



# Q3 YTD/FY2025 Financial Results

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# 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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# Q3 YTD/FY2025 Overview

## **- Strong Momentum Continues; Another Upward Revision of Full-year Forecast -**

### **Q3 YTD Financial Results**

<b>Revenue</b>	Continued strong growth of Strategic Brands (Over +100.0 bil. yen YoY), driving double-digit revenue growth (+10% YoY)
<b>SG&amp;A expenses*</b>	Robust SMT progress, driving continued improvement in SG&A ratio (-2.7ppt YoY)
<b>Core OP</b>	Significant increase driven by Strategic Brands growth and robust SMT progress (+49% YoY) Core OP margin increased to 27.6% (+7.1ppt YoY)

### **Revision of FY2025 Full-year Forecast**

- ✓ Upward revision of Revenue (+70.0 bil. yen), Core OP (+30.0 bil. yen) and Full OP (+100.0 bil. yen)

### **Pipeline Progress**

- ✓ PADCEV (MIBC): US approval based on EV-303 study / Positive topline results from EV-304 study
- ✓ VYLOY (gastric cancer): Promising combination data presented / Phase 3 LUCERNA study ongoing
- ✓ ASP3082: Promising 1L PDAC data presented / Phase 3 study planned to start by March
- ✓ ASP2138: PoC achieved (gastric cancer) / Phase 3 study under preparation

\*Excl. US XTANDI co-promote fee

Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA. SMT (Sustainable Margin Transformation): See [slide 24](#) for overview

MIBC: Muscle-invasive bladder cancer, 1L: First line, PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept

# Agenda



**Q3 YTD/FY2025 Consolidated Financial Results  
FY2025 Revised Forecast**



**Pipeline Progress**

# Q3 YTD/FY2025 Financial Results

Revenue and Core OP each **increased by approx. 150.0 bil. yen YoY**, Full OP increased significantly

(billion yen)	Q3 YTD FY2024	Q3 YTD FY2025	Change	Change (%)	Fx impact (YoY)	FY2025 FCST *
<b>Revenue</b>	<b>1,453.0</b>	<b>1,601.3</b>	<b>+148.3</b>	<b>+10.2%</b>	-2.2	<b>2,030.0</b>
Cost of sales	272.3	314.8	+42.4	+15.6%	+3.4	387.0
SG&A expenses	631.7	625.6	-6.1	-1.0%	-7.1	831.0
US XTANDI co-promote fee	200.1	193.1	-7.0	-3.5%	-4.8	245.0
SG&A excl. the above	431.6	432.6	+0.9	+0.2%	-2.2	586.0
(SG&A ratio**)	29.7%	27.0%	-2.7ppt			28.9%
R&D expenses	251.4	218.9	-32.5	-12.9%	-2.7	322.0
(R&D ratio)	17.3%	13.7%	-3.6ppt			15.9%
<b>Core operating profit</b>	<b>297.5</b>	<b>442.1</b>	<b>+144.5</b>	<b>+48.6%</b>	+4.2	<b>490.0</b>
(Core OP margin)	20.5%	27.6%	+7.1ppt			24.1%
<b>&lt; Full basis &gt;</b>						
Amortisation of intangible assets	104.2	100.2	-4.0	-3.8%		
Other income	4.4	25.4	+21.0	+475.4%		
Other expenses	220.6	35.8	-184.8	-83.8%		
<b>Operating profit</b>	<b>-22.5</b>	<b>333.9</b>	<b>+356.4</b>	-		<b>240.0</b>
Profit before tax	-29.3	328.6	+357.9	-		230.0
<b>Profit</b>	<b>-24.1</b>	<b>248.0</b>	<b>+272.1</b>	-		<b>180.0</b>

\*Disclosed in Oct 2025, \*\*Excl. US XTANDI co-promote fee

Exchange rate assumption of FY2025 FCST: 145 yen/USD, 170 yen/EUR

Actual exchange rates of Q3 YTD/FY2025: 149 yen/USD, 172 yen/EUR (Actual exchange rates of Q3 YTD/FY2024: 152 yen/USD, 165 yen/EUR)

# Q3 YTD/FY2025 Financial Results: Main Brands

*All Brands increased across the board, with Strategic Brands total growing over 100.0 bil. yen YoY*

(billion yen)	Q3 YTD/FY2025	YoY	
<b>Strategic Brands Total</b>	<b>353.2</b>	<b>+109.3 (+45%)</b>	✓ High profitability of Strategic Brands contributing to elevation of core OP margin
 <b>PADCEV™</b>	<b>162.6</b>	<b>+45.6 (+39%)</b>	<ul style="list-style-type: none"> <li>✓ Progress exceeding expectations, driven mainly by the strong US and EST performance</li> <li>✓ US approval of MIBC cis-ineligible in Nov 2025; uptake on track and now included in NCCN guideline</li> <li>✓ Positive TLR achieved in EV-304 study (MIBC cis-eligible); MIBC expected to contribute to FY2026 growth</li> </ul>
 <b>izervay™</b>	<b>55.8</b>	<b>+11.4 (+26%)</b>	<ul style="list-style-type: none"> <li>✓ Continues to grow double digit QoQ, driven by increase in new patient starts</li> <li>✓ Overall progress in line with expectations</li> </ul>
 <b>VYLOY™</b>	<b>46.1</b>	<b>+41.1 (&gt;+100%)</b>	<ul style="list-style-type: none"> <li>✓ Progress exceeding expectations, supported by high Claudin 18 testing rates and low discontinuation rates</li> <li>✓ Effective AE management—particularly in initial cycle—supporting reduced discontinuation</li> </ul>
 <b>VEOZAH™</b>	<b>35.2</b>	<b>+10.8 (+44%)</b>	<ul style="list-style-type: none"> <li>✓ Commercial lives covered (payer coverage) expanded to ~80% with recent new coverage in Jan</li> <li>✓ Recent non-hormonal class launch impact in line with expectations</li> </ul>
 <b>XOSPATA®</b>	<b>53.5</b>	<b>+0.4 (+1%)</b>	<ul style="list-style-type: none"> <li>✓ Overall progress in line with expectations</li> <li>✓ TLR expected in 1H/CY2026 for PASHA study, with newly diagnosed AML as potential new indication</li> </ul>
 <b>Xtandi®</b>	<b>732.2</b>	<b>+29.1 (+4%)</b>	✓ Progress exceeding expectations, driven by continued global demand growth

EST (Established Markets): Europe, Canada, etc., VEOZAH: Approved as "VEOZA" in ex-US.

MIBC: Muscle-invasive bladder cancer, Cis: Cisplatin, NCCN: National Comprehensive Cancer Network, TLR: Topline results, AE: Adverse event, AML: Acute myeloid leukemia

# Q3 YTD/FY2025 Financial Results: Cost Items

- **Cost optimization (SMT):** *Progressing ahead of plan (Q3 YTD: approx. 20.0 bil. yen)*  
*Fully on track to achieve FY2027 cost optimization target of 150.0 bil. yen*
- **SG&A ratio** *improved by 2.7 ppt YoY*

Cost Items	YoY change	Ratio to Revenue	(billion yen)
<b>SG&amp;A expenses*</b>	+0.2% (+0.7% excl. FX impact)	SG&A ratio: 27.0%	<p>YoY increase excl. FX impact: approx. +3.0</p> <ul style="list-style-type: none"> <li>✓ SMT cost optimization: approx. 9.0 (Organizational restructuring, reduction of mature products-related expenses, streamlining IT infrastructure, etc.)</li> </ul> <p>Continue investments in Strategic Brands to maximize potential and SMT investments for further optimization</p>
<b>R&amp;D expenses</b>	-12.9% (-11.9% excl. FX impact)	R&D ratio: 13.7%	<p>YoY decrease excl. FX impact: approx. -30.0</p> <ul style="list-style-type: none"> <li>✓ SMT cost optimization: approx. 8.0 (Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials etc.)</li> <li>✓ Decrease in clinical development costs in Strategic Brands: approx. -9.0</li> <li>✓ One-time co-development cost payments in FY2024, etc.</li> </ul> <p><b>Investments to increase from Q4 and FY2026 onward, aligned with progression to late-stage development</b></p>

\*Excl. US XTANDI co-promote fee  
SMT: Sustainable Margin Transformation

# FY2025 Revised Forecast

- **Another upward revision of Revenue and Core/Full OP, reflecting continued strong momentum**
- **Expect Core OP margin to achieve 24.8% (+4.2ppt vs. FY2024)**

Exchange rates of FY2025 latest forecast: 150 yen/USD, 174 yen/EUR  
(Forecast rates of Q4/FY2025: 154 yen/USD, 180 yen/EUR)

(billion yen)	FY2024 Actual	FY2025			Main items of revision
		Previous FCST	Latest FCST	Change	
<b>Revenue</b>	<b>1,912.3</b>	<b>2,030.0</b>	<b>2,100.0</b>	<b>+70.0</b>	• XTANDI, mirabegron and FX impact
SG&A expenses	843.0	831.0	859.0	+28.0	
US XTANDI co-promote fee	252.6	245.0	259.0	+14.0	
SG&A excl. the above (SG&A ratio*)	590.5 30.9%	586.0 28.9%	600.0 28.6%	+14.0 -0.3ppt	• Similar level excl. FX impact
R&D expenses (R&D ratio)	327.7 17.1%	322.0 15.9%	315.0 15.0%	-7.0 -0.9ppt	• Reflects prioritization of early-stage research programs
<b>Core operating profit</b> (Core OP margin)	<b>392.4</b> 20.5%	<b>490.0</b> 24.1%	<b>520.0</b> 24.8%	<b>+30.0</b> <b>+0.6ppt</b>	

## < Full basis >

<b>Operating profit</b>	<b>41.0</b>	<b>240.0</b>	<b>340.0</b>	<b>+100.0</b>	<ul style="list-style-type: none"> <li>• Other income: 30.0 (fair value remeasurements on contingent consideration, etc.)</li> <li>• Partial release of other expenses previously incorporated: 40.0 (risk of impairment losses, etc.)</li> </ul>
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FY2025 previous FCST announced in Oct 2025. Exchange rates of previous FCST: 145 yen/USD, 170 yen/EUR

\*Excl. US XTANDI co-promote fee

No impairment indication as of Feb 2026

# Agenda



**Q3 YTD/FY2025 Consolidated Financial Results  
FY2025 Revised Forecast**



**Pipeline Progress**

# Strategic Brands: FY2025 Key Expected Events

(Blue: Updates since the last financial results announcement)

Significant progress in development of PADCEV MIBC: US approval just 1 month after sBLA acceptance

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
<b>avacincaptad pegol/ IZERVAY</b>	● Jun	Stargardt disease/ Phase 2b: Primary endpoint not met	★ Sep Approval (Japan)	◆ Oct GATHER2 open-label extension study data (AAO)	<Other update> Approved in Australia in Oct 2025
<b>enfortumab vedotin/ PADCEV</b>	MIBC (Cis-ineligible)/ EV-303 interim analysis: Primary endpoint met	★ Aug Acceptance (US)	★ Oct Approval in 1 month	★ Nov MIBC (Cis-ineligible)/ Approval (US), Filing (Europe)	🎯 MIBC (Cis-ineligible)/ PDUFA date (US) Apr
		● Jul Other solid tumors/ EV-202: Terminated NMIBC/EV-104: Terminated	◆ Oct EV-303 data (ESMO)	★ Jan MIBC (Cis-ineligible)/ Filing (Japan)	
			★ Dec MIBC (Cis-eligible)/ EV-304 interim analysis: Primary endpoint met	◆ Feb EV-304 data (ASCO GU, late-breaking)	
<b>zolbetuximab/ VYLOY</b>			● Oct Pancreatic/GLEAM final analysis: Primary endpoint not met	◆ Jan ILUSTRO data (ASCO GI, late-breaking)	

## <Other Update in Strategic Brands>

- fezolinetant/VEOZAH: Positive topline results obtained from Phase 3 STARLIGHT 2 (Japan pivotal) study in Jan

★ : Key milestone

◆ : Data presentation

As of Feb 2026. VEOZAH: Approved as "VEOZA" in ex-US. MIBC: Muscle-invasive bladder cancer, AAO: American Academy of Ophthalmology, Cis: Cisplatin, NMIBC: Non-muscle-invasive bladder cancer, ESMO: European Society for Medical Oncology, ASCO: American Society of Clinical Oncology, GU: Genitourinary, GI: Gastrointestinal

# zolbetuximab/VYLOY: Latest Status

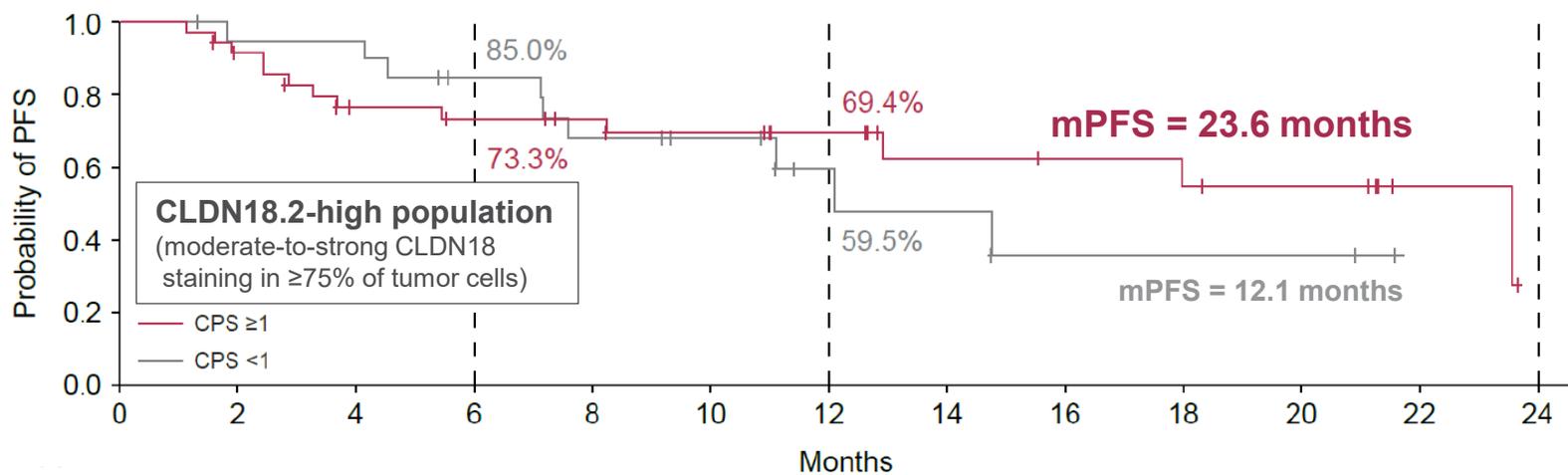
*Promising data supporting combination with checkpoint inhibitor + chemotherapy presented*

## Latest Data<sup>1</sup>

- Phase 2 ILUSTRO study Cohort 4B (zolbetuximab + nivolumab + mFOLFOX6; moderate-to-strong CLDN18 staining in  $\geq 50\%$  of tumor cells)
    - ✓ **mPFS = 14.8 months overall**
      - 18.0 months in CLDN18.2-high**
      - 23.6 months in CLDN18.2-high and CPS  $\geq 1$**
- (Ref) mPFS in zolbetuximab + Chemo: 9.2 months<sup>2</sup>  
nivolumab + Chemo: 7.7 months (all) / 7.5 months (CPS  $\geq 1$ )<sup>3</sup>

## Current Status

- Phase 3 LUCERNA study ongoing
  - ✓ zolbetuximab + pembrolizumab + Chemo vs. placebo + pembrolizumab + Chemo (CAPOX or mFOLFOX6)
  - ✓ CLDN18.2-high and CPS  $\geq 1$
  - ✓ Primary endpoint: Overall survival
  - ✓ Data readout (interim analysis) anticipated for FY2027 or later



1. ASCO GI 2026, 2. N Engl J Med. 2024;391:1159-62, 3. Lancet. 2021;398:27-40

mFOLFOX6: 5-FU, leucovorin and oxaliplatin, CLDN: Claudin, mPFS: Median progression-free survival, CPS: Combined positive score, Chemo: Chemotherapy, CAPOX: Capecitabine and oxaliplatin

# Progress in Focus Area Approach

(Blue: Updates since the last financial results announcement)

- **ASP3082/setidegrasib: Promising data in PDAC with high unmet medical need presented**
- **ASP2138: PoC achieved**

Program (Primary Focus)	FY2024	FY2025				Convergence
		Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
 <b>ASP3082/ setidegrasib</b> (Targeted Protein Degradation)	★ PoC (PDAC)	★ PoC (NSCLC)		◆ NSCLC data (AACR-NCI- EORTC) Oct	◆ <b>PDAC data</b> (ASCO GI) Jan CRC	• Prioritize PF with successful PoC • Accelerate flagship and follow-on programs Sales contribution after XTANDI LOE
 <b>ASP2138</b> (Immuno-Oncology)				◆ Initial data (ESMO) Oct	★ PoC (gastric/GEJ adenocarcinoma)	
 <b>AT845</b> (Genetic Regulation)					Pompe disease	
 <b>ASP7317</b> (Blindness & Regeneration)			◆ Initial data (Retinal Therapeutics Innovation Summit) May		GA secondary to AMD	

\*PoC: Key clinical data supporting a decision to initiate late-stage development from a scientific standpoint

See slide 38 for current status of other programs and slides 39-40 for overview of flagship programs. PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, AACR: American Association for Cancer Research, NCI: National Cancer Institute, EORTC: European Organisation for Research and Treatment of Cancer, ASCO: American Society of Clinical Oncology, GI: Gastrointestinal, ESMO: European Society for Medical Oncology, GEJ: Gastroesophageal junction, GA: Geographic atrophy, AMD: Age-related macular degeneration, PF: Primary Focus, LOE: Loss of exclusivity

- ★ : PoC achieved
- ◆ : Data presentation
- ◀ : PoC judgment

# Progress in ASP3082/setidegrasib & Primary Focus Targeted Protein Degradation

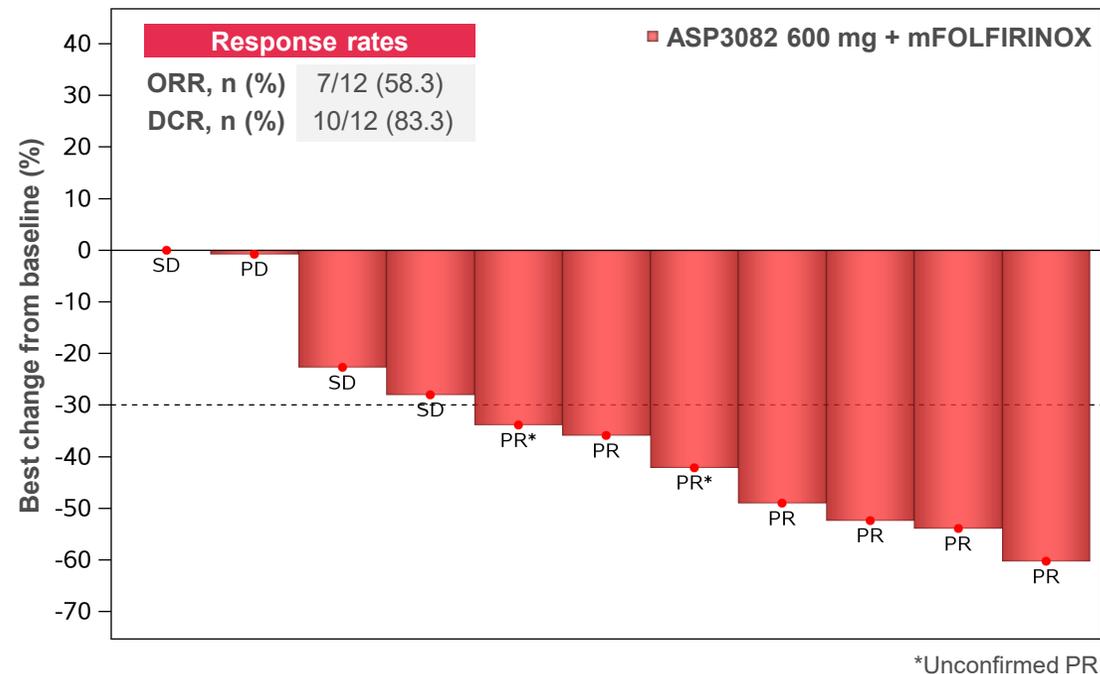
*Promising data in 1L PDAC presented, anticipated to initiate Phase 3 study by March*

## Latest Data<sup>1</sup>

- ASP3082 + mFOLFIRINOX combination showed promising antitumor activity in 1L PDAC
  - ✓ **ORR = 58.3% (7/12), DCR = 83.3% (10/12)**
- No new safety signals observed
- Findings support further development in PDAC

## Current Status

- ASP3082/setidegrasib
  - ✓ PDAC: Plan to initiate Phase 3 study in 1L setting by Mar
  - ✓ NSCLC: Planning is ongoing for registrational studies
  - ✓ CRC: PoC judgment anticipated for Q4
- Follow-on programs
  - ✓ **ASP5834 (Pan-KRAS):**  
**Fast Track designation granted by FDA for NSCLC in Jan**
  - ✓ ASP4396 (KRAS G12D): Terminated to focus on ASP3082



1. ASCO GI 2026

1L: First line, PDAC: Pancreatic ductal adenocarcinoma, mFOLFIRINOX: Leucovorin, fluorouracil, irinotecan and oxaliplatin, ORR: Objective response rate, DCR: Disease control rate, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, PoC: Proof of concept, KRAS: Kirsten rat sarcoma viral oncogene homologue, FDA: Food and Drug Administration, SD: Stable disease, PD: Progressive disease, PR: Partial response

# Key Takeaways



## Strong Momentum Continues in Q3

- **Strategic Brands:**  
Continued strong growth
- **SG&A ratio** continues to improve driven by robust cost optimization progress



## Another Upward Revision of Full-year Forecast

- Revenue **+70.0 bil. yen**
- Core OP **+30.0 bil. yen**
- Full OP **+100.0 bil. yen**

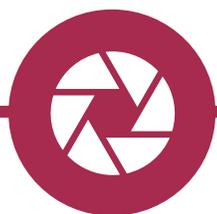


## Significant Advancement of Pipeline

- **PADCEV and VYLOY:**  
Progress in LCM
- **ASP3082 and ASP2138:**  
Progress toward initiation of Phase 3 studies

Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA  
LCM: Lifecycle management

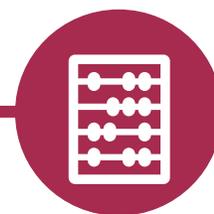
# Upcoming Events



**Sustainability Meeting**  
February 26, 10:00-11:15 (JST)



**R&D Day**  
Late March



**FY2025 Earnings**  
Late April



**Next Corporate  
Strategic Plan**  
Late May

# Appendix



## Strategic Brands: Potential Peak Sales (as of Feb 2026)

Brand	Potential Peak Sales <i>(Global, billions of yen)</i>
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 Feb 2026), 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

# Capital Allocation

**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

# Q3 YTD/FY2025 Actual: FX Rate

## Average rate for the period

Currency	Q3 YTD/FY2024	Q3 YTD/FY2025	Change
USD	152 yen	149 yen	-4 yen
EUR	165 yen	172 yen	+7 yen

## <Impact of exchange rate on financial results>

- Revenue: -2.2 billion yen
- Core OP: +4.2 billion yen

# FY2025 Forecast: FX Rate & FX Sensitivity

Exchange rate Average for the period	FY2025 Previous FCST	FY2025 Latest FCST	Change
USD	145 yen	150 yen	+5 yen
EUR	170 yen	174 yen	+4 yen

Forecast rates of Q4: 154 yen/USD, 180 yen/EUR

## Estimated FX sensitivity of Q4 (Jan-Mar 2026) of FY2025 forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption	
	Revenue	Core OP
USD	Approx. +2.0 bil. yen	Approx. +0.5 bil. yen
EUR	Approx. +0.9 bil. yen	Approx. +0.4 bil. yen

# Balance Sheet & Cash Flow Highlights

(billion yen)	Mar 31, 2025	Dec 31, 2025
Total assets	3,339.5	3,603.9
Cash and cash equivalents	188.4	254.3
Total equity attributable to owners of the parent	1,513.3	1,763.1
Ratio of equity attributable to owners of the parent to total assets (%)	45.3%	48.9%

(billion yen)	Q3 YTD/FY2024	Q3 YTD/FY2025
Cash flows from operating activities	93.4	356.8
Cash flows from investing activities	-86.5	-46.0
Free cash flows	7.0	310.8
Cash flows from financing activities	-170.6	-246.6
Increase/decrease in short-term borrowings and commercial papers	-175.6	-45.3
Proceeds from issuance of bonds and long-term borrowings	200.0	-
Redemption of bonds and repayments of long-term borrowings	-32.7	-62.4
Dividends paid	-129.0	-136.1

# Balance of Bonds and Borrowings Highlights

(billion yen)	Sep 30, 2025	Dec 31, 2025
Balance of bonds and borrowings	740.5	725.3
Non-current liabilities	320.0	320.0
Bonds	220.0	220.0
Long-term borrowings	100.0	100.0
Current liabilities	420.5	405.3
Commercial papers	99.9	119.9
Short-term borrowings	20.0	20.0
Current portion of long-term borrowings	170.6	165.4
Current portion of bonds	130.0	100.0

# Main Intangible Assets (as of Dec 31, 2025)

	Bil. yen	Foreign currency**
AT132	17.0	\$109M
AT845	11.4	\$73M
Gene therapy related technology*	61.9	\$395M
VEOZAH**	86.9	€482M
VYLOY**	55.9	€430M
IZERVAY (US)	589.2	\$3,761M
IZERVAY (Ex-US)	52.9	\$338M
ASP7317	27.0	\$172M

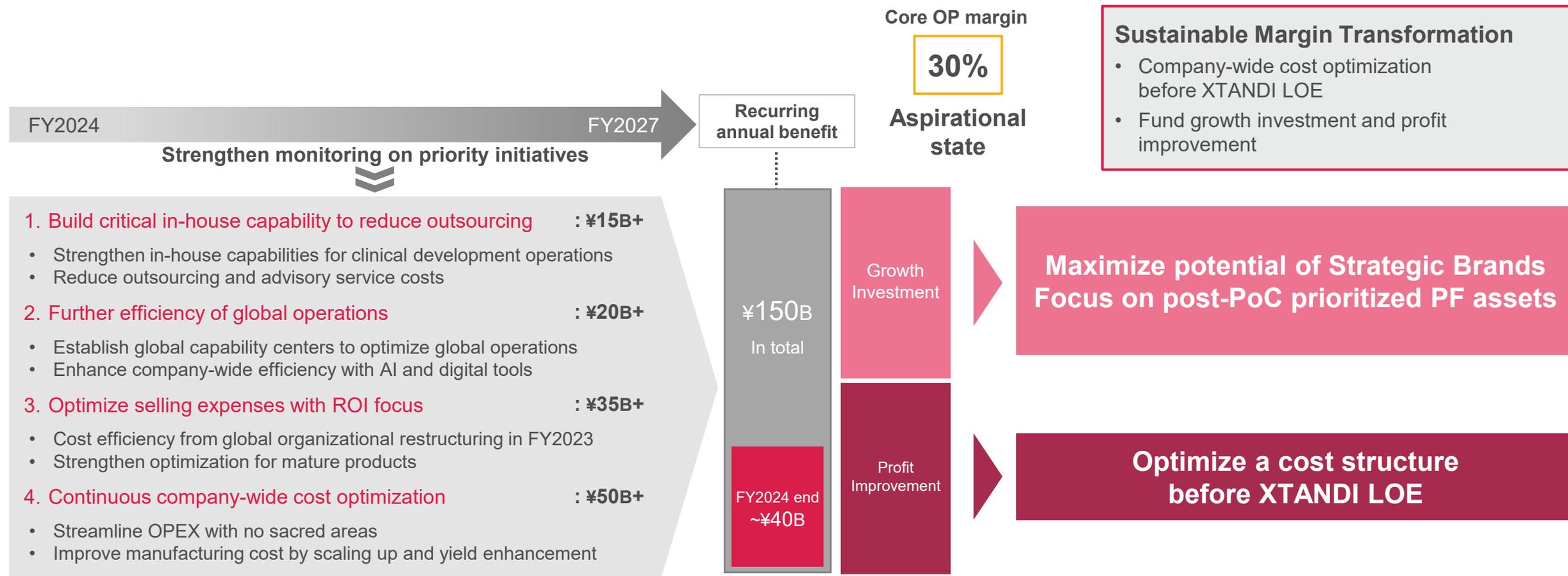
VEOZAH: Approved as "VEOZA" in ex-US

\*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

- **Company-wide cost optimization of 150.0 billion yen before XTANDI LOE**
- **Fund growth investment and profit improvement**



LOE: Loss of exclusivity, ROI: Return On Investment, PoC: Proof of concept, PF: Primary Focus

# Robust Pipeline of Astellas

## Phase 1

gilteritinib (ALK-positive non-small cell lung cancer)
ASP1570
ASP2138
ASP1002
setidegrasib/ASP3082
ASP5834
ASP7317
ASP546C/XNW27011
ASP5502

## Phase 2

gilteritinib (Newly diagnosed AML, HIC-ineligible)
resamirigene bilparvovec/ AT132 (XLMTM)
zocaglusagene nuzaparvovec/ AT845 (Pompe disease)
abiraterone decanoate/ ASP5541/PRL-02 (Prostate cancer)

## Phase 3

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

## Submitted/Filed

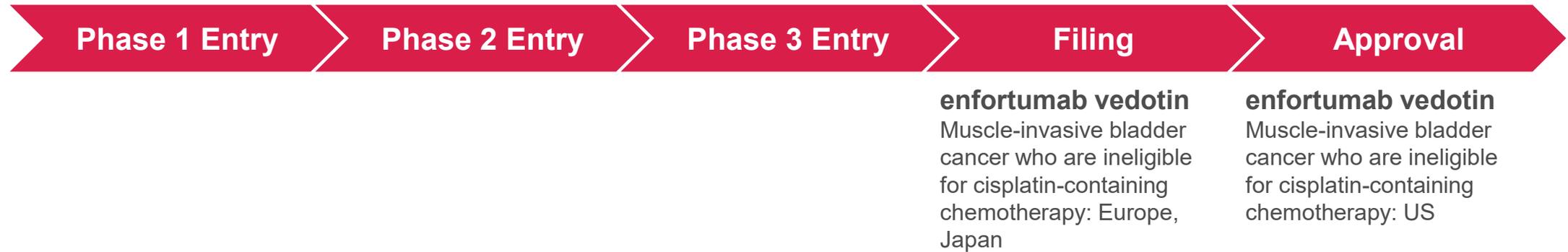
enfortumab vedotin (Cisplatin-ineligible MIBC: Europe, Japan)
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- Strategic Brands
- Programs with Focus Area Approach
- Others

ALK: Anaplastic lymphoma kinase, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, XLMTM: X-linked myotubular myopathy, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease

# Progress in Overall Pipeline

Phase 1 Entry to Approval Since the Last Financial Results Announcement



## Discontinuation

**ASP4396:** Cancer (Phase 1)

**zolbetuximab:** Pancreatic adenocarcinoma (Phase 2)

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.

# Lifecycle Management of Strategic Brands

(Blue: Updates since the last financial results announcement)

Brand	Indication	Current status	Next milestone
 <p><b>PADCEV</b> enfortumab vedotin Injection for IV infusion 20 mg &amp; 30 mg vials</p>	Muscle-invasive bladder cancer	<b>Cis-eligible: Phase 3 EV-304 study primary endpoint met</b>	<b>sBLA filing anticipated for CY2026</b>
		<b>Bladder-sparing: Development plan under consideration</b>	<b>(Under discussion)</b>
 <p><b>izervay</b> (avacincaptad pegol intravitreal solution) 2 mg</p>	GA secondary to AMD	LCM opportunities under consideration (e.g. prefilled syringe, sustained release)	(Under discussion)
 <p><b>VYLOY</b> zolbetuximab for injection 100mg vial</p>	Gastric and GEJ cancer	Phase 3 LUCERNA study in combo with Pembro and Chemo ongoing	Data readout (interim analysis) anticipated for FY2027 or later
 <p><b>VEOZAH</b> (fezolinetant) tablets 45 mg</p>	VMS associated with menopause	<b>Japan: Phase 3 STARLIGHT 2 study primary endpoint met</b>	<b>Phase 3 STARTLIGHT 3 study: Data readout anticipated for FY2026</b>
	VMS in breast cancer women	China: Phase 2 study ongoing	Data readout anticipated for FY2026
 <p><b>XOSPATA</b> gilteritinib 40mg tablets</p>	Newly diagnosed AML (HIC-eligible)	Phase 3 PASHA study ongoing	Data readout (primary analysis) anticipated for 1H/CY2026
	ALK-positive NSCLC	Phase 1 study ongoing	Data readout anticipated for FY2027 or later

As of Feb 2026. Not exhaustively listed. VEOZAH: Approved as "VEOZA" in ex-US.

Cis: Cisplatin, sBLA: Supplemental Biologics License Application, GA: Geographic atrophy, AMD: Age-related macular degeneration, LCM: Lifecycle management, GEJ: Gastroesophageal junction, Pembro: Pembrolizumab, Chemo: Chemotherapy, VMS: Vasomotor symptoms, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, ALK: anaplastic lymphoma kinase, NSCLC: Non-small cell lung cancer

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

## Overview of Development

(Blue: Updates since the last financial results announcement)

<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**	<b>EV-303</b> (combo w/ Pembro)	<b>Approved</b>	<b>20,000***</b>
	Cis-eligible	<b>EV-304</b> (combo w/ Pembro)	<b>FY2025 or later</b>	<b>32,000***</b>
1L mUC		<b>EV-302</b> <b>EV-103 Cohorts</b> [Phase 1b/2 for AA in US] (combo w/ Pembro)	<b>Approved</b> <b>Approved</b> [AA in US]	<b>102,000</b>
2L+ mUC (platinum & PD-1/L1 inhibitor pretreated)		<b>EV-301</b> <b>EV-201 Cohort 1</b> [Phase 2 for AA in US] (monotherapy)	<b>Approved</b>	<b>44,000</b>

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

\*\*Ineligible for or declined cisplatin-based chemotherapy

\*\*\*Excluding China



ADC: Antibody-drug conjugate, MIBC: Muscle-invasive bladder cancer, 1L: First line, mUC: Metastatic urothelial cancer, 2L+: Second or later line, Cis: Cisplatin, Pembro: Pembrolizumab, AA: Accelerated Approval

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

(Blue: Updates since the last financial results announcement)

<b>P3: EV-303 /KEYNOTE-905</b>	<u><a href="#">NCT03924895</a></u>	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=595	<b>sBLA approved in US in Nov 2025</b> <b>Type II variation accepted in Europe in Nov 2025</b> <b>sNDA submitted in Japan in Jan 2026</b>
<b>P3: EV-304 /KEYNOTE-B15</b>	<u><a href="#">NCT04700124</a></u>	MIBC, Cis-eligible; EV + Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=808	<b>Primary endpoint met</b>
<b>P1b/2: EV-103</b>	<u><a href="#">NCT03288545</a></u>	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



MIBC: Muscle-invasive bladder cancer, Cis: Cisplatin, Pembro: Pembrolizumab, RC: Radical cystectomy, (s)BLA: (Supplemental) Biologics License Application, NDA: New Drug Application, Chemo: Chemotherapy, mUC: Metastatic urothelial cancer, mono: Monotherapy

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

(Blue: Updates since the last financial results announcement)

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: HR 0.40*	✓ 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	✓ Endpoint met	✓ HR 0.50* (NR vs. 41.7 mos)	✓ 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)
EFS (MIBC)/ PFS (mUC)	✓ Endpoint met	✓ HR 0.40* (NR vs. 15.7 mos)	✓ 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)
pCR (MIBC)/ ORR (mUC)	✓ Endpoint met	✓ 57.1% vs. 8.6%*	✓ 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	n/a	n/a	✓ 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*

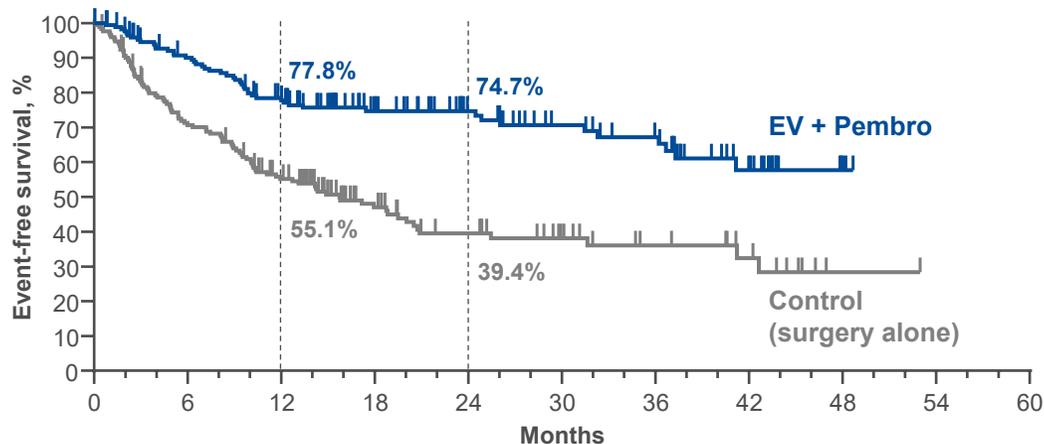
✓: Data obtained, \*: Prespecified interim analysis, \*\*: Updated data

 (m)UC: (Metastatic) Urothelial cancer, MIBC: Muscle-invasive bladder cancer, Cis: Cisplatin, Pembro: Pembrolizumab, mono: Monotherapy, Chemo: Chemotherapy, SoC: Standard of care, EFS: Event-free survival, HR: Hazard ratio, PFS: Progression-free survival, OS: Overall survival, ORR: Objective response rate, (p)CR: (Pathological) Complete response, DoR: Duration of response

# enfortumab vedotin (EV) (4/5): Study Data in Cis-ineligible MIBC (EV-303)

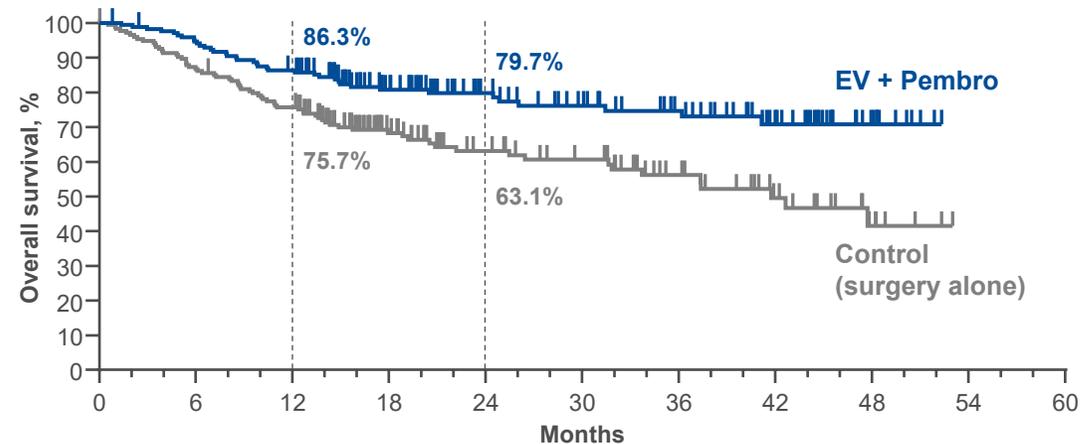
*Unprecedented data in EV-303, showing the potential as a new standard of care for Cis-ineligible MIBC*

<Event-free survival (EFS)>



	N	Events	HR (95% CI)	1-sided P value	Median (95% CI), months
EV + Pembro	170	48	<b>0.40</b> (0.28, 0.57)	<b>&lt;0.0001</b>	<b>NR</b> (37.3, NR)
Control	174	95			<b>15.7</b> (10.3, 20.5)

<Overall survival (OS)>



	N	Events	HR (95% CI)	1-sided P value	Median (95% CI), months
EV + Pembro	170	38	<b>0.50</b> (0.33, 0.74)	<b>0.0002</b>	<b>NR</b> (NR, NR)
Chemo	174	68			<b>41.7</b> (31.8, NR)



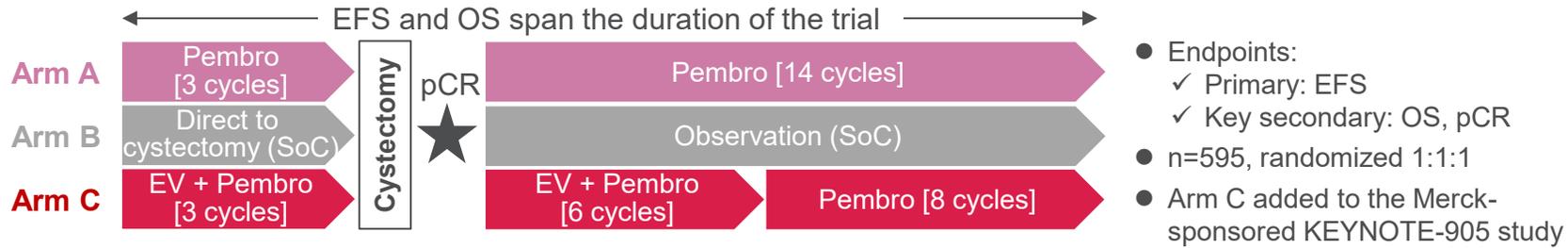
Data presented at ESMO 2025 (Data cutoff: Jun 6, 2025)

Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, Pembro: Pembrolizumab, HR: Hazard ratio, CI: Confidence interval, NR: Not reached

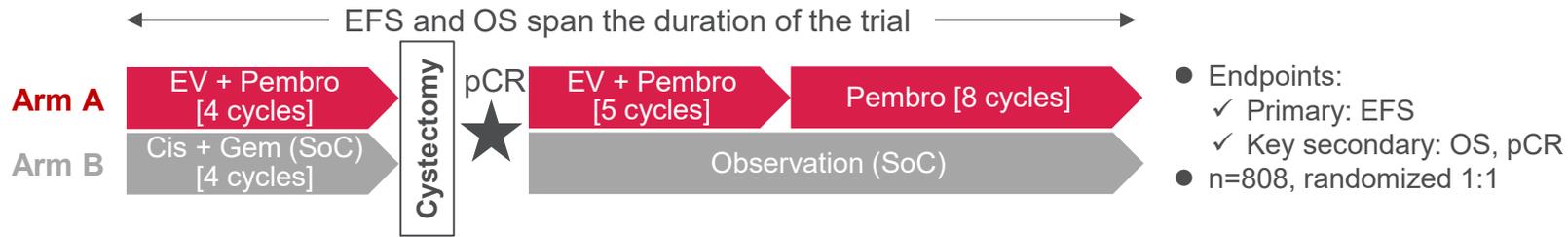


# enfortumab vedotin (EV) (5/5): Development for Muscle-Invasive Bladder Cancer (MIBC)

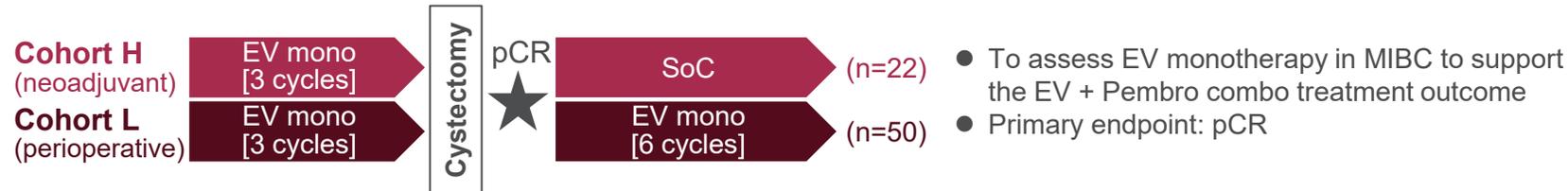
## 1) Phase 3 study in *Cis-ineligible* MIBC (KEYNOTE-905/EV-303): Perioperative EV+Pembro vs. Cystectomy alone



## 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

# zolbetuximab: Anti-Claudin 18.2 Monoclonal Antibody

## 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

## Gastric and GEJ adenocarcinoma

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

Gastric and GEJ adenocarcinoma	<b>P3: LUCERNA</b>	<a href="#">NCT06901531</a>	First line, combo with Pembro and chemo, DB, vs. placebo	n=500	FSD: Jun 2025
	<b>P2: ILUSTRO</b>	<a href="#">NCT03505320</a>	Cohort 1: Third or later line, 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

\*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

# fezolinetant: NK3 Receptor Antagonist

(Blue: Updates since the last financial results announcement)

## 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 life<sup>1</sup>

## Women's Health Initiative (WHI) Study<sup>2</sup>

- 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

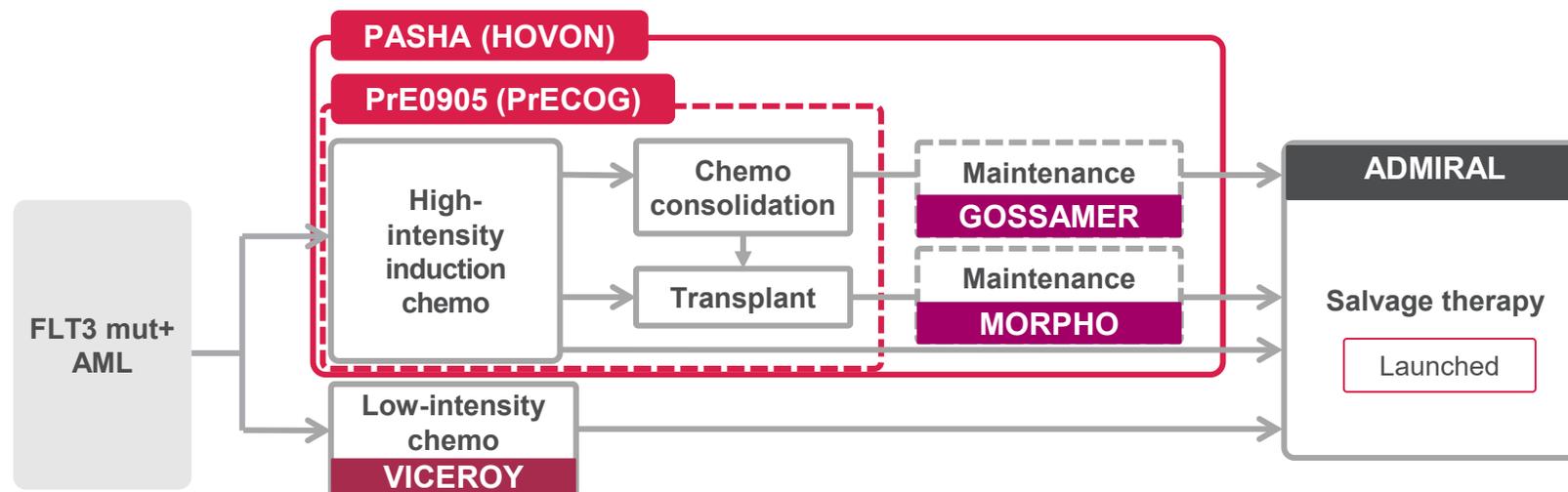
Japan	P3: STARLIGHT 2	<a href="#">NCT06206408</a>	Mild to severe VMS associated with menopause; 8 weeks: DB, 2 doses vs. placebo (1:1:1)	n=410	Primary endpoint met
	P3: STARLIGHT 3	<a href="#">NCT06206421</a>	VMS associated with menopause; 52 weeks: DB, vs. placebo (1:1)	n=277	Enrollment completed
China	P2	<a href="#">NCT06812754</a>	Moderate to severe VMS associated with menopause; 12 weeks: DB, 45 mg vs. placebo (1:1)	n=150	Enrollment completed

## VMS in breast cancer women receiving adjuvant endocrine therapy

P3: HIGHLIGHT 1	<a href="#">NCT06440967</a>	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
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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

# gilteritinib: FLT3 Inhibitor



## Acute myeloid leukemia

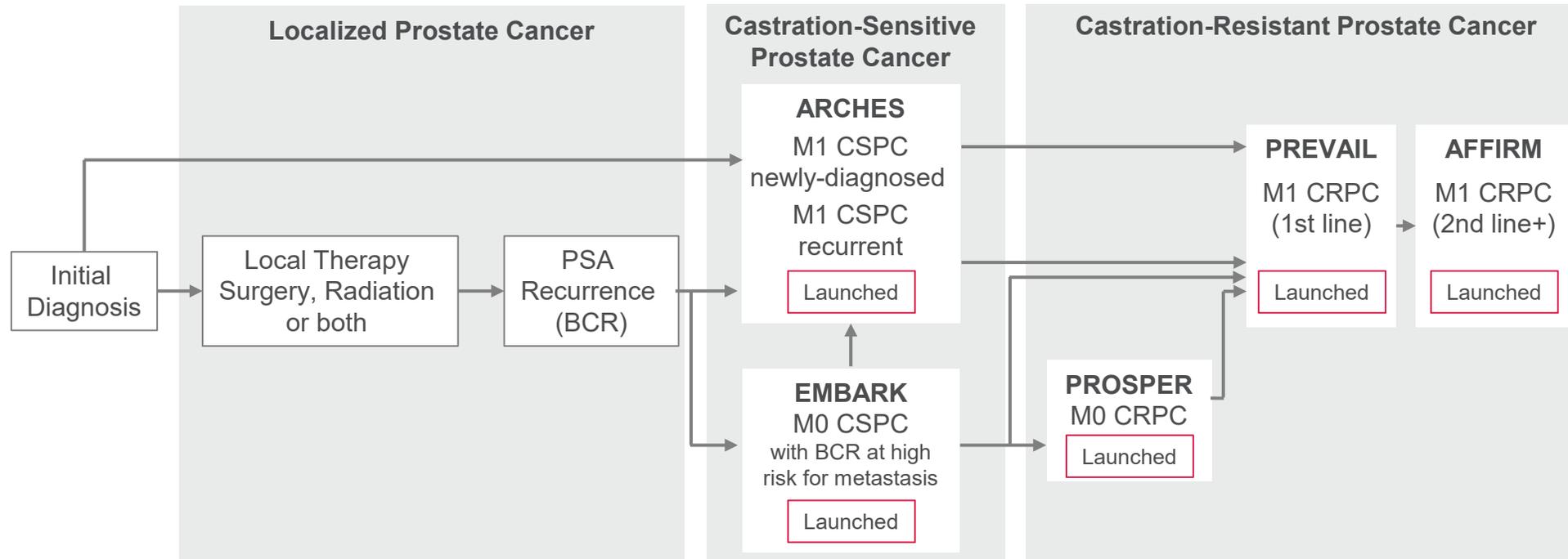
Newly diagnosed (HIC-eligible)	P3: PASHA (HOVON)	<a href="#">NCT04027309</a>	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=766	Enrollment completed (Sponsor: HOVON)
	P2: PrE0905 (PrECOG)	<a href="#">NCT03836209</a>		n=181	Topline results presented at ASH 2024 (Sponsor: PrECOG, LLC.)
Newly diagnosed (HIC-ineligible)	P1/2: VICEROY	<a href="#">NCT05520567</a>	Combo with venetoclax and azacitidine	n=70	FSD: Jan 2023

## Non-small cell lung cancer

ALK-positive	P1	<a href="#">NCT07140016</a>	Monotherapy	n=40	FSD: Oct 2025
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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, FSD: First subject dosed, ASH: American Society of Hematology, ALK: Anaplastic lymphoma kinase

# enzalutamide (1/2): Androgen Receptor Inhibitor



PSA: Prostate-specific antigen, BCR: Biochemical recurrence, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, M0: Non-metastatic, CRPC: Castration-resistant prostate cancer



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

*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	<b>EMBARK</b>	<b>ARCHES</b>	<b>ENZAMET</b>	<b>PROSPER</b>	<b>PREVAIL</b>	<b>AFFIRM</b>
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	✓ HR 0.60	✓ 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

 CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, M0: Non-metastatic, M1: Metastatic, chemo: Chemotherapy, NSAA: Non-steroidal antiandrogen, HR: Hazard ratio, MFS: Metastasis-free survival, rPFS: Radiographic progression-free survival, OS: Overall survival, DoT: Duration of treatment

# 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. <b>PoC achieved in G/GEJ adenocarcinoma</b>
		ASP1002 	Anti-CLDN4 and anti-CD137	Phase 1 study ongoing
Targeted Protein Degradation	Protein degradation	★ ASP3082 	KRAS G12D degrader	Phase 1 study ongoing
		ASP4396 	KRAS G12D degrader	<b>Terminated</b>
		ASP5834 	Pan-KRAS degrader	<b>Fast Track designation granted by FDA for NSCLC in Jan 2026</b>
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
Others (Non-PF)	Long-acting abiraterone prodrug	ASP5541 (PRL-02) 	CYP17 lyase inhibitor	Phase 2 study ongoing
	ADC	ASP546C (XNW27011) 	ADC targeting CLDN18.2	Global Phase 1b/2 study under planning
	Immune modulation	ASP5502 	STING inhibitor	Phase 1 study ongoing

Modality
 Small molecule
 Antibody
 Gene
 Cell

★ : Flagship program

DGK: Diacylglycerol kinase, CLDN: Claudin, PoC: Proof of concept, G/GEJ: Gastric/gastroesophageal junction, KRAS: Kirsten rat sarcoma viral oncogene homologue, FDA: Food and Drug Administration, NSCLC: Non-small cell lung cancer, AAV: Adeno-associated virus, MTM1: Myotubularin 1, GAA: Acid alpha-glucosidase, RPE: Retinal pigment epithelial, PF: Primary Focus, STING: Stimulator of interferon genes

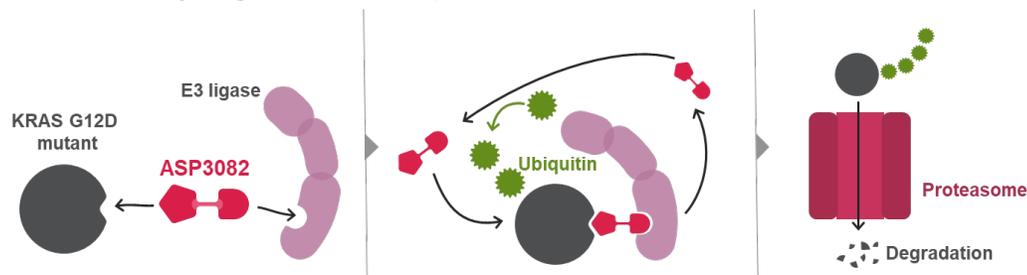
# Overview of Primary Focus Flagship Programs (1/2)

(Blue: Updates since the last financial results announcement)

## ASP3082/setidegrasib (Targeted Protein Degradation)

### Protein degrader targeting KRAS G12D mutant

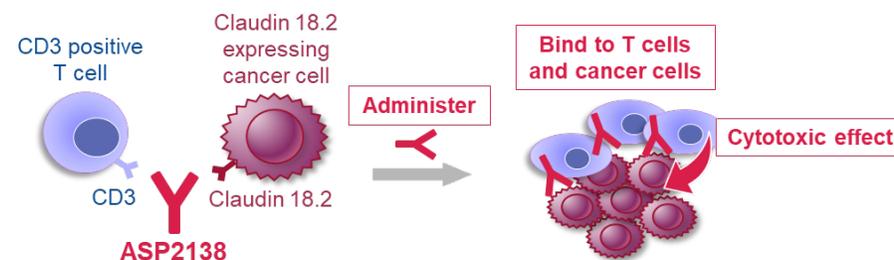
- Target disease: Cancers harboring KRAS G12D mutation
  - ✓ Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~5% in NSCLC, ~15% in CRC<sup>1</sup>
- SoC for metastatic PDAC: Chemotherapy (chemo); for NSCLC: immunotherapy +/- chemo (1L); chemo (2L+)
- Status: Phase 1 study ongoing ([NCT05382559](#))
  - ✓ PDAC: 2L+ (monotherapy), 1L (combo with chemo); PoC achieved based on 2/3L data
  - ✓ NSCLC: 2L+ (monotherapy), 1L (combo with SoC); PoC achieved based on 2L+ data
  - ✓ CRC: 2L+ (monotherapy & combo with cetuximab); PoC judgment anticipated for Q4/FY2025



## ASP2138 (Immuno-Oncology)

### Bispecific antibody targeting CLDN18.2 and CD3 with SC route

- Target disease: Gastric/GEJ (G/GEJ) adenocarcinoma and PDAC
  - ✓ Rate of CLDN18.2-positive patients\*: ~70% in G/GEJ adenocarcinoma<sup>2</sup> and ~60% in PDAC<sup>3</sup>
- SoC (HER2-, advanced G/GEJ adenocarcinoma)
  - ✓ 1L: chemo +/- checkpoint inhibitor or zolbetuximab (CLDN18.2-positive\*)
  - ✓ 2L+: paclitaxel + ramucirumab
- Status: Phase 1 studies ongoing ([NCT05365581](#), [NCT07024615](#))
  - ✓ Monotherapy: G/GEJ adenocarcinoma, PDAC
  - ✓ Combo w/ SoC: 1L & 2L G/GEJ adenocarcinoma, 1L PDAC
  - ✓ Resectable PDAC: neoadjuvant (ASP2138) + adjuvant (chemo)
- **PoC achieved in G/GEJ adenocarcinoma based on 1L data**



Represents % of patients with any level of Claudin 18.2+ staining ( $\geq 1\%$ ; cf.  $\geq 75\%$  for VYLOY). 1. npj Precis Oncol. 2022;6:91, 2. Gastric Cancer. 2024;27:1058, 3. Int J Cancer. 2013;134:731

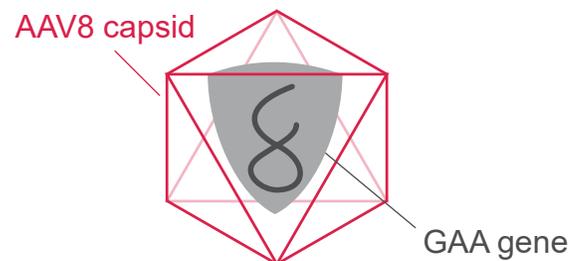
KRAS: Kirsten rat sarcoma viral oncogene homologue, PDAC: Pancreatic ductal adenocarcinoma, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, SoC: Standard of Care, 1L: First line, 2L+: Second or later line, PoC: Proof of concept, 2/3L: Second and third line, CLDN18.2: Claudin 18.2, SC: Subcutaneous, GEJ: Gastroesophageal junction, HER2-: HER2 negative

# Overview of Primary Focus Flagship Programs (2/2)

## AT845 (Genetic Regulation)

Recombinant AAV8 continuously expressing hGAA gene specially in muscle

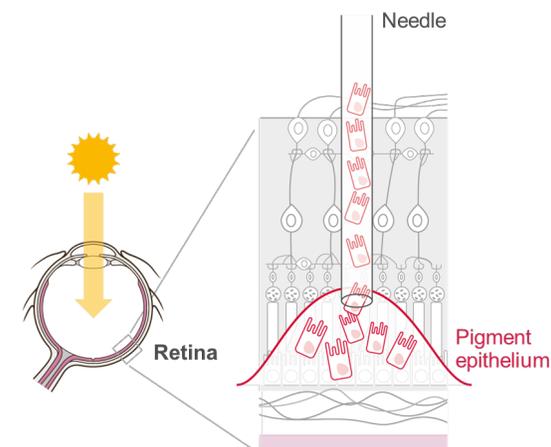
- Target disease: Pompe disease
  - ✓ Estimated incidence: 1 in ~40,000<sup>1</sup>
- Standard of care: Enzyme replacement therapy (ERT)
  - ✓ Chronic, repeated infusions every 2 weeks
  - ✓ Secondary disease progression after 2-3 years on ERT<sup>2,3,4</sup>
  - ✓ Substantial economic burden with high rates of healthcare resource utilization<sup>5</sup>
- Status: Phase 1/2 FORTIS study ongoing ([NCT04174105](https://clinicaltrials.gov/ct2/show/study/NCT04174105))
  - ✓ Five of six participants have discontinued ERT, and remained clinically stable while off ERT for 1-3 years<sup>6</sup>
- Anticipated PoC judgment timing: Q4/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 worldwide<sup>7</sup>
- Approved treatment: Complement inhibitors
  - ✓ Slow disease progression
- Status: Phase 1b study ongoing ([NCT03178149](https://clinicaltrials.gov/ct2/show/study/NCT03178149))
- Anticipated PoC judgment timing: Q4/FY2025



1. NORD (National Organization for Rare Disorders) at <https://rarediseases.org/rare-diseases/pompe-disease/>, 2. Neuromuscul Disord. 2021;31:91-100, 3. J Neurol. 2021;268:2482-2492, 4. Mol Genet Metab. 2012;106:301-309, 5. Mol Genet Metab. 2025;144:Article 108958, 6. WORLDSymposium 2025, 7. Retina. 2017;37:819-835

AAV: Adeno-associated virus, hGAA: Human acid alpha-glucosidase, PoC: Proof of concept, AMD: Age-related macular degeneration

# Pipeline of Primary Focus Targeted Protein Degradation

Program	Mechanism of Action	Target Disease	Origin/Partner	Current Phase	Recent Updates
setidegrasib/ ASP3082	KRAS G12D degrader	KRAS G12D+ solid tumor		<b>Phase 1</b> Discussion ongoing toward registrational studies	<ul style="list-style-type: none"> <li>• PDAC: PoC achieved, Phase 3 study planned to start in Q4/FY2025</li> <li>• NSCLC: PoC achieved</li> <li>• CRC: PoC judgment anticipated for Q4/FY2025</li> </ul>
ASP5834	Pan-KRAS degrader	KRAS+ solid tumor		<b>Phase 1</b>	
Undisclosed	Undisclosed	Cancer		<b>Discovery</b>	
Undisclosed	Cell cycle protein degrader	Cancer		<b>Discovery</b>	
Undisclosed	Undisclosed	Cancer		<b>Discovery</b>	
Undisclosed programs	Degrader / DAC / etc.	Cancer / Non-oncology		<b>Discovery</b> :	

KRAS: Kirsten rat sarcoma viral oncogene homologue, PDAC: Pancreatic ductal adenocarcinoma, PoC, Proof of concept, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer

# Progress in ASP2138 / Primary Focus Immuno-Oncology

Early data showed a benefit of SC administration in combination with SoC

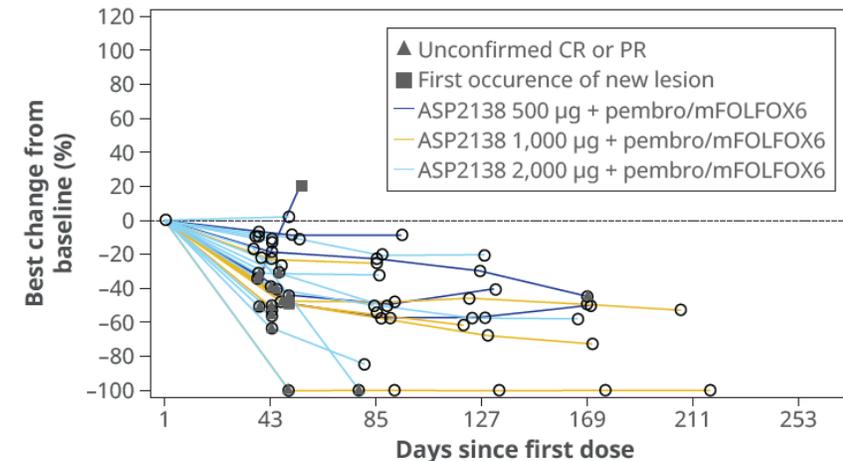
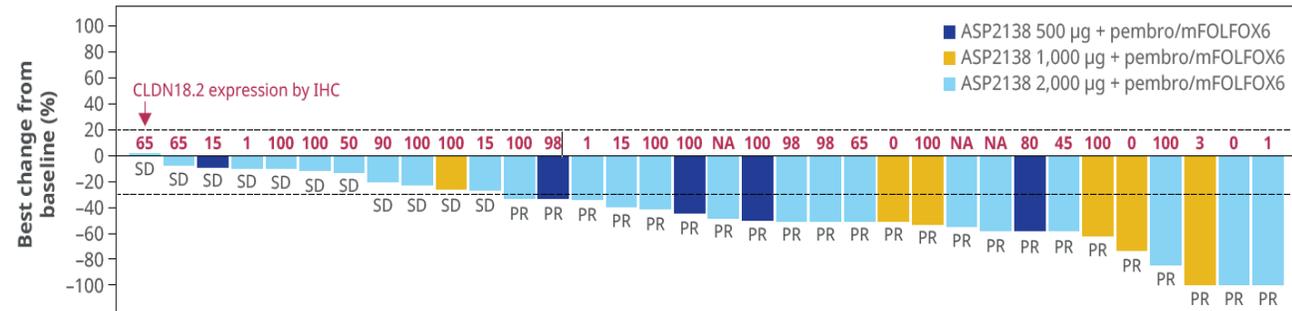
## Latest Data<sup>1</sup>

- Safety and tolerability supports combination with SoC chemotherapy and checkpoint inhibitors
- ASP2138 SC demonstrated clinically meaningful antitumor activity in combination with SoC in G/GEJ adenocarcinoma
  - ✓ **1L: ORR\* = 62.5% (15/24)**; 12-week DCR = 100.0% (6/6)
  - ✓ **2L: ORR\* = 37.5% (9/24)**; 12-week DCR = 60.0% (9/15)
  - \*unconfirmed ORR, at 2,000 µg
- Compelling responses were observed in patients with **both high and medium-to-low CLDN18.2 expression levels**

## Current Status

- Phase 3 study under preparation
- Advancing research and development of follow-on programs
  - ✓ Bispecific immune cell engager: multiple programs in progress
  - ✓ iADC (immunostimulatory ADC): advancing toward FSD

1L G/GEJ adenocarcinoma; ASP2138 SC Q2W + Pembro + mFOLFOX6



1. ESMO 2025; See [Astellas Oncology Pipeline Online Meeting material](#) (October 24, 2025 (JST)) for details

SC: Subcutaneous, SoC: Standard of care, PoC: Proof of concept, G/GEJ: Gastric/gastroesophageal junction, 1L: First line, ORR: Objective response rate, DCR: Disease control rate, 2L: Second line, CLDN: Claudin, ADC: Antibody-drug conjugate, FSD: First subject dosed, Pembro: Pembrolizumab; mFOLFOX6: 5-FU, leucovorin and oxaliplatin

# Portfolio of Claudin 18.2-Targeted Therapies

*Aim to address broader patient population with multiple differentiated assets*

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

\*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

# Progress in ASP7317 (Blindness & Regeneration)

## Encouraging initial clinical data obtained

### 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 worldwide<sup>1</sup>
- Approved treatment: Complement inhibitors
  - ✓ Slow disease progression

### Latest Status

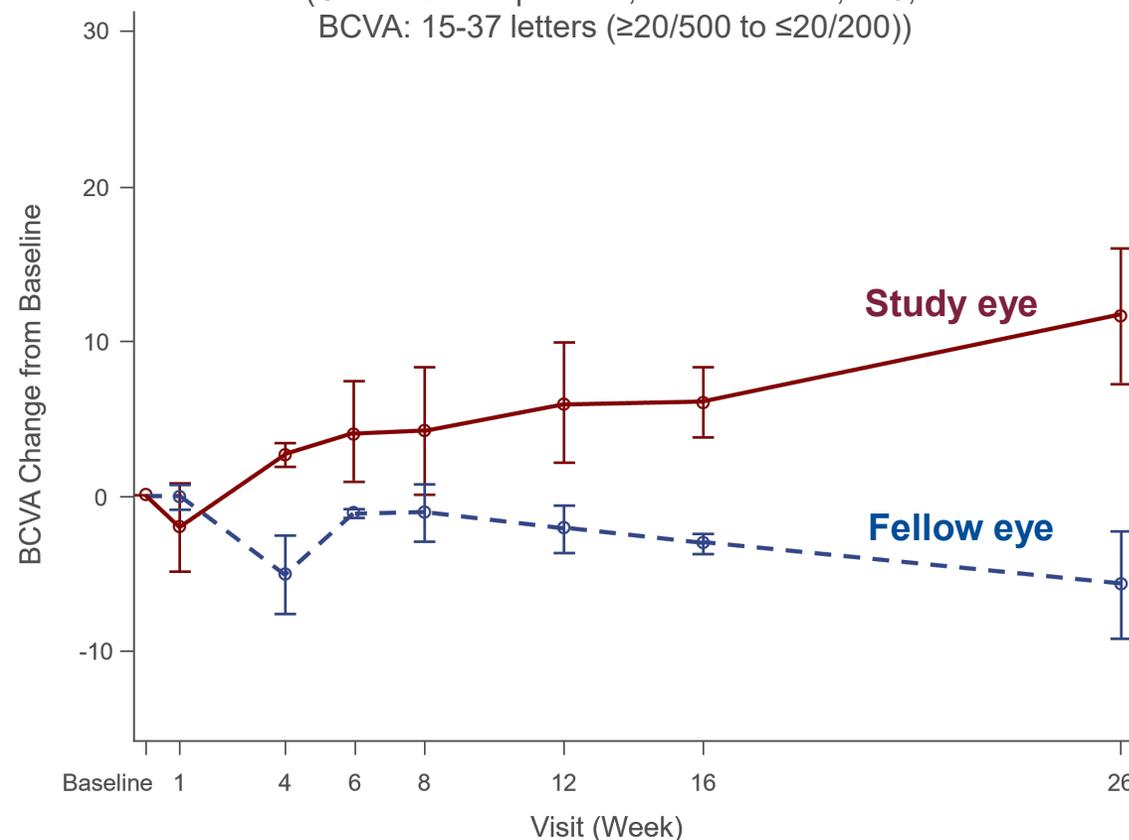
- Initial data from Phase 1b study presented at Retinal Therapeutics Innovation Summit in May 2025
  - ✓ No IOI events and no evidence for ASP7317 cell rejection or graft failure
  - ✓ A possible trend for improving BCVA in SVI (severe visual impairment) patients following ASP7317 transplantation
- PoC judgment anticipated for Q4/FY2025

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

### <Mean BCVA change over time>

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



# Progress in AT845 (Genetic Regulation)

## Encouraging initial clinical data obtained

### Overview of Program

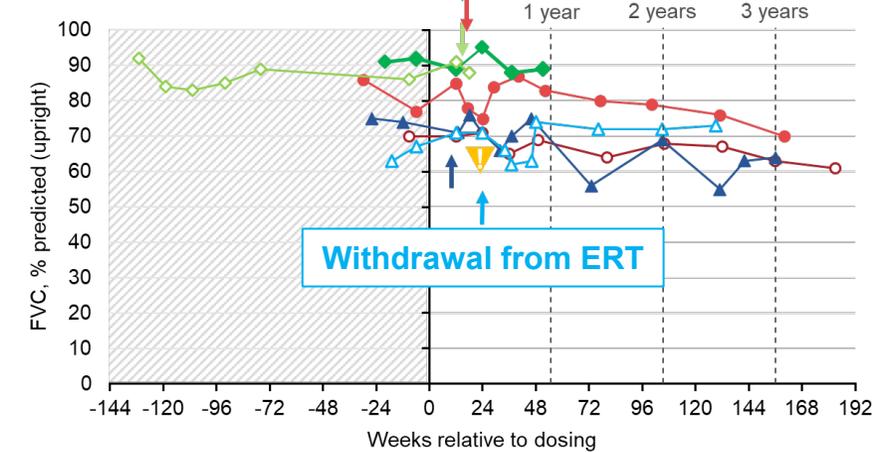
#### Recombinant AAV8 continuously expressing hGAA gene specially in muscle

- Target disease: Pompe disease
  - ✓ Estimated incidence: 1 in ~40,000<sup>1</sup>
- Standard of care: Enzyme replacement therapy (ERT)
  - ✓ Chronic, repeated infusions every 2 weeks
  - ✓ Secondary disease progression after 2-3 years on ERT<sup>2,3,4</sup>
  - ✓ Substantial economic burden with high rates of healthcare resource utilization<sup>5</sup>

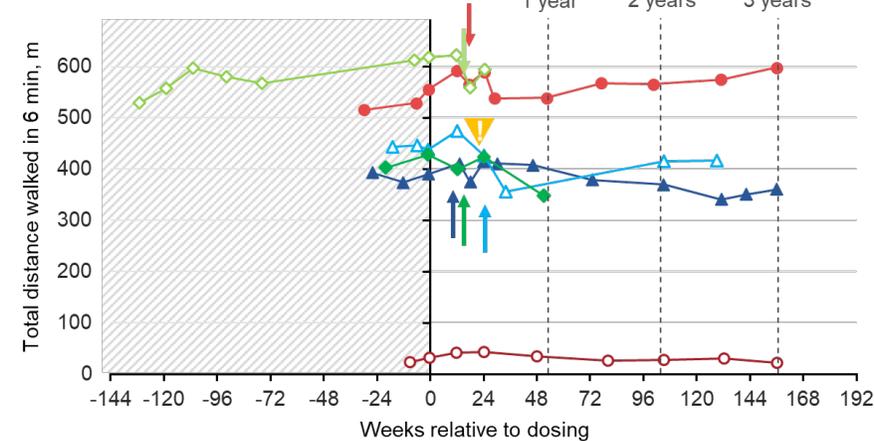
### Latest Status

- Follow-up data from Phase 1/2 FORTIS study presented at *WORLDSymposium* in Feb 2025
  - ✓ Five of six participants have discontinued ERT, and remained clinically stable while off ERT for 1-3 years
- RMAT designation granted by FDA in Feb 2025
- PoC judgment anticipated for Q4/FY2025

#### <Forced vital capacity>



#### <6-minute walk test>



1. NORD (National Organization for Rare Disorders) at <https://rarediseases.org/rare-diseases/pompe-disease/>, 2. Neuromuscul Disord. 2021;31:91-100,, 3. J Neurol. 2021;268:2482-2492, 4. Mol Genet Metab. 2012;106:301-309, 5. Mol Genet Metab. 2025;144:Article 108958. PoC: Proof of concept, AAV: Adeno-associated virus, hGAA: Human acid alpha-glucosidase, RMAT: Regenerative Medicine Advanced Therapy, FDA: Food and Drug Administration, SAE: Serious adverse event