at least in the academic centers, not distinguishing between cis eligible and ineligible and are adopting PADCEV in both patient cohorts. But that also means it will now start leveling off into a single-digit growth rate going forward. That's the picture in the US. As Atsushi said, in the ex-US picture, it's really the reimbursement of the first-line indication that's been very, very strong in Q1.

I hope that answers your question.

Wakao [M]: Yes, very clear. Thank you very much.

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

Ueda [Q]: Ueda from Goldman Sachs Securities speaking.

My first question is about the progress against the full-year forecast for PROGRAF and mirabegron, relatively established products. Their progress might be high compared to your full-year plan. Are they going to decline into the future according to your plan? Mirabegron in the United States is growing a lot. How about the progress against your plan? There can be a huge impact in terms of profit. Could you please comment?

Kitamura [A]: Thank you. First, mirabegron, as has been pointed out, it is better than expected. Looking at the result of Q1, especially the price perspective, it was rather good. Other strategic brands and so on,

basically, they are on track. Toward 2H, there will be the matters of pricing and so on and so, but that taken into consideration, overall, we are on track.

Ueda [Q]: Understood. Thank you very much.

Second question, that is the progress of XTANDI against the plan. Basically, you just mentioned this is also on track. But on the other hand, looking at the situation region-wise, China and International Markets, there is great growth in those regions. Do you think this growth is likely to continue? Are there any differences depending on the regions?

Kitamura [A]: Thank you. XTANDI as a whole, yes, we are on track. As you pointed out, region-wise, sometimes flat, or some areas, growth is confirmed. Talking about the future, which region, there are several events. In the case of the United States, there will be price matter, and in several markets, the loss of exclusivity would be coming. Remaining period, what would happen? Well, depending on the regions, the colors are different. Claus, do you have any additional comment on this?

Zieler [A]*: I think Atsushi correctly explained XTANDI. I mean we are quite proud to have a drug that after 14 years on the market still grows 7% (excl. FX impact). I mean that's quite exceptional. Having said that, of course, our growth rate is coming down. I mean we're having pricing pressures, as Atsushi said, and that also includes gross to net effects in the US. That is something that we're going to have to factor in going forward into the rest of FY2026.

I would say to you, XTANDI actually is in line with expectation. It's not above expectations. It's in line with expectations. What is above expectations is Myrbetriq, as Atsushi pointed out. There are different effects, but it also includes the royalty payments from the generics in the US. You remember that we settled with various generic manufacturers on the Myrbetriq formulation patents. I would say Myrbetriq indeed did exceed, as did also tacrolimus did exceed in Q1. XTANDI is more in line with expectations.

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

Kato [M]: Thank you. Next, UBS, Mr. Seki, please.

Seki [Q]: UBS, Seki is my name. Thank you very much for your explanation.

The revenue is good, and it seems that the accounts receivable is also on the increase. What is the current status about that? Could I confirm about it?

Kitamura [A]: Thank you very much. Q1, the sales is really good. Organically, the sales is really good. Organically, revenue increased 15%, although there is some FX impact. That is because from last year, two years ago, the strategic brands are on the increase. That is the foundation. This is not a onetime factor. In line with that, as you know, the working capital AR is on the increase. The working capital, the improvement, is something we've been working for these two years. With the increase of the sales, then AR also increases. However, with the sales increase, and at the same time, inventory is well controlled. Overall working capital, that is stabilized. That is our understanding.

Seki [Q]: Thank you very much.

Point two, probably to Taniguchi-san, setidegrasib on page 12. For BTC, the result looks really good. The second line, FOLFOX comparison, I think that is really good. Is my understanding is right? Other KRAS, recently developed KRAS product. It's not head-to-head, but if you make a comparison, what is your view? Do you think your product is better?

Taniguchi [A]: Thank you for your questions.

In biliary tract cancer (BTC), as you may know, like pancreatic cancer, prognosis is very poor. It's one of such cancers. The current treatment options are very limited, particularly in the second-line settings and beyond. In BTC, other than chemotherapy, there is no receptive treatment other than chemotherapy right now. Generally speaking, chemotherapy could be used. Then ORR, generally speaking, is around 10% or even under 10% in many cases. Median PFS is up to four months according to my understanding.

Regarding setidegrasib, in BTC, about 10% of the BTC patients have KRAS G12D mutations, and we have Phase I data by targeting them. As you can see, its efficacy ORR overall is 35.7%. In 2L-4L BTC patients, that's 44%. This is unprecedented compared to the existing therapies with a very strong efficacy to reduce tumor. Median PFS, with 1-3 prior lines of treatment, seven months or even more than seven months are the median PFS. Doctors in this field, when we talk with them, this can be very promising according to them and their assessment.

Regarding other KRAS inhibitors by other companies, as far as we know, according to the competitors' data, actually, they haven't published their data, so it's very difficult to compare. setidegrasib, BTC, and gynecological cancer, this is data in a small sample size, but this is a very promising data, in my view.

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

Kato [M]: Thank you very much. Next, Nomura Securities, Mr. Matsubara, please.

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

Kato [M]: Yes, we can hear you.

Matsubara [Q]: Thank you for the presentation.

My first question is about IZERVAY. In Q1, JPY470 billion was the sales. Biogen acquired Apellis. Any change in the prescribing trend and the competitive environment? At the conference by Biogen, there was a focus on SYFOVRE. I'd like to hear your comments.

Kitamura [A]: We don't think there's going to be a big change in the execution, but if there's anything to be added by Claus, please.

Zieler [A]*: Yes, that's correct. I mean we don't expect Biogen to have a different approach to SYFOVRE than Apellis had. We are continuing to compete in the same market for complement inhibitors to treat geographic atrophy, and that remains unchanged.

I do want to point out, however, that we have now, for two years in a row, established our leadership in the new patient share. In the last quarter, it was around 55%. In the last quarter, we, for the first time, established overall market leadership, and you can clearly see that if you compare the disclosed numbers on IZERVAY versus SYFOVRE. We are clearly establishing ourselves, with IZERVAY as the leader in this market. That is quite an achievement, in my view, because as you remember, we were the second to launch in this market. We've come from behind, and we've now overtaken the first mover in this market. I think that clearly points to the profile of IZERVAY in treating geographic atrophy and the adoption by physicians of this treatment to help patients.

Matsubara [Q]: Thank you. Additionally, Biogen is planning to sell prefilled syringe. Do you think this is going to be a threat for you?

Zieler [A]*: We know that prefilled syringes in this market have a preferred usage by some physicians because it simply facilitates their injection routine. The short answer is yes. PFS will have an impact on the market. As you know, we have our own prefilled syringe in development. We'll be launching a little bit after Biogen with a prefilled syringe. That will then level the playing field again. I do not expect the prefilled syringe to change the market leadership that we've established.

Matsubara [Q]: Thank you very much. Now, second question is AT845. AT845 PoC hasn't been established yet. Why does it take time for additional analysis?

Taniguchi [A]: Let me respond to that. AT845, that is for Pompeii disease. This is a gene regulation or genetic therapy. So far, Phase I and Phase Ib have been conducted. In February, data was announced or presented. Currently, together with the data confirmation and at the same time regulatory work, like with the FDA, with EMA in Europe, we've been discussing so that we can identify the overall picture, including what kind of studies will be requested for the future. Having overall knowledge, we would like to make a final decision about the investment. When the final decision is made, then we would like to report to you our decision.

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

Kato [M]: Thank you. Next, SMBC Nikko Securities, Mr. Wada, please.

Wada [M]: Wada from SMBC Nikko Securities. Can you hear me?

Wada [M]: Yes. Please start.

Wada [Q]: I have also two questions.

First question is about your slide 12, ASP546C, that is the Claudin 18.2 franchise. That is the question I would like to ask you. Your competitor's a bit active. For example, AstraZeneca license pipeline from China and its global Phase III second-line development is a success. So Claudin gastric cancer segment, how are you going to win this market? You have VYLOY and also ASP2138 and ASP546C. According to page 10 and 11 of your slides, ASP2138, I think it's almost the same segment like you are doing for VYLOY. How are you going to develop your overall pipeline?

Kitamura [A]: Thank you very much. For Claudin 18.2, as has been pointed out, we are first in market with VYLOY. Following that, ASP2138 and ASP546C that we have. We believe that this is quite an important asset and area.

Our way of thinking toward Claudin 18.2 is now going to be explained by Taniguchi.

Taniguchi [A]: Claudin 18.2, as has been mentioned by Kitamura, of course, we have VYLOY to come first, and this is already approved. This is the strong expression of Claudin that accounts for about 1/3 of gastric cancer. More than 75% of the patients have the expression of that, and that is an indication approved. With the LUCERNA trial, PD-1 strong expression is also what we've been developing, and also, the data is available. 2138, the targeting is 18.2 and its engager is added. 2138 is from Claudin expression low to mid. Even for those patients, efficacy is observed. This is now competing with VYLOY, and Phase III has started.

Now, chemotherapy and checkpoint inhibitor, pembrolizumab and ASP2138 combination versus chemotherapy plus pembrolizumab are compared in a comparative study we initiated. First-line gastric cancer from Claudin low to mid, ASP2138, and VYLOY for high expression, we can separate clearly. ASP546C, Claudin 18.2, ADC, as we showed data earlier, gastric cancer second-line, very high response rate is already shown in the second-line therapy for gastric cancer. For this drug, gastric cancer second-line, as we mentioned before, AstraZeneca is already conducting its study.

As far as we see, our data, in terms of efficacy and safety, our compound is showing very strong efficacy. We think we can offer higher value to the patients. In the second-line settings and beyond, we try to aim to get an indication there. We have to come up with the data in the end. But if possible, chemotherapy-free treatment would reduce burden for the patients, according to our belief. In the future, we'd like to consider such a setting as well when we consider the overall strategy and proceed with the development.

Wada [Q]: Thank you very much. From this slide, Claudin 18.2 expression, according to the top one, more than 20%. The bottom, 5% or so. AstraZeneca has a 25% cutoff. The expression is lower here for ASP546C where you demonstrated its effect.

Taniguchi [A]: The top panel is the gastric and GEJ adenocarcinoma. The bottom is PDAC or pancreatic cancer. Please understand that difference.

Wada [Q]: Okay. Understood. Thank you. Also, another question.

Regarding the induced proximity, you cultivated a TPD, technological competitive advantage, compared to the competition. What is that? Beyond rule five, the size is often like the middle molecule. Compound selection is very difficult. There are many TPD ventures in the United States. They have difficulty when they move on to Phase II. In this area, do you have a competitive advantage? Do you have any other differentiating points in terms of your technology?

Taniguchi [A]: First, with the TPD, we have setidegrasib, which is already in Phase III. Our differentiating point is as follows. setidegrasib, we have a lot of experience with ASP3802. Targeted protein degradation can be used in what kind of patients to demonstrate effectiveness, what kind of biomarkers we should take, and what is going to be the combination to be used in the end. We have lots of experience, maybe more than the competitors, in our view. It's not included in today's imputation. Pan-KRAS degrader is also making progress. We'd like to use our clinical experiences such as ASP5834, and we'd like to develop this compound with a higher value compared to the competitors.

As for the molecules and research, protein binders will be identified. We have to do so. In such a field as KRAS and pan-KRAS protein binders, how to identify and create them, we can use our experiences by now. For other targets, these protein binders can be identified. Compared to other companies, we have more experience, and we have a better structure. We will continue TPD, but RIPTAC and molecular glue, in addition to TPD, would also be addressed. Based on our expertise and experience as a basis, we'd like to expand so that we can cover broader targets. Then we can apply this to other tumor types as well. I think that's a big difference compared to the other companies.

Wada [M]: Thank you very much. I understood it quite well. Thank you.

Kato [M]: Thank you very much. Next, Morgan Stanley MUFG, Muraoka-san, please.

Muraoka [Q]: Thank you. Morgan Stanley, Muraoka is my name.

First question, XTANDI international market, the sales is in yen basis, it's two-folds. I feel something strange here. You cannot make it four-folds. Probably there are some specific reasons with this. If there's nothing particular, then can we make it four-fold? Could you explain the background?

Zieler [A]: Yes, I'm happy to do that. The international effect that you referred to is timing. These are shipment timings. If you look at the underlying demand, that's very much in line with expectations. But the timing essentially draws forward some of the sales, and that's why international looks slightly inflated. That will wash out over the course of the year. We don't believe that's an impact that will continue. I hope that answers your question.

Muraoka [Q]: Thank you very much. Is this happening to certain specific countries, or in many countries, this front-loading took place?

Zieler [A]: It's a tender effect in certain countries like Russia. Tenders are not something you can time with a lot of accuracy. That's why we're seeing this effect in Q1.

Muraoka [Q]: Understood. Thank you very much.

Taniguchi-san, this is a question to you about the induced proximity platform. You have TPD technology. According to my memory, this is for injectables. This technology is difficult to be applied for the oral medicine. This induced proximity, is this also basically injectable alone, or can you apply this for the oral medication? In other words, this technology can cover broader formulation.

Taniguchi [A]: Thank you for your question. As has been pointed out, targeted protein degrader that we have, because of the complexity of molecule structure, it's difficult to make oral medication. However, we are working on basic research so that we can realize oral formulation. We've been making effort. This is water-soluble or the membrane permeability. Those areas are impacted. With using several technologies, we are trying to make oral medication. RIPTAC and molecular glue are a bit smaller compared to protein degrader. Needless to say for molecular glue, there's a high possibility to be made as oral medication. Including what kind of formulation should be made or developed, including the perspectives, we would like to pursue further for our research.

Muraoka [Q]: Thank you very much. For oncology, there will be no problem if it is injectables or not but other diseases than cancers. When we see some ASP compounds for other than oncology, we could expect something oral will be available.

Taniguchi [A]: Well, of course, for some tumor types, oral medications will be viable. We are not really sticking to the injectable for oncology. But just like you mentioned, if it is a chronic disease, oral medication will be better, that is easy to use and less burden for patients. That is the direction that we intend to go.

Muraoka [Q]: Thank you very much. Now, LUCERNA study, the interim analysis readout will be available in the next fiscal year. With that, you are going to submit. For the submission, not only the United States, Japan and China as well, you are going to do the submission based upon LUCERNA study.

Taniguchi [A]: Well, LUCERNA study, as has been explained a little while ago, VYLOY plus chemo and PD-1 inhibitor pembrolizumab combination study is what it is. This study is a global study, so we are aiming at a global submission. This study's purpose is like that.

Muraoka [Q]: If the interim analysis data is good, you can file submission based on this single study.

Taniguchi [A]: Yes, that's our understanding.

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

Kato [M]: Thank you very much. Due to the limited time, we will take the last question. Sanford C. Bernstein, Ms. Sogi, please.

Sogi [Q]: Thank you very much. I have a question about your pipeline.

Claudin 18.2 ADC, AstraZeneca, global Phase III, PFS was not statistically significant. OS endpoint was met with ADC. What's the difference between your company and AstraZeneca for Claudin 18.2? PFS may not be successful, but OS might be met. Any insight from your company?

Taniguchi [A]: I'd like to explain. As for AstraZeneca's product, it was still at the level of press release so I don't know the details yet. Please allow me to refrain from commenting. AstraZeneca's Claudin 18 ADC and our ASP546C, as you can see on the slide, payload is different. We're using Topoisomerase I inhibitor. MediLink linker is mentioned here. This special linker technology is very good, which we use. This linker would be serving as a linker once it's close to the tumor. In terms of safety, it's superior, according to our belief. That's also been demonstrated by the data. The drug's features are demonstrated by the data as well.

Looking at the data, ORR is shown here, overall 65.4%. In second line and beyond, in gastric cancer, the efficacy is very high as a monotherapy. ASP546C can be best-in-class ADC targeting Claudin 18.2. With that belief, we'd like to continue with the development.

Regarding the linker, Tumor Microenvironment Activable Linker, in the more acid environment, this technology would enable the linker to serve as is. There are many different features. For the details, we'd like to explain to Sogi-san on a separate occasion.

Sogi [Q]: Okay. Understood.

Next, I have a question about the induced proximity platform. As a pipeline asset, preclinical compound may be here. Do you have a lead molecule already? Also, Revolution Medicines' compounds, compared to them, effector protein may be different. Of course, the connector protein, the molecule may also be different. Could you explain the difference compared to Revolution Medicines' compounds?

Taniguchi [A]: Regarding the induced proximity, we start from protein degrader with a different target. It's in research stage. We haven't published the information yet, but we have several compounds close to candidate nomination. Targeted protein degraders with a different target or RIPTAC and others, we are making a lot of progress here as well. But from now on, we will accumulate basic data so that they can be brought to clinic. We have to judge. As soon as we understand the situation more clearly, we'd like to share that with you.

Regarding your second question, Revolution Medicines comparison, the difference compared to them. As for RevMed, molecular glue is being used for Revolution Medicines compound, RAS(ON) inhibitor, zoldonrasib KRAS G12D inhibitor. Setidegrasib is protein degrader. The shape of the molecule is very different. As for the binder, the shape is different. We cannot compare generally, but a similar protein binder is going to be found to target KRAS. The basics are similar.

As for the difference, the difference with the inhibitors, prospective several data is already disclosed in molecular glue. The treatment for refractory patients, with what reasons this molecular glue doesn't work? Well, for example, KRAS mutation binding will lead to amplification in different pathway. There are several directions. For protein degrader, we are coming up with data later on. But against the KRAS application, because the protein itself will be degraded, there's a possibility that efficacy is established. If that kind of characteristic is observed or not, that is under the study now. When the data is available, we are happy to show you the difference of the characteristics of the product.

Sogi [Q]: Sorry, I might have misunderstood. For protein degrader, ubiquitin mechanism is utilized. Put the marker to the protein of interest is saying you are not necessary. But this induced proximity, like the molecular glue, physically, in the case of KRAS, GDP or GTP bindings are physically blocked. That's what I assume for this induced proximity as well, but this works more like a degrader.

Taniguchi [A]: The ubiquitin-proteasome protein degradation is what you're assuming? Probably you have a misunderstanding. Induced proximity includes protein degrader, RIPTAC, molecular glue. These three are under the umbrella of induced proximity. This is the name of class. RIPTAC, as you see, effector protein and actual targeted protein are bound, and by doing so, the degradation is started. That's the mechanism. Molecular glue, just like you mentioned, the bound protein signal itself is inhibited. Each has its characteristics,

but the basic technology is closer. That's why those are applied to expand from protein degrader to RIPTAC to molecular glue.

Sogi [M]: I see. Understood. Thank you very much.

Kato [M]: Thank you very much for the many questions. With this, because of the time, we would like to close this session.

Thank you very much for your participation. We would like to close this meeting. Thank you.

[END]

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