



# FY2025 Financial Results

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April 27, 2026



# 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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# Agenda

I

**FY2025 Results**

II

**FY2026 Outlook**

III

**Review of Corporate Strategic Plan 2021**

# FY2025 Overview

**- Record-high Revenue (over 2.1 trillion yen) and Core OP (over 550.0 billion yen) -**

## **Financial Results**

<b>Revenue</b>	Significant growth of Strategic Brands (over +140.0 bil. yen YoY), driving double-digit revenue growth (+12% YoY)
<b>SG&amp;A expenses*</b>	Robust SMT progress, driving improvement in SG&A ratio (-2.3ppt YoY)
<b>Core OP</b>	Significant increase driven by Strategic Brands growth and robust SMT progress (+42% YoY) Core OP margin increased to 26.0% (+5.5ppt YoY)

## **Pipeline Progress**

- ✓ PADCEV: Significant progress in MIBC development
- ✓ 3 PoCs achieved (setidegrasib NSCLC, ASP2138, ASP7317)
- ✓ Phase 3 study initiated (setidegrasib 1L PDAC)\*\*
- ✓ Promising external assets in-licensed (ASP546C, VIR-5500)

\*Excl. US XTANDI co-promote fee, \*\*Apr 2026

Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA. SMT (Sustainable Margin Transformation): See [slide 36](#) for overview

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

# FY2025 Financial Results

**Breaking records across Revenue, Core OP and Full OP - All-time highs**

(billion yen)	FY2024	FY2025	Change	Change (%)	Fx impact (YoY)	FY2025 FCST
<b>Revenue</b>	<b>1,912.3</b>	<b>2,139.2</b>	<b>+226.9</b>	<b>+11.9%</b>	+30.1	<b>2,100.0</b>
Cost of sales	349.2	408.4	+59.2	+17.0%	+10.3	406.0
SG&A expenses	843.0	860.3	+17.3	+2.0%	+3.6	859.0
US XTANDI co-promote fee	252.6	248.2	-4.3	-1.7%	-2.8	259.0
SG&A excl. the above	590.5	612.1	+21.6	+3.7%	+6.3	600.0
(SG&A ratio*)	30.9%	28.6%	-2.3ppt			28.6%
R&D expenses	327.7	314.8	-12.8	-3.9%	-0.5	315.0
(R&D ratio)	17.1%	14.7%	-2.4ppt			15.0%
<b>Core operating profit</b>	<b>392.4</b>	<b>555.7</b>	<b>+163.2</b>	<b>+41.6%</b>	+16.8	<b>520.0</b>
(Core OP margin)	20.5%	26.0%	+5.5ppt			24.8%
<b>&lt; Full basis &gt;</b>						
Amortisation of intangible assets	136.8	136.0	-0.8	-0.6%		
Other income	20.3	32.8	+12.5	+61.2%		
Other expenses	235.8	72.4	-163.3	-69.3%		
<b>Operating profit</b>	<b>41.0</b>	<b>382.6</b>	<b>+341.6</b>	<b>+832.4%</b>		<b>340.0</b>
Profit before tax	31.2	376.6	+345.4	-		330.0
<b>Profit</b>	<b>50.7</b>	<b>291.6</b>	<b>+240.8</b>	<b>+474.6%</b>		<b>250.0</b>






\*Excl. US XTANDI co-promote fee

Actual exchange rates of FY2025: 151 yen/USD, 175 yen/EUR (Actual exchange rates of FY2024: 152 yen/USD, 164 yen/EUR)

Exchange rate assumption of FY2025 FCST: 150 yen/USD, 174 yen/EUR

# FY2025 Financial Results: Main Brands

*All Brands increased across the board, with Strategic Brands total growing over 140.0 bil. yen YoY*

(billion yen)	FY2025 Act	YoY Growth
<b>Strategic Brands Total</b>	<b>480.3</b>	<b>+143.9 (+43%)</b>
 <b>PADCEV™</b>	<b>221.2</b>	<b>+57.1 (+35%)</b>
 <b>izervay™</b>	<b>77.6</b>	<b>+19.3 (+33%)</b>
 <b>VYLOY™</b>	<b>63.1</b>	<b>+50.9 (&gt;+100%)</b>
 <b>VEOZAH™</b>	<b>46.6</b>	<b>+12.8 (+38%)</b>
 <b>XOSPATA®</b>	<b>71.8</b>	<b>+3.9 (+6%)</b>

## Significant growth driving overall revenue and profit growth

### PADCEV


- Sales growth driven by strong 1L mUC penetration
- Early momentum for cis-ineligible MIBC in the US

### IZERVAY

- Sales growth driven by increased momentum in new patient starts
- Steady increase in treatment rate, estimate ~20% on complement inhibitor

### VYLOY

- Sales growth driven by rapid expansion across all regions
- High Claudin 18 testing rates drove strong performance

 <b>Xtandi®</b>	<b>960.8</b>	<b>+48.5 (+5%)</b>
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Steady global sales growth, reaching projected peak levels

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

1L: First line, mUC: Metastatic urothelial cancer, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer

# FY2025 Financial Results: Cost Items

- **Cost optimization (SMT): Achieved ~25.0 bil. yen (SG&A expenses, R&D expenses, cost of sales)**
- **SG&A ratio improved by 2.3ppt YoY**





Cost Items	YoY change	Ratio to Revenue	(billion yen)
<b>SG&amp;A expenses*</b>	+3.7% (+2.6% excl. FX impact)	SG&A ratio: 28.6%	YoY increase excl. FX impact: approx. +15.0 ✓ Strategic Brands-related expenses for further growth: approx. +10.0 ✓ SMT cost optimization: approx. 11.0 (Organizational restructuring, reduction of mature products-related expenses, streamlining IT infrastructure, etc.)
<b>R&amp;D expenses</b>	-3.9% (-3.8% excl. FX impact)	R&D ratio: 14.7%	YoY decrease excl. FX impact: approx. -12.0 ✓ Increase in pipeline clinical development costs (setidegrasib and ASP546C): approx. +5.0 ✓ SMT cost optimization: approx. 10.0 (Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials etc.) ✓ Decrease in Strategic Brands clinical development costs: approx. -5.0

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

# Lifecycle Management of Strategic Brands: FY2025 Achievements

(Blue: Updates since the last financial results announcement)

*Strong development progress toward maximization of Strategic Brands value, notably for PADCEV*

Brand	Indication	Key achievements
	Muscle-invasive bladder cancer (MIBC)	<u>Cis-ineligible:</u> Phase 3 EV-303 study primary endpoint met (Aug) US: sBLA approved (Nov), Europe: Type II variation accepted (Nov), Japan: sBLA submitted (Jan)
		<u>Cis-eligible:</u> Phase 3 EV-304 study primary endpoint met (Dec) <b>Europe: Type II variation accepted (Mar), US: sBLA accepted under priority review (Apr*)</b>
		<u>Bladder-sparing:</u> <b>Phase 2 EV-209 study initiated (Apr*)</b>
	GA secondary to AMD	Japan: Approved (Sep)
	Gastric and GEJ cancer	Phase 3 LUCERNA study initiated (Jun)
	VMS associated with menopause	Japan: Phase 3 STARLIGHT 2 study primary endpoint met (Jan) <b>China: Phase 2 study primary endpoint met (Apr*)</b>

Not exhaustively listed. VEOZAH: Approved as "VEOZA" in ex-US. \*Apr 2026

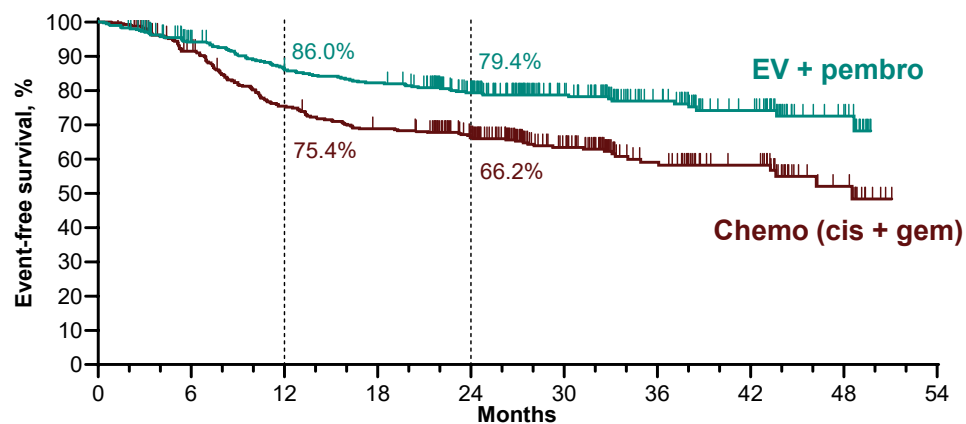
AMD: Age-related macular degeneration, Cis: Cisplatin, GA: Geographic atrophy, GEJ: Gastroesophageal junction, sBLA: Supplemental Biologics License Application, VMS: Vasomotor symptoms

# enfortumab vedotin (EV) / PADCEV: Latest Status

Starting development for **bladder-sparing MIBC** to potentially maximize PADCEV's impact

## Cisplatin-eligible MIBC

- **EV-304 study data<sup>1</sup>:**  
(Perioperative EV + pembro vs. neoadjuvant chemo)
  - ✓ **Event-free survival (EFS): HR=0.53, P<0.0001\***
  - ✓ **Overall survival (OS): HR=0.65, P=0.0029\***
  - ✓ **pCR rate: 55.8% vs. 32.5%, P<0.0001\***



- Regulatory applications accepted in Europe (Mar) and US (Apr<sup>\*\*</sup>)
  - ✓ US PDUFA date: Aug 17, 2026 (priority review)

## Potential upside in MIBC






- **Bladder-sparing MIBC**
  - ✓ ~30% of MIBC patients are ineligible for or refuse radical cystectomy (RC)
  - ✓ High unmet medical need for a treatment option that delays or avoids RC, and preserves the bladder
  - ✓ **Single-arm Phase 2 study (EV-209)<sup>2</sup>:** FSD in Apr 2026
    - MIBC patients who are eligible for but do not undergo RC
    - EV + pembro combo (EV: 9 x 21-day cycles)
    - Primary endpoints: clinical complete response (cCR) rate, bladder-intact EFS (BI-EFS) rate at 2 years
  - ✓ **Registrational Phase 3 study (EV-309)**
    - Under preparation to start in 1H/FY2026
- **China**
  - ✓ Regulatory application under preparation based on EV-303 and EV-304 studies























1. ASCO GU (American Society of Clinical Oncology Genitourinary Cancers Symposium) 2026, 2. [NCT07475806](#). \*1-sided P value, \*\*Apr 2026

chemo: Chemotherapy, cis: Cisplatin, FSD: First subject dosed, gem: Gemcitabine, HR: Hazard ratio, MIBC: Muscle-invasive bladder cancer, pCR: Pathological complete response, PDUFA: Prescription Drug User Fee Act, pembro: Pembrolizumab

# Progress in Focus Area Approach: FY2025 Achievements

**Significant pipeline progress: 3 PoCs achieved, 1 Phase 3 study initiated**  
**3 clinical entries, 2 promising assets in-licensed**

-  Flagship program
-  FSD Initiation of pivotal study
-  PoC PoC achieved
-  FSD Clinical entry
-  NEW Newly in-licensed

Primary Focus	Biology/ Modality/Technology	Program	MoA	Progress			
				Preclinical	Pre-PoC	PoC achieved	Pivotal study
Immuno-Oncology	T-cell engager	ASP2138	 Anti-CLDN18.2/anti-CD3			 <b>PoC</b>	G/GEJ
		VIR-5500	Anti-PSMA/anti-CD3				
	iADC	ASP2998	TROP2-targeted iADC				
Targeted Protein Degradation	Protein degradation	setidegrasib (ASP3082)	 KRAS G12D degrader			 <b>PoC</b>	 <b>FSD</b> <sup>*</sup> PDAC
		ASP5834	Pan-KRAS degrader				 <b>PoC</b> NSCLC
	Gene replacement (AAV)	AT845	 GAA gene				PoC judgement ongoing
Genetic Regulation		ASP2957	MTM1 gene				
Blindness & Regeneration	Cell replacement	ASP7317	 RPE cells			 <b>PoC</b>	
Others (non-PF)	ADC	ASP546C	ADC targeting CLDN18.2				

\*Apr 2026. AAV: Adeno-associated virus, iADC: (immunostimulatory) Antibody-drug conjugate, CLDN: Claudin, GAA: Acid alpha-glucosidase, G/GEJ: Gastric/gastroesophageal junction, KRAS: Kirsten rat sarcoma viral oncogene homologue, MoA: Mechanism of action, MTM1: Myotubularin 1, NSCLC: Non-small cell lung cancer, PDAC: Pancreatic ductal adenocarcinoma, PF: Primary focus, PoC: Proof of concept, PSMA: Prostate-specific membrane antigen, RPE: Retinal pigment epithelial, TROP2: Trophoblast cell-surface antigen 2

# Progress in Focus Area Approach: New Clinical Programs

## Next-generation innovative programs advancing into clinical development

### ASP2998

#### TROP2-targeted immunostimulatory ADC (iADC) with dual payloads

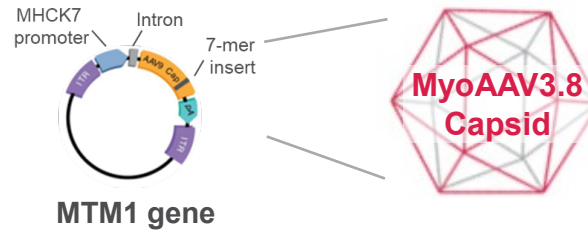
- Target disease: Solid tumor
- TROP2-directed monoclonal antibody conjugated with cytotoxic topoisomerase I inhibitor and immunomodulator STING agonist
- Superior efficacy vs. TROP2-directed toxin ADC demonstrated in mouse model<sup>1</sup>
- FSD in Phase 1b/2 study in Feb 2026 (NCT07287995)



### ASP2957

#### Next-generation gene therapy for XLMTM with novel AAV capsid

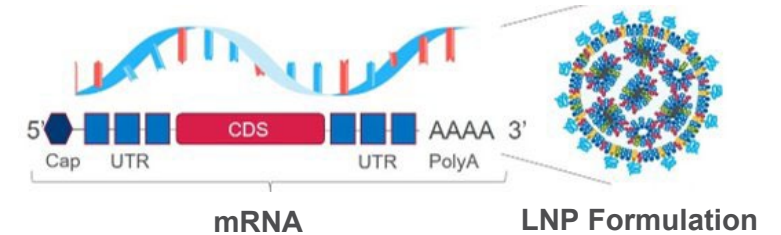
- Target disease: XLMTM
- Delivers a human MTM1 gene using a muscle-targeted MyoAAV3.8 capsid
- High muscle specificity and reduced liver targeting demonstrated in nonclinical studies<sup>2</sup>
- FSD in Phase 1/2 VALOR study in Apr 2026: ~100-fold lower dose level vs. AT132 (NCT07052929)



### ASP2246

#### Direct reprogramming using mRNA-LNP for ischemic stroke recovery

- Target disease: Motor dysfunction associated with ischemic stroke
- mRNA encoding human NeuroD1 encapsulated in novel LNP for neuronal regeneration
- Conversion of astrocytes into neurons and improved motor dysfunction in monkey model demonstrated<sup>3</sup>
- FSD in Phase 1/2 study anticipated for Q1/FY2026 (NCT07318714)



1. American Association for Cancer Research (AACR) 2026, 2. Muscular Dystrophy Association 2026, 3. International Stroke Conference 2026. See slide 37 for nonclinical data.

ADC: Antibody-drug conjugate, AAV: Adeno-associated virus, FSD: First subject dosed, LNP: Lipid nanoparticle, mRNA: Messenger RNA, MTM1: Myotubularin 1, STING: Stimulator of interferon genes, TROP2: Trophoblast cell-surface antigen 2, XLMTM: X-linked myotubular myopathy

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# FY2026 Outlook: Overview

**- Expected to reach record-high Revenue and OP -**

## ***FY2026 Forecast***

- Revenue: Over **2.2 trillion yen** (+4% YoY) driven by significant growth in Strategic Brands (**+130.0 bil. yen, +27% YoY**)
- Cost items: Continue cost optimization through SMT (**~40.0 bil. yen**)
  - ✓ SG&A expenses\*: Further improvement in SG&A ratio (-2.3ppt YoY)
  - ✓ R&D expenses: Expand investments from FY2026 onward aligned with Phase 3 study initiations
- Core OP: Over **600.0 bil. yen** (+12% YoY) and margin **27.9%** (+2.0ppt YoY)

## ***Pipeline***

- PADCEV: Multiple filings and regulatory decisions, Phase 3 study for bladder-sparing MIBC
- Phase 3 studies for setidegrasib and ASP2138

## ***Shareholder Return***

- Dividend per share forecasted at 80 yen, an increase of 2 yen

\*Excl. US XTANDI co-promote fee

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

SMT: Sustainable Margin Transformation, MIBC: Muscle-invasive bladder cancer

# FY2026 Forecast

- **Record-high Revenue over 2.2 trillion yen and Core OP over 600.0 billion yen**
- **Core OP margin to reach 27.9% driven by Strategic Brands growth and SMT cost optimization**

FX rates for FY2026 FCST: 150 yen/USD, 180 yen/EUR

FX rates for FY2025 Actual: 151 yen/USD, 175 yen/EUR

(billion yen)	FY2025 Actual	FY2026 FCST	Change	Main Assumptions
<b>Revenue</b>	<b>2,139.2</b>	<b>2,220.0</b>	<b>+80.8</b>	• Strategic Brands: approx. +130.0, XTANDI: approx. -50.0
SG&A expenses	860.3	800.0	-60.3	• SMT cost optimization: approx. 40.0 (mainly SG&A)
US XTANDI co-promote fee	248.2	216.0	-32.2	
SG&A excl. the above	612.1	584.0	-28.1	
(SG&A ratio*)	28.6%	26.3%	-2.3ppt	Factor for increase in R&D expenses:
R&D expenses	314.8	355.0	+40.2	• Mainly clinical development costs increase incl. Phase 3 study initiations (PADCEV & VYLOY LCM, setidegrasib, ASP2138, ASP546C, VIR-5500, etc.)
(R&D ratio)	14.7%	16.0%	+1.3ppt	
<b>Core operating profit</b>	<b>555.7</b>	<b>620.0</b>	<b>+64.3</b>	• Increase driven by Strategic Brands growth and SMT cost optimization
(Core OP margin)	26.0%	27.9%	+2.0ppt	

## <Full basis>

### Main adjustments excluded on core basis

<b>Operating profit</b>	<b>382.6</b>	<b>395.0</b>	<b>+12.4</b>	• Amortisation of intangible assets: approx. 140.0 • Other expenses: approx. 80.0 (risk of impairment losses**, expenses related to organizational restructuring, etc.)
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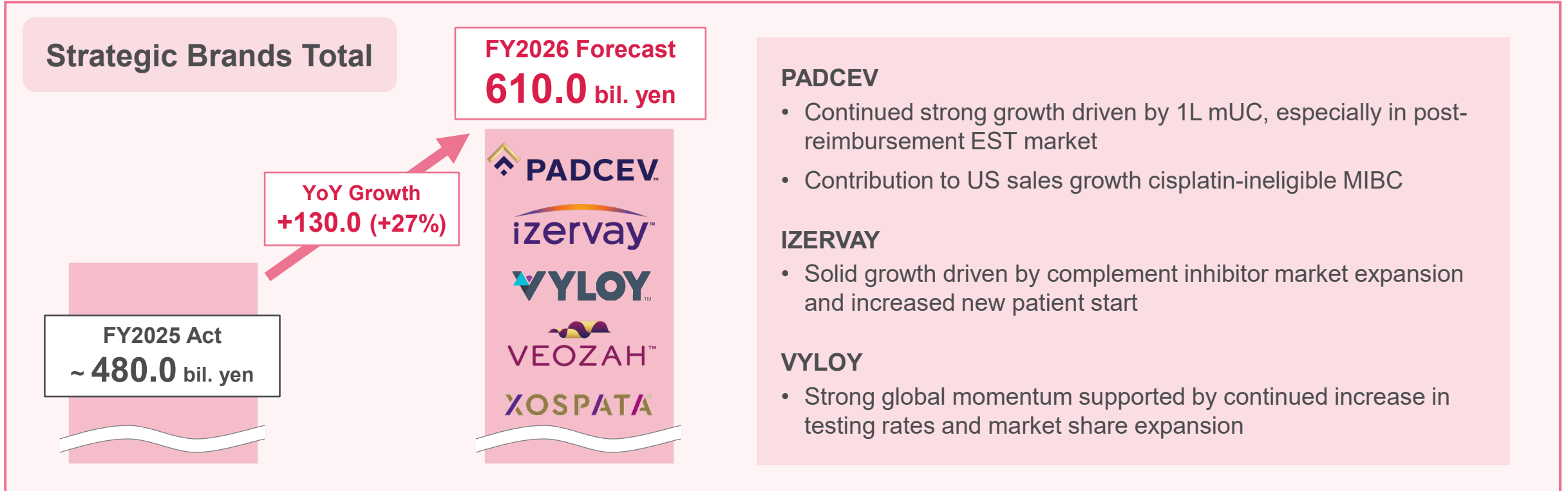
\*Excl. US XTANDI co-promote fee

Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA, SMT: Sustainable Margin Transformation, LCM: Lifecycle Management

\*\*No impairment indication as of April 2026

# FY2026 Forecast: Main Brands

Strategic Brands to **drive overall revenue and profit growth**, led by **PADCEV**, **IZERVAY** and **VYLOY**



FY2026 Forecast  
**910.0** bil. yen

- Project sales to decline against FY2025, primarily due to US IRA negative impact effective from Jan 2027





FX rates for FY2026 FCST: 150 yen/USD, 180 yen/EUR (FX rates for FY2025 Actual: 151 yen/USD, 175 yen/EUR). VEOZAH: Approved as "VEOZA" in ex-US. 1L: First line, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, IRA: Inflation Reduction Act, EST (Established Markets): Europe, Canada, etc.,

# Lifecycle Management of Strategic Brands: FY2026 Key Expected Events

*Expecting multiple regulatory events across Strategic Brands*

Regulatory activity

Study progress

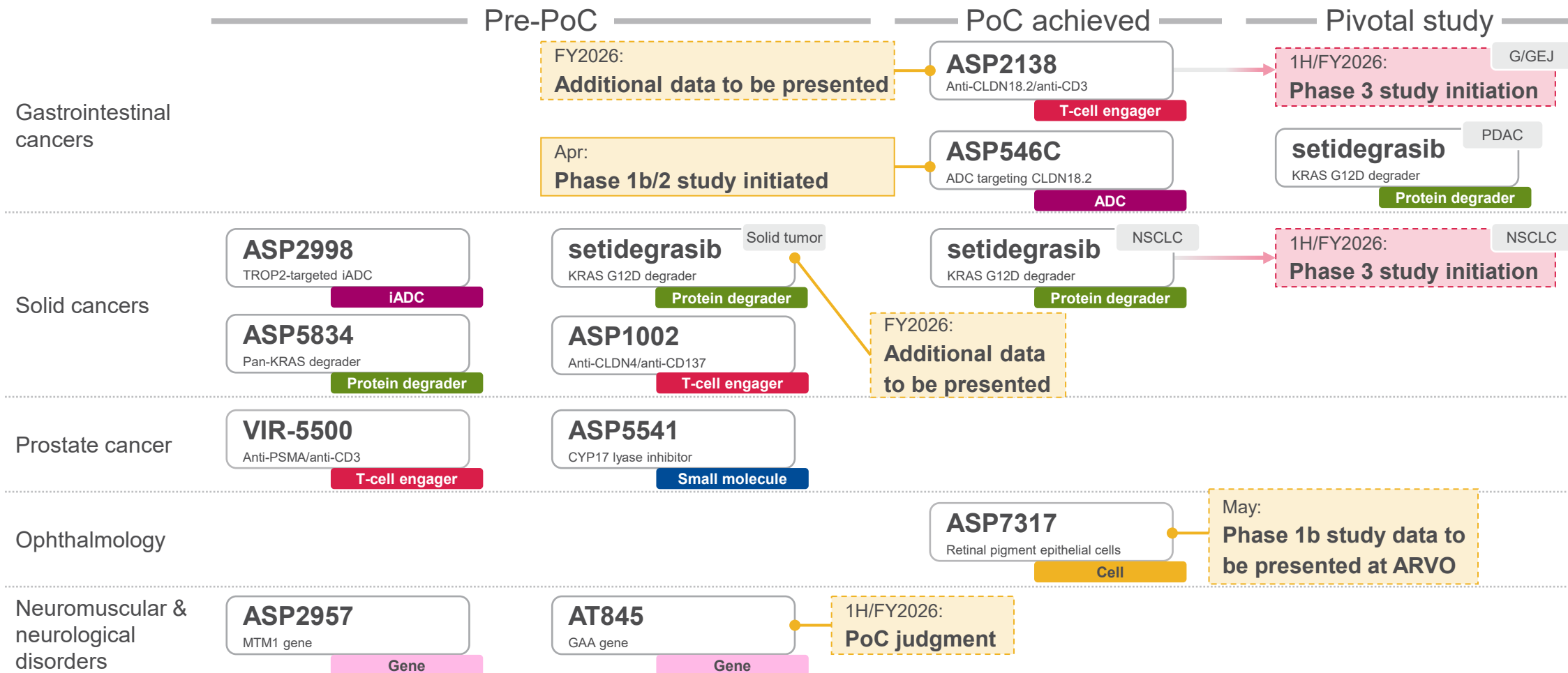
Brand	Indication	FY2026				FY2027+
		Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
	Cis-ineligible	Europe: Regulatory decision		Japan: Regulatory decision		
	Muscle-invasive bladder cancer (MIBC)	China: filing	US: Regulatory decision (PDUFA date: Aug 17)		Europe: Regulatory decision	
	Cis-eligible	Japan: filing				
	Bladder-sparing		Phase 3 EV-309 study initiation			
	GA secondary to AMD	China: filing				
	Gastric and GEJ cancer				Phase 3 LUCERNA study data readout	
	VMS associated with menopause	Phase 3 STARLIGHT 3 study data readout	Japan: filing	China: filing		
	VMS in breast cancer women				Phase 3 HIGHLIGHT 1 study data readout	

VEOZAH: Approved as "VEOZA" in ex-US

AMD: Age-related macular degeneration, Cis: Cisplatin, GA: Geographic atrophy, GEJ: Gastroesophageal junction, PDUFA: Prescription Drug User Fee Act, VMS: Vasomotor symptoms

# Progress in Pipeline: FY2026 Key Expected Events

**Phase 3 studies to be initiated for ASP2138 and setidegrasib (NSCLC)**



As of Apr 2026. Not exhaustively listed. (i)ADC: (immunostimulatory) Antibody-drug conjugate, ARVO: Association for Research in Vision and Ophthalmology, CLDN: Claudin, GAA: Acid alpha-glucosidase, G/GEJ: Gastric/gastroesophageal junction, KRAS: Kirsten rat sarcoma viral oncogene homologue, MTM1: Myotubularin 1, NSCLC: Non-small cell lung cancer, PoC: Proof of concept, PDAC: Pancreatic ductal adenocarcinoma, PSMA: Prostate-specific membrane antigen, TROP2: Trophoblast cell surface antigen-2

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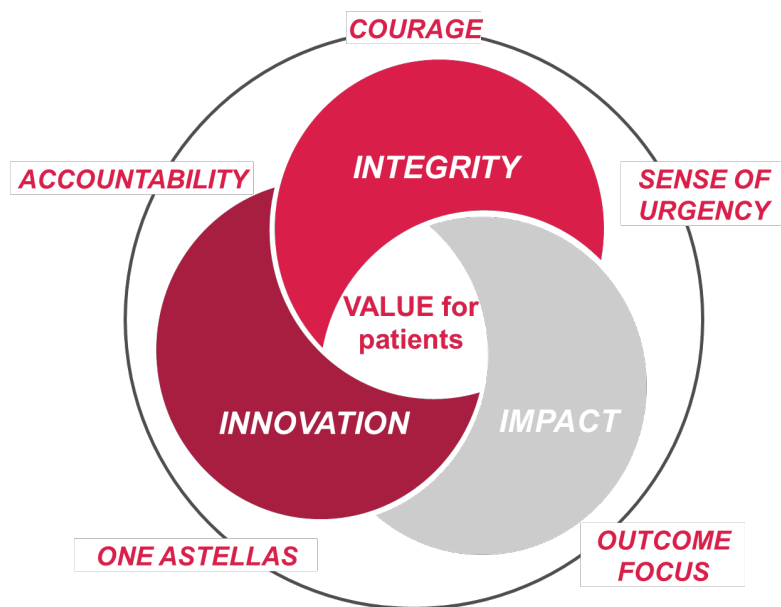
**Review of Corporate Strategic Plan 2021**

# Transformation of Organizational Culture and Operating Model

*Executed initiatives to continuously generate innovations and embedded them across company*

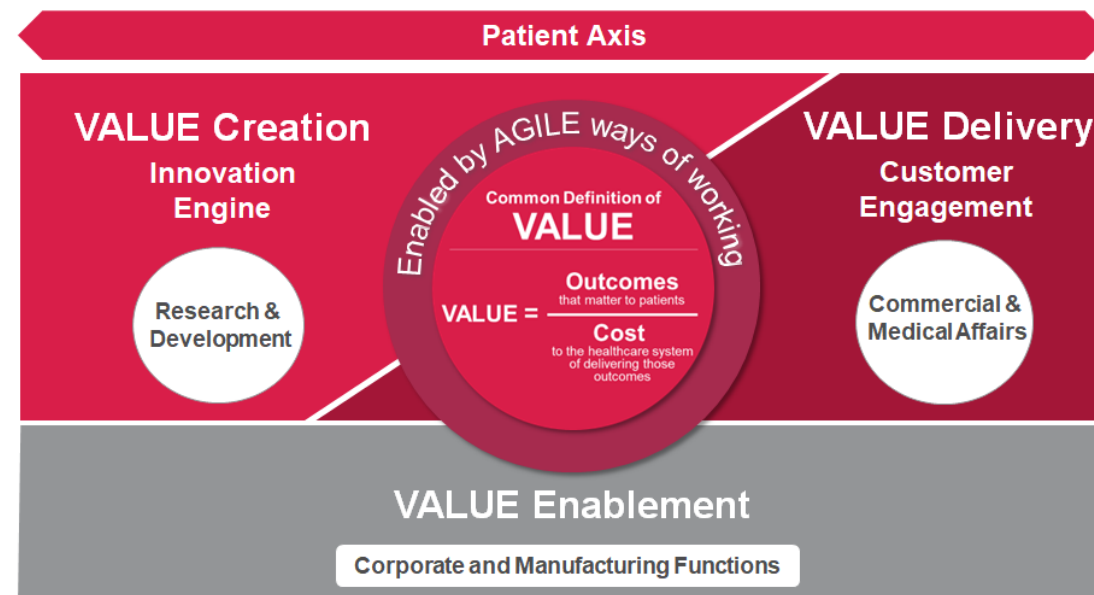
## Fostering organizational culture

- Set Organizational Health Goals
- Defined “Organizational Values & Behaviors” as a culture foundation



## End-to-end operating model

- Shift from region- or function-based to “patient axis”
- Enabled faster decision-making through empowerment and agile ways of working



# Review of Performance Goals in Corporate Strategic Plan 2021

*Established a foundation to overcome XTANDI LOE and deliver sustainable growth*

## Performance Goal 1

### Revenue:

XTANDI and Strategic Brands sales  
≥ ¥1.2T in FY2025

- Acquisition of Iveric Bio
- VEOZAH, IZERVAY, VYLOY launch
- Acceleration of LCM
- **Total sales: over ¥1.4T**

## Performance Goal 2

### Pipeline Value:

Focus Area projects expected sales  
≥ ¥0.5T in FY2030

- Transformation of R&D organization and capabilities
- Turnover of Primary Focuses and programs
- 12 clinical entries, addition of promising external assets
- **4 PoCs from 3 assets achieved**

## Performance Goal 3

### Core OP Margin:

≥ 30% in FY2025

- Formulation and execution of Sustainable Margin Transformation
- **Achieved cost optimization of ¥65.0B**
- **Core OP margin: 26.0% (+4.0ppt vs. FY2020)**

VEOZAH: Approved as "VEOZA" in ex-US

LCM: Lifecycle management, LOE; Loss of exclusivity, PoC: Proof of concept

# Three Enterprise Priorities

*Set “Three Enterprise Priorities” closely linked to Performance Goals and launched full-scale implementation in FY2024*



## **Growth Strategy**

- Maximize potential of Strategic Brands



## **Bold Ambition**

- Increase pipeline value



## **Sustainable Margin Transformation**

- Company-wide cost optimization

# Growth Strategy: Maximize Potential of Strategic Brands

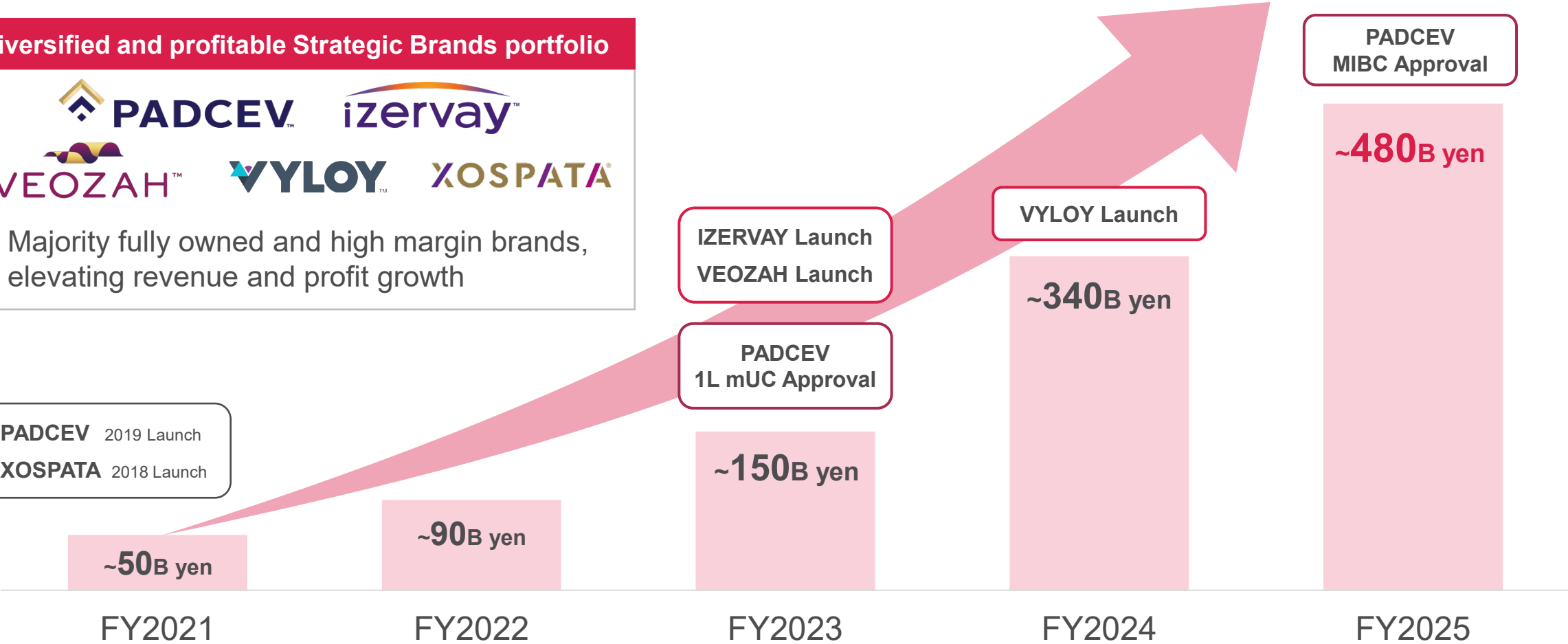
Strategic Brands delivered exceptional growth, Achieving **~10x growth over five years**

**Diversified and profitable Strategic Brands portfolio**



- Majority fully owned and high margin brands, elevating revenue and profit growth

PADCEV 2019 Launch  
XOSPATA 2018 Launch



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

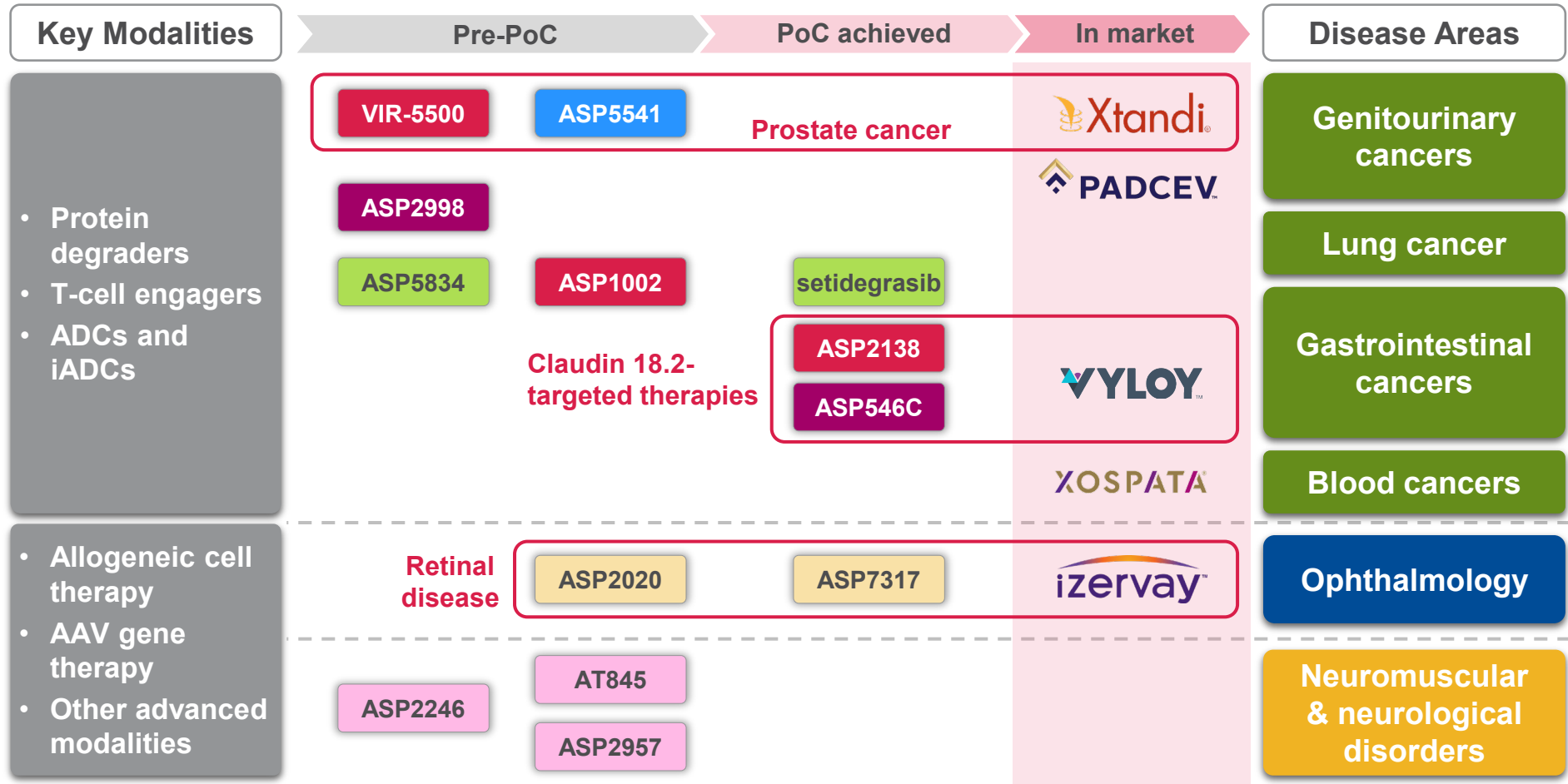
# Bold Ambition: Increase Pipeline Value

- **4 PoCs achieved** from 3 Primary Focus flagship programs
- **Forming franchises** by leveraging strengths, together with follow-on programs and external assets

## Primary Focuses



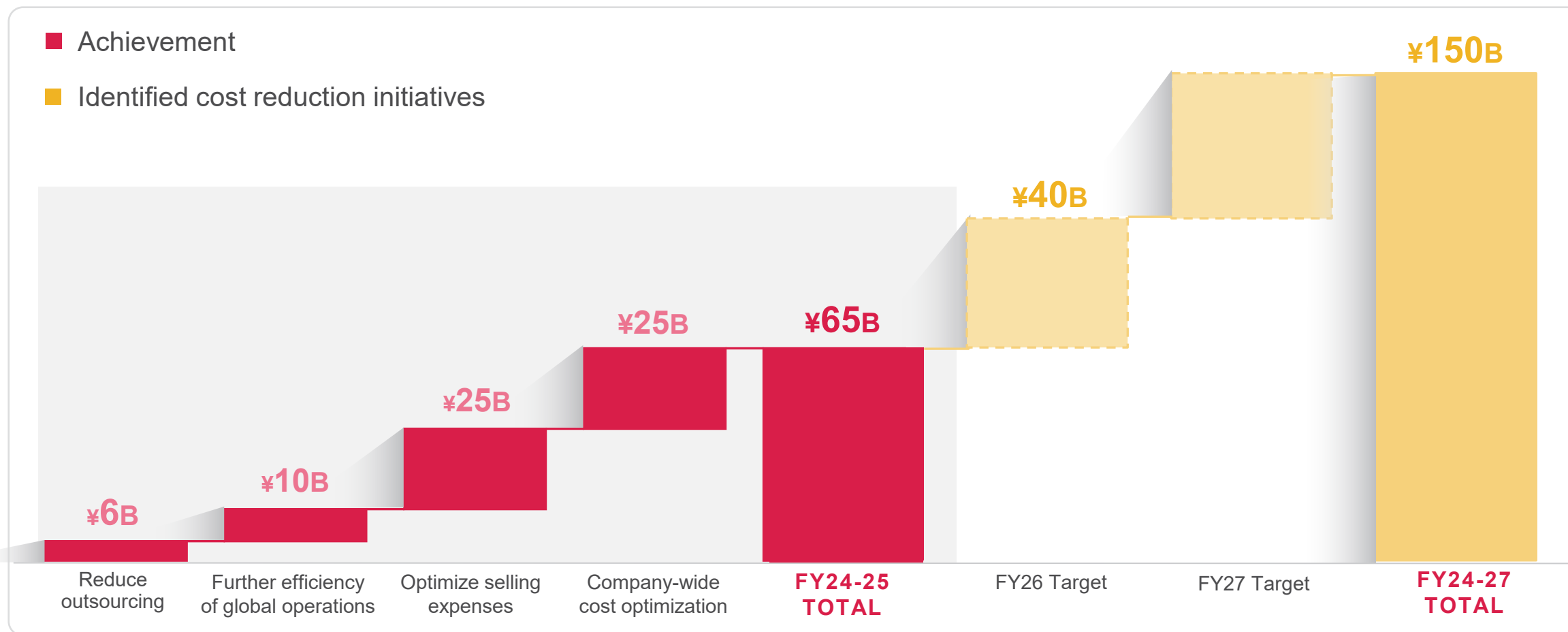
Biotech and Academic Partners



AAV: Adeno-associated virus, (i)ADC: (immunostimulatory) Antibody-drug conjugate, mRNA: messenger RNA, PoC: Proof of concept

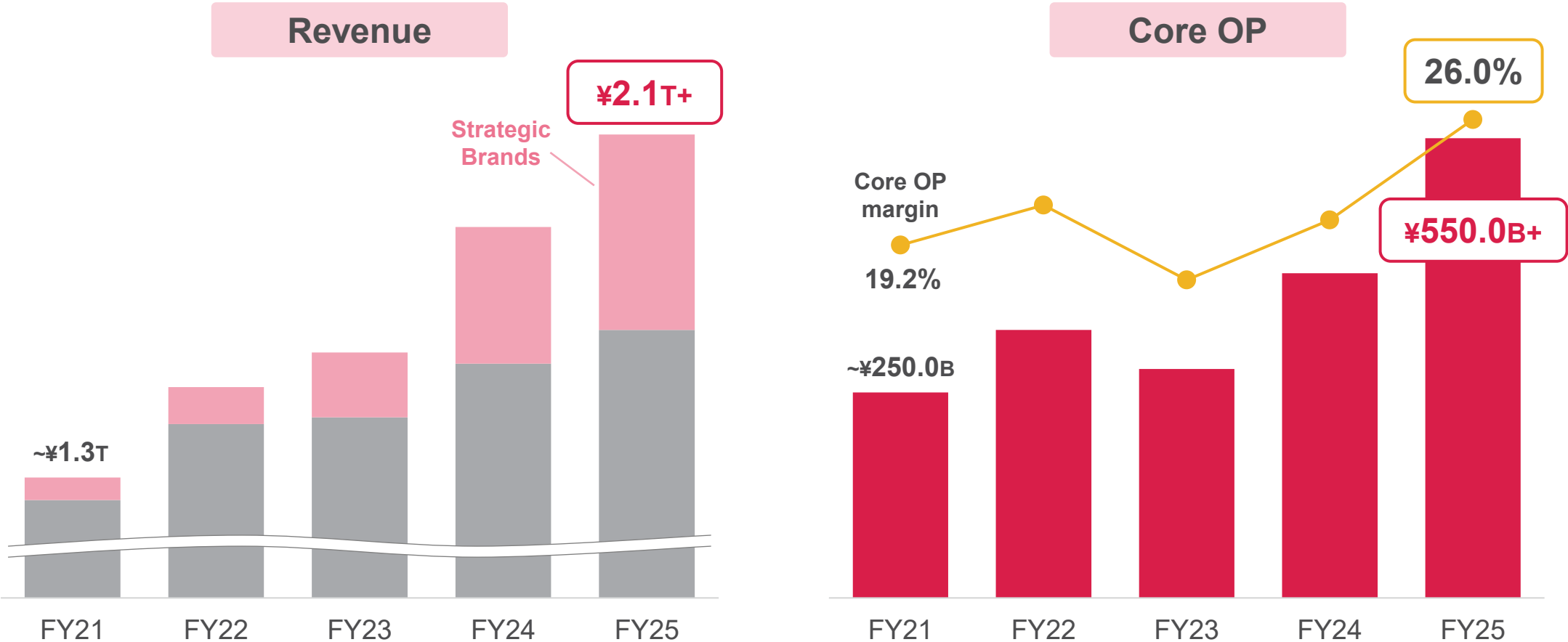
# Sustainable Margin Transformation: Company-wide Cost Optimization

- *Achieved cumulative total **65.0 bil. yen** cost optimization over 2 years*
- *Fully on track to achieve total cost optimization target of **150.0 bil. yen***



# Revenue and Core OP Growth over CSP2021 Period

Significant increase in **Revenue and Core OP** by **1.7x and 2.2x**, respectively, over 5 years



Core OP is based on the new definition introduced in FY2024. Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA  
 CSP: Corporate Strategic Plan

# Key Takeaways

*Established a foundation to overcome XTANDI LOE and deliver sustainable growth*



**Strategic Brands** delivered exceptional growth, raising prospects for further expansion



Established a **robust pipeline**, building confidence towards post-XTANDI LOE growth



Significant progress towards **resilient cost structure** driven by SMT cost optimization

# Upcoming Event



## **Corporate Strategic Plan 2026**

May 26th, 4:00 pm – 5:30 pm (JST)

# Appendix



## Strategic Brands: Potential Peak Sales (as of Apr 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 Apr 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, 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

# FY2025 Actual: FX Rate

## Average rate for the period

Currency	FY2024	FY2025	Change
USD	152 yen	151 yen	-2 yen
EUR	164 yen	175 yen	+11 yen

## <Impact of exchange rate on financial results>

- Revenue: 30.1 billion yen
- Core OP: 16.8 billion yen

# FY2026 Forecast: FX Rate & FX Sensitivity

Exchange rate Average for the period	FY2025	FY2026 FCST	Change
USD	151 yen	150 yen	-1 yen
EUR	175 yen	180 yen	+5 yen

## Estimated FX sensitivity FY2026 forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption	
	Revenue	Core OP
USD	Approx. 8.1 bil. Yen	Approx. 2.3 bil. yen
EUR	Approx. 3.8 bil. yen	Approx. 1.7 bil. Yen

# Balance Sheet & Cash Flow Highlights

(billion yen)	FY2024 end	FY2025 end
Total assets	3,339.5	3,567.0
Cash and cash equivalents	188.4	281.6
Total equity attributable to owners of the parent	1,513.3	1,829.0
Ratio of equity attributable to owners of the parent to total assets (%)	45.3%	51.3%

(billion yen)	FY2024	FY2025
Cash flows from operating activities	194.5	560.2
Cash flows from investing activities	-89.4	-66.7
Free cash flows	105.1	493.5
Cash flows from financing activities	-261.4	-404.8
Increase/decrease in short-term borrowings and commercial papers	-236.4	-185.6
Proceeds from issuance of bonds and long-term borrowings	200.0	-
Redemption of bonds and repayments of long-term borrowings	-52.1	-81.8
Dividends paid	-129.0	-136.1

# Balance of Bonds and Borrowings Highlights

(billion yen)	Dec 31, 2025	Mar 31, 2026
Balance of bonds and borrowings	725.3	566.0
Non-current liabilities	320.0	320.0
Bonds	220.0	220.0
Long-term borrowings	100.0	100.0
Current liabilities	405.3	246.0
Commercial papers	119.9	-
Short-term borrowings	20.0	-
Current portion of long-term borrowings	165.4	146.0
Current portion of bonds	100.0	100.0

# Main Intangible Assets (as of Mar 31, 2026)

	Bil. yen	Foreign currency**
AT845	11.5	\$73M
Gene therapy related technology*	61.0	\$384M
VEOZAH**	85.8	€471M
VYLOY**	54.6	€420M
IZERVAY (US)	572.7	\$3,609M
IZERVAY (Ex-US)	51.9	\$327M
ASP7317	27.3	\$172M

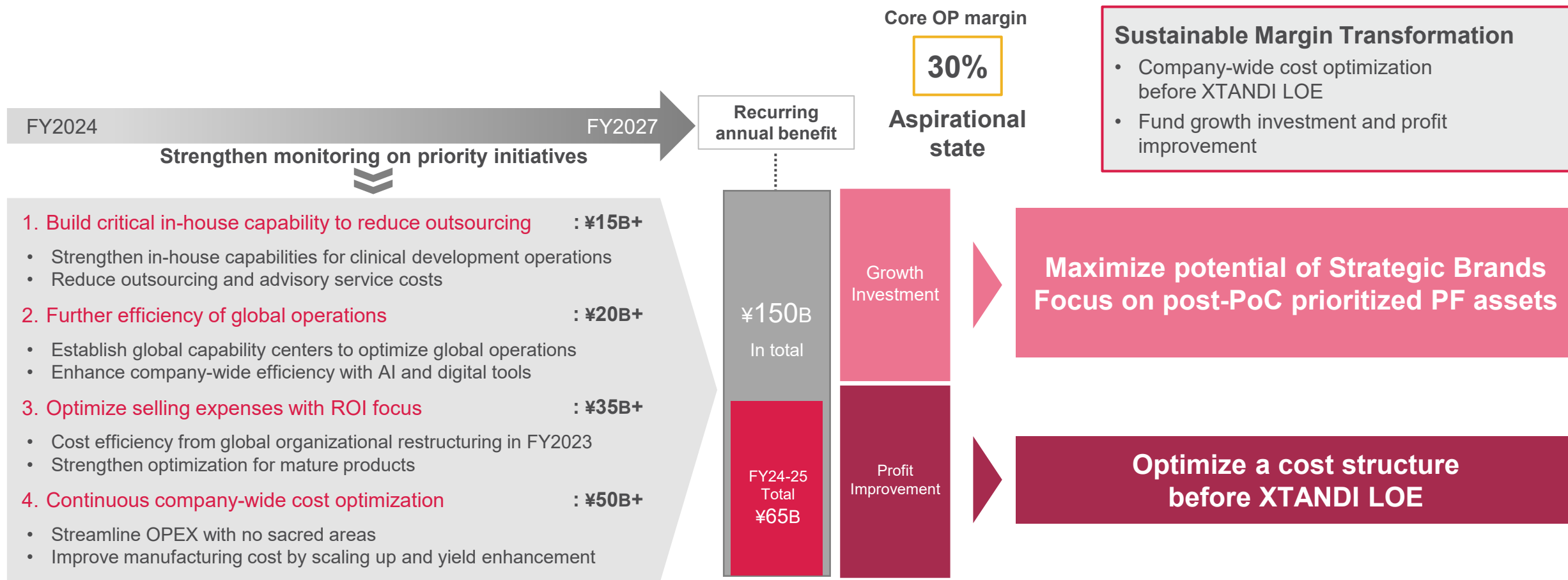
VEOZAH: Approved as "VEOZA" in ex-US

\*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**

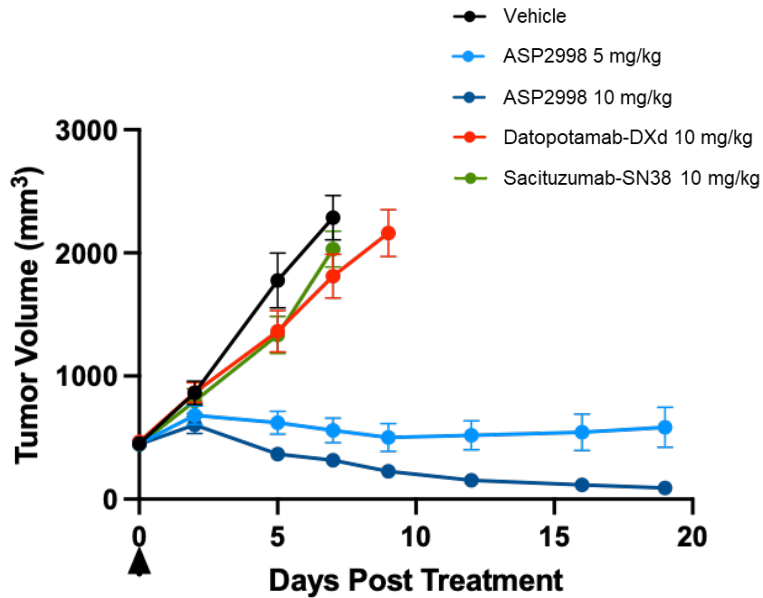


LOE: Loss of exclusivity, ROI: Return On Investment, PoC: Proof of concept, PF: Primary Focus

# Nonclinical data for New Programs

## ASP2998

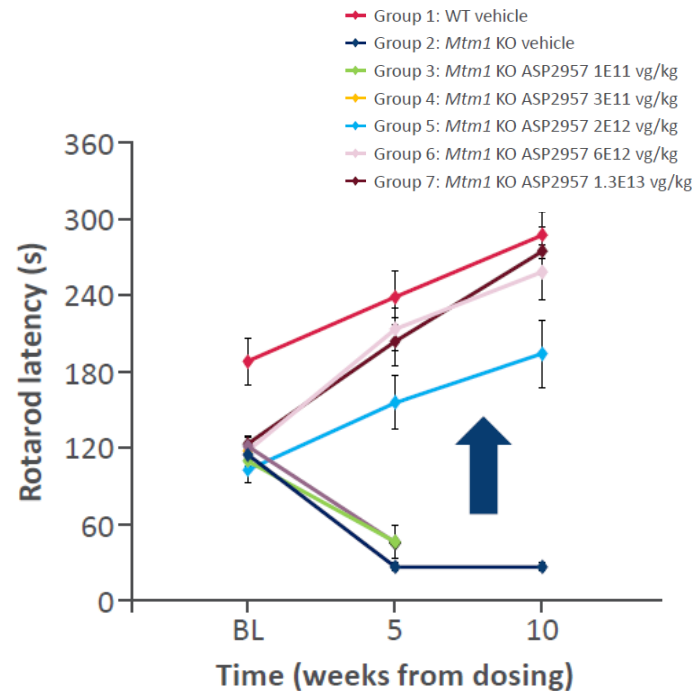
### Antitumor efficacy in mouse model<sup>1</sup>



MC38-huTROP2 cells were inoculated s.c. into C57BL/6 mice (N=10). Mice received a single i.v. administration Day 0.

## ASP2957

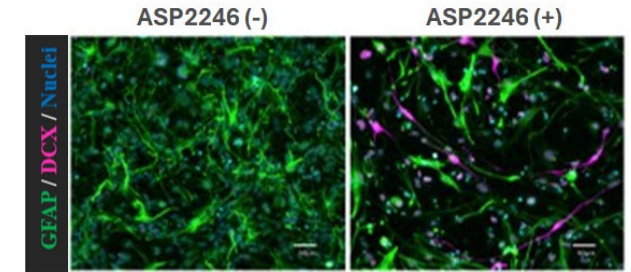
### Dose-dependent efficacy in mouse model (motor function)<sup>2</sup>



WT or *Mtm1* KO mice received a single i.v. administration Day 0.

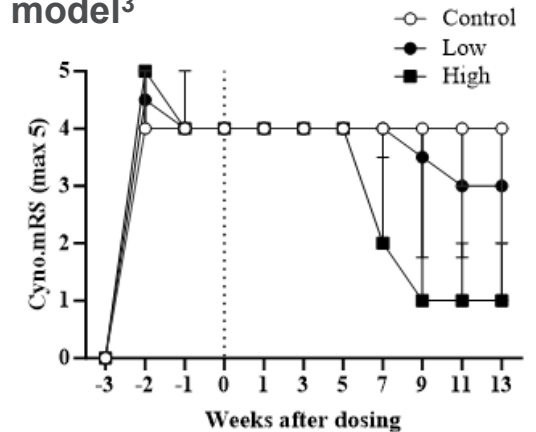
## ASP2246

### Neuronal induction from astrocyte<sup>3</sup>



Cell: U-251 (human astrocytoma)

### Motor function score in monkey chronic stroke model<sup>3</sup>



Monkeys were induced stroke at week -3 and received a single administration Day 0.

1. American Association for Cancer Research (AACR) 2026, 2. Muscular Dystrophy Association 2026, 3. International Stroke Conference 2026  
DCX: Doublecortin, KO: Knock out, TROP2: Trophoblast Cell Surface Antigen-2, WT: Wild type

# Robust Pipeline of Astellas

## Phase 1

gilteritinib (ALK-positive non-small cell lung cancer)
ASP2138
ASP1002
VIR-5500
ASP2998
setidegrasib
ASP5834
ASP7317
ASP2957
ASP546C
ASP5502

## Phase 2

enfortumab vedotin (Bladder-sparing MIBC)
gilteritinib (Newly diagnosed AML, HIC-ineligible)
zocaglusagene nuzaparvovec/ AT845 (Pompe disease)
abiraterone decanoate/ ASP5541/PRL-02 (Prostate cancer)

## Phase 3

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)
setidegrasib (Pancreatic ductal adenocarcinoma)
mirabegron (NDO, pediatric use (aged 6 months to less than 3 years): Europe)
roxadustat (Anemia associated with CKD, pediatric use: Europe)

## Submitted/Filed

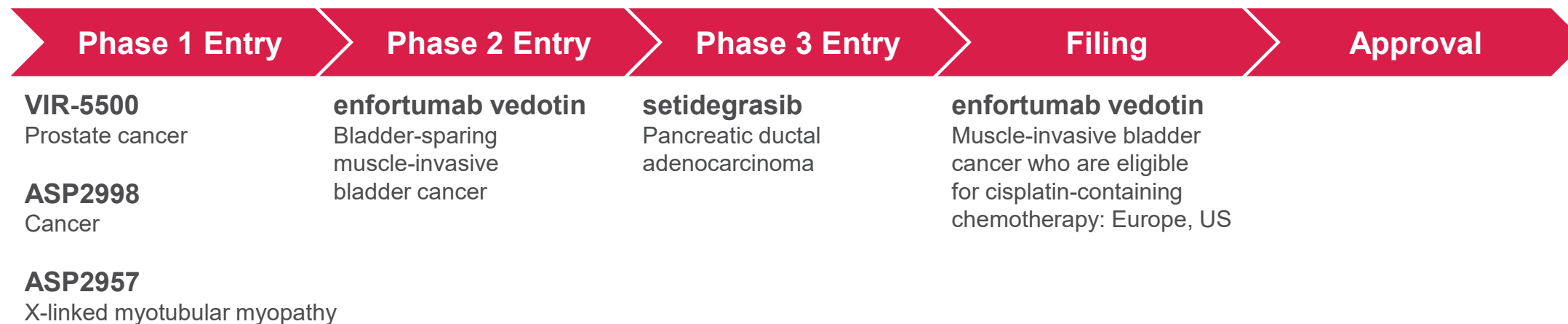
enfortumab vedotin (Cisplatin-ineligible MIBC: Europe, Japan)
enfortumab vedotin (Cisplatin-eligible MIBC: Europe, US)

- Strategic Brands
- Programs with Focus Area Approach
- Others

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

# Progress in Overall Pipeline

## Phase 1 Entry to Approval Since the Last Financial Results Announcement



### Discontinuation

**ASP1570:** Cancer (Phase 1)

**ASP5502:** Primary Sjogren's syndrome (Phase 1)

### Strategic halt

**AT132:** X-linked myotubular myopathy (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.

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

## Number of Eligible Patients

Patient segment		Pivotal study (EV regimen)	Number of eligible patients*
MIBC**	Cis-ineligible	<b>EV-303</b> (combo w/ Pembro)	<b>38,000</b>
	Cis-eligible	<b>EV-304</b> (combo w/ Pembro)	<b>59,000</b>
	Bladder-sparing	<b>EV-309</b> (combo w/ Pembro)	<b>34,000</b>
1L mUC		<b>EV-302</b> (combo w/ Pembro)	<b>115,000</b>
2L+ mUC (platinum & PD-1/L1 inhibitor pretreated)		<b>EV-301</b> (monotherapy)	<b>49,000</b>

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

\*\*MIBC patients intended for RC (EV-303/EV-304) and MIBC patients ineligible for RC or not intended for RC (excluding partial cystectomy or no treatment)



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

# enfortumab vedotin (EV) (2/4): Clinical Studies

(Blue: Updates since the last financial results announcement)

<b>P3: EV-303 /KEYNOTE-905</b>	<a href="#">NCT03924895</a>	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=595	sBLA approved in US in Nov 2025 Type II variation accepted in Europe in Nov 2025 sNDA submitted in Japan in Jan 2026
<b>P3: EV-304 /KEYNOTE-B15</b>	<a href="#">NCT04700124</a>	MIBC, Cis-eligible; EV + Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=808	Primary endpoint met <b>Type II variation accepted in Europe in Mar 2026</b> <b>sBLA accepted in US in Apr 2026</b>
<b>P2: EV-209</b>	<a href="#">NCT07475806</a>	<b>MIBC, eligible but do not undergo cystectomy; EV + Pembro (single-arm study)</b>	<b>n=240</b>	<b>FSD: Apr 2026</b>

# enfortumab vedotin (EV) (3/4): Study Data by Disease Stage

(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.	<b>KN-B15 / EV-304</b>	<b>KN-905 / EV-303</b>	<b>EV-302</b>	<b>EV-103 Cohort K</b>		<b>EV-103 Cohort A &amp; Others</b>	<b>EV-201 Cohort 2</b>	<b>EV-201 Cohort 1</b>	<b>EV-301</b>
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	✓ <b>EFS: HR 0.53*</b>	✓ 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	✓ <b>HR 0.65*</b> (NR vs. NR)	✓ 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)	✓ <b>HR 0.53*</b> (NR vs. 48.5 mos)	✓ 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)	✓ <b>55.8% vs. 32.5%*</b>	✓ 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*

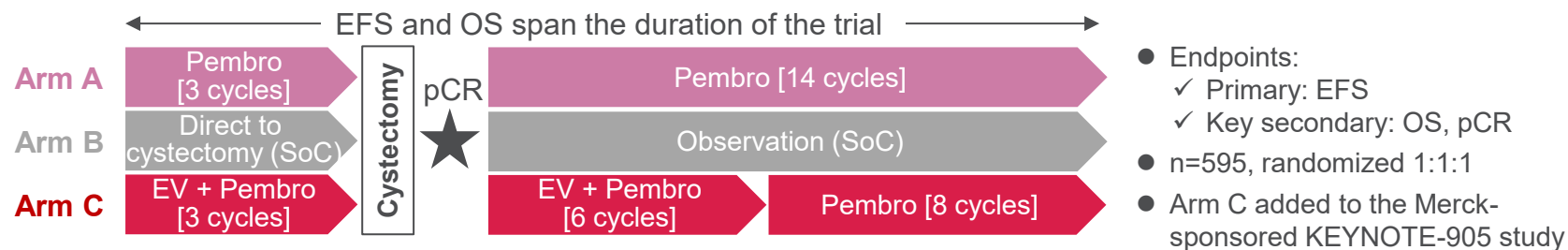
✓: Data obtained, \*: Prespecified interim analysis, \*\*: Updated data



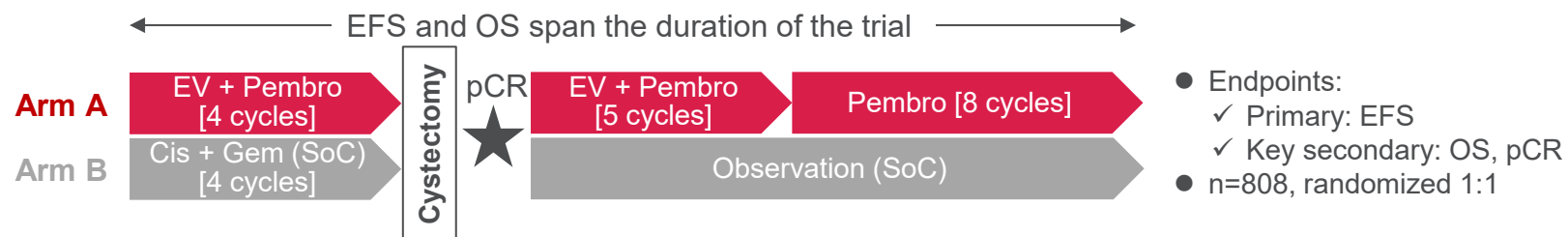
Chemo: Chemotherapy, Cis: Cisplatin, (p)CR: (Pathological) Complete response, DoR: Duration of response, EFS: Event-free survival, HR: Hazard ratio, MIBC: Muscle-invasive bladder cancer, mono: Monotherapy, mUC: Metastatic Urothelial cancer, ORR: Objective response rate, OS: Overall survival, Pembro: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

# enfortumab vedotin (EV) (4/4): 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 2 study in MIBC patients who are eligible but do not undergo cystectomy (EV-209): EV + Pembro



1 cycle = 21 days



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

# zolbetuximab: anti-Claudin 18.2 Monoclonal Antibody

## Overview

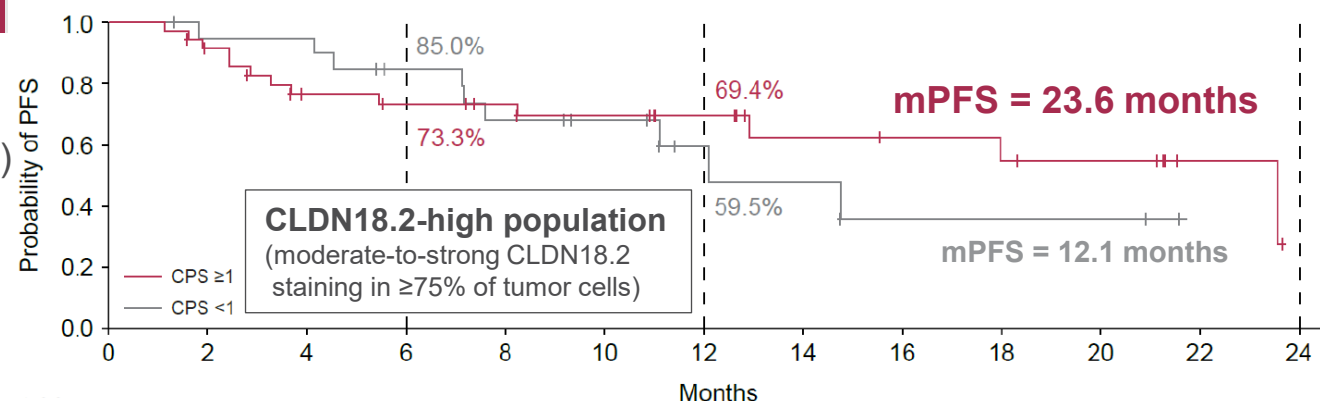
- Claudin (CLDN) is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- 38% of patients had CLDN18.2-positive tumors\* in SPOTLIGHT and GLOW studies for gastric and GEJ adenocarcinoma

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

- Phase 2 ILUSTRO study Cohort 4B (zolbetuximab + nivolumab + mFOLFOX6; moderate-to-strong CLDN18.2 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>



<b>P3: LUCERNA</b>	<a href="#">NCT06901531</a>	First line, combo with pembro and chemo vs. placebo + pembro + chemo (CAPOX or mFOLFOX6), CLDN18.2-high* and CPS $\geq 1$	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

1. ASCO GI 2026, 2. N Engl J Med. 2024;391:1159-62, 3. Lancet. 2021;398:27-40. \*CLDN18.2 positivity is defined as  $\geq 75\%$  of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining, chemo: Chemotherapy, CPS: Combined positive score, FLOT: Fluorouracil, leucovorin, oxaliplatin and docetaxel, FSD: First subject dosed, GEJ: Gastroesophageal junction, mFOLFOX6: 5-FU, leucovorin and oxaliplatin, mPFS: Median progression-free survival, pembro: Pembrolizumab

# 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	<b>Primary endpoint met</b>

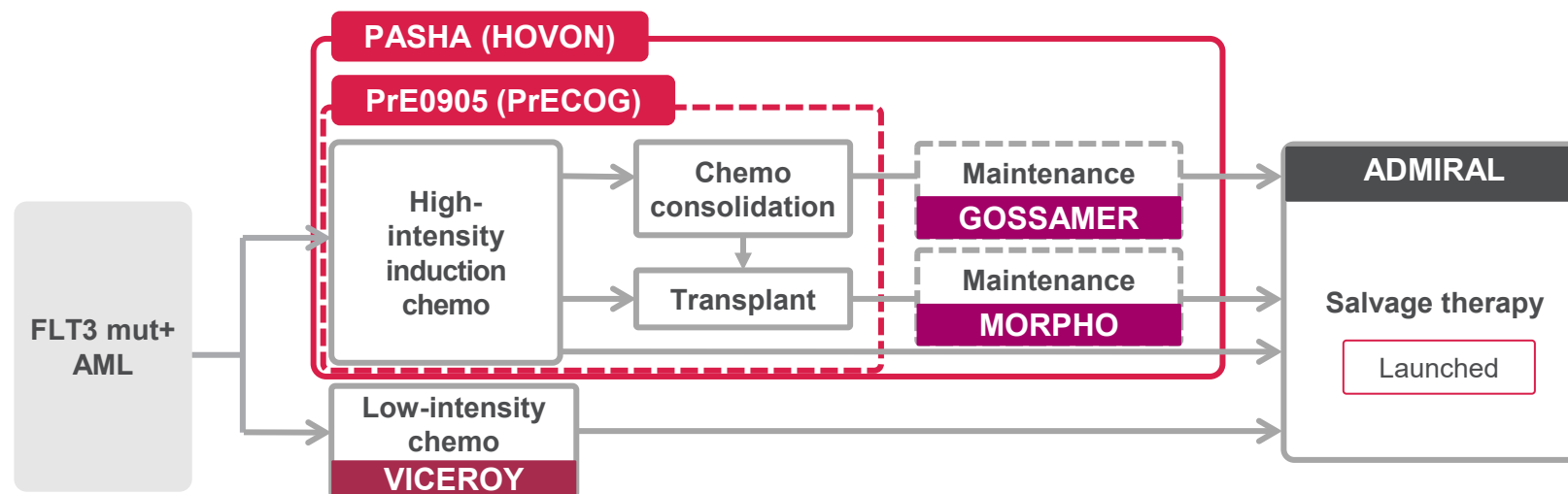
## VMS in breast cancer women receiving adjuvant endocrine therapy

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  
DB: Double-blind, FSD: First subject dosed, HRT: Hormone replacement therapy, NK3: Neurokinin 3, QoL: Quality of life, VMS: Vasomotor symptoms

# 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	<b>Primary endpoint not met</b>
	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

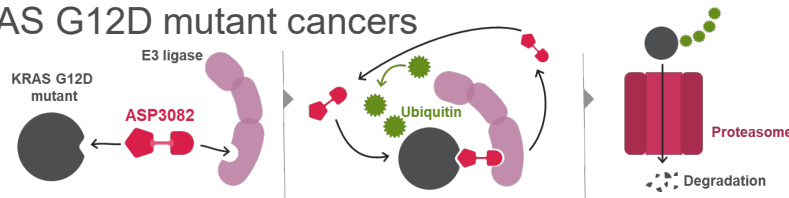
ALK-positive	P1	<a href="#">NCT07140016</a>	Monotherapy	n=40	FSD: Oct 2025
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ALK: Anaplastic lymphoma kinase, AML: Acute myeloid leukemia, ASH: American Society of Hematology, Chemo: Chemotherapy, FLT3 mut+: FLT3 mutation positive, FSD: First subject dosed, HIC: High-intensity chemotherapy, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands

# Progress in setidegrasib

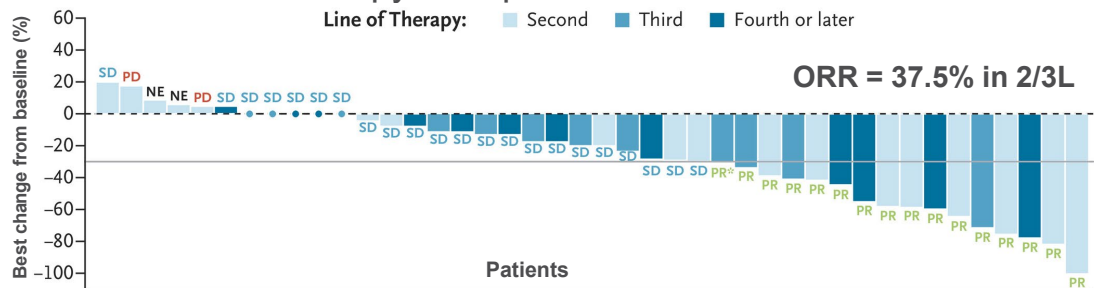
## Overview

- Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~5% in NSCLC<sup>1</sup>
- Phase 1 study ongoing (NCT05382559)
  - ✓ Data generation in progress to support development in other KRAS G12D mutant cancers



## Non-small cell lung cancer (NSCLC)

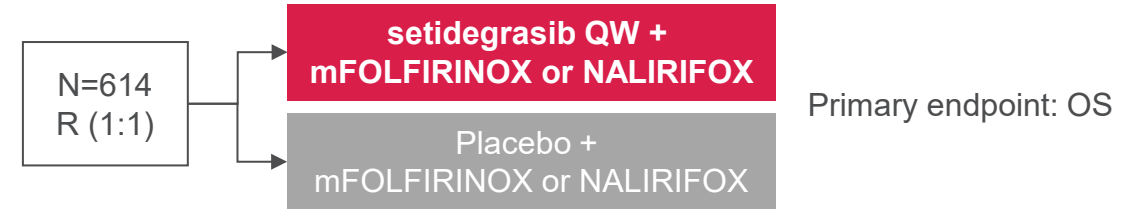
- Phase 3 study in 2L+ NSCLC under preparation
  - ✓ Primary analysis anticipated: FY2028
- PoC achieved
  - ✓ 2L+ monotherapy data presented at ELCC 2026 and NEJM<sup>2</sup>



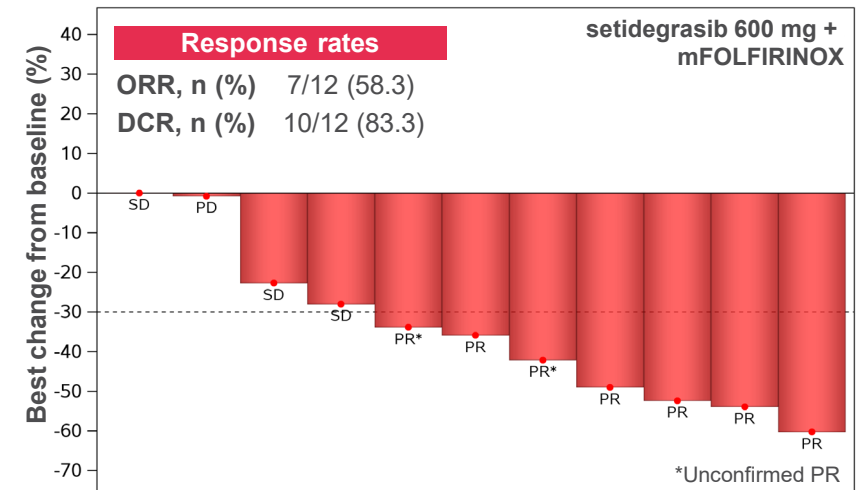
1. npj Precis Oncol. 2022;6:91, 2. N Engl J Med 2026 Mar; doi: 10.1056/NEJMoa2600752. 1L: First line, 2L+: Second or later line, ASCO GI: American Society of Clinical Oncology Gastrointestinal Cancers Symposium, DCR: Disease control rate, ELCC: European Lung Cancer Conference, KRAS: Kirsten rat sarcoma viral oncogene homologue, mFOLFIRINOX: Leucovorin, fluorouracil, irinotecan and oxaliplatin, NALIRIFOX: Leucovorin, fluorouracil, liposomal irinotecan and oxaliplatin, NEJM: The New England Journal of Medicine, ORR: Objective response rate, OS: Overall survival, PoC: Proof of concept

## Pancreatic ductal adenocarcinoma (PDAC)

- Phase 3 study in 1L PDAC ongoing (NCT07409272)
  - ✓ Primary analysis anticipated: FY2029 (interim analysis)





- PoC achieved
  - ✓ 1L data presented at ASCO GI 2026



# Pipeline of Primary Focus Targeted Protein Degradation

(Blue: Updates since the last financial results announcement)

Program	Mechanism of Action	Target Disease	Origin/Partner	Current Phase	Recent Updates
setidegrasib	KRAS G12D degrader	KRAS G12D+ solid tumor		<b>Phase 3</b>	<ul style="list-style-type: none"> <li>PDAC: PoC achieved, <b>Phase 3 study initiated</b></li> <li>NSCLC: PoC achieved, <b>Phase 3 study planned to start in 1H/FY2026</b></li> </ul>
ASP5834	Pan-KRAS degrader	KRAS+ solid tumor		<b>Phase 1</b>	<ul style="list-style-type: none"> <li>Fast Track Designation granted by FDA in NSCLC, <b>PDAC and CRC</b></li> </ul>
Undisclosed	Undisclosed	Cancer		<b>Discovery</b>	
Undisclosed	Undisclosed	Cancer		<b>Discovery</b>	
Undisclosed programs	Degrader / DAC / etc.	Cancer / Non-oncology		<b>Discovery</b> :	

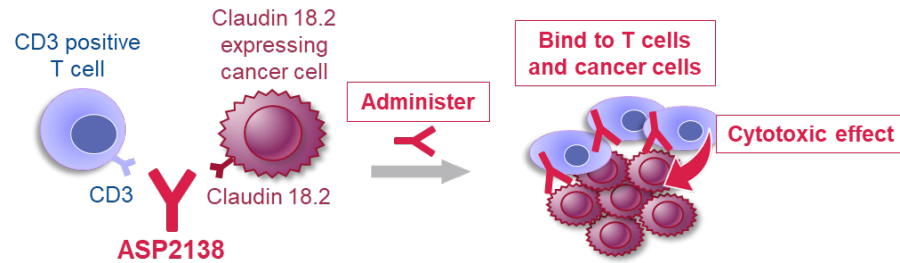
CRC: Colorectal cancer, DAC: Degrader-antibody conjugate, FDA: Food and Drug Administration, KRAS: Kirsten rat sarcoma viral oncogene homologue, NSCLC: Non-small cell lung cancer, PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept

# Progress in ASP2138

## Overview

### 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>1</sup> and ~60% in PDAC<sup>2</sup>



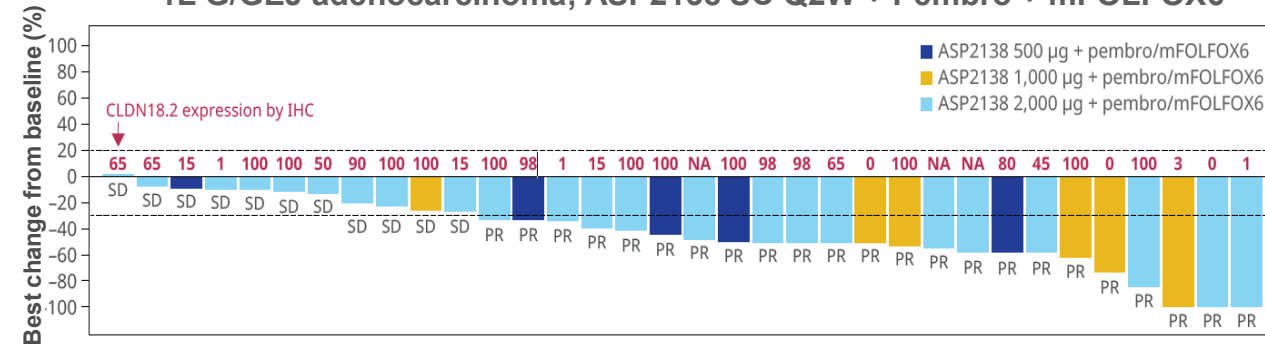
## Current status

- Phase 3 study in 1L G/GEJ under preparation
  - ✓ Patients with low-intermediate CLDN18.2 expression
  - ✓ Primary analysis anticipated: FY2029
- Phase 1 studies ongoing ([NCT05365581](#), [NCT07024615](#))
- PoC achieved in G/GEJ adenocarcinoma

## Latest data<sup>3</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 low-intermediate and high CLDN18.2 expression levels**




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



\*Represents % of patients with any level of CLDN18.2+ staining (≥1%; cf. ≥75% for VYLOY), 1. Gastric Cancer. 2024;27:1058, 2. Int J Cancer. 2013;134:731, 3. European Society for Medical Oncology (ESMO) 2025  
 1L: First line, 2L: Second line, CLDN: Claudin, DCR: Disease control rate, G/GEJ: Gastric/Gastroesophageal junction, mFOLFOX6: 5-FU, leucovorin and oxaliplatin, ORR: Objective response rate, PDAC: Pancreatic ductal adenocarcinoma, Pembro: Pembrolizumab, PoC: Proof of concept, SC: Subcutaneous, SoC: Standard of care

# 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>low-intermediate</b> CLDN18.2+ population in 1L G/GEJ cancer</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

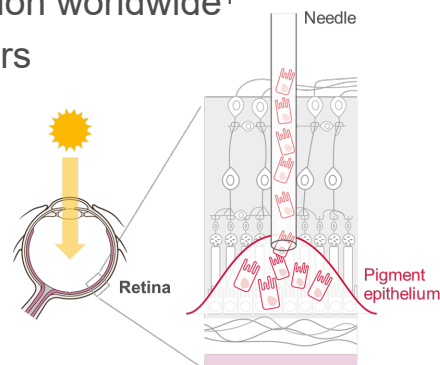
Chemo: Chemotherapy, CLDN: Claudin, CPI: Checkpoint inhibitor, G/GEJ: Gastric/gastroesophageal junction, PDAC: Pancreatic ductal adenocarcinoma, SC: Subcutaneous, SoC: Standard of care

# Progress in ASP7317

## Overview

### Transplantation of 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

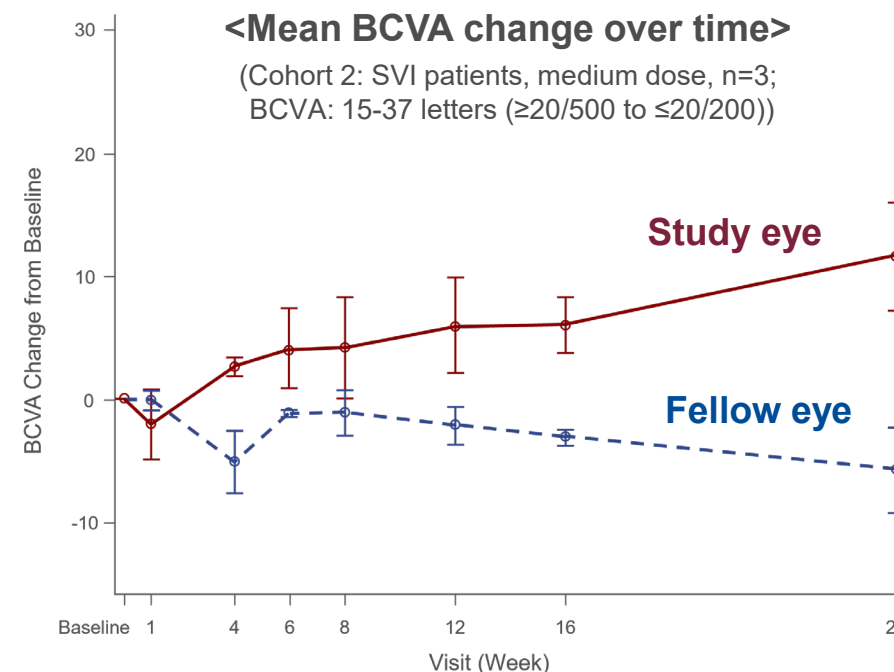


## Current status

- Phase 1b study ongoing ([NCT03178149](#))
- PoC achieved in patients with severe vision impairment due to GA

## Latest data

- Initial data from Phase 1b study presented at Retinal Therapeutics Innovation Summit 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



1. Retina. 2017;37:819-835

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

# Progress in AT845

## Overview

### 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>

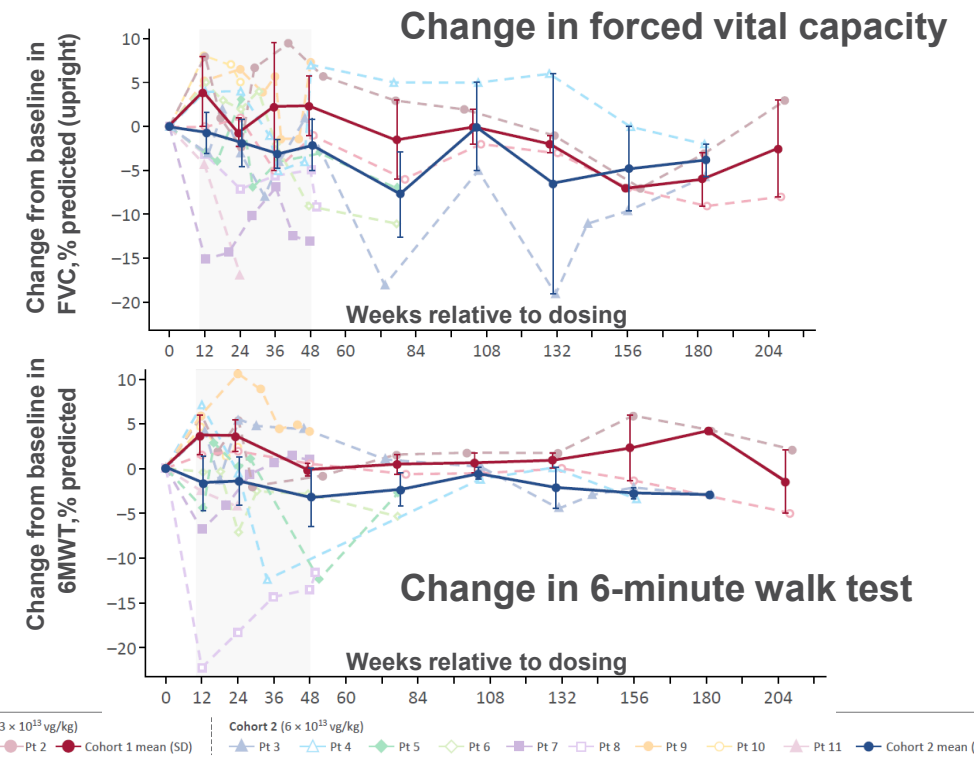


## Current status

- Phase 1/2 FORTIS study ongoing ([NCT04174105](https://clinicaltrials.gov/ct2/show/study/NCT04174105))
- RMAT designation granted by FDA in Feb 2025
- PoC analysis ongoing

## Latest data

- Follow-up data from Phase 1/2 FORTIS study presented at *WORLDSymposium 2026*
  - ✓ Of the 6 participants with ≥1 year follow-up, 5 remained off ERT between 1 and >3.5 years



FORTIS study data cut off: Jul 22, 2025, 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. AAV: Adeno-associated virus, FDA: Food and Drug Administration, hGAA: Human acid alpha-glucosidase, PoC: Proof of concept, RMAT: Regenerative Medicine Advanced Therapy

# VIR-5500

## Overview

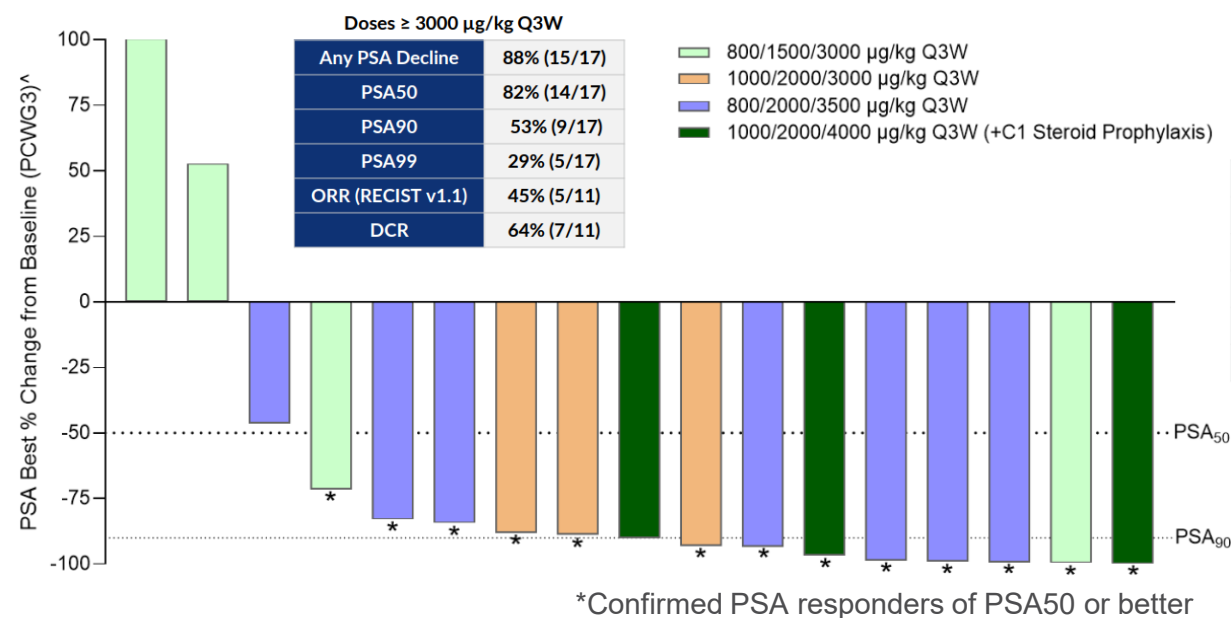
### Dual-masked CD3 T-cell engager targeting PSMA

- Target disease: Prostate cancer
- Phase 1 study ongoing ([NCT05997615](#))

## Latest data

- Preliminary Phase 1 monotherapy dose escalation data presented at ASCO GU 2026<sup>1</sup>
  - ✓ **Encouraging RECIST and PSA responses observed** in heavily pre-treated mCRPC patients
  - ✓ **45% ORR**, 1 patient in treatment for ~300 days
  - ✓ **No DLT**; CRS Mainly Grade 1, Despite No Prophylaxis

### PSA-evaluable participant dosed at $\geq 3000$ $\mu\text{g}/\text{kg}$ Q3W



1. ASCO GU (American Society of Clinical Oncology Genitourinary Cancers Symposium) 2026

PSA50: PSA decline of 50%-100% from baseline, PSA90: PSA decline of 90%-100% from baseline, PSA99: PSA decline of 99%-100% from baseline

CRS: Cytokine release syndrome, DCR: Disease control rate, DLT: dose limiting toxicity, mCRPC: metastatic Castration-Resistant Prostate Cancer, ORR: Objective response rate, PSA: Prostate-specific antigen, PSMA: Prostate-Specific Membrane Antigen, RECIST: Response Evaluation Criteria in Solid Tumors