

Q1 YTD/FY2025 Financial Results



Atsushi Kitamura
Chief Financial Officer (CFO)
Astellas Pharma Inc.
July 30, 2025

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.

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.

Q1 YTD/FY2025 Overview

- Exceptional Q1 Progress Outperforming Expectations -

3

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

Agenda

4

I

Q1 YTD/FY2025 Consolidated Financial Results

II

Pipeline Progress

Q1 YTD/FY2025 Financial Results

5

(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%			Other expenses (Main items)
Operating profit	50.7	94.6	+44.0	+86.8%	160.0		• Impairment loss related to certain Xyphos-related programs: 11.5
Profit before tax	50.5	90.4	+39.9	+79.1%	150.0		
Profit	37.6	68.4	+30.8	+82.0%	130.0		

*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)

Q1 YTD/FY2025 Financial Results: Main Brands

6

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%	<ul style="list-style-type: none"> ✓ Continued strong growth, with notable contribution from VYLOY ✓ Expect continued positive momentum throughout FY2025
 PADCEV™	55.5	+17.1 (+45%)	+52%	<ul style="list-style-type: none"> ✓ Continued robust growth momentum driven by 1L mUC across all regions ✓ Overall progress in line with expectations
 izervay™	15.9	+3.2 (+25%)	+35%	<ul style="list-style-type: none"> ✓ Record-high quarterly sales ✓ Retuned to growth trajectory, with a +22% QoQ growth (vs. Q4/FY2024)
 VEOZAH™	9.6	+3.0 (+46%)	+56%	<ul style="list-style-type: none"> ✓ Solid global sales growth, in line with expectations ✓ Expect steady growth moving forward
 VYLOY™	14.0	+13.7 (>+100%)	>+100%	<ul style="list-style-type: none"> ✓ 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%	<ul style="list-style-type: none"> ✓ Steady global performance and on track overall
 Xtandi®	233.0	+8.7 (+4%)	+10%	<ul style="list-style-type: none"> ✓ 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

IZERVAY: Business Update (US)

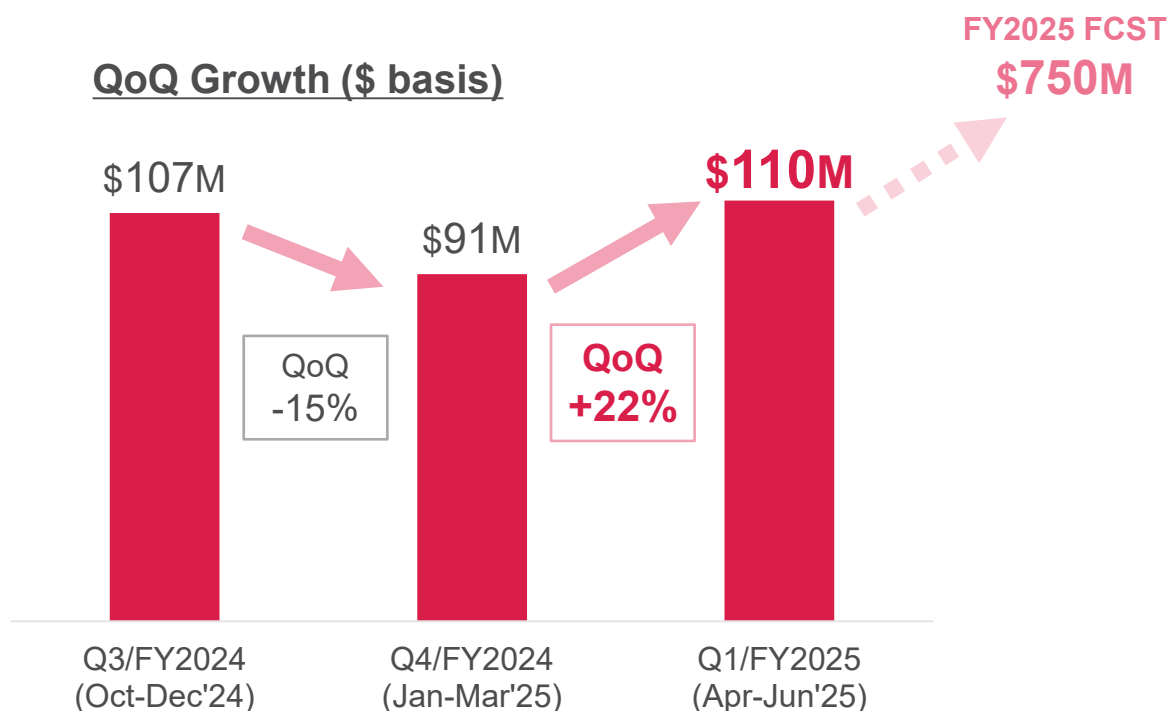
7

	Q1 YTD/FY2025	YoY
¥ basis	15.9 bil. yen	+3.2 (+25%)
\$ basis	\$110M	+29 (+35%)

Q1 Performance - Record high quarterly sales -

- Returned to growth trajectory, with a **+22% QoQ growth**
- Continues to be #1 chosen treatment for new patient start
 - ✓ New patient start share: **~55%** (last 6 months average)
- Available in over 2,000 retina accounts
- **Over 70,000 patients** treated since launch

QoQ Growth (\$ basis)



Drivers to Unlock GA Market Potential

1. Educate Retina Specialists
 2. Educate Patients
 3. Educate Upstream Optometrists & Ophthalmologists
- **Further enhance diagnosis and treatment rates**

Future Outlook

- Continued quarterly growth (high 20s or above) expected throughout FY2025
- Treated patient population expected to reach >35% by 2029

Actual exchange rates of Q1/FY2025: 145 yen/USD, 164 yen/EUR (Actual exchange rates of Q1/FY2024: 156 yen/USD, 168 yen/EUR)

IZERVAY Online Meeting (July 10, 2025): [Presentation Material Link](#)

PADCEV & VYLOY: Business Update

8



Strong growth sales driven by 1L mUC, overall progress in line with expectations

	Q1 YTD/FY2025	YoY
Global Sales	55.5 bil. yen	+17.1 (+45%)
US (\$ basis)	\$219M	+45 (+26%)
EST (€ basis)	€58M	+13 (+29%)
Japan	5.1 bil. yen	+2.6 (>+100%)
CN	7.4 bil. yen	+7.3
INT	1.8 bil. yen	+0.7 (+63%)

- Continued robust growth momentum driven by 1L mUC across all regions
 - ✓ **Ex-US:** Substantial sales growth (+113% YoY), notably accelerated by 1L mUC uptake
 - ✓ **US:** Solid underlying demand growth (demand YoY: +12%, demand QoQ: +7%)
- 1L mUC approval in 21 countries
Anticipate further increase in approval and reimbursement progress
- Q1 sales include one-time inventory channel load benefit in the US and China (both in line with plan); strong underlying growth maintained even excluding this impact



Exceptional start exceeding expectations; raising prospects for outperforming the initial forecast

	Q1 YTD/FY2025	YoY
Global Sales	14.0 bil. yen	+13.7 (>+100%)
US (\$ basis)	\$41M	+41
EST (€ basis)	€10M	+10
Japan	3.1 bil. yen	+2.8 (>+100%)
CN	3.3 bil. yen	+3.3
INT	0.1 bil. yen	+0.1

- Strong global performance across all major markets, sustaining growth momentum
- Driven by above benchmark Claudin 18 testing rates and lower discontinuation
- Continue to expand footprint with approvals in 43 countries and launches in 25 countries
 - ✓ China launch in June off to a strong uptake, reflecting high unmet need in China
Strategic inventory built to ensure sufficient supply
- Well-positioned for further growth, with a potential upside moving forward

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, EST (Established Markets): Europe, Canada, etc. CN (China): China, Hong Kong,

INT (International Markets): Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Taiwan, Korea, Australia, Export sales, etc.



Q1 YTD/FY2025 Financial Results: Cost Items

9

- 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

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

*Excl. US XTANDI co-pro fee

SMT: Sustainable Margin Transformation, SBs: Strategic Brands, PF: Primary Focus, PoC: Proof of concept

Agenda

10

I

Q1 YTD/FY2025 Consolidated Financial Results

II

Pipeline Progress

Strategic Brands: FY2025 Key Expected Events

(Blue: Updates since the last financial results announcement)

11

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)
avacincaptad pegol/ IZERVAY		<div> <div>○</div> <div>Jun</div> </div> Stargardt disease/ Phase 2b: Primary endpoint not met	<div> <div></div> <div></div> </div> MHLW decision (GA secondary to AMD /Japan)	
enfortumab vedotin/ PADCEV		<div> <div>○</div> <div>Jul</div> </div> 1L H&N cancer/EV-202: Terminated (incl. other solid tumors) NMIBC/EV-104: Terminated	<div> <div></div> <div></div> </div> MIBC/EV-303 & EV-304 interim analysis* (registrational)	
zolbetuximab/ VYLOY		<div> <div></div> <div></div> </div> Pancreatic/ GLEAM final analysis* (registrational)		

Data readout
 Regulatory decision

<Other update>

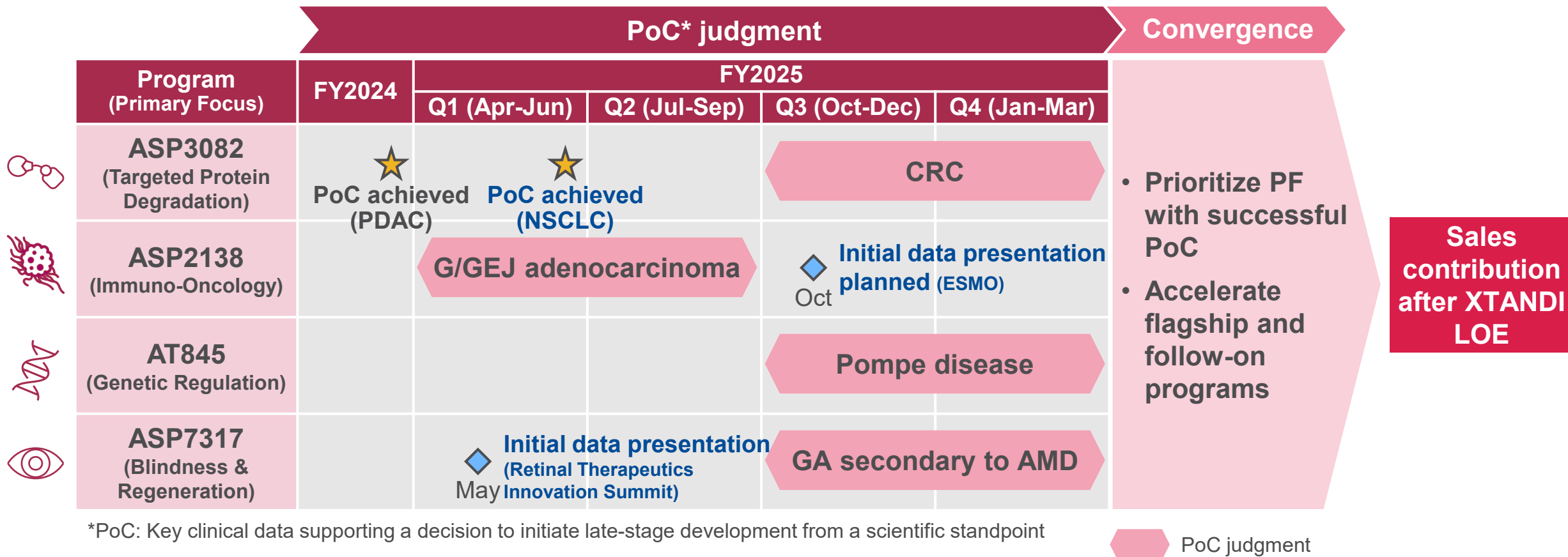
- zolbetuximab / VYLOY: First subject dosed in Phase 3 LUCERNA study (combo with pembrolizumab and chemotherapy) in Jun 2025

As of Jul 2025. *The timeline is subject to shift due to its event-driven nature

MHLW: Ministry of Health, Labour and Welfare, GA: Geographic atrophy, AMD: Age-related macular degeneration, MIBC: Muscle-invasive bladder cancer, 1L: First line, H&N: Head and neck, NMIBC: Non-muscle-invasive bladder cancer

Progress in Focus Area Approach

(Blue: Updates since the last financial results announcement)






See slide 28 for current status of other programs and slides 29-30 for overview of flagship programs.

PoC: Proof of concept, PDAC: Pancreatic ductal adenocarcinoma, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, G/GEJ: Gastric/gastroesophageal junction, ESMO: European Society for Medical Oncology, GA: Geographic atrophy, AMD: Age-related macular degeneration, PF: Primary Focus, LOE: Loss of exclusivity

Progress in Primary Focus Targeted Protein Degradation

(Blue: Updates since the last financial results announcement)

13

Program	Mechanism of action	Target disease	Origin/Partner	Current phase	Remarks
ASP3082	KRAS G12D degrader	KRAS G12D+ solid tumor		<div>Phase 1</div> Discussion ongoing toward registrational studies	<ul style="list-style-type: none"> • PoC achieved in PDAC (based on 2/3L data) and NSCLC (based on 2L+ data) • PoC judgment in CRC anticipated for 2H/FY2025 • Data presentation aiming for 2H/FY2025
ASP4396	KRAS G12D degrader (different E3 from ASP3082)	KRAS G12D+ solid tumor		<div>Phase 1</div>	
ASP5834	Pan-KRAS degrader	KRAS+ solid tumor		<div>IND cleared</div>	<ul style="list-style-type: none"> • FSD target: Q2/FY2025
ASPxxxx	KRAS degrader + antibody (DAC: degrader-antibody conjugate)	KRAS+ solid tumor		<div>IND enabling</div>	
Undisclosed	Undisclosed	Cancer		<div>Discovery</div>	
Undisclosed	Cell cycle protein degrader	Cancer		<div>Discovery</div>	
Undisclosed	Undisclosed	Cancer		<div>Discovery</div>	
Undisclosed programs	Degrader / DAC / etc.	Cancer / Non-oncology		<div>Discovery</div> :	

KRAS: Kirsten rat sarcoma viral oncogene homologue, PoC: Proof of concept, PDAC: Pancreatic ductal adenocarcinoma, 2/3L: Second and third line, NSCLC: Non-small cell lung cancer, 2L+: Second or later line, CRC: Colorectal cancer, IND: Investigational New Drug, FSD: First subject dosed

Progress in Focus Area Approach: ASP7317 (Blindness & Regeneration)

14

Progressing toward PoC judgment in 2H/FY2025 with encouraging initial clinical data

Overview of Program

Replacement therapy with retinal pigment epithelial cells aiming to maintain and restore visual functions

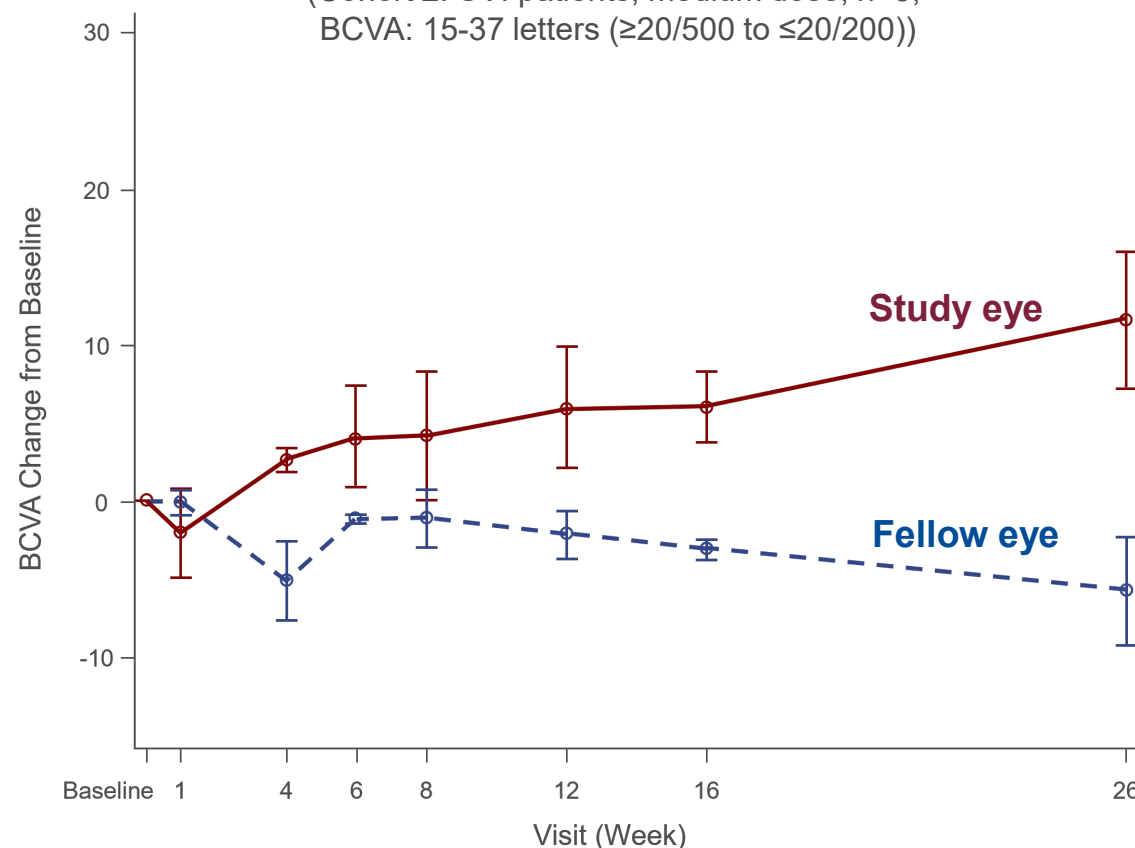
- Target disease: GA secondary to AMD
 - ✓ Estimated Number of patients: ~5 million worldwide¹
- Approved treatment: Complement inhibitors
 - ✓ Slow disease progression

Latest Status

- Initial data from Phase 1b study presented at Retinal Therapeutics Innovation Summit in May
 - ✓ No IOI events and no evidence for ASP7317 cell rejection or graft failure
 - ✓ A possible trend for improving BCVA in SVI (severe visual impairment) patients following ASP7317 transplantation
- PoC judgment anticipated for 2H/FY2025

<Mean BCVA change over time>

(Cohort 2: SVI patients, medium dose, n=3;
BCVA: 15-37 letters (≥20/500 to ≤20/200))



1. Retina. 2017;37:819-835

PoC: Proof of concept, GA: Geographic atrophy, AMD: Age-related macular degeneration, IOI: Intraocular inflammation, BCVA: Best corrected visual acuity

Exclusive License Agreement with Evopoint

15

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

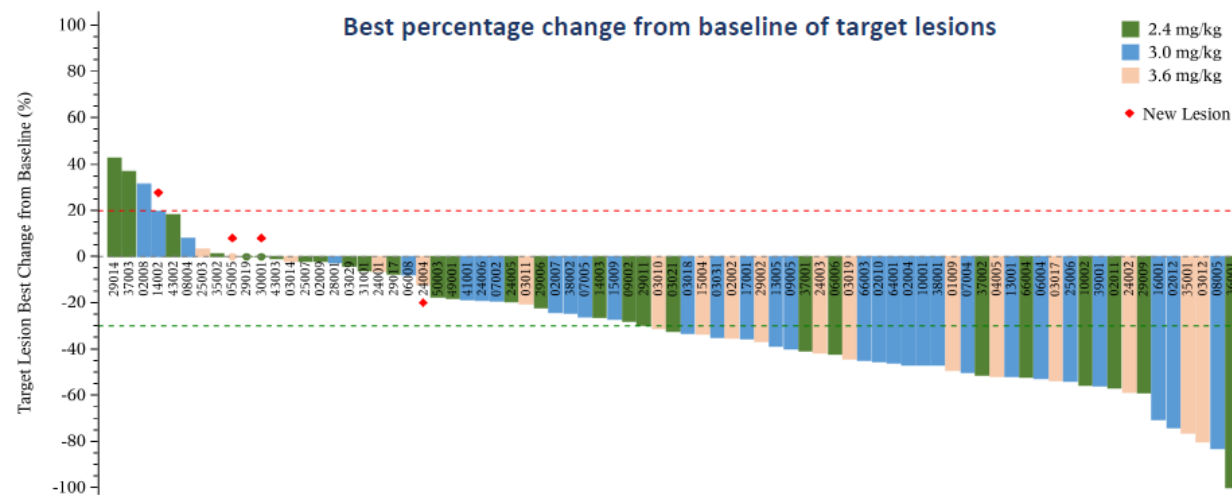
- Payload: Proprietary topoisomerase I inhibitor, Drug-to-antibody ratio: 8
- Linker: MediLink's TMALIN (Tumor Microenvironment Activable LINKer) technology
- Fast Track designation by FDA granted (gastric cancer)
- Phase 3 study initiated in China in G/GEJ cancer, Global Phase 1b/2 study under planning



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

(CLDN18.2+: CLDN18.2 expression $\geq 5\%$, IHC $\geq 2+$)

	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 ($\geq 20\%$ 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



Portfolio of Claudin 18.2-Targeted Therapies

16

Aim to address broader patient population with multiple differentiated assets

	VYLOY 	ASP2138 	ASP546C 
Modality	<ul style="list-style-type: none"> Monoclonal antibody 	<ul style="list-style-type: none"> Bispecific antibody (T-cell engager) 	<ul style="list-style-type: none"> Antibody-drug conjugate
Mode of action	<ul style="list-style-type: none"> Immune cell-mediated 	<ul style="list-style-type: none"> Immune cell-mediated 	<ul style="list-style-type: none"> Direct action of payload
Clinical data	<ul style="list-style-type: none"> Prolonged survival in combo w/ Chemo (SPOTLIGHT/GLOW) Evaluating combo w/ Chemo + CPI (LUCERNA) 	<ul style="list-style-type: none"> Evaluating combo w/ SoC regimens as well as monotherapy in G/GEJ cancer and PDAC 	<ul style="list-style-type: none"> Promising antitumor activity with monotherapy in G/GEJ cancer and PDAC with manageable tolerability
Future potential	<ul style="list-style-type: none"> SoC for CLDN18.2+ high* G/GEJ cancer: ~40% of patients Expansion to CLDN18.2+ high PDAC: ~30% of patients 	<ul style="list-style-type: none"> Enhanced immune response Expansion to all CLDN18.2+ population Ease of use with SC route 	<ul style="list-style-type: none"> “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

Key Takeaways

Exceptional Q1 progress outperforming expectations

Expect continued positive momentum throughout FY2025

Strategic Brands

- Expect continued strong momentum to drive overall revenue and profit growth

Focus Area approach

- Further PoC judgment of flagship programs
- Accelerate programs aligned with PoC achievement

Sustainable Margin Transformation

- Pursue further cost optimization to generate growth investment and improve profit margin

Appendix



Strategic Brands: Potential Peak Sales (as of Jul 2025)

19

Brand	Potential Peak Sales (Global, billions of yen)
PADCEV (enfortumab vedotin) *	400.0 – 500.0
IZERVAY (avacincaptad pegol)	200.0 – 400.0 (US alone)
VEOZAH (fezolinetant)	150.0 – 250.0
VYLOY (zolbetuximab)	100.0 – 200.0
XOSPATA (gilteritinib)	100.0 – 200.0

Only indications undergoing pivotal studies are included for projection (as of Jul 2025), VEOZAH: Approved as “VEOZA” in ex-US

*Disclosed as “in-market sales,” not Astellas revenue. Sales for Americas are calculated based on the sales booked by Pfizer

- 1 Top priority is investment for business growth
- 2 Raise dividend level aligned with profit / cashflow plan and actual performance throughout CSP2021 period
- 3 Flexibly execute share buyback by excess cash

<Appropriate leverage level>

- **Gross Debt*/EBITDA** of 1.0x to 1.5x**

Continue to pursue further debt reduction in FY2025, while maintaining the priorities outlined in our Capital Allocation policy

Furthermore, in case of undertaking a large-scale investment deemed beneficial for enhancing corporate value even if it involves a temporary deterioration of our financial soundness, will adhere to the Gross Debt/EBITDA capped at around 3.0x, regardless of the aforementioned level

*Gross Debt: Interest-bearing debt + Lease liabilities + Retirement benefit liabilities, etc,

**EBITDA: Profit before tax + Amortisation of Intangible Assets (incl. software, etc.) + Depreciation (PP&E) + Interest expenses + Other expenses

CSP: Corporate Strategic Plan

Q1 YTD/FY2025 Actual: FX Rate

21

Average rate for the period

Currency	Q1 YTD/FY2024	Q1 YTD/FY2025	Change
USD	156 yen	145 yen	-11 yen
EUR	168 yen	164 yen	-4 yen

<Impact of exchange rate on financial results>

- Revenue: -26.1 billion yen
- Core OP: -7.1 billion yen

FY2025 Forecast: FX Rate & FX Sensitivity

22

Exchange rate Average for the period	FY2024	FY2025 FCST	Change
USD	152 yen	140 yen	-12 yen
EUR	164 yen	160 yen	-4 yen

Estimated FX sensitivity of FY2025 forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption	
	Revenue	Core OP
USD	Approx. +7.8 bil. yen	Approx. +1.7 bil. yen
EUR	Approx. +3.4 bil. yen	Approx. +1.5 bil. yen

Balance Sheet & Cash Flow Highlights

23

(billion yen)	Mar 31, 2025	Jun 30, 2025
Total assets	3,339.5	3,335.8
Cash and cash equivalents	188.4	215.4
Total equity attributable to owners of the parent	1,513.3	1,481.8
Equity ratio (%)	45.3%	44.4%
(billion yen)	Q1 YTD/FY2024	Q1 YTD/FY2025
Cash flows from operating activities	12.6	54.8
Cash flows from investing activities	-39.3	-16.7
Free cash flows	-26.7	38.1
Cash flows from financing activities	-11.9	-11.0
Increase/decrease in short-term borrowings and commercial papers	71.8	65.6
Redemption of bonds and repayments of long-term borrowings	-6.7	-6.7
Dividends paid	-62.8	-66.2

Balance of Bonds and Borrowings Highlights

24

(billion yen)	Mar 31, 2025	Jun 30, 2025
Balance of bonds and borrowings	831.4	889.5
Non-current liabilities	564.9	558.1
Bonds	320.0	320.0
Long-term borrowings	244.9	238.1
Current liabilities	266.5	331.4
Commercial papers	164.9	230.7
Short-term borrowings	20.0	20.0
Current portion of long-term borrowings	51.7	50.7
Current portion of bonds	30.0	30.0

Main Intangible Assets (as of Jun 30, 2025)

25

	Bil. yen	Foreign currency**
AT132	15.6	\$109M
AT845	10.5	\$73M
Gene therapy related technology*	60.0	\$417M
VEOZAH**	83.4	€503M
VYLOY**	58.4	€450M
IZERVAY (US)	585.5	\$4,066M
IZERVAY (Ex-US)	49.7	\$345M
ASP7317	24.8	\$172M

VEOZAH: Approved as “VEOZA” in ex-US

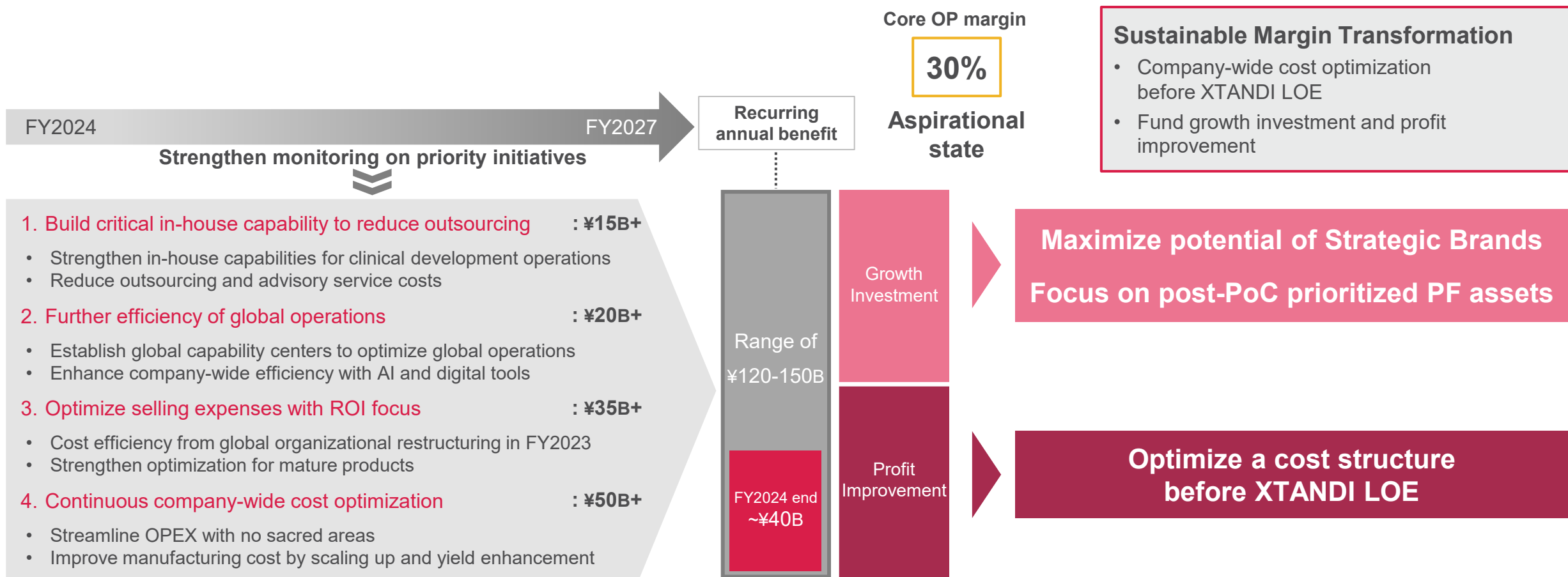
*Acquired during the acquisition of Audentes (now Astellas Gene Therapies)

**VEOZAH, VYLOY: foreign currency is a reference value based on the currency at the time of acquisition of the intangible asset

Sustainable Margin Transformation

26






- *Company-wide cost optimization of 120-150 billion yen before XTANDI LOE*
- *Fund growth investment and profit improvement*



Lifecycle Management of Strategic Brands

(Blue: Updates since the last financial results announcement)

27

Brand	Indication	Current status	Next milestone
 enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	Muscle-invasive bladder cancer	Phase 3 EV-303 & EV-304 studies ongoing	Data readout (interim analysis) anticipated for Q2-Q4/FY2025
 (avacincaptad pegol intravitreal solution) 2 mg	GA secondary to AMD	Japan: NDA under review	Regulatory decision anticipated for Q3/FY2025
		LCM opportunities under consideration (e.g. prefilled syringe, sustained release)	(Under discussion)
 (fezolinetant) tablets 45 mg	VMS associated with menopause	Japan: Phase 3 STARLIGHT 2 & 3 studies ongoing	Data readout anticipated for FY2026
		China: Phase 2 study ongoing	Data readout anticipated for FY2026
	VMS in breast cancer women	Phase 3 HIGHLIGHT 1 study ongoing	Data readout anticipated for FY2027
 zolbetuximab for injection 100mg vial	Gastric and GEJ cancer	Phase 3 LUCERNA study in combo with Pembro and Chemo ongoing	Data readout (interim analysis) anticipated for FY2027 or later
	Pancreatic cancer	Registrational Phase 2 GLEAM study ongoing	Data readout (final analysis) anticipated for Q2/FY2025
 gilteritinib 40mg tablets	Newly diagnosed AML (HIC-eligible)	Phase 3 PASHA study ongoing	Data readout (primary analysis) anticipated for 1H/FY2026

As of Jul 2025. Not exhaustively listed. VEOZAH: Approved as "VEOZA" in ex-US

GA: Geographic atrophy, AMD: Age-related macular degeneration, NDA: New Drug Application, LCM: Lifecycle management, VMS: Vasomotor symptoms,

GEJ: Gastroesophageal junction, Pembro: Pembrolizumab, Chemo: Chemotherapy, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy

Progress in Focus Area Approach: Current Status of Programs in Clinical Trial

(Blue: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology	Program	Mechanism of action	Current status
Immuno-Oncology	Checkpoint	ASP1570	● DGKζ inhibitor	Phase 1/2 study ongoing
	Bispecific immune cell engager	★ ASP2138	● Anti-CLDN18.2 and anti-CD3	Phase 1 study ongoing. Initial data to be presented at ESMO in Oct 2025
		ASP1002	● Anti-CLDN4 and anti-CD137	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	● Leptin-IL-2	Discontinued
Targeted Protein Degradation	Protein degradation	★ ASP3082	● KRAS G12D degrader	Phase 1 study ongoing. PoC in NSCLC achieved
		ASP4396	● KRAS G12D degrader	Phase 1 study ongoing
Genetic Regulation	Gene replacement (AAV)	AT132	● MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		★ AT845	● GAA gene	Phase 1/2 study ongoing
Blindness & Regeneration	Cell replacement	★ ASP7317	● RPE cells	Phase 1b study ongoing. Initial data presented at Retinal Therapeutics Innovation Summit in May 2025
Others (Non-PF)	Long-acting abiraterone prodrug	ASP5541 (PRL-02)	● CYP17 lyase inhibitor	Phase 2 study under preparation to start in Q2/FY2025
	Antibody-drug conjugate (ADC)	ASP546C (XNW27011)	● ADC targeting CLDN18.2	Phase 3 study initiated in China in G/GEJ cancer
	Immune modulation	ASP5502	● STING inhibitor	Phase 1 study ongoing

Modality	
●	Small molecule
●	Antibody
●	Gene
●	Cell

★ : Flagship program

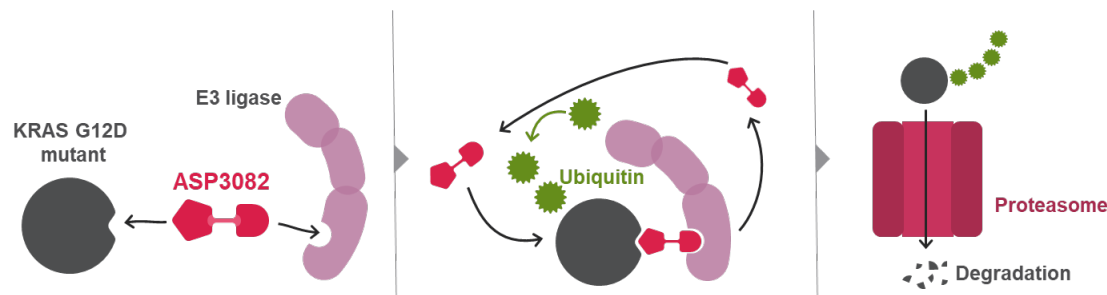
Overview of Primary Focus Flagship Programs (1/2)

29

ASP3082 (Targeted Protein Degradation)

Protein degrader targeting KRAS G12D mutant

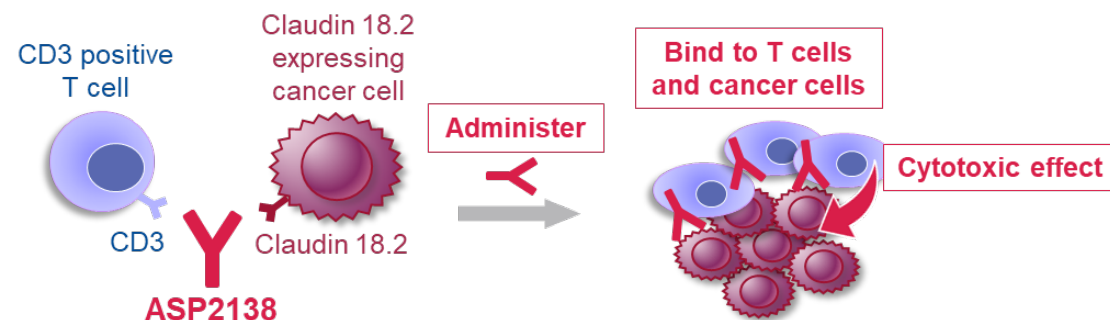
- Target disease: Cancers harboring KRAS G12D mutation
 - ✓ Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~5% in non-squamous NSCLC, ~15% in CRC¹
- Standard of care (metastatic PDAC): Chemotherapy
- Status: Phase 1 study ongoing ([NCT05382559](#))
 - ✓ PDAC: 2L+ (monotherapy), 1L (combo with chemotherapy); PoC achieved based on 2/3L data
 - ✓ NSCLC: 2L+ (monotherapy & combo with SoC), 1L (combo with SoC); PoC achieved based on 2L+ data
 - ✓ CRC: 2L+ (monotherapy & combo with cetuximab); PoC judgment anticipated for 2H/FY2025



ASP2138 (Immuno-Oncology)

Bispecific antibody targeting CLDN18.2 and CD3

- Target disease: Gastric/GEJ (G/GEJ) adenocarcinoma, PDAC
 - ✓ Rate of CLDN18.2-positive patients*: ~70% in G/GEJ adenocarcinoma² and ~60% in PDAC³
- Standard of care (HER2-, advanced G/GEJ adenocarcinoma)
 - ✓ 1L: chemotherapy +/- checkpoint inhibitor or zolbetuximab (CLDN18.2-positive)
 - ✓ 2L+: paclitaxel + ramucirumab
- Status: Phase 1 study ongoing ([NCT05365581](#), [NCT07024615](#))
 - ✓ G/GEJ adenocarcinoma: 1L & 2L, monotherapy & combo
 - ✓ Resectable PDAC: neoadjuvant (+ adjuvant chemotherapy)
- Anticipated PoC judgment timing: 1H/FY2025



*Represents % of patients with any level of Claudin 18.2+ staining ($\geq 1\%$). 1. npj Precis Oncol. 2022;6:91, 2. Gastric Cancer. 2024;27:1058, 3. Int J Cancer. 2013;134:731
KRAS: Kirsten rat sarcoma viral oncogene homologue, PDAC: Pancreatic ductal adenocarcinoma, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer,
2L+: Second or later line, 1L: First line, PoC: Proof of concept, 2/3L: Second and third line, GEJ: Gastroesophageal junction, CLDN18.2: Claudin 18.2, HER2-: HER2 negative

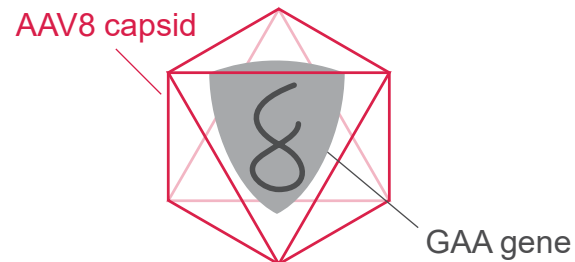
Overview of Primary Focus Flagship Programs (2/2)

30

AT845 (Genetic Regulation)

Recombinant AAV8 continuously expressing hGAA gene specially in muscle

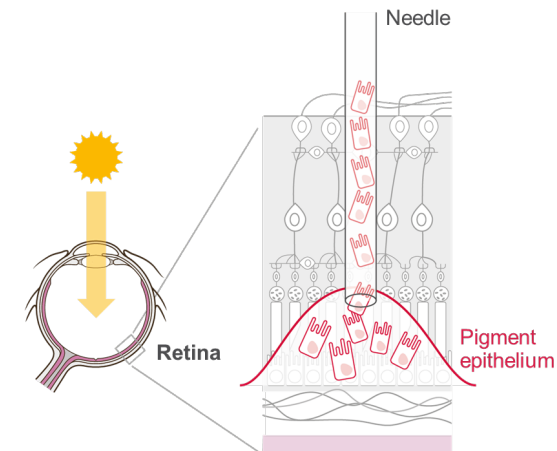
- Target disease: Pompe disease
 - ✓ Estimated incidence: 1 in ~40,000¹
- Standard of care: Enzyme replacement therapy (ERT)
 - ✓ Chronic, repeated infusions every 2 weeks
 - ✓ Secondary disease progression after 2-3 years on ERT^{2,3,4}
 - ✓ Substantial economic burden with high rates of healthcare resource utilization⁵
- Status: Phase 1/2 FORTIS study ongoing ([NCT04174105](#))
 - ✓ Five of six participants have discontinued ERT, and remained clinically stable while off ERT for 1-3 years⁶
- Anticipated PoC judgment timing: 2H/FY2025



ASP7317 (Blindness & Regeneration)

Replacement therapy with retinal pigment epithelial cells aiming to maintain and restore visual functions

- Target disease: Geographic atrophy secondary to AMD
 - ✓ Estimated Number of patients: ~5 million worldwide⁷
- Approved treatment: Complement inhibitors
 - ✓ Slow disease progression
- Status: Phase 1b study ongoing ([NCT03178149](#))
- Anticipated PoC judgment timing: 2H/FY2025



Robust Pipeline of Astellas

31

Phase 1

ASP1570
ASP2138
ASP1002
ASP3082
ASP4396
ASP7317
abiraterone decanoate/ ASP5541/PRL-02
ASP5502
ASP546C/XNW27011

Phase 2

gilteritinib (Newly diagnosed AML, HIC-ineligible)
zolbetuximab (Pancreatic adenocarcinoma)
avacincaptad pegol (Stargardt disease)
resamirigene bilparvovec/ AT132 (XLMTM)
zocaglusagene nuzaparvovec/ AT845 (Pompe disease)

Phase 3

enfortumab vedotin (MIBC)
gilteritinib (Earlier-stage AML, pediatric use)
fezolinetant (VMS due to menopause: China, Japan; VMS in breast cancer patients on adjuvant endocrine therapy)
zolbetuximab (Gastric and GEJ adenocarcinoma, combo with pembrolizumab and chemotherapy)
mirabegron (NDO, pediatric use (aged 6 months to less than 3 years): Europe)
roxadustat (Anemia associated with CKD, pediatric use: Europe)

Submitted/Filed

avacincaptad pegol (GA secondary to AMD: Japan)
--

- Strategic Brands
- Programs with Focus Area approach
- Others

Please refer to R&D pipeline list for details including target disease.

AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, XLMTM: X-linked myotubular myopathy, MIBC: Muscle-invasive bladder cancer, VMS: Vasomotor symptoms, GEJ: Gastroesophageal junction, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, GA: Geographic atrophy, AMD: Age-related macular degeneration



Progress in Overall Pipeline

Phase 1 Entry to Approval Since the Last Financial Results Announcement



ASP546C/XNW27011
Cancer

Discontinuation

ASP1012: Cancer (Phase 1)
enfortumab vedotin: Other solid tumors (Phase 2), Non-muscle-invasive bladder cancer (Phase 1)

Note: Phase 1 entry and Phase transition are defined by first subject dosed.
Filing is defined as submission of application to health authorities.
Discontinuation is defined by the decision of company decision body.

Strategic Brands: Status Update

(Blue: Updates since the last financial results announcement)

Generic / Brand name	Indication	Current status
enfortumab vedotin/ PADCEV	Muscle-invasive bladder cancer	• Phase 3 studies ongoing (enrollment completed)
	Non-muscle-invasive bladder cancer	• Terminated
	Other solid tumors	• Terminated
avacincaptad pegol/ IZERVAY	GA secondary to AMD	• NDA submitted in Japan in Feb 2025
	Stargardt disease	• Primary endpoint not met in Phase 2b study
fezolinetant/ VEOZAH	VMS due to menopause	• Japan: Phase 3 studies ongoing • China: Phase 2 study ongoing
	VMS in breast cancer patients on adjuvant endocrine therapy	• Phase 3 study ongoing
zolbetuximab/ VYLOY	Gastric and GEJ adenocarcinoma	• FSD in Phase 3 study in combo with pembrolizumab and chemotherapy in Jun 2025
	Pancreatic adenocarcinoma	• Phase 2 study ongoing (enrollment completed)
gilteritinib/ XOSPATA	AML, post-HSCT maintenance	• Development based on Phase 3 MORPHO study discontinued
	AML, newly diagnosed (HIC-eligible)	• Phase 3 study ongoing (enrollment completed)
	AML, newly diagnosed (HIC-ineligible)	• Phase 2 study ongoing
	AML, post-chemotherapy	• Obtained topline results from Phase 2 GOSSAMER study

VEOZAH: Approved as "VEOZA" in ex-US.

GA: Geographic atrophy, AMD: Age-related macular degeneration, NDA: New Drug Application, VMS: Vasomotor symptoms, GEJ: Gastroesophageal junction, FSD First subject dosed, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy

enfortumab vedotin (EV) (1/5): Nectin-4 Targeted ADC

Overview of Development

34

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

<Already approved / pivotal phase> (Included in potential peak sales)

Patient segment		Pivotal study (EV regimen)	Target filing timing	Number of eligible patients*
MIBC	Cis-ineligible	EV-303 (combo w/ Pembro)	FY2025 or later	19,000**
	Cis-eligible	EV-304 (combo w/ Pembro)	FY2025 or later	64,000**
1L mUC		EV-302 EV-103 Cohorts [Phase 1b/2 for AA in US] (combo w/ Pembro)	Approved Approved [AA in US]	87,000
2L+ mUC	PD-1/L1 inhibitor pretreated & Cis-ineligible	EV-201 Cohort 2 (monotherapy)	Approved	1,500 (US, Cis-ineligible)
	Platinum & PD-1/L1 inhibitor pretreated	EV-301 EV-201 Cohort 1 [Phase 2 for AA in US] (monotherapy)	Approved	46,000

*US, Germany, France, Italy, Spain, UK, Japan, China (based on internal estimates)

**Excluding China

enfortumab vedotin (EV) (2/5): Clinical Studies

(Blue: Updates since the last financial results announcement)

35

Urothelial cancer

P3: EV-303 /KEYNOTE-905	NCT03924895	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=595	Enrollment completed
P3: EV-304 /KEYNOTE-B15	NCT04700124	MIBC, Cis-eligible; EV + Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=808	Enrollment completed
P1b/2: EV-103	NCT03288545	Cohorts A - G and K (mUC): A-G: Combo with Pembro and other chemo K: EV mono, EV + Pembro Cohorts H, J and L (MIBC, Cis-ineligible, + RC): H: EV mono (neoadjuvant) J (optional): EV + Pembro (neoadjuvant) L: EV mono (perioperative)	n=348	Dose Escalation/Cohort A and Cohort K: sBLA approved (under the Accelerated Approval program) in US in Apr 2023. Enrollment completed
P1: EV-104	NCT05014139	NMIBC, High-risk BCG-unresponsive; Intravesical EV mono	n=58	Terminated

Other solid tumors

P2: EV-202	NCT04225117	HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric and esophageal adenocarcinoma including GEJ adenocarcinoma, Esophageal squamous cell carcinoma; EV mono Head and neck squamous cell carcinoma; EV + Pembro	n=329	Terminated
-------------------	-----------------------------	---	-------	-------------------

enfortumab vedotin (EV) (3/5): Study Data by Disease Stage of UC

36

Disease stage	Early stage		Late stage						
	MIBC		mUC						
	Surgery eligible		Previously untreated (first line)				PD-1/L1 inhibitor pretreated		
	Cis-eligible	Cis-ineligible	Platinum eligible	Cis-ineligible			Platinum naïve & Cis-ineligible	Platinum pretreated	
Study phase	Phase 3	Phase 3	Phase 3	Phase 1b/2		Phase 1b/2	Phase 2	Phase 2	Phase 3
Study No.	KN-B15 / EV-304	KN-905 / EV-303	EV-302	EV-103 Cohort K		EV-103 Cohort A & Others	EV-201 Cohort 2	EV-201 Cohort 1	EV-301
No. of subjects	808 (2 arms)	595 (3 arms)	886	76	73	45	89	125	608 (2 arms)
EV regimen	Combo w/ Pembro (perioperative)	Combo w/ Pembro (perioperative)	Combo w/ Pembro	Combo w/ Pembro	Mono	Combo w/ Pembro	Mono	Mono	Mono
Control	Chemo (neoadjuvant)	SoC	Chemo	n/a	n/a	n/a	n/a	n/a	Chemo
Primary endpoint	EFS	EFS	✓ PFS: HR 0.48 ** ✓ OS: HR 0.51 **	✓ ORR 64% (CR 11%)	✓ ORR 45% (CR 4%)	✓ ORR 73% ** (CR 16% **)	✓ ORR 51% ** (CR 22% **)	✓ ORR 44% (CR 12%)	✓ OS HR 0.70 *
OS	(Ongoing)	(Ongoing)	✓ HR 0.51 ** (33.8 mos vs. 15.9 mos)	n/a	✓ (21.7 mos)	✓ (26.1 mos **)	✓ (14.7 mos)	✓ (12.4 mos **)	✓ HR 0.70 * (12.9 mos vs.9.0 mos)
PFS	(Ongoing)	(Ongoing)	✓ HR 0.48 ** (12.5 mos vs. 6.3 mos)	n/a	✓ (8.2 mos)	✓ (12.7 mos **)	✓ (5.8 mos)	✓ (5.8 mos)	✓ HR 0.62 * (5.6 mos vs.3.7 mos)
ORR	(Ongoing)	(Ongoing)	✓ 67.5% vs. 44.2% ** (CR 30.4% vs. 14.5%)	✓ 64% (CR 11%)	✓ 45% (CR 4%)	✓ 73% ** (CR 16% **)	✓ 52% (CR 20%)	✓ 44% (CR 12%)	✓ 41% vs.18% * (CR 4.9% vs.2.7%)
DoR	(Ongoing)	(Ongoing)	✓ 23.3 mos vs. 7.0 mos **	n/a	✓ 13.2 mos	✓ 22.1 mos **	✓ 13.8 mos **	✓ 7.6 mos	✓ 7.4 mos vs. 8.1 mos *

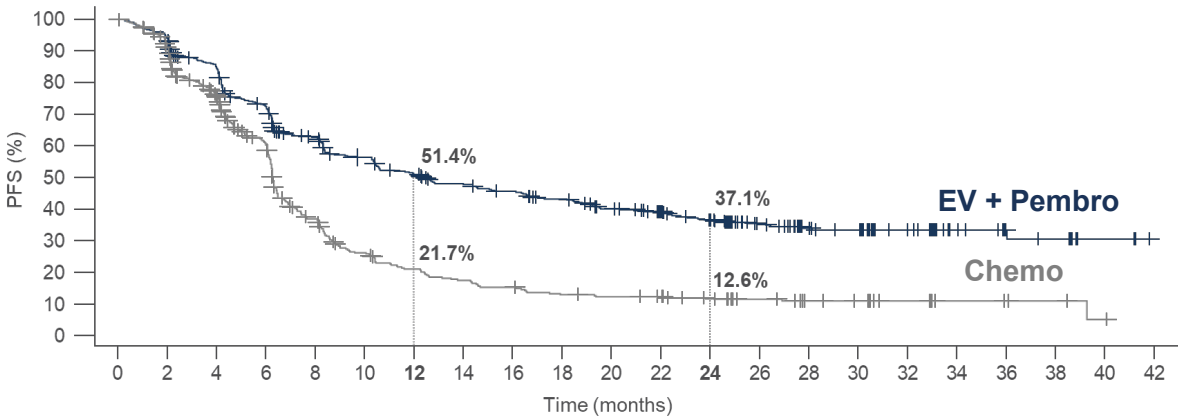
✓: Data obtained, *: Prespecified interim analysis, **: Updated data

enfortumab vedotin (EV) (4/5): Study Data in 1L mUC (EV-302)

37

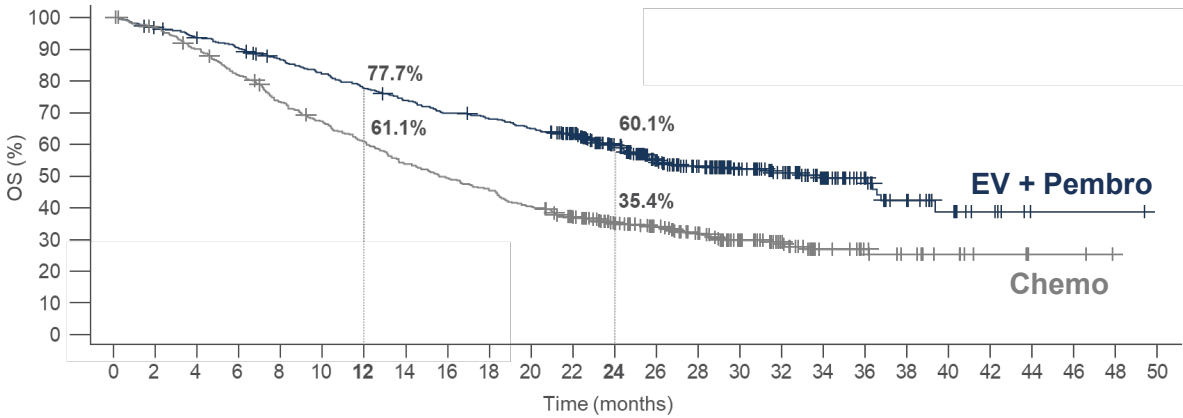
Statistically significant and clinically meaningful improvement over chemotherapy with nearly doubled mOS and mPFS

<Progression-free survival>



	N	Events	HR (95% CI)	2-sided P value	mPFS (95% CI), months
EV + Pembro	442	262	0.48 (0.41, 0.57)	<0.00001	12.5 (10.4, 16.6)
Chemo	444	317			6.3 (6.2, 6.5)

<Overall survival>



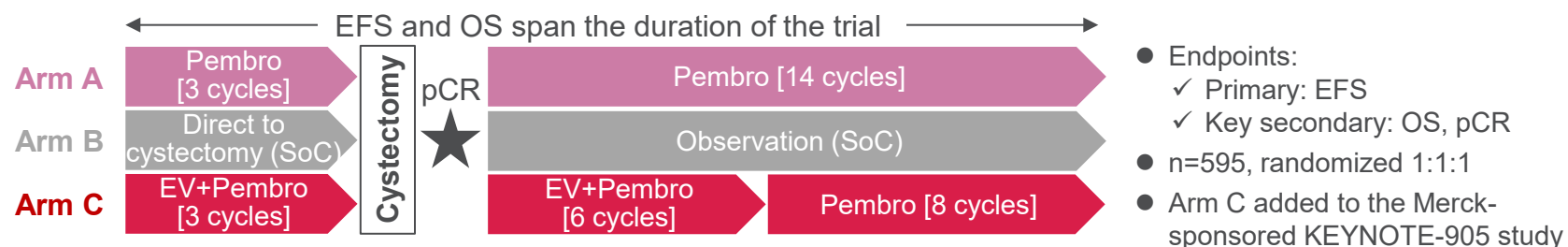
	N	Events	HR (95% CI)	2-sided P value	mOS (95% CI), months
EV + Pembro	442	203	0.51 (0.43, 0.61)	<0.00001	33.8 (26.1, 39.3)
Chemo	444	297			15.9 (13.6, 18.3)

- Chemo: cisplatin or carboplatin + gemcitabine
- 30.4% of patients in Chemo arm received subsequent avelumab maintenance therapy

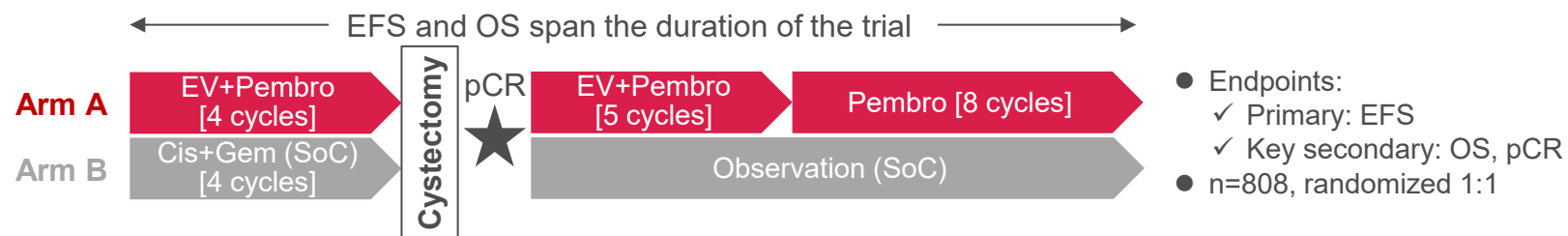
enfortumab vedotin (EV) (5/5): Development for Muscle-invasive bladder cancer (MIBC)

38

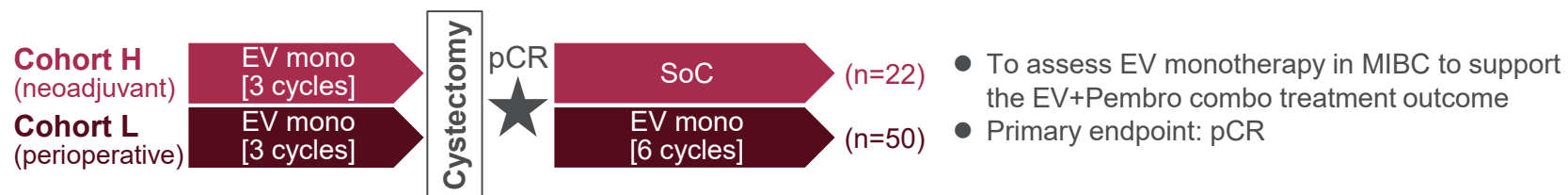
1) Phase 3 study in *Cis-ineligible* MIBC (KEYNOTE-905/EV-303): Perioperative EV+Pembro vs. Cystectomy alone



2) Phase 3 study in *Cis-eligible* MIBC (KEYNOTE-B15/EV-304): Perioperative EV+Pembro vs. Neoadjuvant chemo



3) Phase 1b/2 study in *Cis-ineligible* MIBC (cohorts in EV-103): Neoadjuvant/Perioperative EV mono



<Results>

Cohort	pCR	pDS
H	36.4%	50.0%
L	34.0%	42.0%

1 cycle = 21 days

avacincaptad pegol (ACP): Complement C5 Inhibitor / Pegylated RNA Aptamer

(Blue: Updates since the last financial results announcement)

Geographic atrophy (GA)

- Advanced form of dry age-related macular degeneration (AMD)
- Globally, approximately 5 million people are estimated to have GA at least in one eye¹
- Without timely treatment, an estimated 66% of people with GA may become blind or severely visually impaired²

Characteristics of ACP

- Pegylated RNA aptamer (chemically synthesized)
- ACP inhibits complement C5, and slows inflammation and cell death associated with development and progression of GA

GA secondary to AMD	P2/3: GATHER1	NCT02686658	Part 1: 1 mg, 2 mg vs. sham (n=77) Part 2: 2 mg, 4 mg vs. sham (n=209)	n=286	NDA submitted in Japan in Feb 2025
	P3: GATHER2	NCT04435366	2 mg vs. sham	n=448	
Stargardt disease	P2b	NCT03364153	vs. sham	n=121	Primary endpoint not met

1. Retina. 2017;37:819-835, 2. JAMA Ophthalmol. 2021;139:743-750
(s)NDA: (Supplemental) New Drug Application

fezolinetant: NK3 receptor antagonist

VMS has a significant negative impact on QoL

- Physical symptoms include hot flashes and night sweats, which can impact sleep
- Physical symptoms may lead to emotional impact including embarrassment, irritability, anxiety, and sadness
- Symptoms have a negative impact on multiple aspects of everyday life¹

Women’s Health Initiative (WHI) Study²

- Initial data analyses showed an association between chronic HRT use and increased risk of cardiovascular disease and breast cancer
- Since WHI’s findings, use of HRT has dropped
- Although subsequent analysis of the WHI data have demonstrated that HRT is safe and effective when initiated in the appropriate patient in the appropriate manner (i.e. right time, formulation, dose and duration), prescriptions have not rebounded, leaving some women with minimal options to satisfactorily manage their VMS

VMS associated with menopause

Japan	P3: STARLIGHT 2	NCT06206408	Mild to severe VMS associated with menopause; 12 weeks: DB, 2 doses vs. placebo (1:1:1)	n=390	FSD: Mar 2024
	P3: STARLIGHT 3	NCT06206421	VMS associated with menopause; 52 weeks: DB, vs. placebo (1:1)	n=277	Enrollment completed
China	P2	NCT06812754	Moderate to severe VMS associated with menopause; 12 weeks: DB, 45 mg vs. placebo (1:1)	n=150	FSD: Apr 2025

VMS in breast cancer women receiving adjuvant endocrine therapy

P3: HIGHLIGHT 1	NCT06440967	Moderate to severe VMS associated with adjuvant endocrine therapy for breast cancer; 52 weeks (efficacy endpoints at 4 and 12 weeks): DB, vs. placebo (1:1)	n=540	FSD: Aug 2024
-----------------	-----------------------------	---	-------	---------------

1: DelveInsight, Epidemiology Forecast, Jun 2018. 2: Data Source - IMS NPA (2000-2016), IMS NSP (2000-2016). (3 HTs and SSRI) NAMS 2015 Position Statement
NK3: Neurokinin 3, VMS: Vasomotor symptoms, QoL: Quality of life, HRT: Hormone replacement therapy, DB: Double-blind, FSD: First subject dosed



zolbetuximab: Anti-Claudin 18.2 Monoclonal Antibody

(Blue: Updates since the last financial results announcement)

41

Target: Claudin 18.2 (CLDN18.2)

- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- 38% of patients had CLDN18.2-positive tumors* in SPOTLIGHT and GLOW studies for gastric and GEJ adenocarcinoma
- 27.7% of patients had CLDN18.2-positive tumors* in GLEAM study for pancreatic adenocarcinoma

Gastric and GEJ adenocarcinoma

- Five-year survival rate is ~6% for metastatic gastric cancer patients at Stage IV

Pancreatic adenocarcinoma

- Five-year survival rate is <5% for patients at the metastatic stage

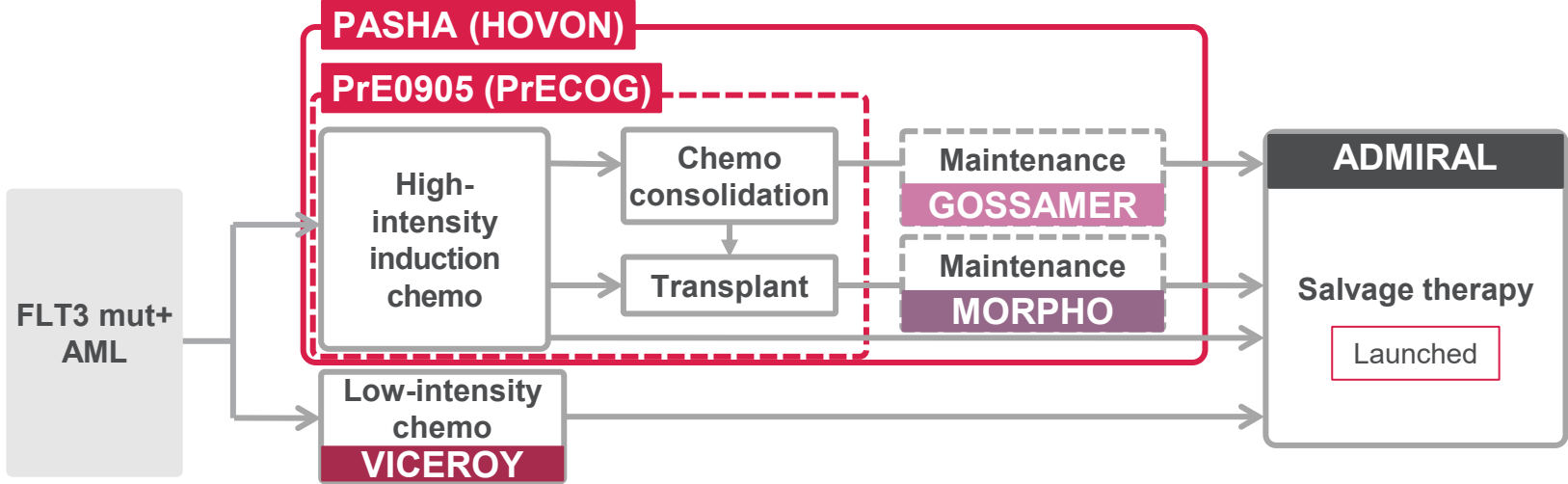
Gastric and GEJ adenocarcinoma	P3: LUCERNA	NCT06901531	First line, combo with Pembro and chemo, DB, vs. placebo	n=500	FSD: Jun 2025
	P2: ILUSTRO	NCT03505320	Cohort 1: Third or later line, zolbetuximab monotherapy Cohort 2: First line, combo with mFOLFOX6 Cohort 3: Third or later line, combo with Pembro Cohort 4: First line, combo with mFOLFOX6 and nivolumab Cohort 5: Perioperative, combo with FLOT	n=143	Enrollment completed
Pancreatic adenocarcinoma	P2: GLEAM	NCT03816163	First line, combo with nab-paclitaxel and gemcitabine, open	n=393	Enrollment completed

*CLDN18.2 positivity is defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining

GEJ: Gastroesophageal junction, Pembro: Pembrolizumab, chemo: Chemotherapy, DB: Double-blind, FSD: First subject dosed, mFOLFOX6: 5-FU, leucovorin and oxaliplatin,

FLOT: Fluorouracil, leucovorin, oxaliplatin and docetaxel

gilteritinib: FLT3 Inhibitor



Relapsed or refractory	P3: ADMIRAL	NCT02421939	Monotherapy vs. salvage chemo (2:1)	n=371	Launched in US, JP, and Europe
Newly diagnosed (HIC-eligible)	P3: PASHA (HOVON)	NCT04027309	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=766	Enrollment completed (Sponsor: HOVON)
	P2: PrE0905 (PrECOG)	NCT03836209		n=181	Topline results presented at ASH 2024 (Sponsor: PrECOG, LLC.)
Post-HSCT maintenance	P3: MORPHO	NCT02997202	Monotherapy vs. placebo (1:1)	n=356	Development based on MORPHO study discontinued
Post-chemo maintenance	P2: GOSSAMER	NCT02927262	Monotherapy vs. placebo (2:1)	n=98	Topline results obtained in Aug 2021
Newly diagnosed (HIC-ineligible)	P1/2: VICEROY	NCT05520567	Combo with venetoclax and azacitidine	n=70	FSD: Jan 2023

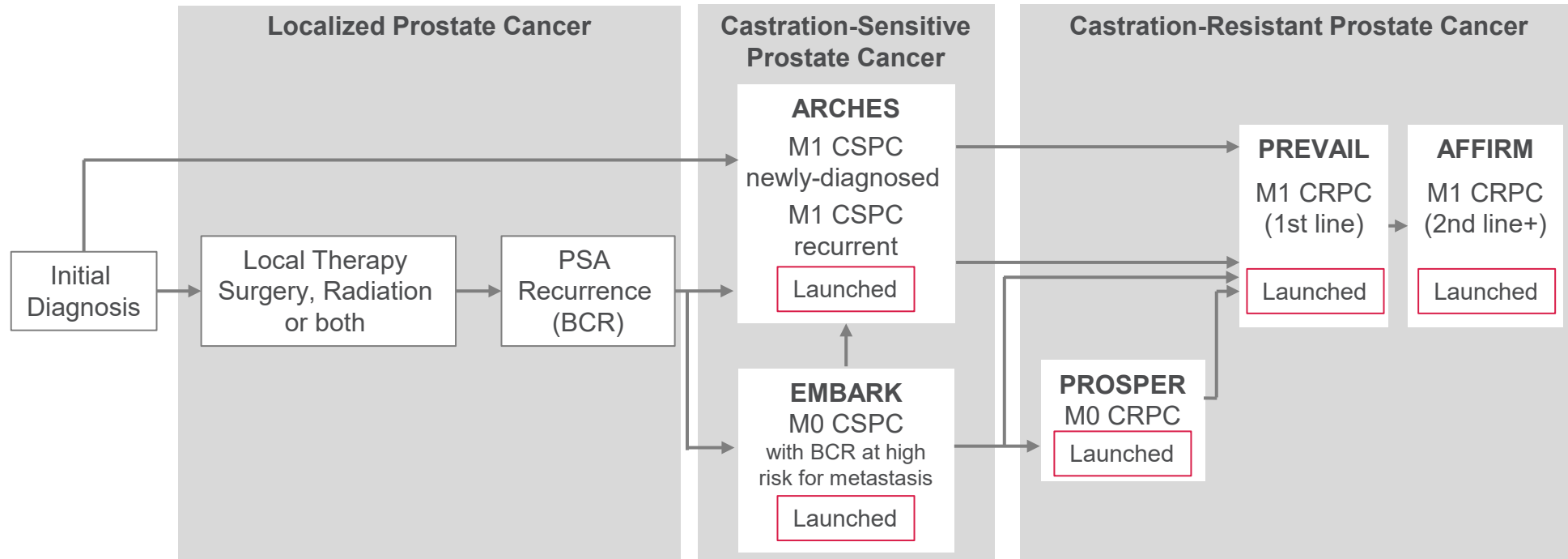
- China**
- **R/R AML:** Conditional approval obtained in Jan 2021 based on ADMIRAL study data. Phase 3 COMMODORE study (including China and other countries) stopped due to efficacy based on the planned interim analysis and full approval obtained in Jan 2025

FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, Chemo: Chemotherapy, HIC: High-intensity chemotherapy, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands, ASH: American Society of Hematology, HSCT: Hematopoietic stem cell transplant, FSD: First subject dosed, R/R: Relapsed or refractory



enzalutamide (1/2): Androgen Receptor Inhibitor

43



enzalutamide (2/2): Phase 3 Study Data by Disease Stage

(Blue: Updates since the last financial results announcement)

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

Disease stage	Early stage			Late stage		
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	EMBARK	ARCHES	ENZAMET	PROSPER	PREVAIL	AFFIRM
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary endpoint	✓ MFS HR 0.42	✓ rPFS HR 0.39	✓ OS HR 0.67	✓ MFS HR 0.29	✓ rPFS HR 0.17 ✓ OS HR 0.71*	✓ OS HR 0.63
OS	✓ Endpoint met	✓ HR 0.66	✓ HR 0.67	✓ HR 0.73	✓ HR 0.77	✓ HR 0.63
DoT	✓ 32.4 months**	✓ 40.2 months	✓ 29.5 months	✓ 33.9 months	✓ 17.5 months	✓ 8.3 months

✓: Data obtained, *: Prespecified interim analysis, **: excluding treatment suspension period

**On the forefront of healthcare change
to turn innovative science
into VALUE for patients**

