



# Q2 YTD/FY2025 Financial Results

Naoki Okamura  
President and CEO  
Astellas Pharma Inc.

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# Q2 YTD/FY2025 Overview

**- Exceptional Progress Outperforming Expectations, Significant Upward Revision of Full-year Forecast -**

## Q2 YTD Financial Results

### Revenue

- ✓ Significant increase in Revenue driven by continued strong growth of Strategic Brands (underlying growth excl. FX impact: +12% YoY)

### SG&A expenses\*

- ✓ Significant improvement in SG&A ratio driven by robust SMT progress (-3.1ppt YoY)

### Core operating profit

- ✓ Significant increase driven by Strategic Brands growth and robust SMT progress (underlying growth excl. FX impact: +57% YoY)
- ✓ Core OP margin increased to 27.4% (+7.9ppt YoY)

## FY2025 Revised Forecast

- ✓ Upward revision of Revenue (+100.0 bil. yen) and Core/Full OP (+80.0 bil. yen each) based on exceptional progress

## Pipeline Progress

- ✓ PADCEV (MIBC): Unprecedented EV-303 data, sBLA acceptance in US
- ✓ ASP3082 & ASP2138: Promising initial data presentation, registrational studies under preparation

\*Excl. US XTANDI co-pro fee

Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA

SMT (Sustainable Margin Transformation): See [slide 24](#) for overview. MIBC: Muscle-invasive bladder cancer, sBLA: Supplemental Biologics License Application

# Agenda

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**Q2 YTD/FY2025 Consolidated Financial Results  
FY2025 Revised Forecast**

II

**Pipeline Progress**

# Q2 YTD/FY2025 Financial Results

Revenue and Core/Full OP all **increased by approx. 100.0 bil. yen** YoY

(billion yen)	Q2 YTD FY2024	Q2 YTD FY2025	Change	Change (%)	FY2025 Initial FCST*	FX impact (YoY)	Underlying Growth (Excl. FX Impact)
<b>Revenue</b>	<b>935.6</b>	<b>1,030.1</b>	<b>+94.5</b>	<b>+10.1%</b>	<b>1,930.0</b>	-22.2	<b>+12%</b>
Cost of sales	173.8	200.4	+26.5	+15.3%	373.0	-1.4	
SG&A expenses	406.4	403.8	-2.6	-0.6%	805.0	-12.5	
US XTANDI co-pro fee	126.0	127.2	+1.1	+0.9%	229.0	-5.6	
SG&A excl. the above	280.4	276.7	-3.7	-1.3%	576.0	-6.9	
(SG&A ratio**)	30.0%	26.9%	-3.1ppt		29.8%		
R&D expenses	172.3	143.3	-29.0	-16.9%	342.0	-3.8	
(R&D ratio)	18.4%	13.9%	-4.5ppt		17.7%		
<b>Core operating profit</b>	<b>183.1</b>	<b>282.6</b>	<b>+99.6</b>	<b>+54.4%</b>	<b>410.0</b>	-4.5	<b>+57%</b>
(Core OP margin)	19.6%	27.4%	+7.9ppt		21.2%		

## < Full basis >

Amortisation of intangible assets	69.2	65.5	-3.7	-5.4%	
Other income	4.5	5.2	+0.7	+16.0%	
Other expenses	26.9	25.4	-1.6	-5.8%	
<b>Operating profit</b>	<b>93.7</b>	<b>199.4</b>	<b>+105.7</b>	<b>+112.8%</b>	<b>160.0</b>
Profit before tax	89.0	194.6	+105.6	+118.6%	150.0
<b>Profit</b>	<b>73.5</b>	<b>147.6</b>	<b>+74.1</b>	<b>+100.8%</b>	<b>130.0</b>

\*Disclosed in Apr 2025, \*\*Excl. US XTANDI co-pro fee







Exchange rate assumption of FY2025 initial FCST: 140 yen/USD, 160 yen/EUR

Actual exchange rates of Q2/FY2025: 146 yen/USD, 168 yen/EUR (Actual exchange rates of Q2/FY2024: 152 yen/USD, 166 yen/EUR)



# Q2 YTD/FY2025 Financial Results: Main Brands

**Strategic Brands exceeds 220.0 bil. yen, driven primarily by strong growth in PADCEV and VYLOY**

(billion yen)	Q2 YTD/FY2025	YoY (Incl. FX Impact)	Underlying Growth (Excl. FX Impact)	
<b>Strategic Brands Total</b>	<b>220.5</b>	<b>+66.2 (+43%)</b>	<b>+47%</b>	<ul style="list-style-type: none"> <li>✓ Major driver for overall revenue and profit growth</li> <li>✓ Strong growth momentum expected to continue in 2H</li> </ul>
 <b>PADCEV™</b>	<b>102.5</b>	<b>+27.1 (+36%)</b>	<b>+39%</b>	<ul style="list-style-type: none"> <li>✓ Robust global growth driven by <b>strong 1L mUC demand momentum</b></li> <li>✓ 1L mUC approval expanded to 25 countries; continued contribution expected</li> <li>✓ Next <b>growth opportunity</b> expected from potential <b>MIBC</b> indication approval</li> </ul>
 <b>izervay™</b>	<b>34.1</b>	<b>+6.0 (+21%)</b>	<b>+27%</b>	<ul style="list-style-type: none"> <li>✓ Patient affordability headwinds weighed on NPS and sales; FCST revised downward</li> <li>✓ 2H growth expected; driven by NPS recovery (signs from Aug), favorable long-term efficacy (increased benefit) and consistent safety profile</li> </ul>
 <b>VEOZAH™</b>	<b>22.9</b>	<b>+8.1 (+55%)</b>	<b>+61%</b>	<ul style="list-style-type: none"> <li>✓ Solid growth driven by US performance, anticipate steady growth trajectory ahead</li> <li>✓ Potential market growth with recent non-hormonal class approval</li> </ul>
 <b>VYLOY™</b>	<b>26.6</b>	<b>+25.3 (&gt;+100%)</b>	<b>&gt;+100%</b>	<ul style="list-style-type: none"> <li>✓ <b>Outstanding performance exceeding expectations</b>, driven by exceptional Claudin 18 testing rate penetration and lower discontinuation</li> <li>✓ <b>FCST significantly revised upward</b>, based on strong global momentum</li> </ul>
 <b>XOSPATA®</b>	<b>34.4</b>	<b>-0.4 (-1%)</b>	<b>+1%</b>	<ul style="list-style-type: none"> <li>✓ Overall performance largely on track, with some regional differences</li> <li>✓ Anticipate moderate growth moving forward within current indication</li> </ul>
 <b>Xtandi®</b>	<b>477.0</b>	<b>+25.3 (+6%)</b>	<b>+8%</b>	<ul style="list-style-type: none"> <li>✓ Sales expanded in all regions</li> <li>✓ FCST revised upward, reflecting strong global performance</li> </ul>

Actual exchange rates of Q2/FY2025: 146 yen/USD, 168 yen/EUR (Actual exchange rates of Q2/FY2024: 152 yen/USD, 166 yen/EUR)

1L: First line, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, NPS: New patient start, VEOZAH: Approved as "VEOZA" in ex-US. See [slides 34-35](#) for IZERVAY AAO presentation data.

# Q2 YTD/FY2025 Financial Results: Cost Items

- *Cost optimization through SMT progress exceeds expectations (total approx. 16.0 bil. yen)*
- *SG&A ratio improved by 3.1 ppt YoY*

Cost Items	YoY change	Ratio to Revenue	(billion yen)
<b>SG&amp;A expenses*</b>	-1.3% (+1.1% excl. FX impact)	SG&A ratio: 26.9%	<p>YoY increase excl. FX impact: approx. +3.0</p> <p>✓ SMT cost optimization: approx. 7.0 (Organizational restructuring, reduction of mature products-related expenses, streamlining IT infrastructure etc.)</p> <p>Continue investments in Strategic Brands to maximize potential and SMT investments for further optimization</p>
<b>R&amp;D expenses</b>	-16.9% (-14.6% excl. FX impact)	R&D ratio: 13.9%	<p>YoY decrease excl. FX impact: approx. -25.0</p> <p>✓ SMT cost optimization: approx. 7.0 (Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials etc.)</p> <p>✓ Decrease in clinical development costs in Strategic Brands: approx. -6.0</p> <p>✓ One-time co-development cost payments in FY2024 etc.</p> <p>Expand investments aligned with Primary Focus progress</p>

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

# FY2025 Revised Forecast

- **Significant Upward revision of Revenue and Core/Full OP based on exceptional progress**
- **Expect Core OP margin 24.1% (+2.9ppt vs. initial forecast)**

Exchange rates of FY2025 revised forecast: 145 yen/USD, 170 yen/EUR  
(Forecast rates Q3/FY2025 onwards: 144 yen/USD, 172 yen/EUR)

(billion yen)	FY2024 Actual	FY2025			Main items of revision
		Initial FCST	Revised FCST	Change	
<b>Revenue</b>	<b>1,912.3</b>	<b>1,930.0</b>	<b>2,030.0</b>	<b>+100.0</b>	• VYLOY: +20.0, PADCEV: +10.0, XTANDI: +70.0
SG&A expenses	843.0	805.0	831.0	+26.0	
US XTANDI co-pro fee	252.6	229.0	245.0	+16.0	
SG&A excl. the above (SG&A ratio*)	590.5 30.9%	576.0 29.8%	586.0 28.9%	+10.0 -1.0ppt	• Expect decrease excl. FX impact • Reflects robust SMT progress
R&D expenses (R&D ratio)	327.7 17.1%	342.0 17.7%	322.0 15.9%	-20.0 -1.9ppt	• Reflects operational efficiency in R&D reorganization
<b>Core operating profit</b> (Core OP margin)	<b>392.4</b> 20.5%	<b>410.0</b> 21.2%	<b>490.0</b> 24.1%	<b>+80.0</b> <b>+2.9ppt</b>	• Reflects robust core business progress

## <Full basis>

<b>Operating profit</b>	<b>41.0</b>	<b>160.0</b>	<b>240.0</b>	<b>+80.0</b>
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FY2025 Initial FCST announced in Apr 2025. Exchange rates of initial FCST: 140 yen/USD, 160 yen/EUR

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



# Agenda



**Q2 YTD/FY2025 Consolidated Financial Results  
FY2025 Revised Forecast**



**Pipeline Progress**

# Strategic Brands: FY2025 Key Expected Events

(Blue: Updates since the last financial results announcement)

Success in PADCEV EV-303 study, sBLA accepted in US

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
avacincaptad pegol/ IZERVAY		Stargardt disease/ Phase 2b: Primary endpoints not met ● Jun	★ Sep Approval (Japan) ◆ Oct GATHER2 open-label extension study data presentation (AAO)		<Other update> Approved in Australia in Oct 2025
enfortumab vedotin/ PADCEV		MIBC (Cis-ineligible)/ EV-303 interim analysis: Primary endpoint met ★ Aug	◆ Oct EV-303 data presentation (ESMO) ★ Oct MIBC (Cis-ineligible)/ sBLA acceptance (US) MIBC (Cis-eligible)/ EV-304 interim analysis* (registrational)		🎯 PDUFA date (US) Apr
		Other solid tumors/EV-202: Terminated NMIBC/EV-104: Terminated ● Jul			
zolbetuximab/ VYLOY			● Oct Pancreatic/GLEAM final analysis: Primary endpoint not met		📦 : Data readout

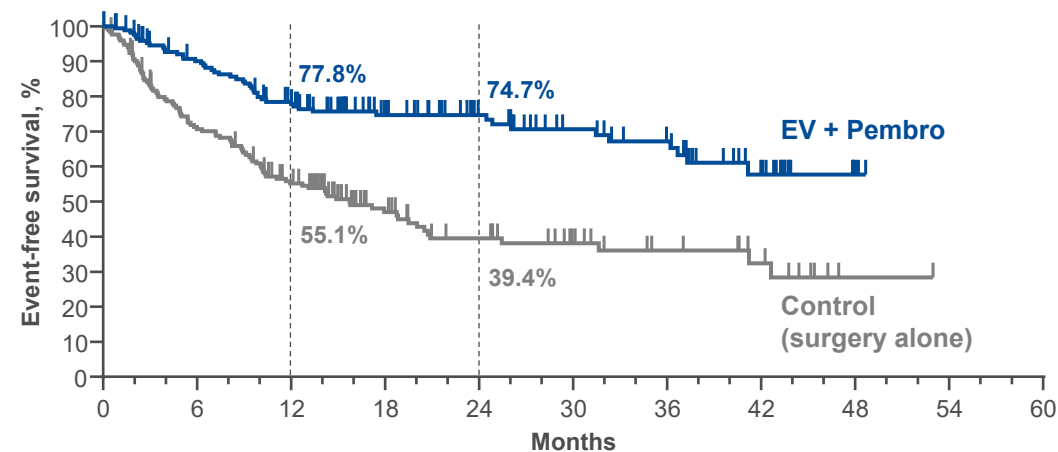
As of Oct 2025. \*The timeline is subject to shift due to its event-driven nature. See slides 34-35 for IZERVAY AAO presentation data.  
sBLA: Supplemental Biologics License Application, AAO: American Academy of Ophthalmology, MIBC: Muscle-invasive bladder cancer, Cis: Cisplatin, ESMO: European Society for Medical Oncology,  
PDUFA: Prescription Drug User Fee Act, NMIBC: Non-muscle-invasive bladder cancer



# enfortumab vedotin (EV) / PADCEV: Latest Status

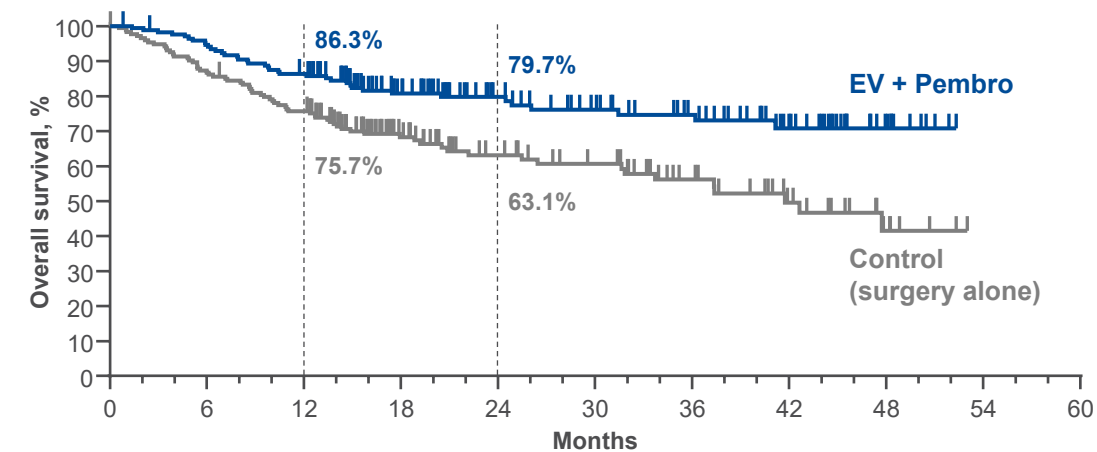
*Unprecedented data in EV-303, showing the potential as a new standard of care for Cis-ineligible MIBC*

<Event-free survival (EFS)>



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

<Overall survival (OS)>



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

<Development status for MIBC>

- Cis-ineligible/EV-303: sBLA accepted in US in Oct (Priority Review; PDUFA date: April 7, 2026)
- Cis-eligible/EV-304: Interim analysis anticipated for 2H/FY2025









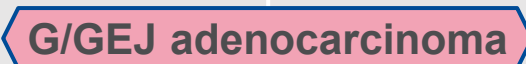






Data presented at ESMO 2025 (Data cutoff: Jun 6, 2025); See [Astellas Oncology Pipeline Online Meeting material](#) (October 24, 2025 (JST)) for details.  
Pembro: Pembrolizumab, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, HR: Hazard ratio, CI: Confidence interval, NR: Not reached, sBLA: Supplemental Biologics License Application, PDUFA: Prescription Drug User Fee Act




# Progress in Focus Area Approach

(Blue: Updates since the last financial results announcement)

*Promising data in ASP3082 and ASP2138 presented*

PoC* judgment						Convergence
Program (Primary Focus)	FY2024	FY2025				
		Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
 <b>ASP3082</b> (Targeted Protein Degradation)	 PoC achieved (PDAC)	 PoC achieved (NSCLC)		 <b>CRC</b>  <b>NSCLC data presentation</b> (AACR-NCI-EORTC) Oct		<ul style="list-style-type: none"><li>• Prioritize PF with successful PoC</li><li>• Accelerate flagship and follow-on programs</li></ul>
 <b>ASP2138</b> (Immuno-Oncology)				 <b>G/GEJ adenocarcinoma</b>  <b>Initial data presentation</b> (ESMO) Oct		
 <b>AT845</b> (Genetic Regulation)				 <b>Pompe disease</b>		
 <b>ASP7317</b> (Blindness & Regeneration)		 <b>Initial data presentation</b> (Retinal Therapeutics Innovation Summit) May		 <b>GA secondary to AMD</b>		

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

 : PoC judgment

**Sales contribution after XTANDI LOE**

**Sales contribution after XTANDI LOE**

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

 : PoC judgment

See slide 41 for current status of other programs and slides 42-43 for overview of flagship programs.

PoC: Proof of concept, PDAC: Pancreatic ductal adenocarcinoma, 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, 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 ASP3082 / Primary Focus Targeted Protein Degradation

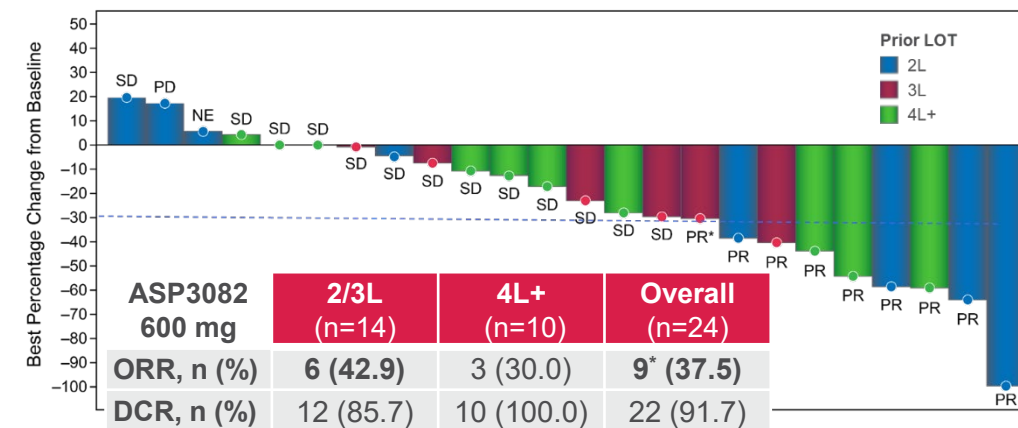
*Promising data in NSCLC presented, registrational studies under preparation for PDAC and NSCLC*

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

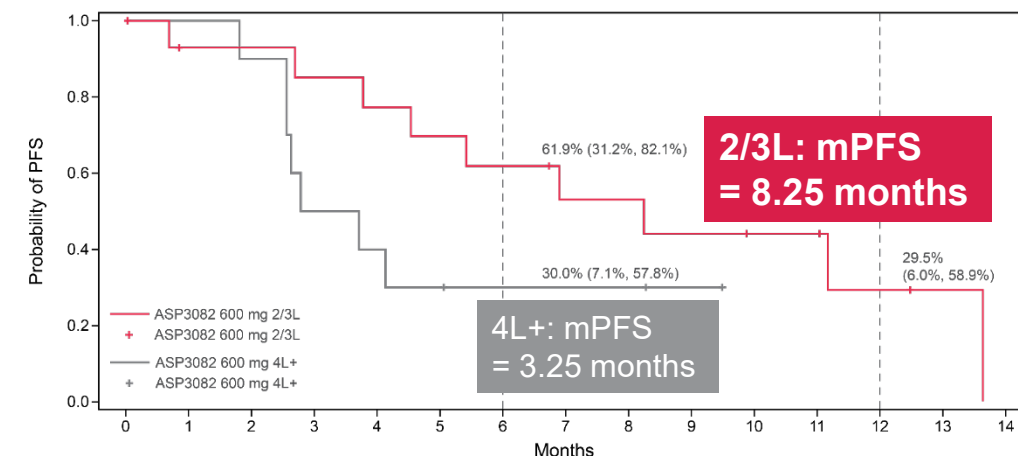
- ASP3082 monotherapy showed promising antitumor activity in an advanced NSCLC patient population
  - ✓ **ORR = 37.5% (9/24) in overall and 42.9% (6/14) in 2/3L**
  - ✓ **mDoR = 9.72 months**
  - ✓ **mPFS = 8.25 months in 2/3L**
- Safety events were generally manageable
  - ✓ **No TRAEs leading to drug discontinuation (0/25)**

## Current Status

- PDAC: Aiming **2H/FY2025** for **initiation of registrational study in 1L** and data presentation
- NSCLC: Planning is ongoing for registrational studies
- CRC: PoC judgment anticipated for 2H/FY2025
- Advancing research and development of follow-on programs
  - ✓ **ASP5834 (Pan-KRAS degrader): FSD in Phase 1 study achieved in Aug (27 days after IND clearance)**



\*8 confirmed + 1 unconfirmed



1. AACR-NCI-EORTC 2025; See [Astellas Oncology Pipeline Online Meeting material](#) (October 24, 2025 (JST)) for details. NSCLC: Non-small cell lung cancer, PDAC: Pancreatic ductal adenocarcinoma, ORR: Objective response rate, 2/3L: Second and third line, (m)DoR: (Median) Duration of response, PFS: Progression-free survival, TRAE: Treatment-related adverse event, 1L: First line, CRC: Colorectal cancer, PoC: Proof of concept, KRAS: Kirsten rat sarcoma viral oncogene homologue, FSD: First subject dosed, IND: Investigational New Drug, 4L+: Fourth or later line, DCR: Disease control rate, LOT: Line of therapy



# Progress in ASP2138 / Primary Focus Immuno-Oncology

*Early data showed a benefit of SC administration in combination with SoC, progressing toward PoC*

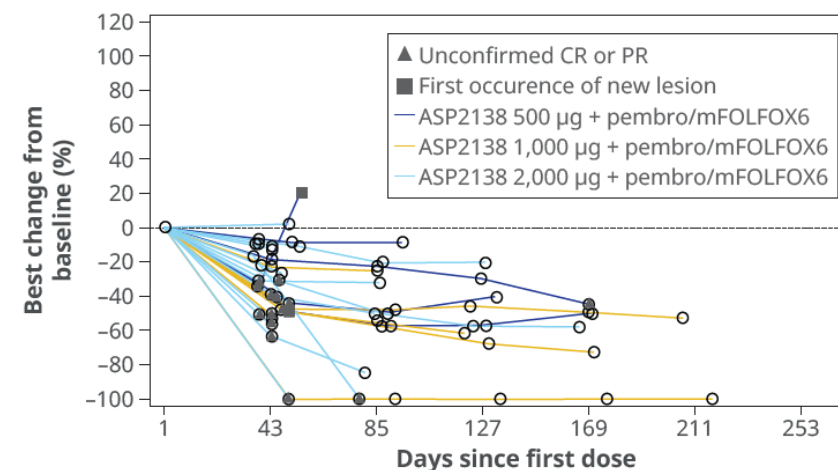
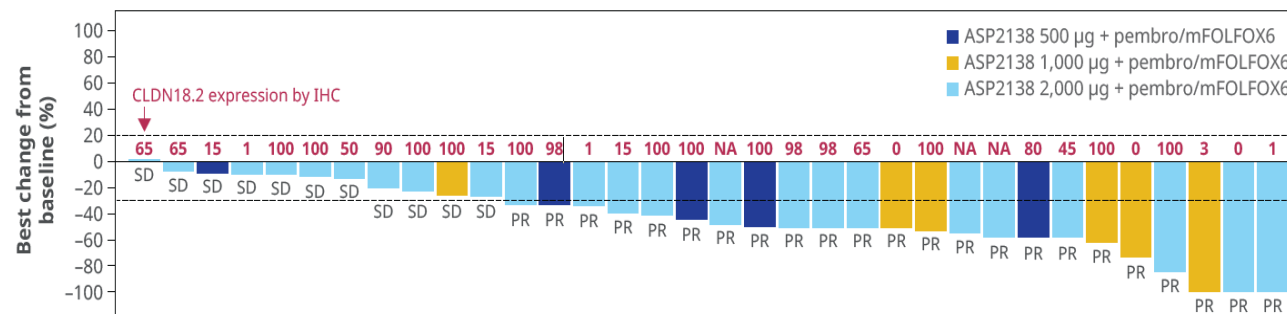
## Latest Data<sup>1</sup>

- 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

- Planning is ongoing for registrational studies
- Advancing research and development of follow-on programs
  - ✓ Bispecific immune cell engager: multiple programs in progress
  - ✓ iADC (immunostimulatory ADC): advancing toward IND

### 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, IND: Investigational New Drug, Pembro: Pembrolizumab; mFOLFOX6: 5-FU, leucovorin and oxaliplatin

# Key Takeaways

## *Exceptional Q2 YTD Financial Results*

- Strong growth of Strategic Brands driven by **PADCEV** and **VYLOY**
- Robust cost optimization through **SMT**

## *Significant Upward Revision of Full-year Forecast*

- Upward revision of Revenue (**+100.0 bil. yen**) and Core/Full OP (**+80.0 bil. yen** each)

## *Robust Pipeline Progress*

- Unprecedented data in **PADCEV EV-303** (MIBC)
- Promising data in **ASP3082** and **ASP2138**

Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA  
SMT: Sustainable Margin Transformation, MIBC: Muscle-invasive bladder cancer

# Appendix



## Strategic Brands: Potential Peak Sales (as of Oct 2025)

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 Oct 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

# 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



# Q2 YTD/FY2025 Actual: FX Rate

## Average rate for the period

Currency	Q2 YTD/FY2024	Q2 YTD/FY2025	Change
USD	152 yen	146 yen	-6 yen
EUR	166 yen	168 yen	+2 yen

## <Impact of exchange rate on financial results>

- Revenue: -22.2 billion yen
- Core OP: -4.5 billion yen

# FY2025 Forecast: FX Rate & FX Sensitivity

Exchange rate Average for the period	FY2025 Initial FCST	FY2025 Revised FCST	Change
USD	140 yen	145 yen	+5 yen
EUR	160 yen	170 yen	+10 yen

Forecast rates Q3 onwards: 144 yen/USD, 172 yen/EUR

## Estimated FX sensitivity (Q3 onwards) of FY2025 forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption	
	Revenue	Core OP
USD	Approx. +3.9 bil. yen	Approx. +0.8 bil. yen
EUR	Approx. +1.7 bil. yen	Approx. +0.8 bil. yen

# Balance Sheet & Cash Flow Highlights

(billion yen)	Mar 31, 2025	Sep 30, 2025
Total assets	3,339.5	3,450.3
Cash and cash equivalents	188.4	287.1
Total equity attributable to owners of the parent	1,513.3	1,612.4
Equity ratio (%)	45.3%	46.7%

(billion yen)	Q2 YTD/FY2024	Q2 YTD/FY2025
Cash flows from operating activities	77.4	282.6
Cash flows from investing activities	-55.7	-30.2
Free cash flows	21.7	252.4
Cash flows from financing activities	-66.3	-155.8
Increase/decrease in short-term borrowings and commercial papers	-159.9	-65.5
Proceeds from issuance of bonds and long-term borrowings	200.0	-
Redemption of bonds and repayments of long-term borrowings	-26.0	-25.5
Dividends paid	-62.8	-66.2

# Balance of Bonds and Borrowings Highlights

(billion yen)	Jun 30, 2025	Sep 30, 2025
Balance of bonds and borrowings	889.5	740.5
Non-current liabilities	558.1	320.0
Bonds	320.0	220.0
Long-term borrowings	238.1	100.0
Current liabilities	331.4	420.5
Commercial papers	230.7	99.9
Short-term borrowings	20.0	20.0
Current portion of long-term borrowings	50.7	170.6
Current portion of bonds	30.0	130.0

# Main Intangible Assets (as of Sep 30, 2025)

	Bil. yen	Foreign currency**
AT132	16.1	\$109M
AT845	10.7	\$73M
Gene therapy related technology*	60.1	\$406M
VEOZAH**	83.8	€493M
VYLOY**	57.1	€440M
IZERVAY (US)	578.8	\$3,914M
IZERVAY (Ex-US)	51.0	\$345M
ASP7317	25.5	\$172M

VEOZAH: Approved as “VEOZA” in ex-US

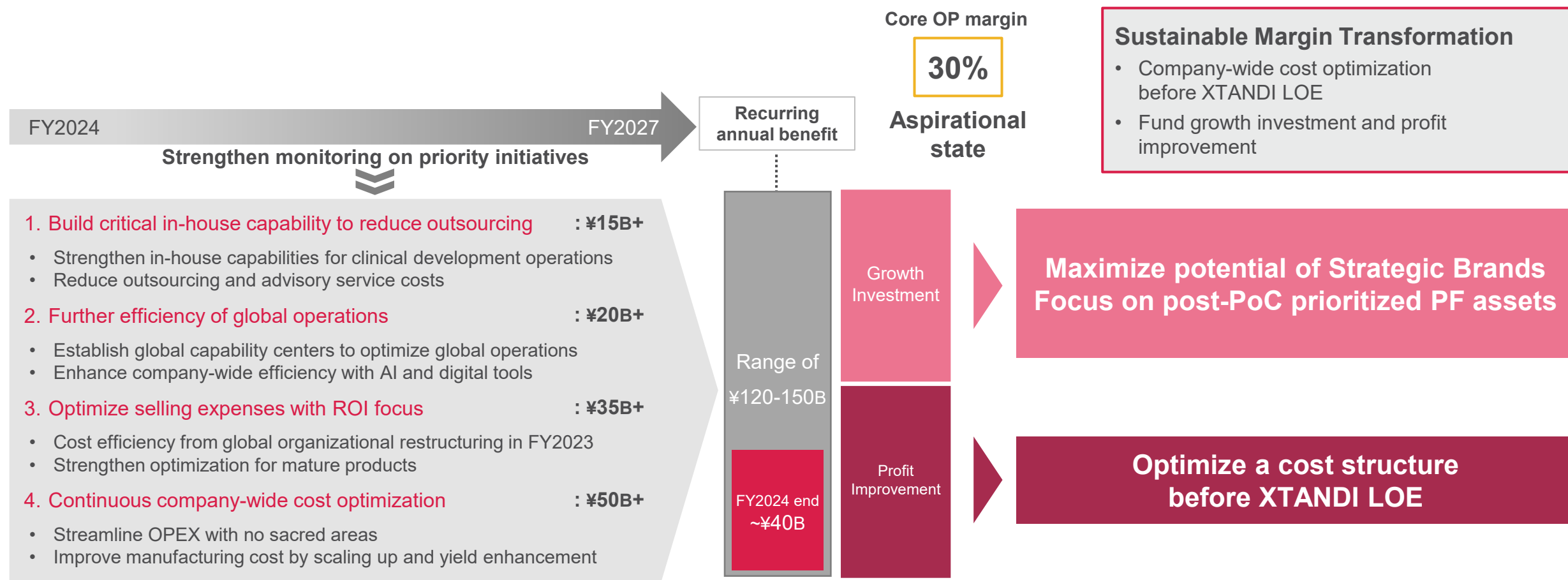
\*Acquired during the acquisition of Audentes (now Astellas Gene Therapies)

\*\*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 120-150 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
ASP3082
ASP4396
ASP5834
ASP7317
ASP546C/XNW27011
ASP5502

## Phase 2

gilteritinib (Newly diagnosed AML, HIC-ineligible)
zolbetuximab (Pancreatic adenocarcinoma)
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: US)
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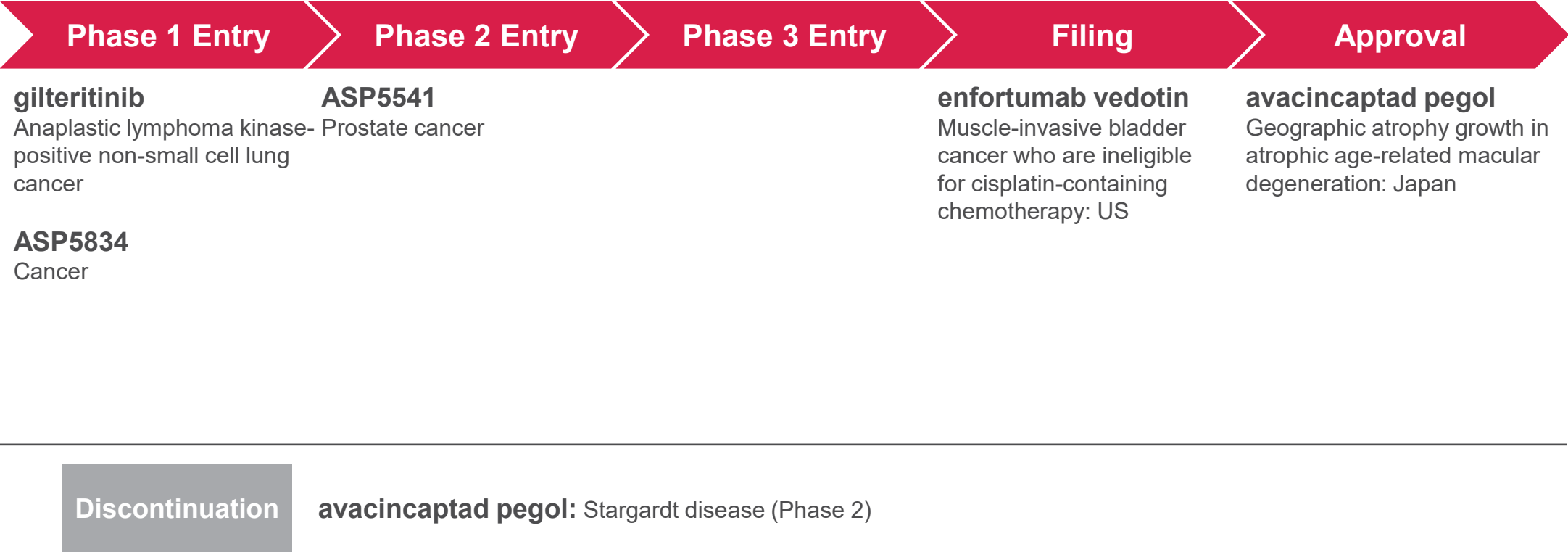
- Strategic Brands
- Programs with Focus Area Approach
- Others

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



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
 enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	Muscle-invasive bladder cancer	<b>Cis-ineligible: sBLA under review (US)</b>  Cis-eligible: Phase 3 EV-304 study ongoing	<b>PDUFA date: Apr 7, 2026</b>  Data readout (interim analysis) anticipated for 2H/FY2025
 (avacincaptad pegol intravitreal solution) 2 mg	GA secondary to AMD	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 China: Phase 2 study ongoing	Data readout anticipated for FY2025 or later Data readout anticipated for FY2026
 (fezolinetant) tablets 45 mg	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
 gilteritinib 40mg tablets	Newly diagnosed AML (HIC-eligible)	Phase 3 PASHA study ongoing	Data readout (primary analysis) anticipated for 1H/FY2026
 gilteritinib 40mg tablets	<b>ALK-positive NSCLC</b>	<b>Phase 1 study ongoing</b>	<b>Data readout anticipated for FY2027 or later</b>

As of Oct 2025. Not exhaustively listed. VEOZAH: Approved as “VEOZA” in ex-US. Cis: Cisplatin, sBLA: Supplemental Biologics License Application, PDUFA: Prescription Drug User Fee Act, GA: Geographic atrophy, AMD: Age-related macular degeneration, LCM: Lifecycle management, VMS: Vasomotor symptoms, GEJ: Gastroesophageal junction, Pembro: Pembrolizumab, Chemo: Chemotherapy, 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

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

\*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, 1L: First line, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder 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>NCT03924895</u>	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=595	<b>sBLA accepted in US in Oct 2025</b>
<b>P3: EV-304 /KEYNOTE-B15</b>	<u>NCT04700124</u>	MIBC, Cis-eligible; EV + Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=808	Enrollment completed
<b>P1b/2: EV-103</b>	<u>NCT03288545</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, sBLA: Supplemental Biologics License 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	(Ongoing)	✓ 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)	(Ongoing)	✓ 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)	(Ongoing)	✓ 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*

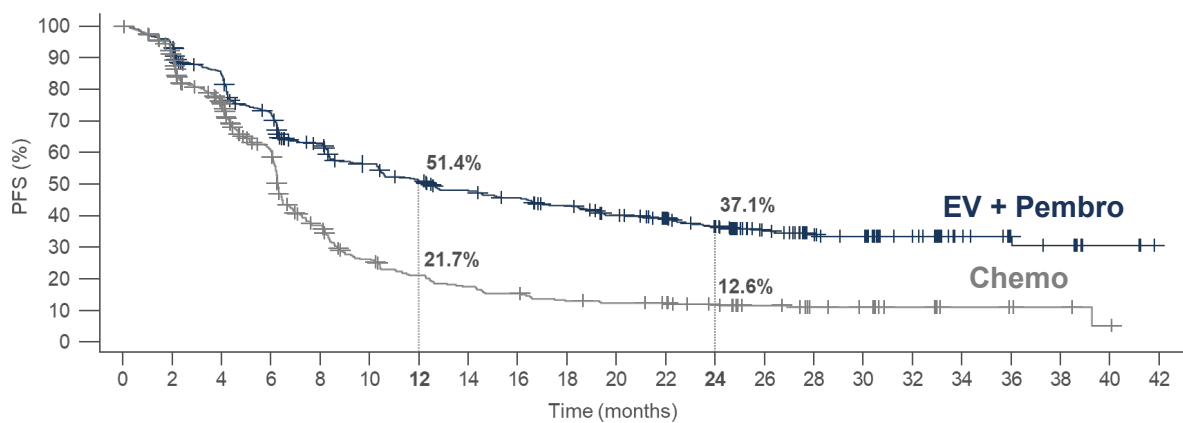
✓: Data obtained, \*: Prespecified interim analysis, \*\*: Updated data

 (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 1L mUC (EV-302)

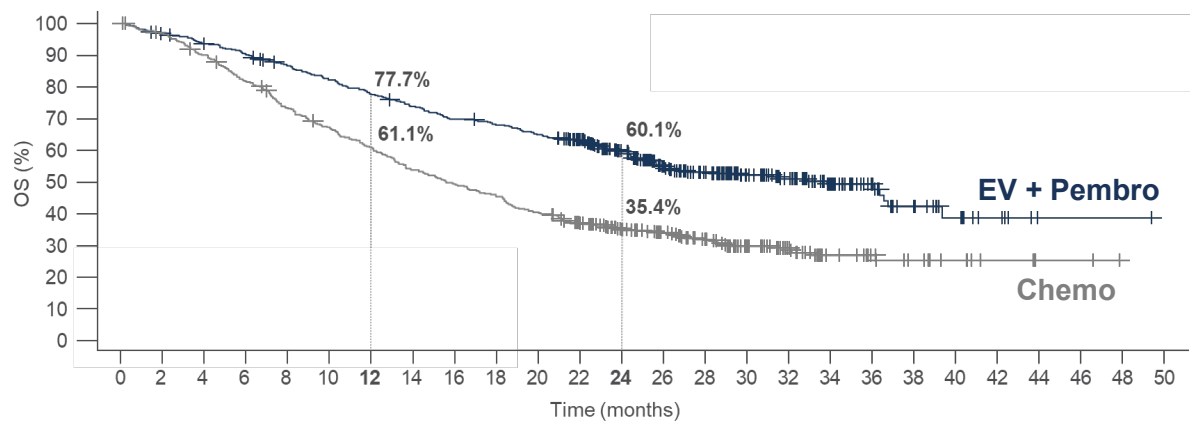
Statistically significant and clinically meaningful improvement over chemotherapy with nearly doubled mOS and mPFS

<Progression-free survival>



	N	Events	HR (95% CI)	2-sided P value	Median (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>

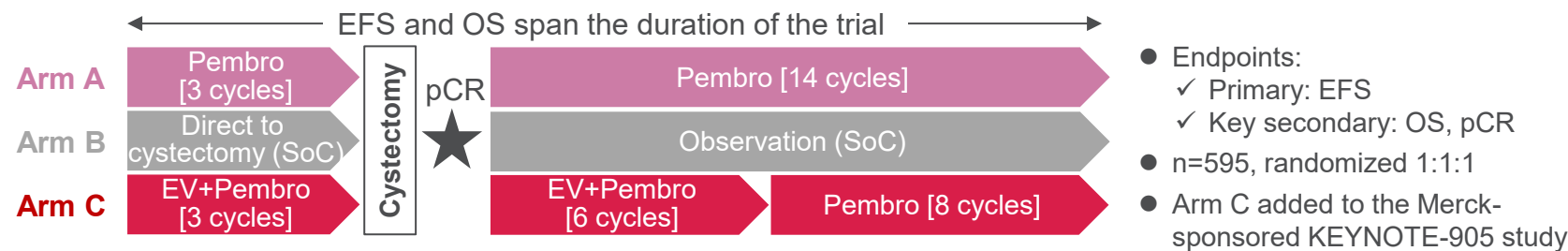


	N	Events	HR (95% CI)	2-sided P value	Median (95% CI), months
EV + Pembro	442	203	0.51 (0.43, 0.61)	<0.00001	33.8 (26.1, 39.3)
Chemo	444	297			15.9 (13.6, 18.3)

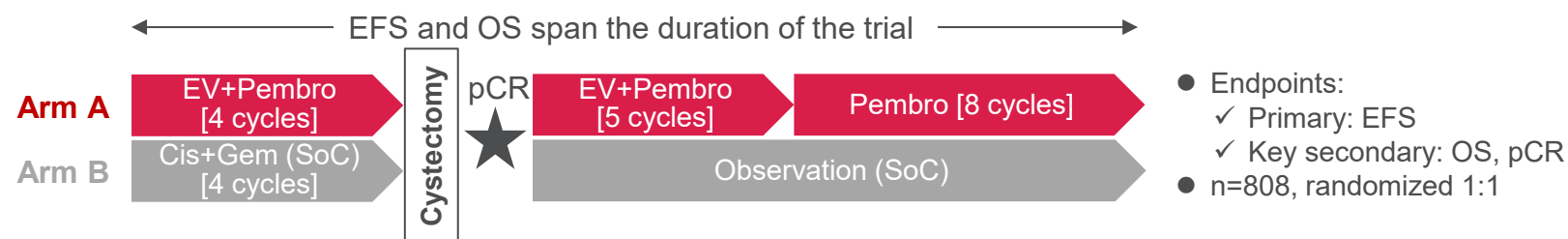
- Chemo: cisplatin or carboplatin + gemcitabine
- 30.4% of patients in Chemo arm received subsequent avelumab maintenance therapy

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

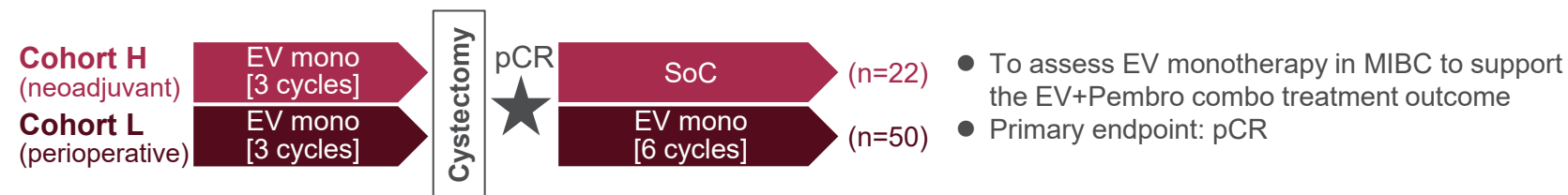
## 1) Phase 3 study in *Cis-ineligible* MIBC (KEYNOTE-905/EV-303): Perioperative EV+Pembro vs. Cystectomy alone



## 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



Cis: Cisplatin, Pembro: Pembrolizumab, SoC: Standard of care, EFS: Event-free survival, OS: Overall survival, pCR: Pathological complete response, chemo: Chemotherapy, Gem: Gemcitabine, mono: Monotherapy, pDS: Pathological downstaging

# 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 eye<sup>1</sup>
- Without timely treatment, an estimated 66% of people with GA may become blind or severely visually impaired<sup>2</sup>

## 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

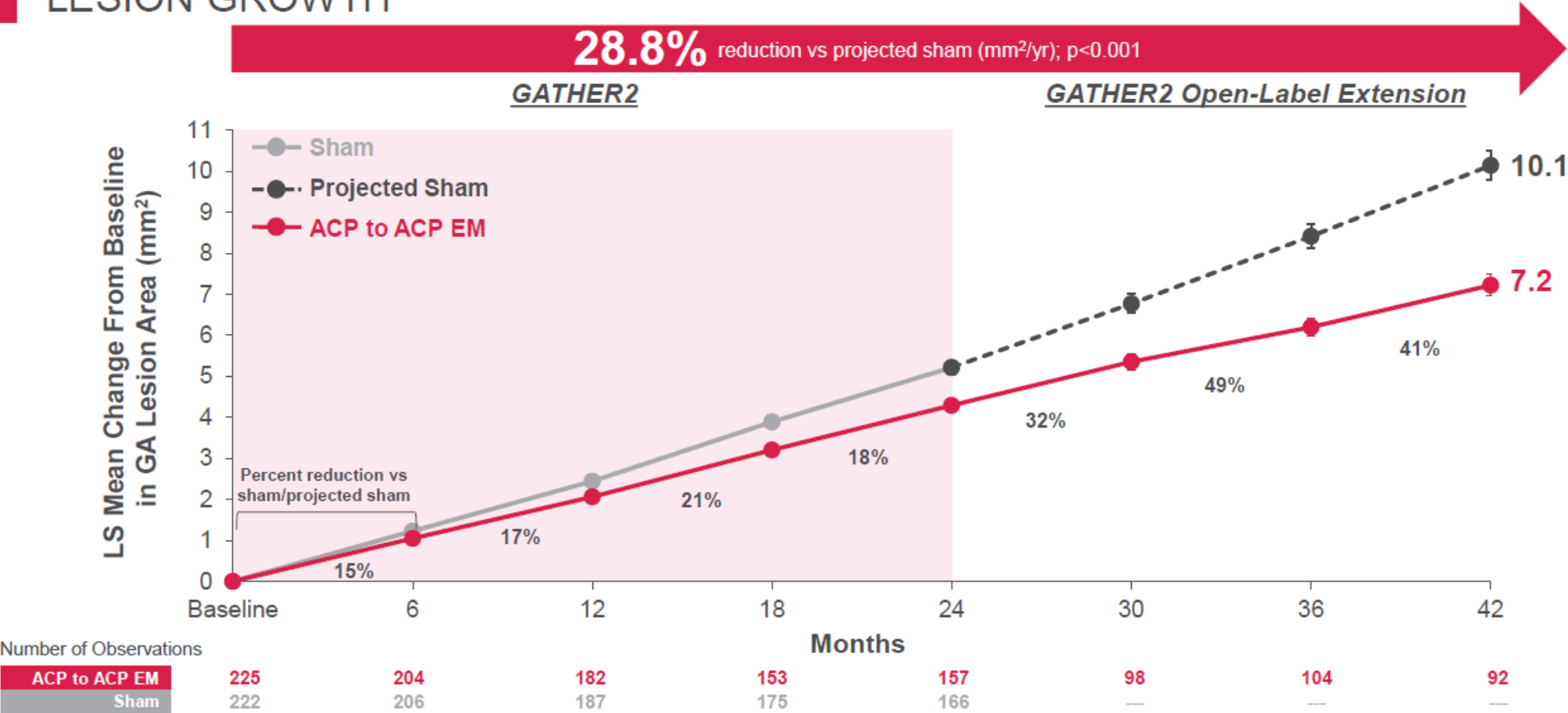
GA secondary to AMD	P2/3: GATHER1	<a href="#">NCT02686658</a>	Part 1: 1 mg, 2 mg vs. sham (n=77) Part 2: 2 mg, 4 mg vs. sham (n=209)	n=286	Approved in Japan in Sep 2025
	P3: GATHER2	<a href="#">NCT04435366</a>	2 mg vs. sham	n=448	

1. Retina. 2017;37:819-835, 2. JAMA Ophthalmol. 2021;139:743-750



# IZERVAY: Data Presented at AAO 2025 (1/2)

ACP 2 MG SHOWED INCREASING BENEFIT OVER TIME IN SLOWING GA LESION GROWTH



Note: For each group (ACP or sham) in GATHER2 ITT population, a separate piecewise MMRM model was applied using square root transformed GA area data from baseline through Month 42, with study ID, GATHER2 randomization stratification factors, time (in days) in each study, and 6-month knots in each study. GA lesion growth rates were then converted from the square root transformed scale to the untransformed scale. A jackknife method was used to compute the associated standard error. For projected sham, GA lesion growth rate from Month 24 to Month 42 was first calculated as the average of the transformed GA growth rates from the four 6-month intervals spanning from baseline through Month 24 in GATHER2 sham group and subsequently converted to the untransformed scale. ACP, avacincaptad pegol; EM, every month; GA, geographic atrophy; ITT, intent-to-treat; LS, least squares; MMRM, mixed model for repeated measures.

# IZERVAY: Data Presented at AAO 2025 (2/2)

## SAFETY PROFILE OF ACP DURING 18-MONTH OPEN-LABEL EXTENSION WAS CONSISTENT WITH GATHER2 TRIAL

Ocular TEAEs ≥2% During Open-Label Extension	ACP to ACP EM (N=125)	Sham to ACP EM (N=151)
Ocular TEAEs in the study eye, n (%)	74 (59.2)	88 (58.3)
IOP increased	19 (15.2)	20 (13.2)
Cataract	16 (12.8)	11 (7.3)
Conjunctival hemorrhage	13 (10.4)	15 (9.9)
Vitreous detachment	7 (5.6)	1 (0.7)
Visual acuity reduced	7 (5.6)	20 (13.2)
New-onset CNV <sup>a</sup>	7 (5.6)	14 (9.3)
Punctate keratitis	4 (3.2)	9 (6.0)
Transient visual loss	4 (3.2)	3 (2.0)
Posterior capsule opacification	3 (2.4)	7 (4.6)

- 1 case of endophthalmitis in the sham to ACP group (0.7%)
- 5 cases of IOI out of 4203 total injections (0.1%) – all events were anterior
  - None were serious or related to ACP; all resolved with no reoccurrence during continued use of ACP
- **No cases of retinal vasculitis or occlusive vasculitis**

<sup>a</sup>New-onset CNV includes patients with CNV incidence during open-label extension portion but not CNV that occurred during the GATHER2 trial.

ACP, avacincaptad pegol; CNV, choroidal neovascularization; EM, every month; IOI, intraocular inflammation; IOP, intraocular pressure; TEAE, treatment-emergent adverse event.

# 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; 12 weeks: DB, 2 doses vs. placebo (1:1:1)	n=410	Enrollment completed
	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	FSD: Apr 2025

## 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





# zolbetuximab: Anti-Claudin 18.2 Monoclonal Antibody

(Blue: Updates since the last financial results announcement)

## 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

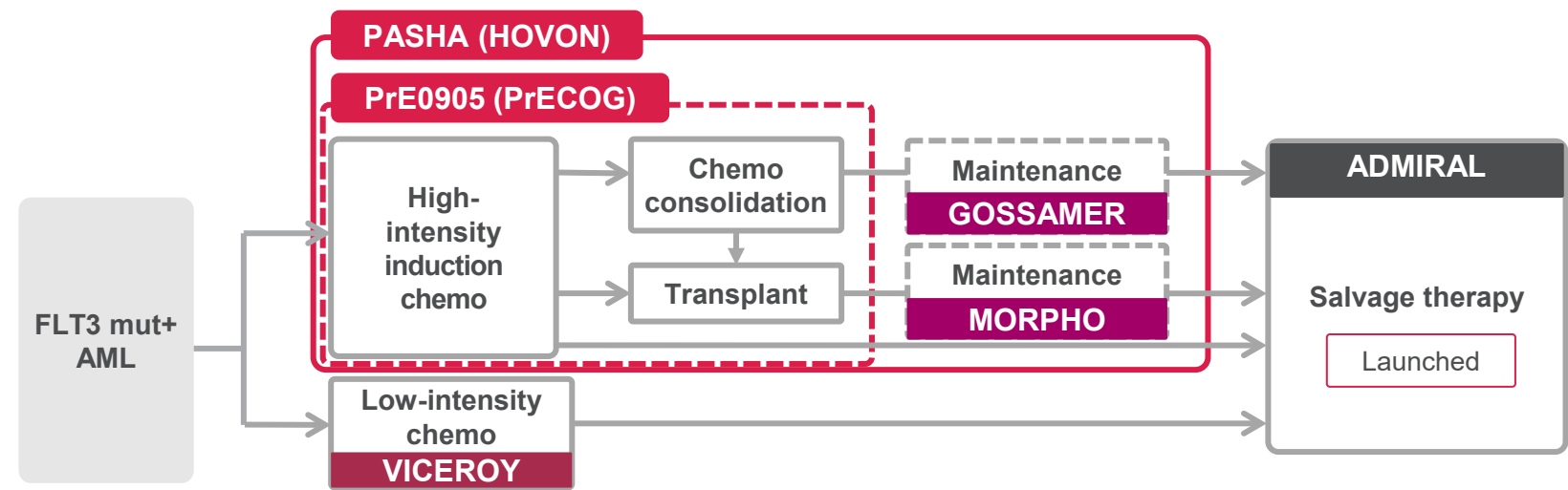
Gastric and GEJ adenocarcinoma	P3: LUCERNA	<a href="#">NCT06901531</a>	First line, combo with Pembro and chemo, DB, vs. placebo	n=500	FSD: Jun 2025
	P2: ILUSTRO	<a href="#">NCT03505320</a>	Cohort 1: Third or later line, monotherapy Cohort 2: First line, combo with mFOLFOX6 Cohort 3: Third or later line, combo with Pembro Cohort 4: First line, combo with mFOLFOX6 and nivolumab Cohort 5: Perioperative, combo with FLOT	n=143	Enrollment completed
Pancreatic adenocarcinoma	P2: GLEAM	<a href="#">NCT03816163</a>	First line, combo with nab-paclitaxel and gemcitabine, open	n=393	Primary endpoint not met

\*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

(Blue: Updates since the last financial results announcement)



## Acute myeloid leukemia

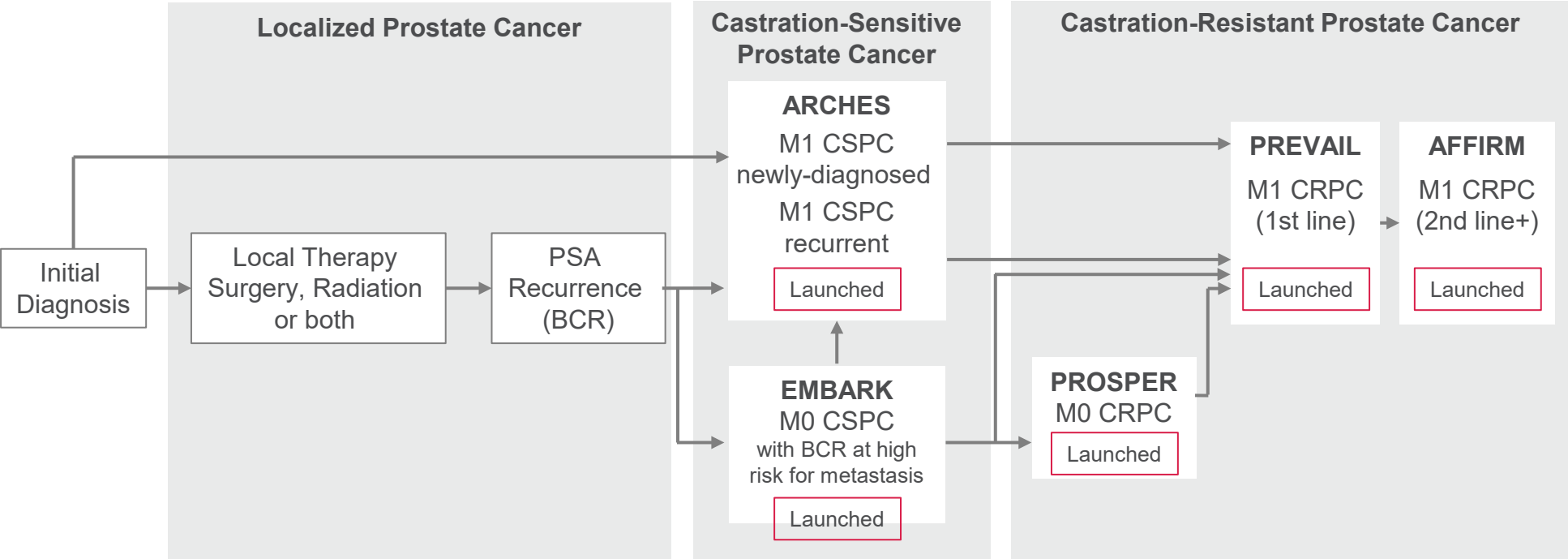
Newly diagnosed (HIC-eligible)	P3: PASHA (HOVON)	<a href="#">NCT04027309</a>	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=766	Enrollment completed (Sponsor: HOVON)
	P2: PrE0905 (PrECOG)	<a href="#">NCT03836209</a>		n=181	Topline results presented at ASH 2024 (Sponsor: PrECOG, 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

(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	✓ 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>Initial data presented at ESMO in Oct 2025</b>
		ASP1002 	Anti-CLDN4 and anti-CD137	Phase 1 study ongoing
Targeted Protein Degradation	Protein degradation	★ ASP3082 	KRAS G12D degrader	Phase 1 study ongoing. <b>NSCLC data presented at AACR-NCI-EORTC in Oct 2025</b>
		ASP4396 	KRAS G12D degrader	Phase 1 study ongoing
		<b>ASP5834</b> 	<b>Pan-KRAS degrader</b>	<b>FSD in Phase 1 study in Aug 2025</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	<b>FSD in Phase 2 study in Sep 2025</b>
	Antibody-drug conjugate (ADC)	ASP546C (XNW27011) 	ADC targeting CLDN18.2	Global Phase 1b/2 study under planning
	Immune modulation	ASP5502 	STING inhibitor	Phase 1 study ongoing

★ : Flagship program

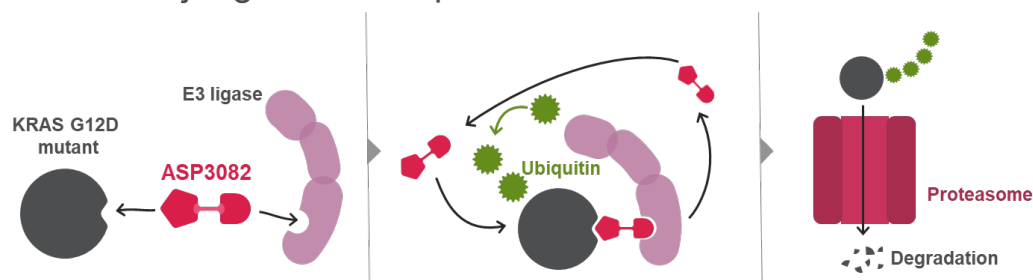
DGK: Diacylglycerol kinase, CLDN: Claudin, G/GEJ: Gastric/gastroesophageal junction, ESMO: European Society for Medical Oncology, KRAS: Kirsten rat sarcoma viral oncogene homologue, NSCLC: Non-small cell lung cancer, AACR: American Association for Cancer Research, NCI: National Cancer Institute, EORTC: European Organisation for Research and Treatment of Cancer, FSD: First subject dosed, AAV: Adeno-associated virus, MTM1: Myotubularin 1, FDA: Food and Drug Administration, GAA: Acid alpha-glucosidase, RPE: Retinal pigment epithelial, PF: Primary Focus, STING: Stimulator of interferon genes

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

## ASP3082 (Targeted Protein Degradation)

### Protein degrader targeting KRAS G12D mutant

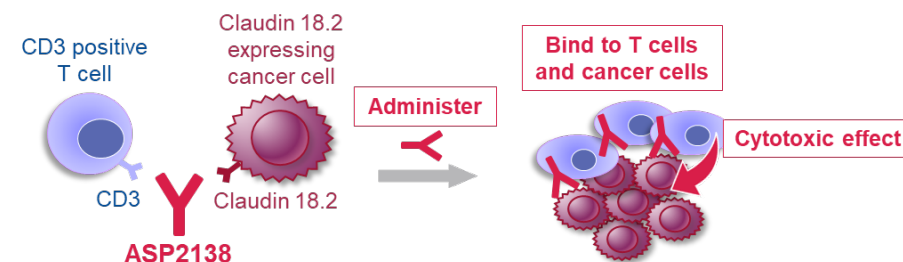
- Target disease: Cancers harboring KRAS G12D mutation
  - ✓ Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~5% in NSCLC, ~15% in CRC<sup>1</sup>
- SoC for metastatic PDAC: Chemotherapy (chemo); for NSCLC: immunotherapy +/- chemo (1L); chemo (2L+)
- Status: Phase 1 study ongoing ([NCT05382559](#))
  - ✓ 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 2H/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)
- Anticipated PoC judgment timing: 2H/FY2025



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

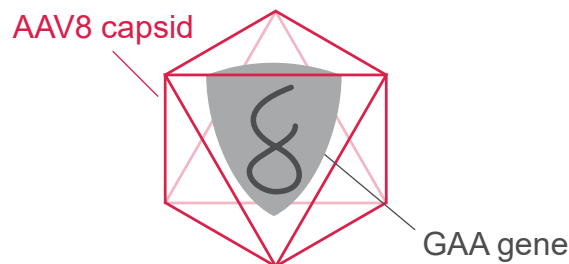
KRAS: Kirsten rat sarcoma viral oncogene homologue, PDAC: Pancreatic ductal adenocarcinoma, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, SoC: Standard of Care, 1L: First line, 2L+: Second or later line, PoC: Proof of concept, 2/3L: Second and third line, CLDN18.2: Claudin 18.2, SC: Subcutaneous,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

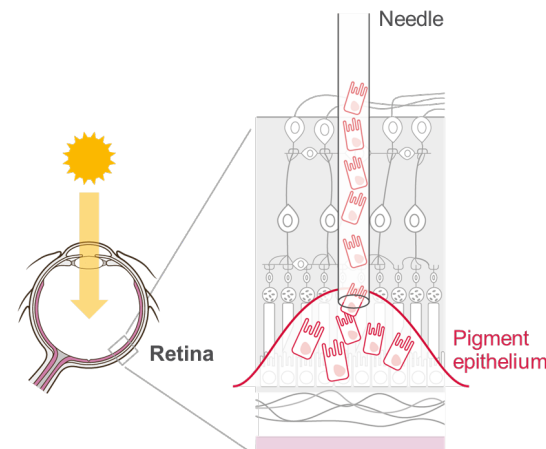
- Target disease: Pompe disease
  - ✓ Estimated incidence: 1 in ~40,000<sup>1</sup>
- Standard of care: Enzyme replacement therapy (ERT)
  - ✓ Chronic, repeated infusions every 2 weeks
  - ✓ Secondary disease progression after 2-3 years on ERT<sup>2,3,4</sup>
  - ✓ Substantial economic burden with high rates of healthcare resource utilization<sup>5</sup>
- Status: Phase 1/2 FORTIS study ongoing ([NCT04174105](#))
  - ✓ 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: 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 worldwide<sup>7</sup>
- Approved treatment: Complement inhibitors
  - ✓ Slow disease progression
- Status: Phase 1b study ongoing ([NCT03178149](#))
- Anticipated PoC judgment timing: 2H/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