Q2 YTD/FY2026 Financial Results

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Astellas Tsukuba Research Center

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Q2 YTD/FY2026 Overview

- Strong Progress Outperforming Expectations, Upward Revision of Full-Year Forecast -

- Continued Progress in Strengthening the Pipeline across all Stages -

Q2 YTD Financial Results

- ✓ Robust growth in Revenue (**+23%** YoY) and Core OP (**+50%** YoY)
- ✓ Driven by strong Strategic Brands growth and disciplined cost optimization, with favorable FX impacts

FY2026 Full-Year Revised Forecast

- ✓ Upward revision of Revenue (**+110** bil. Yen) and Core OP (**+80** bil. Yen) reflecting strong business performance
- ✓ Core OP expected to reach **700** billion Yen and **achieve 30% Core OP margin**

Pipeline Progress

- ✓ Strategic Brands: PADCEV approval for cisplatin-eligible MIBC (Europe), VEOZAH filing (Japan, China)
- ✓ Two Phase 3 studies FSD achieved (setidegrasib NSCLC, ASP2138 G/GEJ)
- ✓ PoC achieved (ASP6958/VIR-5500 mCRPC)
- ✓ Three new programs advanced into clinical stage (ASP388B, ASP2020, ASP2767)

Strategic Brands: PADCEV, IZERVAY, VYLOY, VEOZAH, XOSPATA. VEOZAH: Approved as “VEOZA” in ex-US. See slide 23 for overview of cost optimization
FSD: First subject dosed, G/GEJ: Gastric/gastroesophageal junction, mCRPC: Metastatic castration-resistant prostate cancer, MIBC: Muscle-invasive bladder cancer, NSCLC: Non-small cell lung cancer, PoC: Proof of concept

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Agenda

I **Q2 YTD/FY2026 Consolidated Financial Results**

FY2026 Revised Forecast

II **Pipeline Progress**

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Q2 YTD/FY2026 Financial Results

Significant growth across Revenue, Core OP and Full OP

(billion yen)	Q2 YTD FY2025	Q2 YTD FY2026	Change	Change (%)	FX impact (YoY)	FY2026 Initial FCST*
Revenue	**1,030.1**	**1,270.9**	**+240.7**	**+23.4%**	+99.3	**2,220.0**
Cost of sales	200.4	247.9	+47.5	+23.7%	+14.1	445.0
SG&A expenses	403.8	430.4	+26.5	+6.6%	+33.8	800.0
US XTANDI co-promote fee	127.2	131.8	+4.7	+3.7%	+11.0	216.0
SG&A excl. the above	276.7	298.5	+21.9	+7.9%	+22.8	584.0
(SG&A ratio**)	26.9%	23.5%	-3.4ppt			26.3%
R&D expenses	143.3	167.7	+24.4	+17.0%	+10.3	355.0
(R&D ratio)	13.9%	13.2%	-0.7ppt			16.0%
Core operating profit	**282.6**	**424.9**	**+142.3**	**+50.3%**	+41.2	**620.0**
(Core OP margin)	27.4%	33.4%	+6.0ppt			27.9%
＜Full basis＞						
Amortisation of intangible assets	65.5	71.3	+5.8	+8.8%		
Other income	5.2	2.5	-2.7	-52.7%		
Other expenses	25.4	38.2	+12.8	+50.3%		
Operating profit	**199.4**	**316.6**	**+117.2**	+58.8%		**395.0**
Profit before tax	194.6	317.5	+122.8	+63.1%		385.0
Profit	**147.6**	**241.5**	**+93.9**	+63.6%		**300.0**

*Disclosed in Apr 2026, **Excl. US XTANDI co-promote fee
Actual exchange rates of Q2 YTD/FY2026: 159 yen/USD, 184 yen/EUR (Actual exchange rates of Q2 YTD/FY2025: 146 yen/USD, 168 yen/EUR)
Exchange rate assumption of FY2026 initial FCST: 150 yen/USD, 180 yen/EUR

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Q2 YTD/FY2026 Financial Results: Main Brands

Strategic Brands achieved over 50% YoY growth, led by PADCEV, IZERVAY and VYLOY

(billion yen)	Q2 YTD/FY2026	YoY Growth
Strategic Brands Total	**333.9**	**+113.4 (+51%)**
PADCEV	158.3	+55.9 (+55%)
izervay	56.2	+22.0 (+65%)
VYLOY	45.9	+19.3 (+73%)
VEOZAH	30.7	+7.7 (+34%)
XOSPATA	42.9	+8.4 (+25%)
Xtandi	533.7	+56.7 (+12%)

Full-year forecast for Strategic Brands total raised to 680 bil. Yen
Primarily reflecting strong PADCEV performance

PADCEV

- Continued growth driven by further penetration in global 1L mUC and US MIBC
- Full-year forecast raised, primarily reflecting strong US and EST performance

IZERVAY

- Increasing adoption among retinal specialists and expansion of treated GA patient population, driving solid sales growth in line with expectations

VYLOY

- Continued penetration across all regions, driving solid sales growth in line with expectations

Sales broadly in line with prior-year period excl. FX impact, with sales expected to decline in 2H due to US IRA impact

VEOZAH: Approved as “VEOZA” in ex-US.
1L: First line, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, GA: Geographic atrophy, IRA: Inflation Reduction Act, EST (Established Markets): Europe, Canada, etc.

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Q2 YTD/FY2026 Financial Results: Cost Items

- ***SG&A expenses* held flat YoY through disciplined management, ratio improved by 3.4ppt YoY***
- ***Cost optimization (SMT): Approx. -22 billion Yen YoY (Total of SG&A expenses, R&D expenses, cost of sales)***

(yen)

Cost Items	YoY change	Ratio to Revenue	
SG&A expenses (excl. US XTANDI co-promote fee)	+7.9% (-0.3% excl. FX impact)	SG&A ratio: 23.5%	Held flat YoY excl. FX impact • Increase in Strategic Brands-related investments for further growth • SMT cost optimization: approx. -10 bil. ✓ Efficiency benefits from Global Capability Center establishment, AI and digital capabilities ✓ Standardization of promotional content and streamlined content development, etc.
R&D expenses	+17.0% (+9.9% excl. FX impact)	R&D ratio: 13.2%	YoY increase excl. FX impact: approx. +14 bil. • Increase in pipeline clinical development costs: approx. +11 bil. ✓ setidegrasib, ASP2138, ASP546C, ASP6958/VIR-5500, etc. • SMT cost optimization: approx. -8 bil. ✓ Outsourcing costs reduction through insourcing development capabilities, incl. clinical trials, etc.

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

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FY2026 Revised Forecast

- ***Upward revision to Revenue and Core/Full OP, based on strong progress outperforming expectations***
- ***Core OP expected to reach 700 billion Yen and achieve 30% Core OP margin***

(billion yen)	FY2025 Actual	FY2026 Initial FCST	FY2026 Revised FCST	FY2026 Change	Main items of revision
Revenue	**2,139.2**	**2,220.0**	**2,330.0**	**+110.0**	• PADCEV, mirabegron, FX impact
SG&A expenses	860.3	800.0	815.0	+15.0	
US XTANDI co-pro fee	248.2	216.0	230.0	+14.0	
SG&A excl. the above	612.1	584.0	585.0	+1.0	• Decrease from initial FCST excl. FX impact
(SG&A ratio*)	28.6%	26.3%	25.1%	-1.2ppt	• Reflecting progress in enterprise productivity improvement
R&D expenses	314.8	355.0	360.0	+5.0	
(R&D ratio)	14.7%	16.0%	15.5%	-0.5ppt	
Core operating profit	**555.7**	**620.0**	**700.0**	**+80.0**	• Reflecting robust core business progress
(Core OP margin)	26.0%	27.9%	30.0%	+2.1ppt	

<Full basis>

Operating profit	**382.6**	**395.0**	**460.0**	**+65.0**

Exchange rates of FY2026 revised forecast: 158 yen/USD, 181 yen/EUR
(Forecast rates Q3/FY2026 onwards: 156 yen/USD, 177 yen/EUR)

FY2026 Initial FCST announced in Apr 2026. Exchange rates of initial FCST: 150 yen/USD, 180 yen/EUR, *Excl. US XTANDI co-pro fee

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Agenda

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FY2026 Revised Forecast

II **Pipeline Progress**

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Strategic Brands: Progress of Lifecycle Management

(Blue: Updates since the last financial results announcement)

Key milestones achieved in PADCEV MIBC and VEOZAH geographic expansion

Regulatory activity | Study progress

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

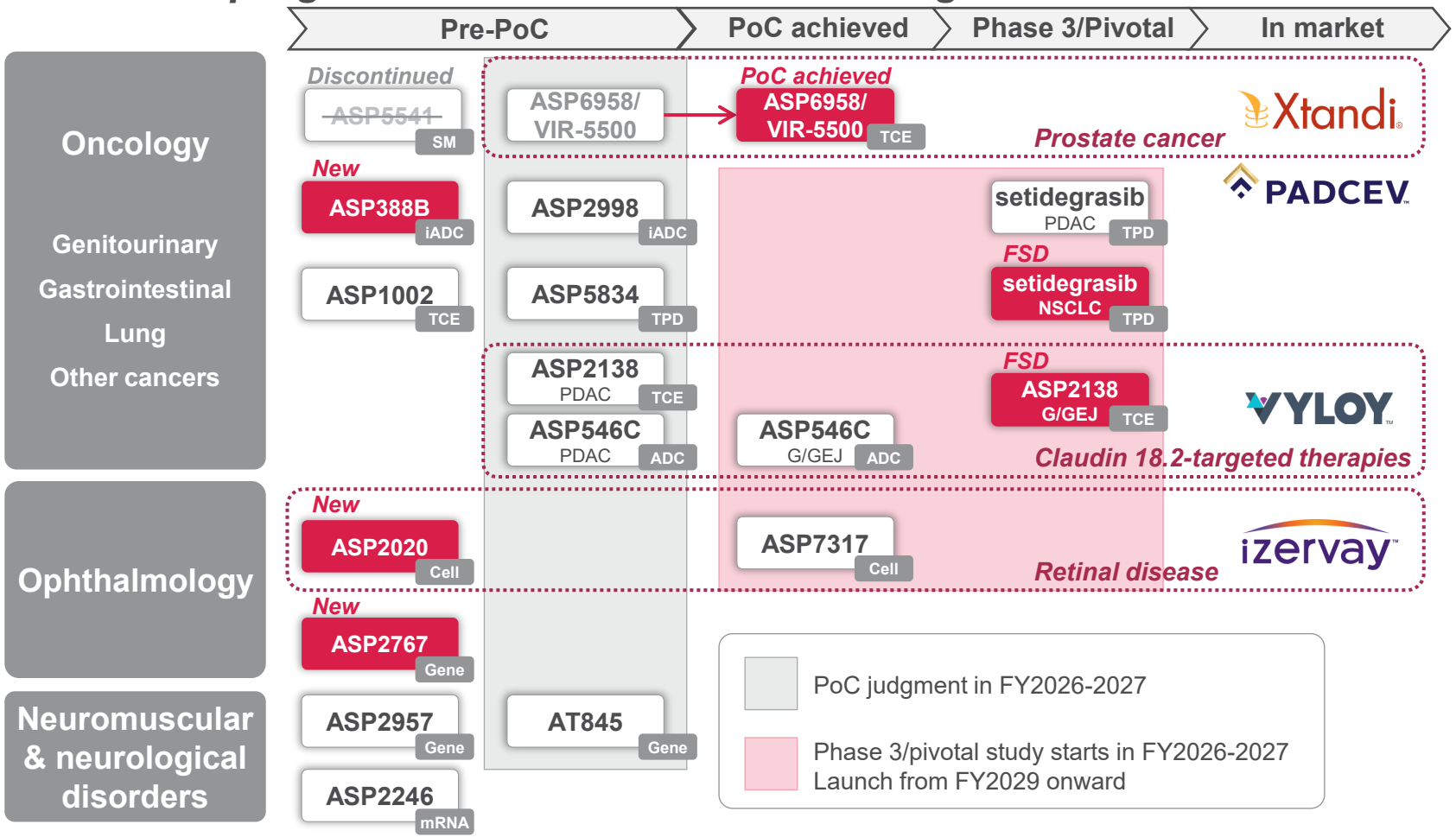
VEOZAH: Approved as “VEOZA” in ex-US

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

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Pipeline Progress

Two Phase 3 studies FSD achieved, ASP6958/VIR-5500 PoC achieved
Three new programs advanced into clinical stage



Major progress

setidegrasib
- Phase 3 study for NSCLC FSD achieved in Sep (NCT07566052)
- Translational mechanism of response and resistance data presented at AACR Pancreatic Cancer in Sep

ASP2138
- Phase 3 study for G/GEJ FSD achieved in Aug (NCT07673887)

ASP6958/VIR-5500
- PoC achieved for mCRPC

ASP388B
- Phase 1b/2 study FSD achieved in Sep (NCT07730021)

ASP2020
- Phase 1b study FSD achieved in Aug (NCT07734064)

ASP2767
- Phase 1/2 study IND cleared (US) (NCT07770685)

As of Oct 2026. Not exhaustively listed.
AACR: American Association for Cancer Research, (i)ADC: (immunostimulatory) Antibody-drug conjugate, FSD: First subject dosed, G/GEJ: Gastric/gastroesophageal junction, mCRPC: Metastatic castration-resistant prostate cancer, mRNA: Messenger RNA, NSCLC: Non-small cell lung cancer, IND: Investigational New Drug Application, PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept, SM: Small molecule, TCE: T-cell engager, TPD: Targeted protein degrader

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Progress in Focus Area Approach (1/2): Immuno-Oncology

Key milestones achieved across multiple programs, further strengthening the Immuno-Oncology pipeline

Key milestone achievements

ASP2138

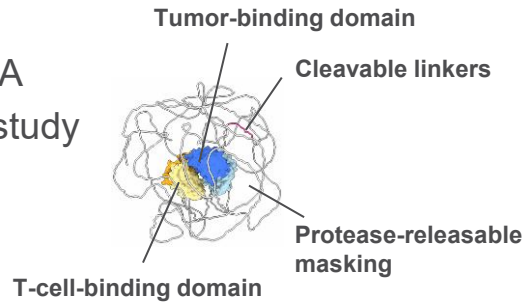
T-cell engager targeting CLDN18.2 and CD3 with SC route

- G/GEJ: FSD in Phase 3 study in 1L in Aug (NCT07673887)
- PDAC: Phase 1 study ongoing (NCT05365581), PoC judgment anticipated for FY2026

ASP6958/VIR-5500

Dual-masked CD3 T-cell engager targeting PSMA

- **PoC achieved in mCRPC**
- Fast Track designation granted by FDA
- Planning is ongoing for registrational study



New programs

ASP388B

B7-H3 targeted iADC with dual payloads

- Target disease: Solid tumor
- B7-H3-directed monoclonal antibody conjugated with cytotoxic topoisomerase I inhibitor and immunomodulator STING agonist
- FSD in Phase 1b/2 study in Sep (NCT07730021)



DAX-044

Immune-targeted IL-12 antibody-cytokine fusion

- Exclusive option to obtain worldwide license to develop and commercialize DAX-044 granted from Audax
- Phase 1 study expected to commence in 2027

audax

CLDN18.2: Claudin 18.2, FDA: Food and Drug Administration, FSD: First subject dosed, G/GEJ: Gastric/gastroesophageal junction, iADC: immunostimulatory antibody-drug conjugate, IL-12: Interleukin-12, mCRPC: Metastatic castration-resistant prostate cancer, PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept, PSMA: Prostate-specific membrane antigen, SC: Subcutaneous, STING: Stimulator of interferon genes

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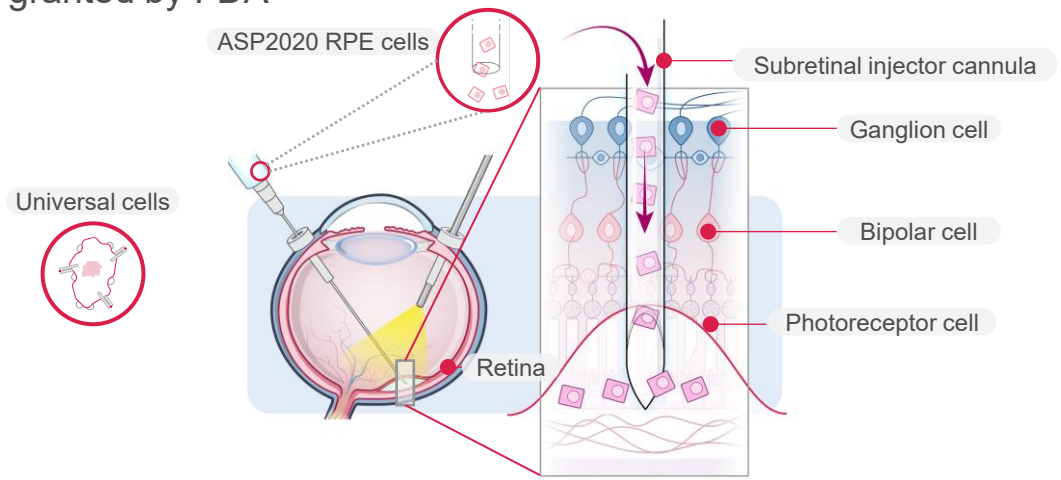
Progress in Focus Area Approach (2/2): Blindness and Regeneration

Next-generation ophthalmology programs advancing into clinical development

ASP2020

iPSC-derived RPE cell therapy with Universal Cell technology

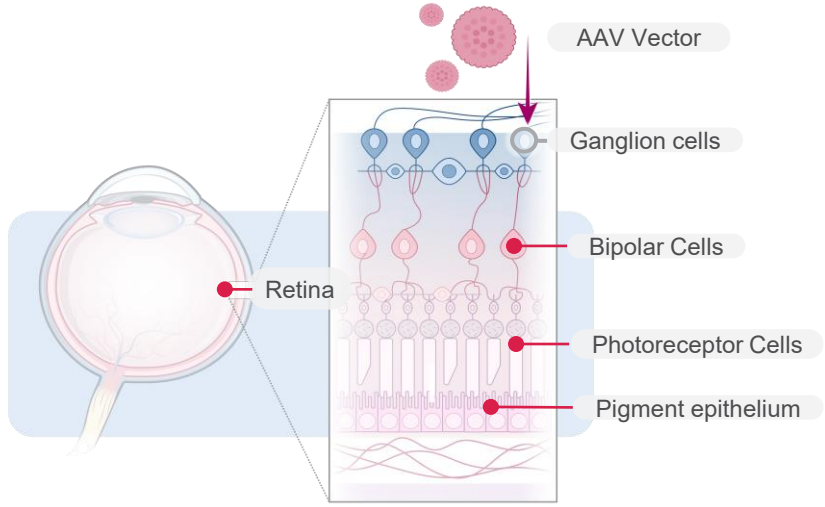
- Target disease: Stargardt-type macular dystrophies
- Aims to complement and/or replace RPE cells and improve vision
- Designed to avoid immune rejection through HLA gene editing (Universal Cell technology)
- Phase 1b study FSD achieved in Aug (NCT07734064)
- Fast Track designation and Rare pediatric disease designation granted by FDA



ASP2767

AAV-based gene therapy delivering dual transgene BDNF and TrkB

- Target disease: Optic neuropathy due to glaucoma
- Delivers dual transgene BDNF and its receptor (TrkB) to protect retinal ganglion cells and help maintain visual function
- Phase 1/2 study IND cleared (US) (NCT07770685)
- Fast Track designation granted by FDA



See slide 42 for Universal Cell technology. AAV: Adeno-associated virus, BDNF: Brain-derived neurotrophic factor, FDA: Food and Drug Administration, FSD: First subject dosed, HLA: Human leukocyte antigen, IND: Investigational New Drug Application, iPSC: Induced pluripotent stem cell, RPE: Retinal pigment epithelium, TrkB: Tropomyosin receptor kinase B

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Key Takeaways

Continued strong momentum driving upward revision toward 30% Core OP margin
Pipeline progress across all stages in line with CSP2026

Robust Financial Performance

- **Strong Strategic Brands growth**
  Achieved over 50% YoY growth driving robust revenue and profit growth
- **Disciplined cost optimization**
  SG&A expenses held flat YoY*
- **Upward revision of Full-Year Forecast**
  Core OP margin expected to achieve 30%

Solid Pipeline Progress

- **Multiple regulatory milestones achieved in LCM**
  PADCEV, VEOZAH
- **Two Phase 3 studies FSD achieved**
  setidegrasib NSCLC, ASP2138 G/GEJ
- **PoC achieved**
  ASP6958/VIR-5500 mCRPC
- **Three programs advanced into clinical stage**
  ASP388B, ASP2020, ASP2767

*Excl. US XTANDI co-promote fee and FX impact
CSP: Corporate Strategic Plan, FSD: First subject dosed, G/GEJ: Gastric/gastroesophageal junction, LCM: Lifecycle management, mCRPC: Metastatic castration-resistant prostate cancer, NSCLC: Non-small cell lung cancer, PoC: Proof of concept

LINK to CSP2026 presentation material

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Appendix



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Strategic Brands: Potential Peak Sales (as of Oct 2026)

PADCEV™	VYLOY™	XOSPATA®	izervay™	VEOZAH™
Oncology	Oncology	Oncology	Ophthalmology	Women's Health
Peak Sales: **400-500B Yen** **($2.7-3.3B)**	**Peak Sales:** **100-200B Yen** **($0.7-1.3B)**	**Peak Sales:** **100-200B Yen** **($0.7-1.3B)**	**Peak Sales:** **200-400B Yen** **($1.3-2.7B)**	**Peak Sales:** **150-250B Yen** **($1.0-1.7B)**

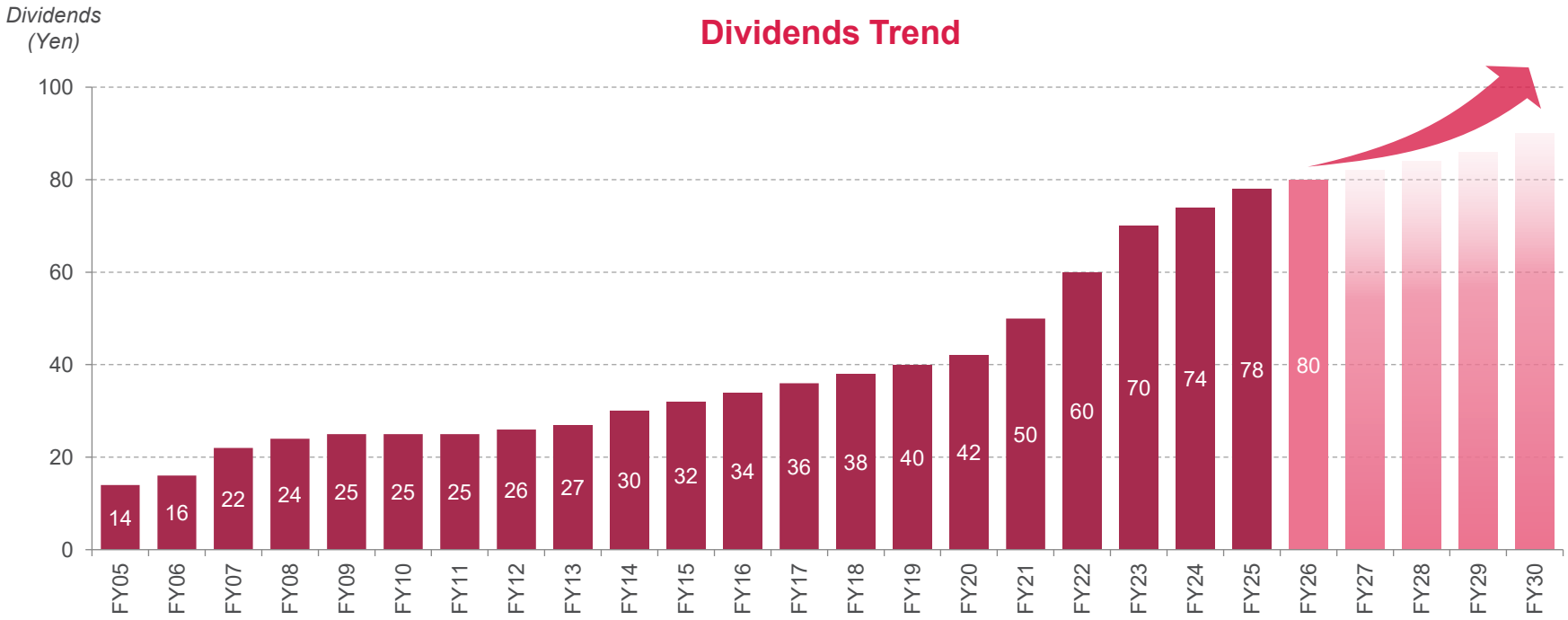
Converted at 1 USD = 150 Yen. PADCEV peak sales are disclosed as "in-market sales," not Astellas revenue. Sales for the Americas are calculated based on sales booked by our partner.

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Capital Allocation Policy

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

Maintain Gross Debt*/EBITDA** of **1.0x to 1.5x** to keep adequate debt capacity for potential large-scale investment



Minimum annual 2 Yen dividend increase throughout CSP2026 period

For illustrative purposes only

FY2026 is forecast. *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

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Q2 YTD/FY2026 Actual: FX Rate

Average rate for the period

Currency	Q2 YTD/FY2025	Q2 YTD/FY2026	Change
USD	146 yen	159 yen	+13 yen
EUR	168 yen	184 yen	+16 yen

<Impact of exchange rate on financial results>

- Revenue: +99.3 billion yen
- Core OP: +41.2 billion yen

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FY2026 Forecast: FX Rate & FX Sensitivity

Exchange rate Average for the period	FY2026 Initial FCST	FY2026 Revised FCST	Change
USD	150 yen	158 yen	+8 yen
EUR	180 yen	181 yen	+1 yen

Forecast rates Q3 onwards: 156 yen/USD, 177 yen/EUR

Estimated FX sensitivity (Q3 onwards) of FY2026 forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption	
	Revenue	Core OP
USD	Approx. +8.6 bil. yen	Approx. +2.7 bil. yen
EUR	Approx. +3.8 bil. yen	Approx. +1.7 bil. yen

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Balance Sheet & Cash Flow Highlights

(billion yen)	Mar 31, 2026	Sep 30, 2026
Total assets	3,567.0	3,527.8
Cash and cash equivalents	281.6	238.2
Total equity attributable to owners of the parent	1,829.0	1,981.7
Ratio of equity attributable to owners of the parent to total assets (%)	51.3%	56.2%

(billion yen)	Q2 YTD/FY2025	Q2 YTD/FY2026
Cash flows from operating activities	282.6	270.1
Cash flows from investing activities	-30.2	-81.9
Free cash flows	252.4	188.2
Cash flows from financing activities	-155.8	-230.4
Increase/decrease in short-term borrowings and commercial papers	-65.5	104.7
Proceeds from issuance of bonds and long-term borrowings	-	50.0
Redemption of bonds and repayments of long-term borrowings	-25.5	-296.6
Dividends paid	-66.2	-69.9

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Balance of Bonds and Borrowings Highlights

(billion yen)	Jun 30, 2026	Sep 30, 2026
Balance of bonds and borrowings	589.9	424.9
Non-current liabilities	320.0	270.0
Bonds	220.0	220.0
Long-term borrowings	100.0	50.0
Current liabilities	269.9	154.9
Commercial papers	30.0	74.9
Short-term borrowings	-	30.0
Current portion of long-term borrowings	139.9	50.0
Current portion of bonds	100.0	-

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Main Intangible Assets (as of Sep 30, 2026)

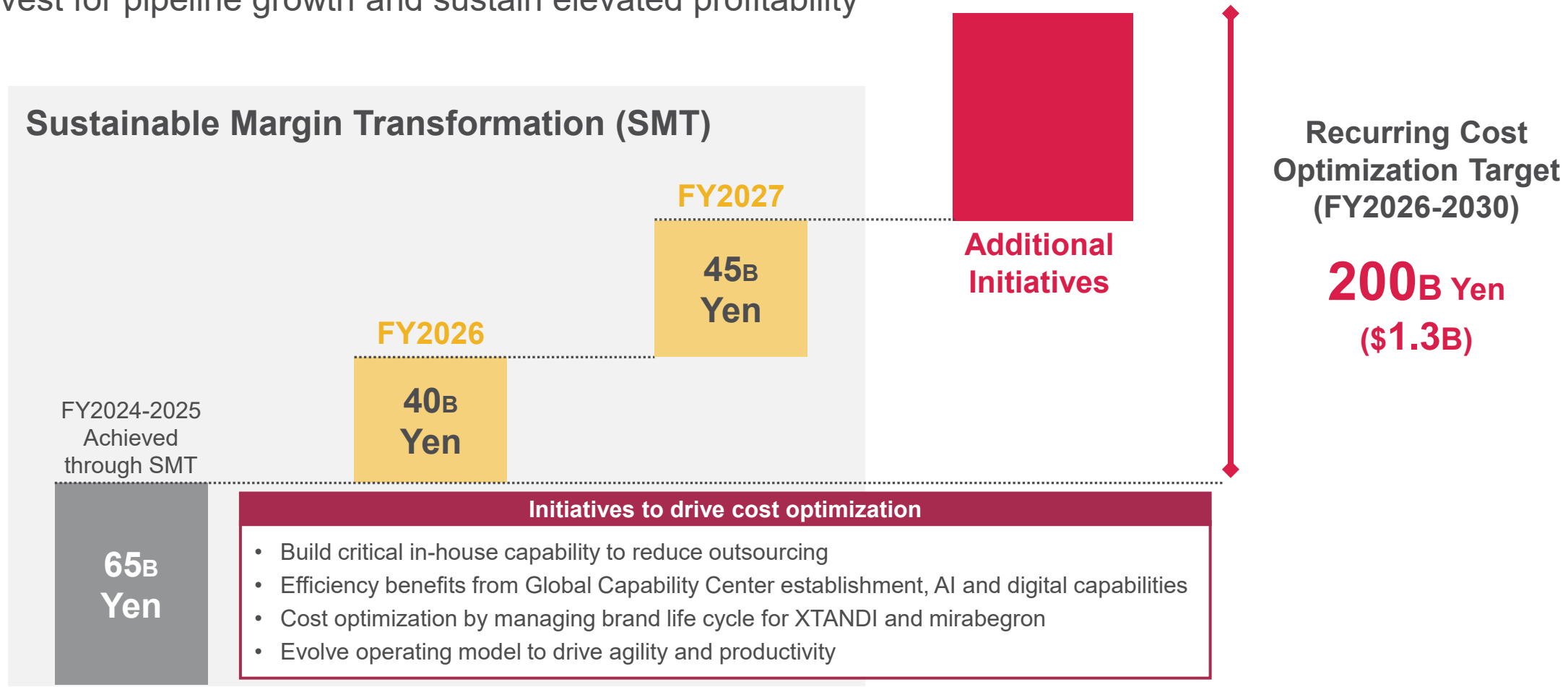
	Bil. yen	Foreign currency**
AT845	11.4	$73M
Gene therapy related technology*	57.0	$362M
VEOZAH**	81.5	€450M
VYLOY**	52.0	€400M
IZERVAY（US）	520.0	$3,304M
IZERVAY (Ex-US）	48.0	$305M
ASP7317	27.1	$172M
ASP6958/VIR-5500	37.8	$240M
ASP546C	23.0	n/a

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

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Disciplined Cost Optimization

- Recurring cost optimization target 200B Yen over CSP2026 period
- Reinvest for pipeline growth and sustain elevated profitability



Converted at 1 USD = 150 Yen.

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Our Pipeline

Prostate Cancer	Phase
XTANDI (enzalutamide)	In market
ASP6958/VIR-5500	1

Urothelial Cancer	Phase
PADCEV (enfortumab vedotin) mUC, Cisplatin-ineligible/eligible MIBC	In market
enfortumab vedotin Bladder-sparing MIBC	3

Upper GI and Pancreatic Cancer	Phase
VYLOY (zolbetuximab) Gastric and GEJ cancer	In market
zolbetuximab Gastric and GEJ cancer, combo with pembrolizumab and chemotherapy	3
ASP2138 Gastric, GEJ	3
setidegrasib PDAC	3
ASP2138 Pancreatic cancer	1
ASP546C	1

Acute Myeloid Leukemia	Phase
XOSPATA (gilteritinib) AML	In market
gilteritinib Earlier-stage AML, pediatric use	3
gilteritinib Newly diagnosed AML, HIC-ineligible	2

Solid Tumors	Phase
setidegrasib NSCLC	3
gilteritinib ALK-positive NSCLC	1
ASP1002	1
ASP5834	1
ASP2998	1
ASP388B	1

Ophthalmology	Phase
IZERVAY (avacincaptad pegol) GA secondary to AMD	In market
ASP7317 GA secondary to AMD	1
ASP2020 Stargardt-type macular dystrophies	1
ASP2767 Optic neuropathy due to glaucoma	IND cleared (US)

Neuromuscular & Neurological	Phase
AT845 Pompe disease	2
ASP2957 X-linked myotubular myopathy	1
ASP2246 Motor dysfunction associated with ischemic stroke	CTN open (Japan)

Vasomotor Symptoms (VMS)	Phase
VEOZAH (fezolinetant) VMS due to menopause	In market
fezolinetant VMS in breast cancer women	3

As of Oct 2026. Not exhaustively listed

ALK: Anaplastic lymphoma kinase, AMD: Age-related macular degeneration, AML: Acute myeloid leukemia, CTN: Clinical Trial Notification, GA: Geographic atrophy, GEJ: Gastroesophageal junction, GI: Gastrointestinal, HIC: High-intensity chemotherapy, IND: Investigational New Drug Application, MIBC: Muscle-invasive bladder cancer, mUC: Metastatic urothelial carcinoma, NSCLC: Non-small cell lung cancer, PDAC: Pancreatic ductal adenocarcinoma

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Key Upcoming Milestones

FY2026	FY2027	FY2028	FY2029
PoC judgment ✓ AT845 (Pompe disease) ✓ ASP2138 (PDAC)	VYLOY™ (G/GEJ combo with pembro and chemo) ✓ Phase 3 LUCERNA study data readout VEOZAH™ (VMS in breast cancer women) ✓ Phase 3 HIGHLIGHT 1 study data readout	**setidegrasib** (2L+ NSCLC) ✓ Phase 3 study data readout	**setidegrasib** (1L PDAC) ✓ Phase 3 study data readout **ASP2138** (1L G/GEJ) ✓ Phase 3 study data readout

Phase 3/pivotal study starts in FY2026-2027

- ✓ ASP7317 (GA secondary to AMD)
- ✓ ASP546C (G/GEJ)

PADCEV™ (Bladder-sparing MIBC)

- ✓ Phase 3 EV-309 study data readout in FY2028-2030

iZervay™ (GA secondary to AMD)

- ✓ Prefilled syringe launch in FY2028-2029

As of Oct 2026. Not exhaustively listed. 1L: First line, 2L+: Second or later line, AMD: Age-related macular degeneration, chemo: chemotherapy, GA: Geographic atrophy, G/GEJ: Gastric/gastroesophageal junction, MIBC: Muscle-invasive bladder cancer, NSCLC: Non-small cell lung cancer, pembro: Pembrolizumab, PDAC: Pancreatic ductal adenocarcinoma, PoC: Proof of concept, VMS: Vasomotor symptoms

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Progress in Overall Pipeline

Phase 1 Entry to Approval Since the Last Financial Results Announcement

Phase 1 Entry	Phase 2 Entry	Phase 3 Entry	Filing	Approval
ASP2020 Stargardt-type macular dystrophies		**ASP2138** Gastric and gastroesophageal junction adenocarcinoma	**fezolinetant** Vasomotor symptoms associated with menopause: Japan, China	**enfortumab vedotin** Muscle-invasive bladder cancer who are eligible for cisplatin-containing chemotherapy: Europe
ASP388B Cancer		**setidegrasib** Non-small cell lung cancer		

Discontinuation

ASP5541: Prostate Cancer (Phase 2)

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.

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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	**EV-303** (combo w/ Pembro)	**38,000**
	Cis-eligible	**EV-304** (combo w/ Pembro)	**59,000**
	Bladder-sparing	**EV-309** (combo w/ Pembro)	**34,000**
1L mUC		**EV-302** (combo w/ Pembro)	**115,000**
2L+ mUC (platinum & PD-1/L1 inhibitor pretreated)		**EV-301** (monotherapy)	**49,000**

*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

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

(Blue: Updates since the last financial results announcement)

	P3: EV-303 /KEYNOTE-905	NCT03924895	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=595	sBLA approved in US in Nov 2025 Type II variation approved in Europe in Jun 2026 sNDA submitted in Japan in Jan 2026 sBLA accepted in China in Jul 2026
	P3: EV-304 /KEYNOTE-B15	NCT04700124	MIBC, Cis-eligible; EV + Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=808	sBLA approved in US in Jul 2026 **Type II variation approved in Europe in Oct 2026** sNDA submitted in Japan in May 2026 sBLA accepted in China in Jul 2026
	P3: EV-309	NCT07566156	MIBC, ineligible or refused cystectomy; EV + Pembro vs. Concurrent CRT	n=390	FSD: Jun 2026
	P2: EV-209	NCT07475806	MIBC, eligible but do not undergo cystectomy; EV + Pembro (single-arm study)	n=240	FSD: Apr 2026

Chemo: Chemotherapy, Cis: Cisplatin, CRT: Chemoradiotherapy, FSD: First subject dosed, MIBC: Muscle-invasive bladder cancer, mUC: Metastatic urothelial cancer, Pembro: Pembrolizumab, RC: Radical cystectomy, sBLA: Supplemental Biologics License Application, sNDA: Supplemental New Drug Application

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

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: HR 0.53*	✓ 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	✓ HR 0.65* (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)	✓ HR 0.53* (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)	✓ 55.8% vs. 32.5%*	✓ 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*

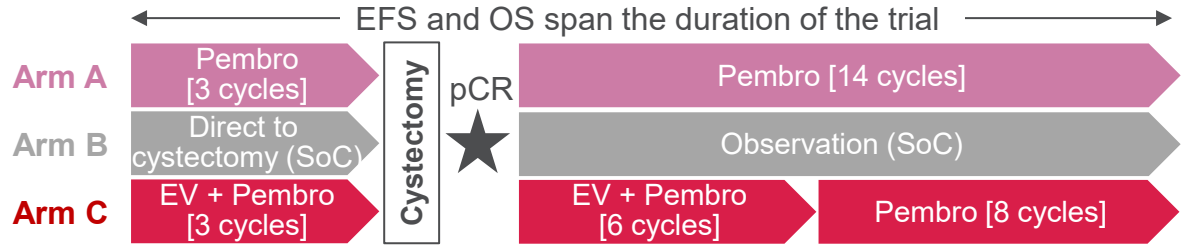
✓: Data obtained, *: Prespecified interim analysis, **: Updated data

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

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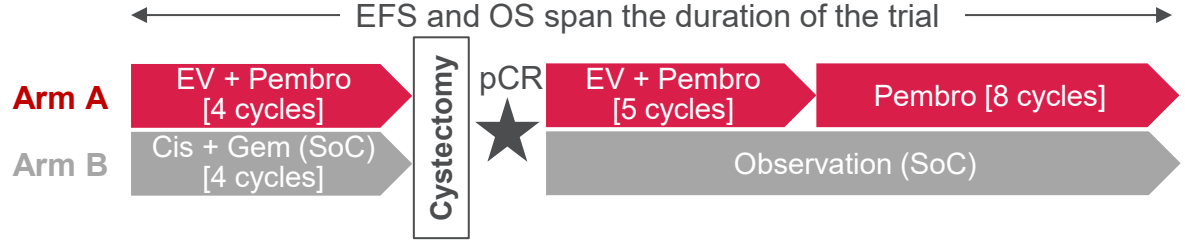
enfortumab vedotin (EV) (4/4): Development for Muscle-Invasive Bladder Cancer (MIBC)

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



- Endpoints:
  - ✓ Primary: EFS
  - ✓ Key secondary: OS, pCR
- n=595, randomized 1:1:1
- Arm C added to the Merck-sponsored KEYNOTE-905 study

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



- Endpoints:
  - ✓ Primary: EFS
  - ✓ Key secondary: OS, pCR
- n=808, randomized 1:1

3) Phase 3 study in MIBC patients who are ineligible or refused cystectomy (EV-309): EV + Pembro vs. Concurrent CRT



- Primary endpoint: BI-EFS assessed by BICR, OS
- n=390, randomized 1:1

1 cycle = 21 days

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

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zolbetuximab: anti-Claudin 18.2 Monoclonal Antibody

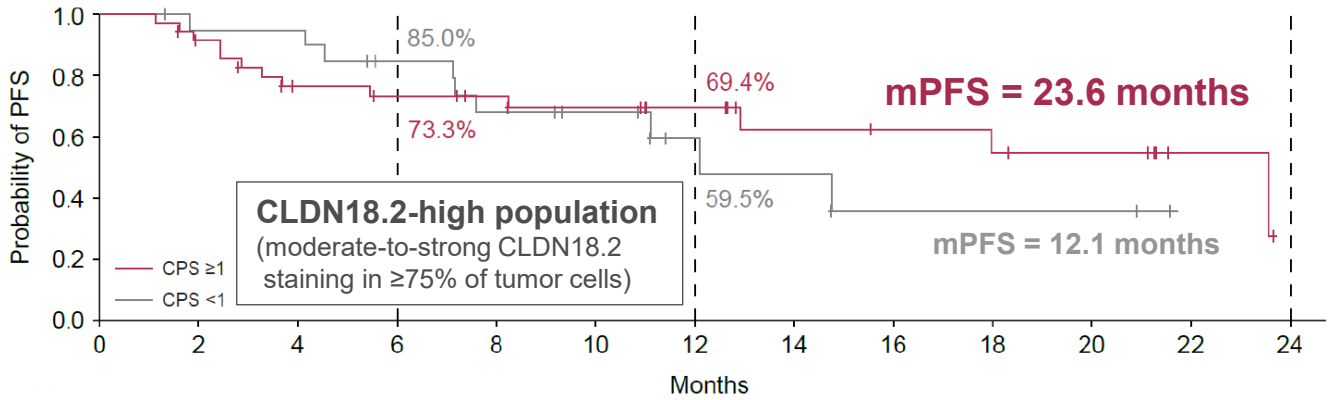
Overview

- 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[1]

- Phase 2 ILUSTRO study Cohort 4B
  (zolbetuximab + nivolumab + mFOLFOX6;
  moderate-to-strong CLDN18.2 staining in ≥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 ≥1

  (Ref) mPFS in zolbetuximab + Chemo: 9.2 months[2]
  nivolumab + Chemo: 7.7 months (all) / 7.5 months (CPS ≥1)[3]



Gastric and GEJ adenocarcinoma	**P3: LUCERNA**	NCT06901531	First line, combo with pembro and chemo vs. placebo + pembro + chemo (CAPOX or mFOLFOX6), CLDN18.2-high* and CPS ≥1	n=500	Target enrollment achieved
	P2: ILUSTRO	NCT03505320	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 ≥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

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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[1]

Women's Health Initiative (WHI) Study[2]

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

VMS associated with menopause

	Japan	P3: STARLIGHT 2	NCT06206408	Mild to severe VMS associated with menopause; 8 weeks: DB, 2 doses vs. placebo (1:1:1)	n=410	**NDA submitted in Japan in Aug 2026**
		P3: STARLIGHT 3	NCT06206421	VMS associated with menopause; 52 weeks: DB, vs. placebo (1:1)	n=277	
	China	P2	NCT06812754	Moderate to severe VMS associated with menopause; 12 weeks: DB, 45 mg vs. placebo (1:1)	n=150	**NDA accepted in China in Oct 2026**

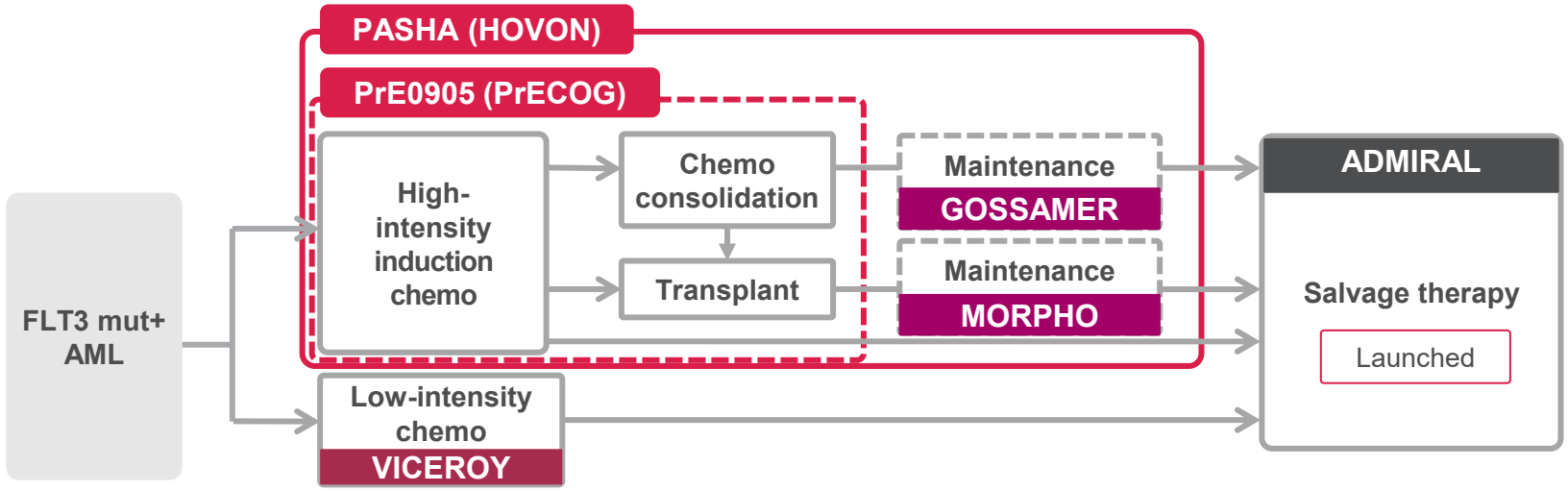
VMS in breast cancer women receiving adjuvant endocrine therapy

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

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

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gilteritinib: FLT3 Inhibitor



Acute myeloid leukemia

Newly diagnosed (HIC-eligible)	**P3: PASHA (HOVON)**	NCT04027309	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=766	Primary endpoint not met
	P2: PrE0905 (PrECOG)	NCT03836209		n=181	Topline results presented at ASH 2024 (Sponsor: PrECOG, LLC.)
Newly diagnosed (HIC-ineligible)	**P1/2: VICEROY**	NCT05520567	Combo with venetoclax and azacitidine	n=70	FSD: Jan 2023

Non-small cell lung cancer

ALK-positive	**P1**	NCT07140016	Monotherapy	n=40	FSD: Oct 2025

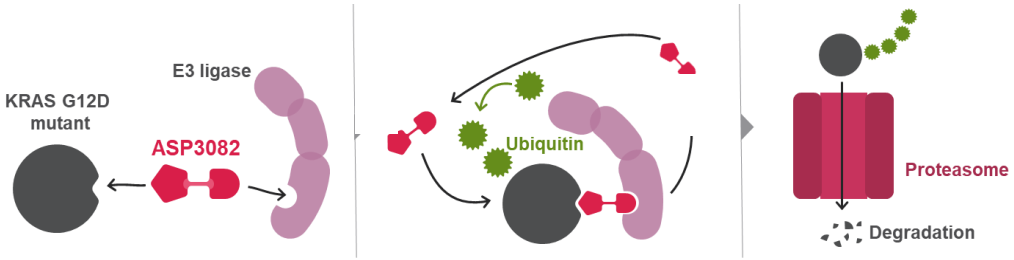
ALK: Anaplastic lymphoma kinase, AML: Acute myeloid leukemia, ASH: American Society of Hematology, Chemo: Chemotherapy, FLT3 mut+: FLT3 mutation positive, FSD: First subject dosed, HIC: High-intensity chemotherapy, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands

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setidegrasib: KRAS G12D Degrader (1/2)

Overview

- Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~5% in NSCLC[1]



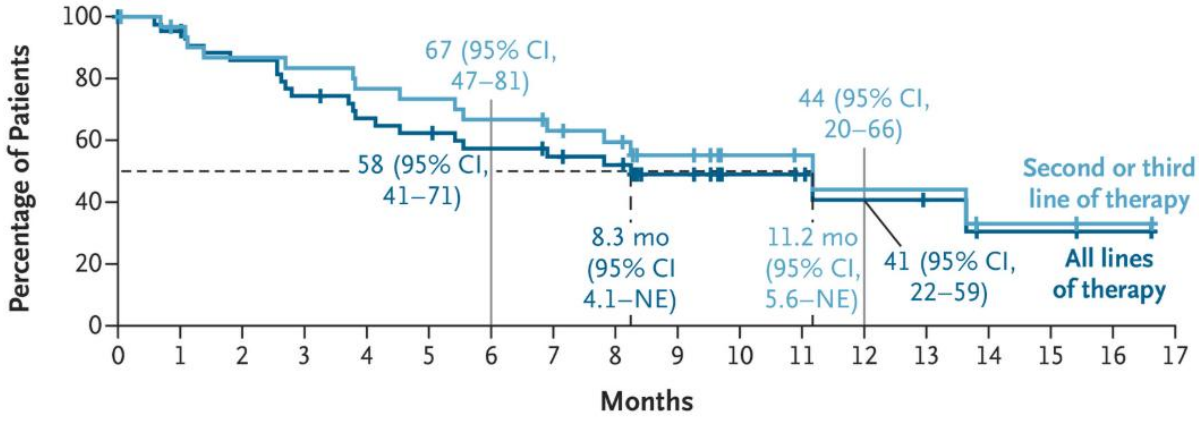
Non-small cell lung cancer (NSCLC)

- Phase 3 study in 2L+ NSCLC ongoing (NCT07566052)
  - ✓ Primary analysis anticipated: FY2028

N=356
R (1:1)
→ setidegrasib QW
→ Docetaxel

Primary endpoint: PFS, OS

- Phase 1 study 2L+ monotherapy data presented at ELCC 2026 and NEJM[2]
  - ✓ mPFS=11.2 months in 2/3L, ORR=37.5% in 2/3L



1. npj Precis Oncol. 2022;6:91, 2. N Engl J Med 2026 Mar; doi: 10.1056/NEJMoa2600752. 2L+: Second or later line, ELCC: European Lung Cancer Conference, KRAS: Kirsten rat sarcoma viral oncogene homologue, NEJM: The New England Journal of Medicine, ORR: Objective response rate, OS: Overall survival, PFS: Progression-free survival

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setidegrasib: KRAS G12D Degrader (2/2)

(Blue: Updates since the last financial results announcement)

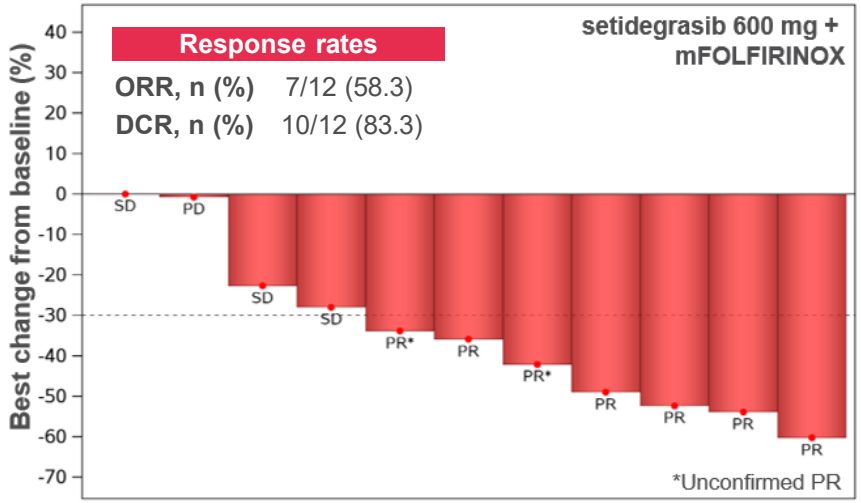
Pancreatic ductal adenocarcinoma (PDAC)

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



Primary endpoint: OS

- Phase 1 study 1L data presented at ASCO GI 2026



- **Translational mechanism of response and resistance data presented at AACR Pancreatic Cancer 2026**

  Findings support further development of KRAS G12D-targeted therapy

  - ✓ ~95.5% KRAS G12D protein degradation translated into molecular and clinical responses in PDAC
  - ✓ Resistance appeared heterogenous, supporting a differentiated resistance profile

End-of-treatment ctDNA analyses

Resistance category	Setidegrasib (n = 15[a])	Daraxonrasib[1] (n = 44)	HRS-4642[2] (n = 70)
***KRAS* amplification**	7% (1/15) *KRAS G12D* gain	36% (16/44)	10% (7/70)
***KRAS* secondary mutations**	None identified	*RAS Y64/Y71* alterations reported in resistance analyses[b]	90% (63/70)
Upstream RTK-RAS bypass	13% (2/15)	9% (4/44)	37% (26/70)
MAPK pathway alteration	None identified	25% (11/44)	Upstream: 4% (3/70) Downstream: 3% (2/70)
PI3K/AKT/PTEN pathway	13% (2/15)	9% (4/44)	27% (19/70)
MYC pathway	7% (1/15)	2% (1/44)	7% (5/70)

[a] Includes four low-shedding patients. [b] Non-PDAC cohort.

1. Nat Med. 2026;32(8):2865–2877. 2. Ann Oncol. 2025;36(2):S558–S559. 1L: First line, AACR: American Association for Cancer Research, ASCO GI: American Society of Clinical Oncology Gastrointestinal Cancers Symposium, DCR: Disease control rate, KRAS: Kirsten rat sarcoma viral oncogene homologue, mFOLFIRINOX: Leucovorin, fluorouracil, irinotecan and oxaliplatin, NALIRIFOX: Leucovorin, fluorouracil, liposomal irinotecan and oxaliplatin, ORR: Objective response rate, OS: Overall survival

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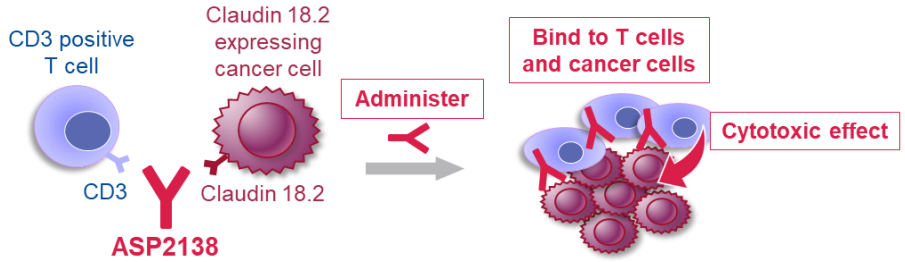
ASP2138: T-cell Engager Targeting Claudin 18.2 and CD3

(Blue: Updates since the last financial results announcement)

Overview

T-cell engager 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[1] and ~60% in PDAC[2]



Latest data[3]

- 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
- Responses were observed in patients with **both low-intermediate and high CLDN18.2 expression levels**

Current status

- Phase 3 study in 1L G/GEJ ongoing (NCT07673887)
  - ✓ Patients with low-intermediate CLDN18.2 expression
  - ✓ Primary analysis anticipated: FY2029

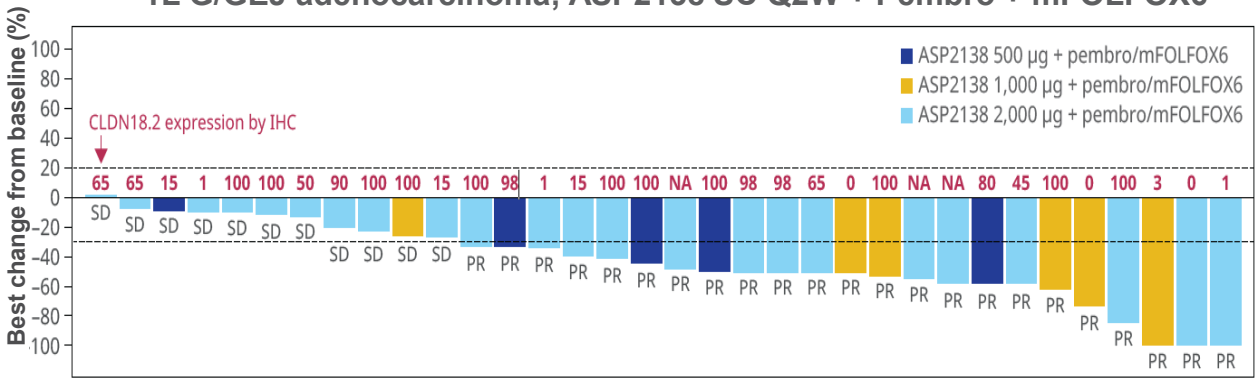
N=570
R (1:1)

- **ASP2138 + pembro + (mFOLFOX6 or CAPOX)**
- Placebo + (pembro or placebo) (mFOLFOX6 or CAPOX)

Primary endpoint: OS, PFS

- Phase 1 studies ongoing (NCT05365581, NCT07024615)
- **PoC judgment for PDAC planned in FY2026**

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, CLDN18.2: Claudin 18.2, 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

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ASP546C: Antibody-Drug Conjugate (ADC) Targeting Claudin 18.2

Overview

Antibody-drug conjugate (ADC) targeting CLDN18.2

- Payload: Proprietary topoisomerase I inhibitor, Drug-to-antibody ratio: 8
- Linker: MediLink's TMALIN (Tumor Microenvironment Activable LINker) technology
- Fast Track designation granted by FDA (gastric cancer)
- Exclusive license to develop and commercialize worldwide, excluding China's mainland, Hong Kong, Macao and Taiwan region

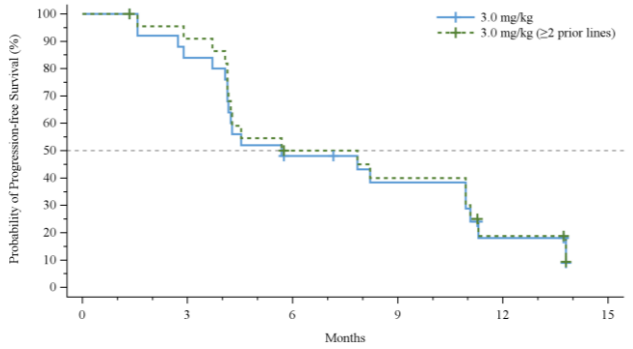
Current status

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

Latest data

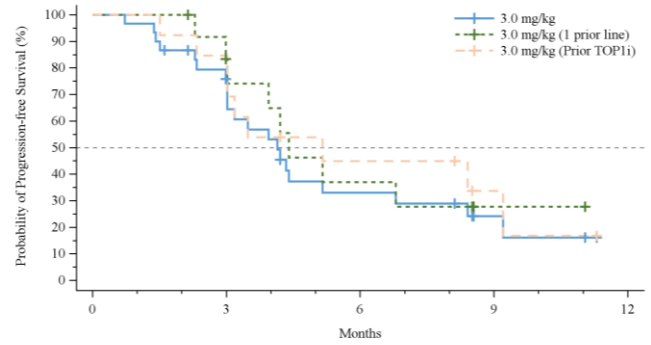
- Clinical data from China Phase 2 study presented at ASCO 2026

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



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

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



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

*Unconfirmed

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

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Portfolio of Claudin 18.2-Targeted Therapies

Aim to address broader patient population with multiple differentiated assets

	VYLOY 	ASP2138 	ASP546C 
Modality	• Monoclonal antibody	• T-cell engager (Bispecific antibody)	• Antibody-drug conjugate
Mode of action	• Immune cell-mediated	• Immune cell-mediated	• Direct action of payload
Clinical data	• Prolonged survival in **combo w/ Chemo** (SPOTLIGHT/GLOW) • Evaluating **combo w/ Chemo** + CPI (LUCERNA)	• Evaluating **combo w/ SoC** regimens as well as monotherapy in G/GEJ cancer and PDAC	• Promising antitumor activity with monotherapy in G/GEJ cancer and PDAC with manageable tolerability
Future potential	• **SoC** for CLDN18.2+ **high*** G/GEJ cancer: ~38% of patients	• **Enhanced immune response** • Expansion to **low-intermediate** CLDN18.2+ population in 1L G/GEJ cancer: ~35% of patients • Ease of use with SC route	• **"SoC Chemo-free" regimen** • **All** CLDN18.2+ population eligible (G/GEJ cancer and PDAC) • Expansion to other CLDN18.2+ tumor types

*VYLOY: CLDN18.2 positivity is defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining
1L: First line, Chemo: Chemotherapy, CLDN18.2: Claudin 18.2, CPI: Checkpoint inhibitor, G/GEJ: Gastric/gastroesophageal junction, PDAC: Pancreatic ductal adenocarcinoma, SC: Subcutaneous, SoC: Standard of care

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PDAC:
Accelerating development targeting KRAS G12D mutation and CLDN18.2

- Estimated number of patients* (overall PDAC): ~**176,000** in 1L, ~**40,000** in 2L
- SoC for metastatic PDAC: Chemotherapy

KRAS G12D +
~**40**% in PDAC[1]

setidegrasib

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



Primary endpoint:
OS

CLDN18.2 +**
~**60**% in PDAC[2]

ASP2138

Phase 1 studies ongoing
(NCT05365581, NCT07024615)

PoC judgment planned in FY2026

ASP546C

Phase 1b/2 solid tumor study FSD achieved in May 2026
(NCT07488676)

*US, Germany, France, Italy, Spain, UK, Japan (based on internal estimates), **Represents % of patients with any level of CLDN18.2+ staining (≥1%; cf. ≥75% for VYLOY), 1. npj Precis Oncol. 2022;6:91, 2. Int J Cancer. 2013;134:731
1L: First line, 2L: Second line, CLDN18.2: Claudin 18.2, KRAS: Kirsten rat sarcoma viral oncogene homologue, mFOLFIRINOX: Leucovorin, fluorouracil, irinotecan and oxaliplatin, FSD: First subject dosed,
NALIRIFOX: Leucovorin, fluorouracil, liposomal irinotecan and oxaliplatin, OS: Overall survival, PDAC: Pancreatic ductal adenocarcinoma, QW: Once weekly, SoC: Standard of care

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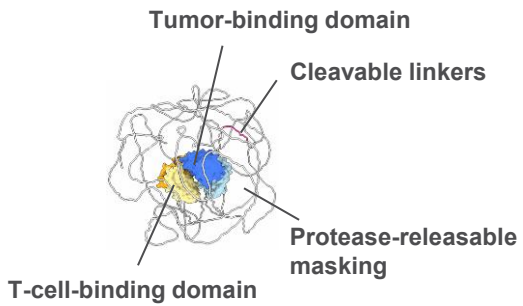
ASP6958/VIR-5500: Dual-masked CD3 T-cell Engager Targeting PSMA

(Blue: Updates since the last financial results announcement)

Overview

Dual-masked CD3 T-cell engager targeting PSMA

- Target disease: Prostate cancer



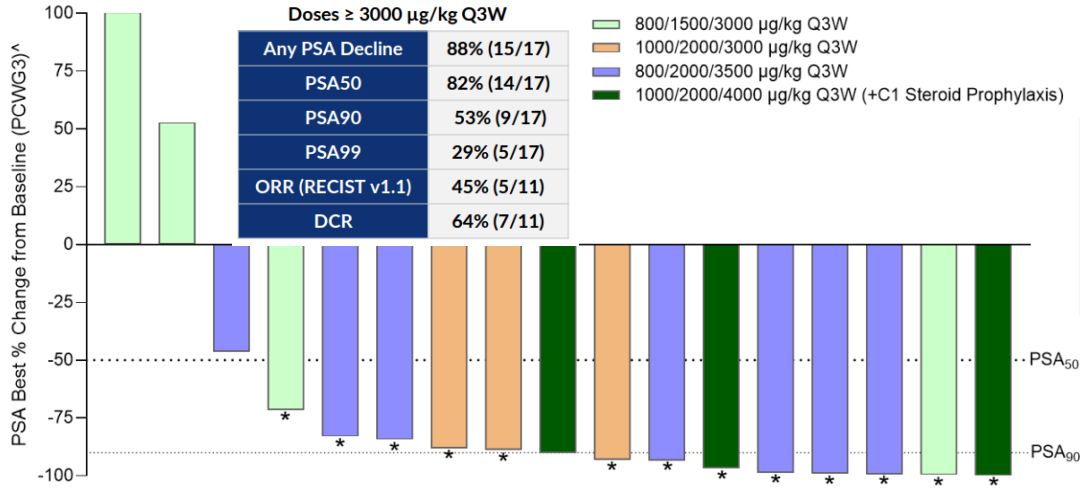
Current status

- Phase 1 study ongoing (NCT05997615)
- **PoC achieved in mCRPC**
- **Fast Track designation granted by FDA**
- **Planning ongoing for registrational studies**

Latest data

- Preliminary Phase 1 monotherapy dose escalation data presented at ASCO GU 2026
  - ✓ **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 ≥ 3000 ug/kg Q3W



*Confirmed PSA responders of PSA50 or better

PSA50: PSA decline of 50%-100% from baseline, PSA90: PSA decline of 90%-100% from baseline, PSA99: PSA decline of 99%-100% from baseline, ASCO GU: American Society of Clinical Oncology Genitourinary Cancers Symposium, CRS: Cytokine release syndrome, DCR: Disease control rate, DLT: Dose limiting toxicity, FDA: Food and Drug Administration, mCRPC: Metastatic castration-resistant prostate cancer, ORR: Objective response rate, PoC: Proof of concept, PSA: Prostate-specific antigen, PSMA: Prostate-specific membrane antigen, RECIST: Response Evaluation Criteria in Solid Tumors, TCE: T-cell engager

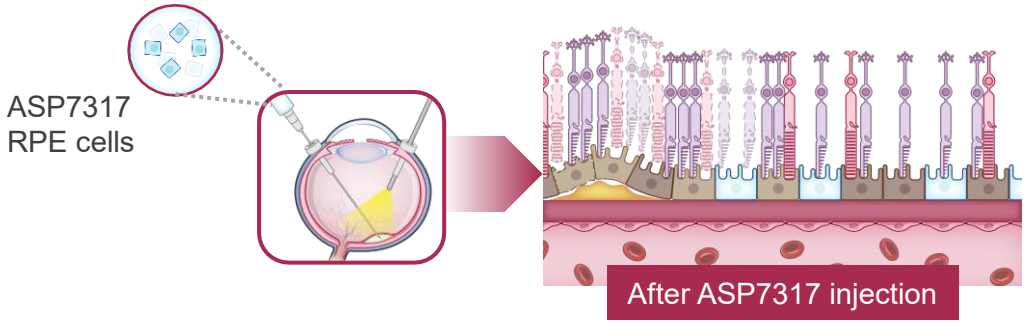
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ASP7317: Retinal Pigment Epithelial Cell

Overview

Transplantation of retinal pigment epithelial cells aiming to maintain and potentially repair visual functions

- Target disease: GA secondary to AMD
  - ✓ Estimated Number of patients: ~5 million worldwide[1]
- Approved treatment: Complement inhibitors
  - ✓ Slow disease progression



Current status

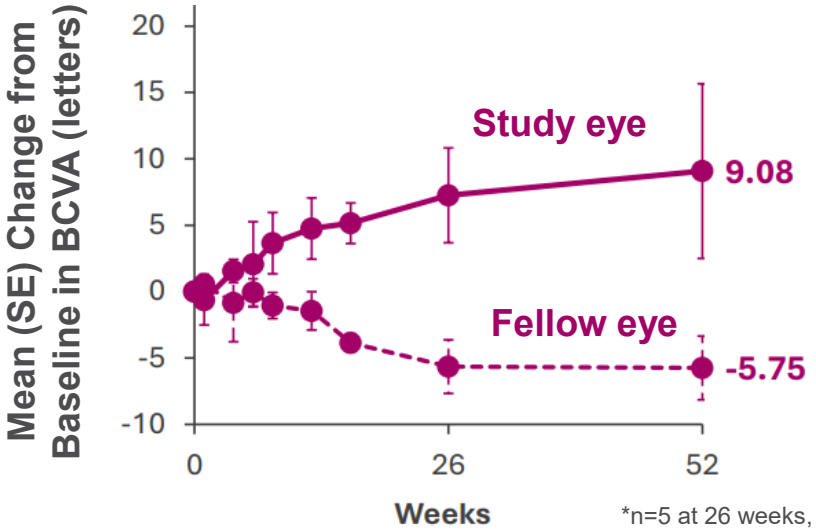
- Phase 1b study ongoing (NCT03178149)
- PoC achieved in patients with severe vision impairment due to GA

Latest data

- Initial data from Phase 1b study presented at Association for Research in Vision and Ophthalmology (ARVO) 2026
  - ✓ Well-tolerated with no IOI events and no evidence for ASP7317 cell rejection or graft failure, and no tumors
  - ✓ A possible trend for improving BCVA in SVI (severe vision impairment) patients following ASP7317 transplantation

<Mean BCVA change over time>

(Cohort 2 and 2b: SVI patients, medium dose, n=3-5*;
BCVA: 15-37 letters (≥20/500 to ≤20/200))



*n=5 at 26 weeks, n=3 at 52 weeks

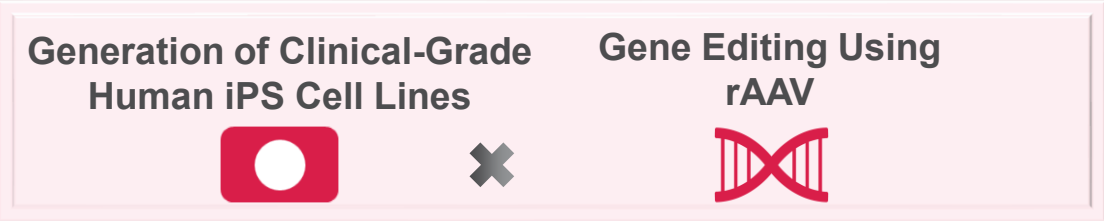
1. Retina. 2017;37:819-835

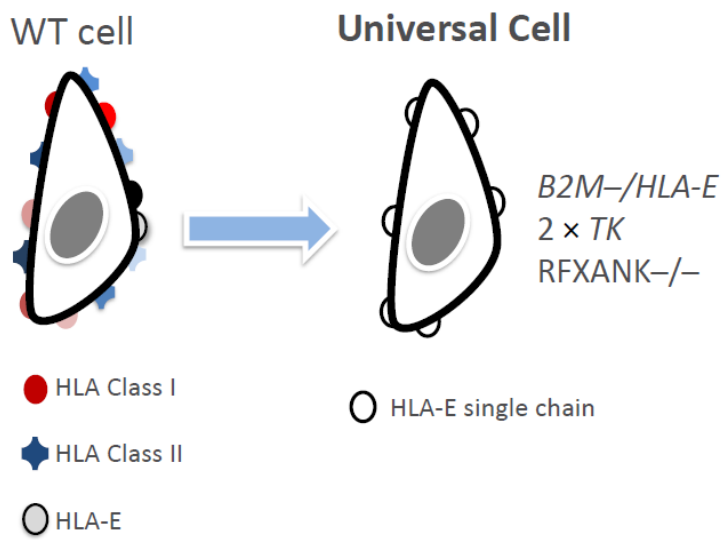
AMD: Age-related macular degeneration, BCVA: Best corrected visual acuity, GA: Geographic atrophy, IOI: Intraocular inflammation, PoC: Proof of concept, RPE: Retinal pigment epithelial

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Avoiding Immune Rejection through “Universal Cell”

Universal Cells
AN ASTELLAS COMPANY





- **Designed to avoid Immune Rejection by HLA Gene Editing**
  - ➢ Removal of HLA Class I/II to evade T cell-mediated attack
  - ➢ Expression of HLA-E to avoid NK cell-mediated attack

(Background)
- T cells recognize HLA molecules expressed on the cell membrane to distinguish non-self cells and eliminate them, leading to immune rejection.
- NK cells recognize and eliminate abnormal cells with insufficient HLA Class I expression.

Ref: International Society for Stem Cell Research (ISSCR) iPSC 20th Anniversary Symposium
(r)AAV: (recombinant) Adeno-associated virus, B2M: β2-macroglobulin, HLA: Human leukocyte antigen, NK cell: Natural killer cell, iPS Cell: Induced Pluripotent stem cell, RFXANK: Regulatory factor X-associated ankyrin-containing protein, WT: Wild Type

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AT845: AAV8 Based Gene Therapy Expressing hGAA Gene

Overview

Recombinant AAV8 continuously expressing hGAA gene specially in muscle

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

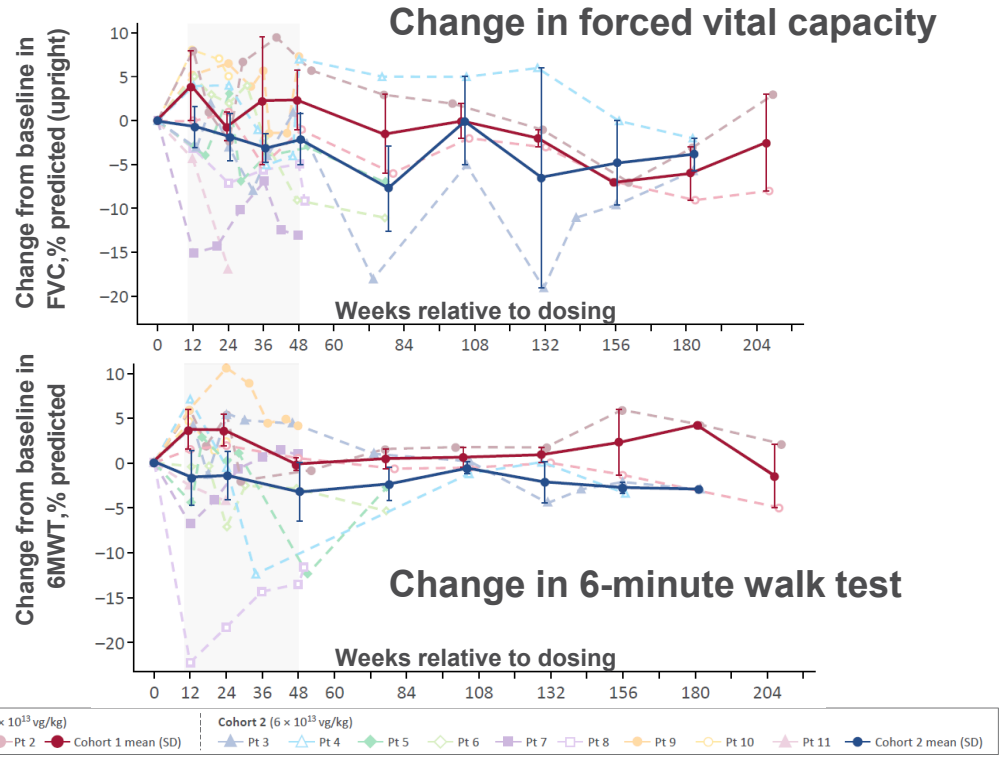


Current status

- Phase 1/2 FORTIS study ongoing (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 WORLD*Symposium* 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

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