FY2024 Financial Results

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April 25, 2025

Cautionary Statement Regarding Forward-Looking Information

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Agenda

I FY2024 Consolidated Financial Results

II FY2024 Pipeline Update

III FY2025 Outlook

FY2024 Financial Results: Overview

*Revenue and Core operating profit reached **record high** since establishment of Astellas*

Revenue

- **Increased significantly YoY (+19%)**
- Strategic Brands: Expanded to approx. 340.0 bil. yen (approx. **+180.0 bil. yen** YoY)

*SG&A expenses**

- Achieved SMT target (optimization of 40.0 bil. yen), SG&A ratio **improved by 3.1ppt** YoY

Core operating profit

- **Increased significantly YoY (+42%)** driven by growth of Strategic Brands and SMT cost optimization
- Core OP margin increased to 20.5% (**+3.3ppt** YoY)

*Excl. US XTANDI co-pro fee
Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA
SMT (Sustainable Margin Transformation): See slide 32 for overview

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FY2024 Financial Results

(billion yen)	FY2023	FY2024	Change	Change (%)	FY2024 FCST	FX impact (YoY)
Revenue	**1,603.7**	**1,912.3**	**+308.7**	**+19.2%**	**1,900.0**	+68.1
Cost of sales	292.5	349.2	+56.7	+19.4%	345.0	+6.9
SG&A expenses	740.1	843.0	+102.9	+13.9%	845.0	+34.9
US XTANDI co-pro fee	194.9	252.6	+57.7	+29.6%	255.0	+13.1
SG&A excl. the above	545.2	590.5	+45.2	+8.3%	590.0	+21.8
(SG&A ratio*)	34.0%	30.9%	-3.1ppt		31.1%	
R&D expenses	294.2	327.7	+33.5	+11.4%	340.0	+11.1
(R&D ratio)	18.3%	17.1%	-1.2ppt		17.9%	
Core operating profit**	**276.9**	**392.4**	**+115.5**	**+41.7%**	**370.0**	+15.1
(Core OP margin)	17.3%	20.5%	+3.3ppt		19.5%	
＜Full basis＞						
Amortisation of intangible assets	98.8	136.8	+37.9	+38.4%		
Other income	8.7	20.3	+11.7	+134.1%		
Other expenses	167.8	235.8	+68.0	+40.5%		
Operating profit	**25.5**	**41.0**	**+15.5**	**+60.8%**	**11.0**	
Profit before tax	25.0	31.2	+6.3	+25.1%	1.0	
Profit	**17.0**	**50.7**	**+33.7**	**+197.7%**	**14.0**	

Note) Amortisation of IZERVAY's intangible assets started from Q2/FY2023

Other expenses（Main items）

- Impairment losses on intangible assets: 187.6
  Major impairment losses include:
  IZERVAY (Ex-US): 115.1,
  AT466: 51.8, iota: 8.0

FX rate assumption for FY2024: 153 yen/USD, 164 yen/EUR, Actual FX rates for FY2024: 152 yen/USD, 164 yen/EUR
*Excl. US XTANDI co-pro fee, **The definition of core-basis was changed from Q1/FY2024. In addition to the old definition's adjustments, 'Amortisation of intangible assets', 'Gain on divestiture of intangible assets' and 'Share of profit (loss) of investments accounted for using equity method' were newly excluded as new adjustment items.

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FY2024 Financial Results: Main Brands

Strategic Brands achieved over 2x growth, significantly ***driving overall revenue and profit growth***

(billion yen)	FY2024 Act	YoY	
Strategic Brands Total	**336.4**	**+176.5 (+110%)**	✓ Delivered over 2x growth YoY, demonstrating substantial growth ✓ Strategic Brands' **profitability** played a major role in **driving overall profit growth**
PADCEV™	**164.1**	**+78.7 (+92%)**	✓ Sales growth driven by expansion across all regions, with global sales nearly doubling ✓ Increase in 1L mUC approval countries, with rapid market penetration in each region
izervay™	**58.3**	**+46.2 (+381%)**	✓ #1 chosen treatment for new patient starts since Q2/FY2024 ✓ Temporary growth softness due to CRL impact; signs of upward trend following label update
VEOZAH™	**33.8**	**+26.5 (+364%)**	✓ Solid global sales growth, led by the US with contributions from EST and INT ✓ Steady regional expansion (Approved in 43 countries and launched in 24 countries)
VYLOY™	**12.2**	**+12.2**	✓ Global growth exceeded expectations, starting with Japan launch in June 2024 ✓ Higher-than-expected rates of CLDN18.2 testing drove strong performance
XOSPATA®	**68.0**	**+12.9 (+23%)**	✓ Steady global sales growth ✓ Strong market share maintained in current indication setting

(billion yen)	FY2024 Act	YoY	
Xtandi®	**912.3**	**+161.8 (22%)**	✓ Sales growth across all regions, with global sales reaching projected peak level ✓ Impact from US Medicare Part D redesign generally in line with expectations

Actual FX rates for FY2024: 152 yen/USD, 164 yen/EUR
1L: First line, mUC: Metastatic urothelial cancer, CRL: Complete response letter, CLDN18.2: Claudin 18.2, VEOZAH: Approved as "VEOZA" in ex-US, EST (Established Markets): Europe, Canada, etc., INT (International Markets): Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Taiwan, Korea, Australia, Export sales, etc.

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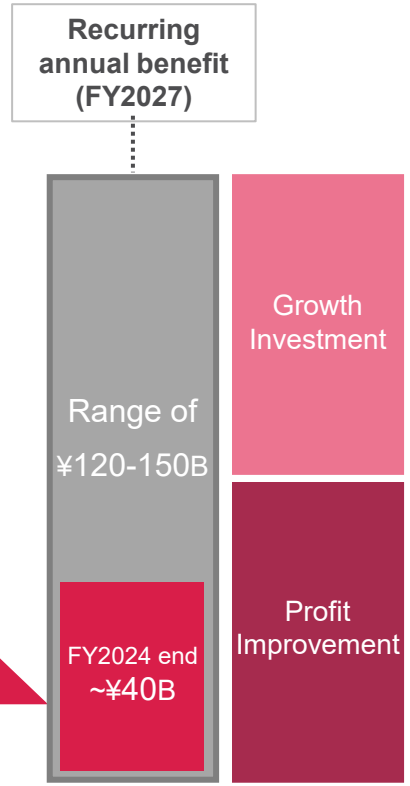
FY2024 Financial Results：SMT (Sustainable Margin Transformation)

- *Achieved cost optimization of **40.0 bil. yen** through SMT*
- *Improved SG&A* ratio to 30.9% (**-3.1 ppt** YoY)*
- *Allocated resources generated by SMT to growth investments (Strategic Brands and Primary Focus)*

Key results in FY2024 (billion yen)

1. Build critical in-house capability to reduce outsourcing
   - Promoting in-house clinical trials, etc., previously outsourced (Approx. -5.0 YoY)
2. Further efficiency of global operations
   - Enhance company-wide efficiency with AI and digital tools (Approx. -6.0 YoY)
3. Optimize selling expenses with ROI focus
   - Global organizational restructuring (Approx. -15.0 YoY)
   - Reduction of mature products-related expenses (Approx. -10.0 YoY)
   - Global reduction in promotional material costs (Approx. -2.0 YoY)
4. Continuous company-wide cost optimization
   - Streamline OPEX with no sacred areas



Maximize potential of Strategic Brands

Focus on post-PoC prioritized PF assets

Optimize a cost structure before XTANDI LOE

*Excl. US XTANDI co-pro fee
ROI: Return On Investment, PoC: Proof of concept, LOE: Loss of exclusivity, PF: Primary Focus

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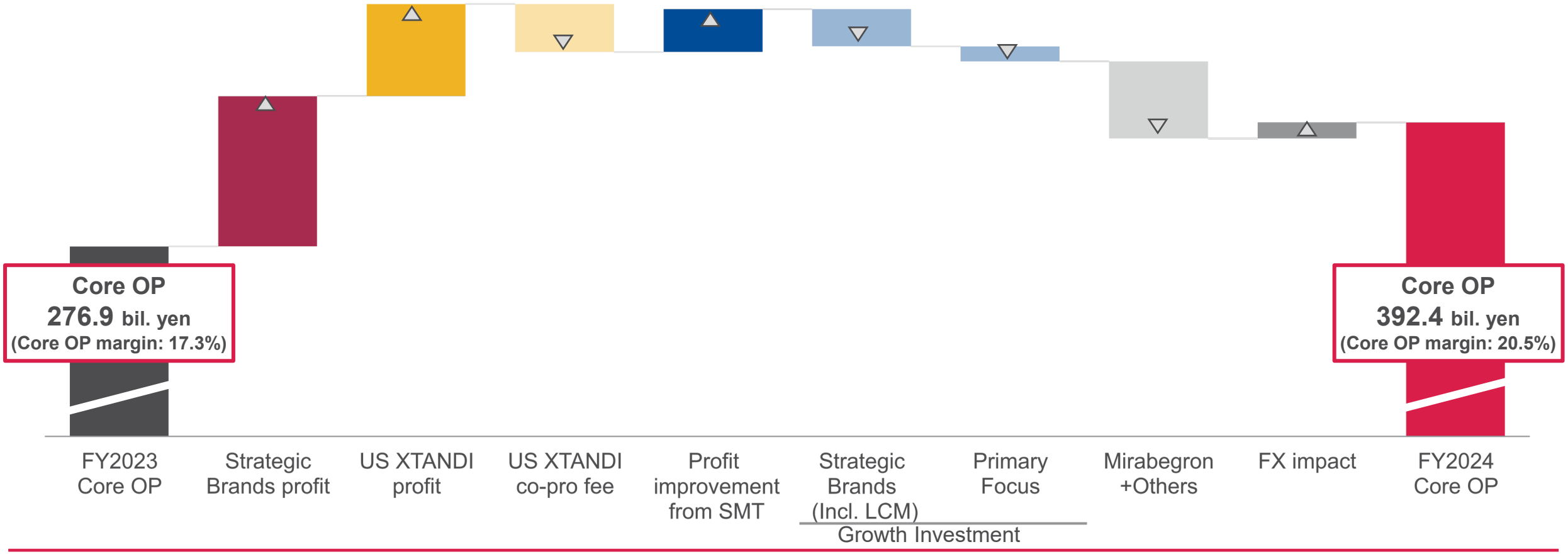
Drivers of Core OP Growth

- *FY2024 Core OP increased significantly YoY (+115.5 bil. yen)*
- *Strategic Brands' profitability contributed substantially to Core OP growth*
- *Strong SMT progress, generated further growth investment*



SMT: Sustainable Margin Transformation, LCM: Lifecycle management

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Main Brands: FY2024 Key Events

(Blue: Updates since the last financial results announcement)

Achieved label/indication/geographic expansion for IZERVAY, PADCEV and VYLOY as key growth drivers

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)
avacincaptad pegol/ IZERVAY		Complete response (Label update/US) Nov Withdrawal of MAA (Europe) Oct	Resubmission acknowledgment	Jan Feb Approval (Label update/US) Feb Submission (Japan)
enfortumab vedotin/ PADCEV		Aug Approval (2L+ mUC/China, 1L mUC/Europe) Sep Approval (1L mUC/Japan)		Jan Approval (1L mUC/China)
zolbetuximab/ VYLOY	May Resubmission acknowledgment (US)	Sep Approval (Europe)	Oct Approval (US) Dec Interim analysis (Pancreatic)	Dec Approval (China) IDMC recommended study continuation to final analysis
enzalutamide/ XTANDI		Jun Approval (M1 CSPC/China)		

<Other update>

- enfortumab vedotin / PADCEV: Follow-up data from EV-302 study presented at ASCO GU in Feb 2025 (See slides 42-43 for details)
- fezolinetant / VEOZAH: First subject first treatment in China Phase 2 study* in Apr 2025

As of Apr 2025. VEOZAH: Approved as "VEOZA" in ex-US. *fezolinetant dose: 45 mg
MAA: Marketing Authorization Application, 2L+: Second or later line, mUC: Metastatic urothelial cancer, 1L: First line, IDMC: Independent Data Monitoring Committee, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, ASCO GU: American Society of Clinical Oncology Genitourinary Cancers Symposium

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Progress in Focus Area Approach (1/2): ASP3082 (Targeted Protein Degradation)

***Successfully achieved the first PoC**, leading to acceleration of the flagship and follow-on programs*

Overview of Program

Protein degrader targeting KRAS G12D mutant

- Target disease: Cancers harboring KRAS G12D mutation
  - ✓ Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~5% in non-squamous NSCLC, ~15% in CRC[1]

Latest Status

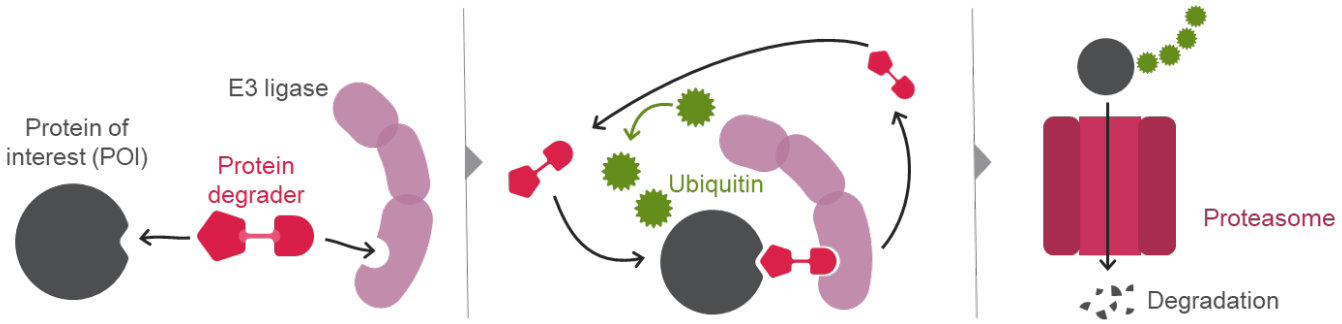
PoC in PDAC achieved based on 2/3L data

- Discussion ongoing to proceed with a registrational study
- Other cohorts ongoing in Phase 1 study
  - ✓ PDAC: 1L (combo with chemotherapy)
  - ✓ NSCLC: 2L+ (monotherapy); PoC judgment anticipated for 1H/FY2025
  - ✓ CRC: 2L+ (monotherapy & combo with cetuximab); PoC judgment anticipated for 2H/FY2025
- Additional data presentation: Aiming for 2H/FY2025

Potential of TPD as a Platform

Overcome limitations of traditional small molecules and address "undruggable" targets

- Accelerate research and development of follow-on programs
  - ✓ Pan-KRAS degrader: Targeting FSFT in FY2025
  - ✓ Expansion to other oncology targets
- Create new generation of protein degraders through combining internal capabilities with external collaborations



1. npj Precis Oncol. 2022;6:91

PoC: Proof of concept, KRAS: Kirsten rat sarcoma viral oncogene homologue, PDAC: Pancreatic ductal adenocarcinoma, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, 2/3L: Second and third line, 1L: First line, 2L+: Second or later line, TPD: Targeted Protein Degradation, FSFT: First subject first treatment

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Progress in Focus Area Approach (2/2): AT845 (Genetic Regulation)

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

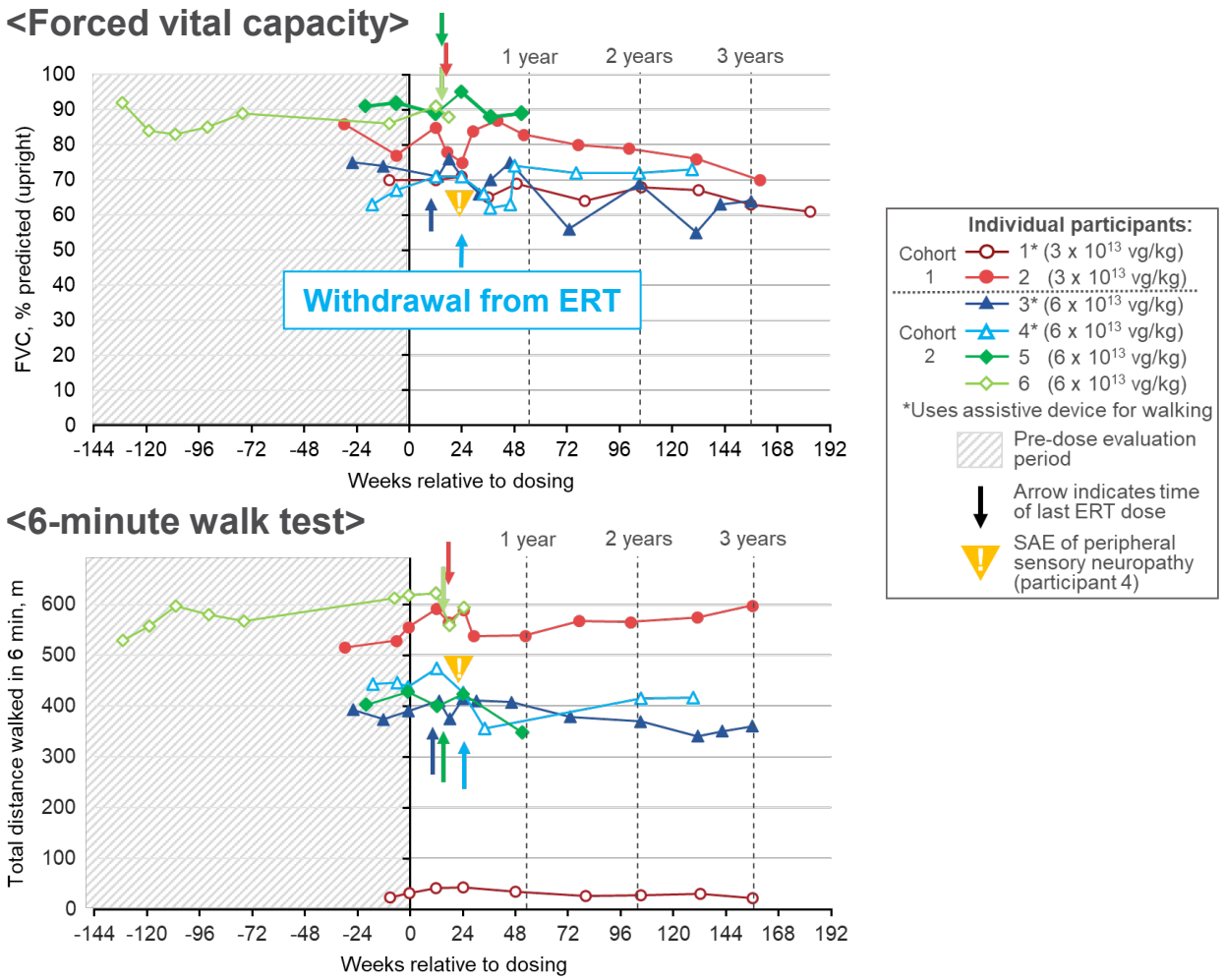
Overview of Program

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]

Latest Status

- Follow-up data from Phase 1/2 FORTIS study presented at WORLD*Symposium* in Feb
  - ✓ Five of six participants have discontinued ERT, and remained clinically stable while off ERT for 1-3 years
- RMAT designation granted by FDA in Feb
- Enrollment completed (total 11 participants), PoC judgment anticipated for 2H/FY2025



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

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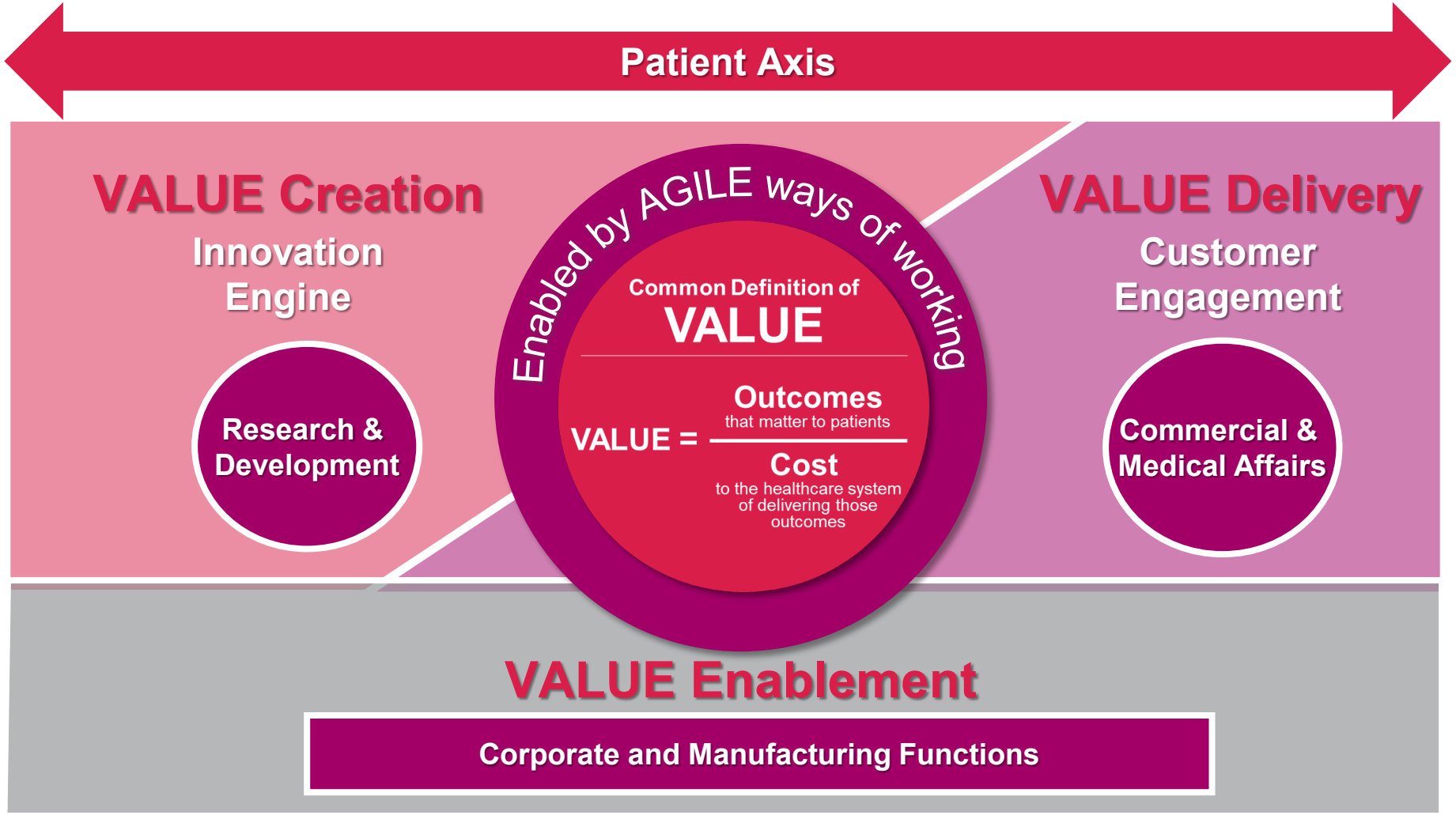
End-to-End Activities Along Patient Axis

Promote activities swiftly and efficiently from early research through to commercialization and LCM



LCM: Lifecycle management

FY2025 Outlook: Overview

Strategic Brands

- Continued strong momentum to drive overall revenue and profit growth (underlying growth excluding FX impact: **+50%**)
- Expect multiple data readouts from studies for lifecycle management

Focus Area approach

- Expect further PoC judgment of flagship programs

FY2025 Forecast

- Revenue: Forecasted to increase (underlying growth excluding FX impact: **+7%**)
- SG&A expenses: Continue cost optimization through SMT, expect further improvement in SG&A ratio (-1.0ppt)
- R&D expenses: Expand investment in Primary Focus with achieved PoC
- Core OP: Forecasted to increase (underlying growth excluding FX impact: **+11%**)

Shareholder Return

- Dividend per share forecasted at 78 yen, an increase of 4 yen

*Excl. US XTANDI co-pro fee
Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA
PoC: Proof of concept, SMT: Sustainable Margin Transformation

FY2025 Forecast: Main Brands

Continued strong momentum in Strategic Brands to ***drive overall revenue and profit growth***

(billion yen)	FY2025 FCST	YoY (vs. FY2024)	
Strategic Brands Total	**470.0**	**+133.6 (+40%)**	✓ Robust growth to continue in FY2025 (underlying growth excl. FX impact: **+50%** YoY) ✓ **IZERVAY**, **PADCEV**, and **VYLOY** to be key drivers
PADCEV	**200.0**	**+35.9 (+22%)**	✓ Continued strong global sales growth ✓ Substantial growth from ex-US markets driven by 1L mUC approvals
izervay	**105.0**	**+46.7 (+80%)**	✓ Returned to growth following the US label update, raising prospects for a strong outlook ✓ Transition from upfront investment phase to profit generating phase
VEOZAH	**50.0**	**+16.2 (+48%)**	✓ Global sales projected to grow steadily ✓ Growth in launched markets, supported by anticipated new launches in EST and INT
VYLOY	**40.0**	**+27.8 (+228%)**	✓ Significant sales growth expected, driven primarily by the US and Japan ✓ Sales contribution from China expected post-launch
XOSPATA	**75.0**	**+7.0 (+10%)**	✓ Continued steady growth in launched markets ✓ Next potential growth driver to be anticipated additional indication of newly diagnosed AML (PASHA study), contribution expected from FY2026 onwards post-approval
Xtandi	**868.0**	**-44.3 (-5%)**	✓ Global sales expected to be the similar level YoY (excl. FX impact), with growth of ex-US markets mitigating the negative impact of US Medicare Part D redesign

FX rates for FY2025 FCST: 140 yen/USD, 160 yen/EUR (FX rates for FY2024 Actual: 152 yen/USD, 164 yen/EUR)
1L: First line, mUC: Metastatic urothelial cancer, AML: Acute myeloid leukemia, VEOZAH: Approved as “VEOZA” in ex-US, EST (Established Markets): Europe, Canada, etc., INT (International Markets): Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Taiwan, Korea, Australia, Export sales, etc.

PADCEV & VYLOY: Business Update and Outlook

PADCEV

*Sales growth across all markets, driving sales toward **200.0 bil. yen***

	FY2025 FCST	YoY (vs. FY2024)
Global sales	**200.0 bil. yen**	**+35.9 (+22%)**
US ($ basis)	$790M	+74 (+10%)
EST (€ basis)	€250M	+50 (+25%)
Japan	27.0 bil. Yen	+14.4 (+114%)
CN	12.0 bil. Yen	+8.1 (+208%)
INT	9.0 bil. yen	+3.3 (+58%)

- Strong global sales growth expected, driven by 1L mUC
- 1L mUC approval countries increased to 21
  Further increase in approval and reimbursement progress anticipated in FY2025
- All regions contributing to sales expansion
  - ✓ Japan, CN, INT expected to scale toward impactful sales level
  - ✓ US growth expected to be moderate, reflecting already high 1L mUC market share

VYLOY

***Significant growth** driven primarily by US and Japan, combined with regional expansion*

	FY2025 FCST	YoY (vs. FY2024)
Global sales	**40.0 bil. yen**	**+27.8 (+228%)**
US ($ basis)	$120M	+88 (+275%)
EST (€ basis)	€30M	+17 (+131%)
Japan	14.0 bil. yen	+8.8 (+169%)
CN	4.0 bil. yen	+4.0
INT	1.0 bil. yen	+1.0

- FY2025 poised for significant growth, with substantial contribution from US and Japan
- Approved in 43 countries, launched in 15 countries
  Launch footprint steadily expanding; broader expansion expected in FY2025
- China launch anticipated in Q1, with sales contribution expected post-launch
- CLDN18.2 testing rates projected to increase globally, supporting efforts to expand market share

FX rates for FY2025 FCST: 140 yen/USD, 160 yen/EUR (FX rates for FY2024 Actual: 152 yen/USD, 164 yen/EUR)
1L: First line, mUC: Metastatic urothelial cancer, CLDN18.2: Claudin 18.2, EST (Established Markets): Europe, Canada, etc. CN (China): China, Hong Kong,
INT (International Markets): Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Taiwan, Korea, Australia, Export sales, etc.

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IZERVAY: Business Update and Outlook (US)

*Return to **growth trajectory** following temporary downturn. High profitability to drive strong **profit contribution***

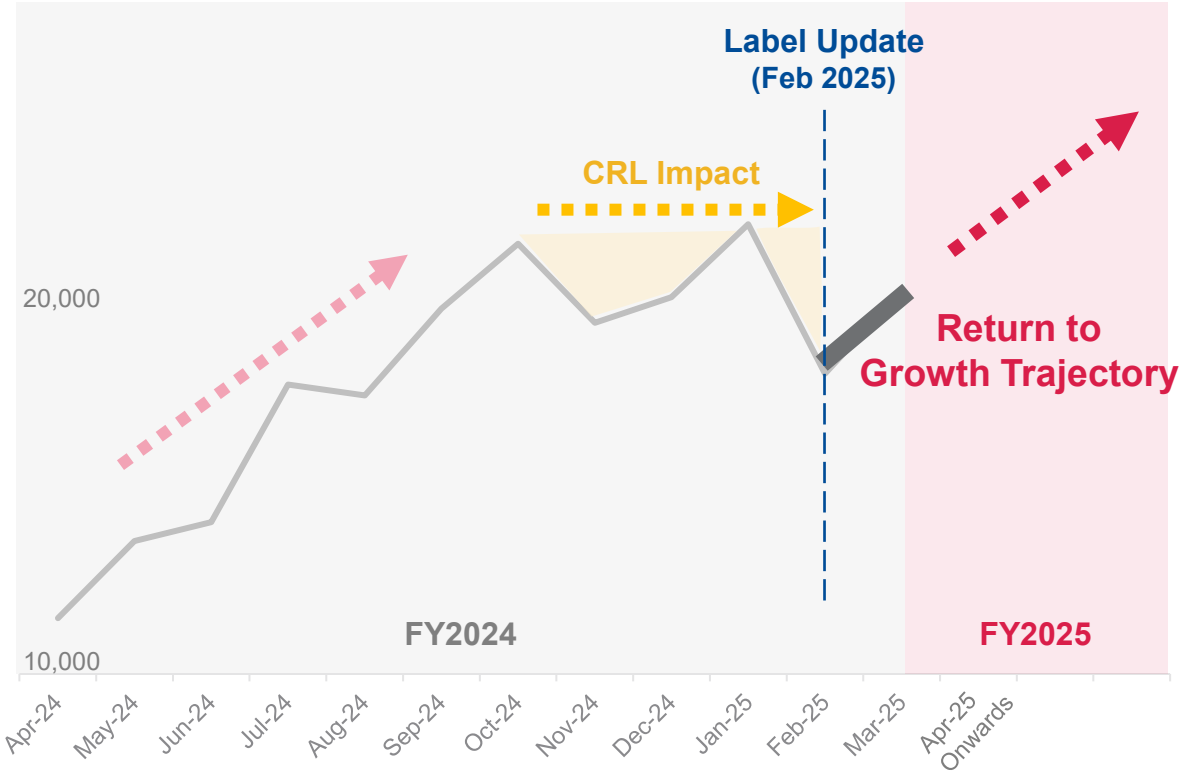
	FY2025 FCST	YoY (vs. FY2024)
	105.0 bil. yen	**+46.7 (+80%)**
$ basis	$750M	+368 (+96%)

- Temporary demand softness in Nov-Feb due to CRL impact
- Returned to **upward trend in Mar** following label update

- Widely available in retina practices and continues to be the favored GA product for new patients
  - ✓ New patient starts recovered to **~60%** in Feb after temporary decline in Dec due to CRL
  - ✓ Available in over 2,000 retina accounts
  - ✓ Over 50,000 patients treated sinch launch
  - ✓ Post-marketing safety profile remains consistent with clinical trial

- DTC efforts leading signs of increased diagnosis and treatment rates
- Signs of growth momentum in Apr, raising prospects for a strong outlook
- Transition from upfront investment phase to **profit generating phase**

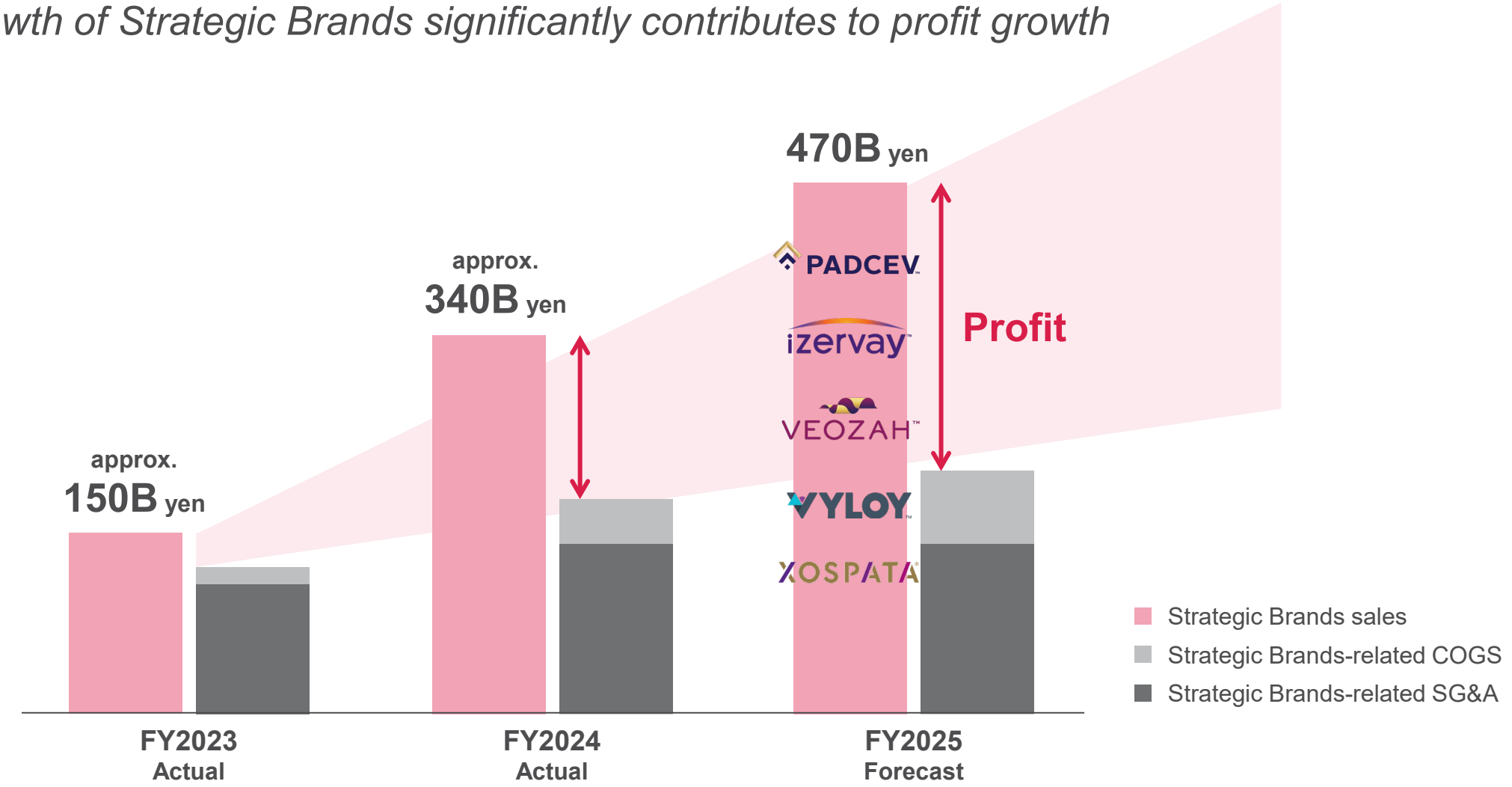
Demand Trend (Vials)



FX rates for FY2025 FCST: 140 yen/USD, 160 yen/EUR (FX rates for FY2024 Actual: 152 yen/USD, 164 yen/EUR)
GA: Geographic atrophy, CRL: Complete response letter, DTC: Direct-to-consumer

Image of Profit Contribution from Strategic Brands

Sales growth of Strategic Brands significantly contributes to profit growth



Strategic Brands: FY2025 Key Expected Events

Expect multiple data readouts from studies for lifecycle management

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)
avacincaptad pegol/ IZERVAY		Stargardt disease/ Phase 2b	MHLW decision (GA secondary to AMD /Japan)	
enfortumab vedotin/ PADCEV	1L head & neck/ EV-202	MIBC/EV-303 & EV-304 interim analysis* (registrational)	NMIBC/EV-104	
zolbetuximab/ VYLOY		Pancreatic/ GLEAM final analysis* (registrational)		

Data readout

Regulatory decision

As of Apr 2025. *The timeline is subject to shift due to its event-driven nature
MHLW: Ministry of Health, Labour and Welfare, GA: Geographic atrophy, AMD: Age-related macular degeneration, 1L: First line, MIBC: Muscle-invasive bladder cancer, NMIBC: Non-muscle-invasive bladder cancer

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Focus Area Approach: Future Outlook

Advance PoC judgment of flagship programs and converge to prioritized Primary Focuses

	FY2024	FY2025 Q1 (Apr-Jun)	FY2025 Q2 (Jul-Sep)	FY2025 Q3 (Oct-Dec)	FY2025 Q4 (Jan-Mar)
ASP3082 (Targeted Protein Degradation)	★ PoC Achieved (PDAC)	NSCLC	NSCLC	CRC	CRC
ASP2138 (Immuno-Oncology)		G/GEJ adenocarcinoma	G/GEJ adenocarcinoma		
AT845 (Genetic Regulation)				Pompe disease	Pompe disease
ASP7317 (Blindness & Regeneration)				GA secondary to AMD	GA secondary to AMD

PoC judgment → Convergence

- Prioritize PF with successful PoC
- Accelerate flagship and follow-on programs

Sales contribution after XTANDI LOE

ASP7317: Initial data to be presented at Retinal Therapeutics Innovation Summit in May 2025

See slides 35-36 for overview of flagship programs.

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

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FY2025 Forecast

- *Increase in Revenue and Core OP. Solid underlying growth excluding FX impact*
- *Continuous cost optimization through SMT, expect further improvement of SG&A ratio*

FX rates for FY2025 FCST: 140 yen/USD, 160 yen/EUR
FX rates for FY2024 Actual: 152 yen/USD, 164 yen/EUR

(billion yen)	FY2024 Actual	FY2025 FCST	Change (%)	Main Assumptions	Underlying growth excl. FX impact FY2025 FCST
Revenue	**1,912.3**	**1,930.0**	**+17.7 (+1%)**	• Strategic Brands: +133.6, XTANDI: -44.3, Mirabegron: -36.0	**2,036.0 (+7%)**
SG&A expenses	843.0	805.0	-38.0		
US XTANDI co-pro fee	252.6	229.0	-23.6	• Decrease in US XTANDI co-pro fee payment linked with sales decline	
SG&A excl. the above	590.5	576.0	-14.5	• Cost optimization through SMT: approx. -20.0	
(SG&A ratio*)	30.9%	29.8%	-1.0ppt	• Cost increase due to inflation	
R&D expenses	327.7	342.0	+14.3	• Investment to Strategic Brands (LCM) and Primary Focus: approx. +15.0	
(R&D ratio)	17.1%	17.7%	+0.6ppt		
Core operating profit	**392.4**	**410.0**	**+17.6 (+5%)**	• Forecast include a certain level of potential business risk	**435.0 (+11%)**
(Core OP margin)	20.5%	21.2%	+0.7ppt		

＜Full basis＞

Operating profit	**41.0**	**160.0**	**+119.0**

Main adjustments excluded on core basis

- Amortisation of intangible assets: approx. 140.0
- Other expenses: approx. 110.0 (risk of Impairment losses**, expenses related to organizational restructuring, foreign exchange losses, etc.)

*Excl. US XTANDI co-pro fee, **No impairment indication as of April 2025
Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA, SMT: Sustainable Margin Transformation, LCM: Lifecycle management

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Key Takeaways

Record-high Revenue and Core OP in FY2024
Further growth in FY2025, with double-digit underlying profit growth

- Robust growth of Strategic Brands
  Expect further growth in FY2025, transition to substantial profit generating phase

- PoC achieved in Targeted Protein Degradation
  Accelerate flagship and follow-on programs
  Continually judge PoC in other Primary Focuses

- Solid outcome from SMT
  Pursue further cost optimization

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

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

Brand	Potential Peak Sales *(Global, billions of yen)*
PADCEV (enfortumab vedotin) *	400.0 – 500.0
IZERVAY (avacincaptad pegol)	200.0 – 400.0
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 2025), VEOZAH: Approved as “VEOZA” in ex-US
*Disclosed as “in-market sales,” not Astellas revenue. Sales for Americas are calculated based on the sales booked by Pfizer

Capital Allocation

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

<Appropriate leverage level>

- **Gross Debt/EBITDA* of 1.0x to 1.5x**
  Continue to pursue further debt reduction in FY2025, while maintaining the priorities outlined in our Capital Allocation policy

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

*Gross Debt: Interest-bearing debt + Lease liabilities +Retirement benefit liabilities, etc,
EBITDA: Profit before tax + Amortisation of Intangible Assets (incl. software, etc.) + Depreciation (PP&E) + Interest expenses + Other expenses
CSP: Corporate Strategic Plan

FY2024 Actual: FX Rate

Average rate for the period

Currency	FY2023	FY2024	Change
USD	145 yen	152 yen	+8 yen
EUR	157 yen	164 yen	+7 yen

<Impact of exchange rate on financial results>

- Revenue: +68.1 billion yen
- Core OP: +15.1 billion yen

FY2025 Forecast: FX Rate & FX Sensitivity

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

Estimated FX sensitivity of FY2025 forecasts by 1 yen depreciation

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

Balance Sheet & Cash Flow Highlights

(billion yen)	FY2023 end	FY2024 end
Total assets	3,569.6	3,339.5
Cash and cash equivalents	335.7	188.4
Total equity attributable to owners of the parent	1,596.0	1,513.3
Equity ratio (%)	44.7%	45.3%

(billion yen)	FY2023	FY2024
Cash flows from operating activities	172.5	194.5
Cash flows from investing activities	-845.8	-89.4
Free cash flows	-673.3	105.1
Cash flows from financing activities	614.1	-261.4
Increase/decrease in short-term borrowings and commercial papers	324.3	-236.4
Proceeds from issuance of bonds and long-term borrowings	472.3	200.0
Redemption of bonds and repayments of long-term borrowings	-25.4	-52.1
Dividends paid	-116.7	-129.0

Balance of Bonds and Borrowings Highlights

(billion yen)	Dec 31, 2024	Mar 31, 2025
Balance of bonds and borrowings	915.4	831.4
Non-current liabilities	585.5	564.9
Bonds	320.0	320.0
Long-term borrowings	265.5	244.9
Current liabilities	329.9	266.5
Commercial papers	179.8	164.9
Short-term borrowings	67.2	20.0
Current portion of long-term borrowings	52.9	51.7
Current portion of bonds	30.0	30.0

Main Intangible Assets (as of Mar 31, 2025)

	Bil. yen	Foreign currency*
AT132	16.3	$109M
AT845	10.9	$73M
Gene therapy related technology**	64.2	$428M
VEOZAH*	86.2	€514M
VYLOY*	59.7	€460M
IZERVAY（US）	632.6	$4,218M
IZERVAY (Ex-US）	51.7	$345M
ASP7317	25.8	$172M

VEOZAH: Approved as “VEOZA” in ex-US
*VEOZAH, VYLOY: foreign currency is a reference value based on the currency at the time of acquisition of the intangible asset
**Acquired during the acquisition of Audentes (now Astellas Gene Therapies)

Sustainable Margin Transformation

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

FY2024 → FY2027

Strengthen monitoring on priority initiatives

1. Build critical in-house capability to reduce outsourcing **: ¥15B+**
   - Strengthen in-house capabilities for clinical development operations
   - Reduce outsourcing and advisory service costs
2. Further efficiency of global operations **: ¥20B+**
   - Establish global capability centers to optimize global operations
   - Enhance company-wide efficiency with AI and digital tools
3. Optimize selling expenses with ROI focus **: ¥35B+**
   - Cost efficiency from global organizational restructuring in FY2023
   - Strengthen optimization for mature products
4. Continuous company-wide cost optimization **: ¥50B+**
   - Streamline OPEX with no sacred areas
   - Improve manufacturing cost by scaling up and yield enhancement

Recurring annual benefit

Range of ¥120-150B

FY2024 end ~¥40B

Core OP margin

30%

Aspirational state

Growth Investment → **Maximize potential of Strategic Brands**

Focus on post-PoC prioritized PF assets

Profit Improvement → **Optimize a cost structure before XTANDI LOE**

Sustainable Margin Transformation

- Company-wide cost optimization before XTANDI LOE
- Fund growth investment and profit improvement

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

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Lifecycle Management of Strategic Brands

(Blue: Updates since the last financial results announcement)

Brand	Indication	Current status	Next milestone
PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	MIBC	Phase 3 EV-303 & EV-304 studies ongoing	Data readout (interim analysis) anticipated for **2H/CY2025**
	NMIBC	Phase 1 EV-104 study ongoing	Data readout anticipated for **Q3/FY2025**
	Head and neck cancer	2L+: Next step under discussion	(Under discussion)
		1L: Phase 2 EV-202 study ongoing	Data readout anticipated for **Q1/FY2025**
izervay (avacincaptad pegol intravitreal solution) 2 mg	GA secondary to AMD	Japan: **NDA under review**	**Regulatory decision anticipated for Q3/FY2025**
		LCM opportunities under consideration (e.g. prefilled syringe, sustained release)	(Under discussion)
	Stargardt disease	Phase 2 study ongoing	Data readout anticipated for **Q2/FY2025**
VEOZAH (fezolinetant) tablets 45 mg	VMS associated with menopause	Japan: Phase 3 STARLIGHT 2 & 3 studies ongoing	Data readout anticipated for FY2026
		China: Phase 2 study ongoing	**Data readout anticipated for FY2026**
	VMS in breast cancer women	Phase 3 HIGHLIGHT 1 study ongoing	Data readout anticipated for FY2027
VYLOY zolbetuximab for injection 100mg vial	Gastric and GEJ cancer	Phase 3 study in combo with pembrolizumab and chemotherapy under preparation	Study start in Q1/FY2025
	Pancreatic cancer	Registrational Phase 2 GLEAM study ongoing	Data readout (final analysis) anticipated for **Q2/FY2025**
XOSPATA gilteritinib 40mg tablets	Newly diagnosed AML (HIC-eligible)	Phase 3 PASHA study ongoing	Data readout (primary analysis) anticipated for **1H/FY2026**

As of Apr 2025. Not exhaustively listed. VEOZAH: Approved as "VEOZA" in ex-US. MIBC: Muscle-invasive bladder cancer, NMIBC: Non-muscle-invasive bladder cancer, GA: Geographic atrophy, AMD: Age-related macular degeneration, NDA: New Drug Application, LCM: Lifecycle management, VMS: Vasomotor symptoms, GEJ: Gastroesophageal junction, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy

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

(Blue: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology	Program	Mechanism of Action	Current status
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1/2 study ongoing
	Bispecific immune cell engager	★ ASP2138	Anti-CLDN18.2 and anti-CD3	Phase 1 study ongoing
		ASP1002	Anti-CLDN4 and anti-CD137	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	Phase 1 study ongoing
Targeted Protein Degradation	Protein degradation	★ ASP3082	KRAS G12D degrader	Phase 1 study ongoing. **PoC in PDAC achieved**
		ASP4396	KRAS G12D degrader	Phase 1 study ongoing
Genetic Regulation	Gene replacement (AAV)	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		★ AT845	GAA gene	Phase 1/2 study ongoing **(Enrollment completed)**. **Follow-up data from Phase 1/2 study presented at WORLD*Symposium* in Feb 2025**. **RMAT designation granted by FDA in Feb 2025**
Blindness & Regeneration	Cell replacement	★ ASP7317	RPE cells	Phase 1b study ongoing. **Initial data to be presented at Retinal Therapeutics Innovation Summit in May 2025**
Others (Non-PF)	Long-acting abiraterone prodrug	ASP5541 (PRL-02)	CYP17 lyase inhibitor	Phase 1 study ongoing
	Immune modulation*	ASP5502	STING inhibitor	Phase 1 study ongoing

Modality
- Small molecule
- Antibody
- Gene
- Cell

★: Flagship program

DGK: Diacylglycerol kinase, CLDN: Claudin, IL-2: Interleukin-2, KRAS: Kirsten rat sarcoma viral oncogene homologue, PoC: Proof of concept, PDAC: Pancreatic ductal adenocarcinoma, AAV: Adeno-associated virus, MTM1: Myotubularin 1, FDA: Food and Drug Administration, GAA: Acid alpha-glucosidase, RMAT: Regenerative Medicine Advanced Therapy, RPE: Retinal pigment epithelial, PF: Primary Focus, STING: Stimulator of interferon genes

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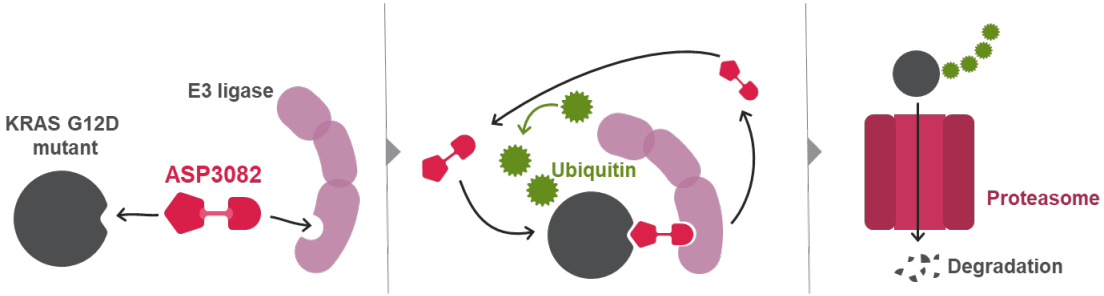
Overview of Primary Focus Flagship Programs (1/2)

ASP3082 (Targeted Protein Degradation)

Protein degrader targeting KRAS G12D mutant

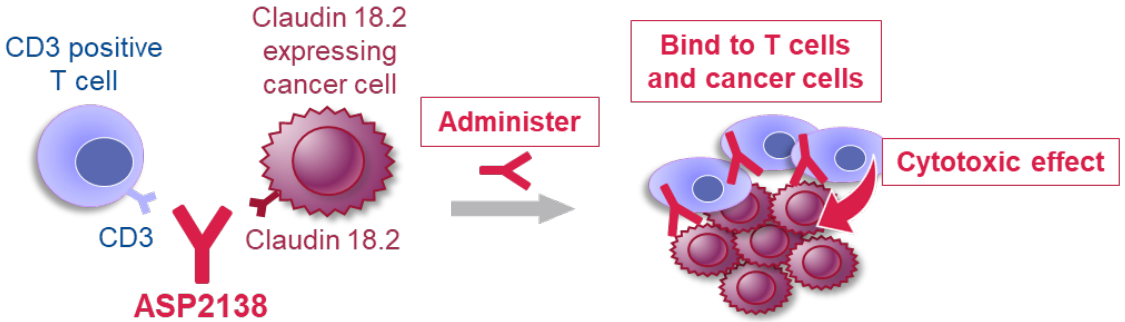
- Target disease: Cancers harboring KRAS G12D mutation
  - ✓ Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~5% in non-squamous NSCLC, ~15% in CRC[1]
- Standard of care (metastatic PDAC): Chemotherapy
- Status: Phase 1 study ongoing (NCT05382559)
  - ✓ PDAC: 2L+ (monotherapy), 1L (combo with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



ASP2138 (Immuno-Oncology)

Bispecific antibody targeting Claudin 18.2 and CD3

- Target disease: Gastric and GEJ (G/GEJ) adenocarcinoma, pancreatic adenocarcinoma
  - ✓ Rate of Claudin 18.2-positive patients*: ~70% in G/GEJ adenocarcinoma[2] and ~60% in pancreatic adenocarcinoma[3]
- Standard of care (HER2-, advanced G/GEJ adenocarcinoma)
  - ✓ 1L: chemotherapy +/- checkpoint inhibitor or zolbetuximab (Claudin 18.2-positive)
  - ✓ 2L+: paclitaxel + ramucirumab
- Status: Phase 1 study ongoing (NCT05365581)
  - ✓ G/GEJ adenocarcinoma, 1L & 2L, monotherapy & combo
- Anticipated PoC judgment timing: 1H/FY2025



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

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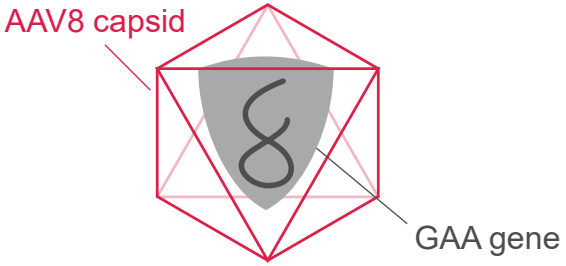
Overview of Primary Focus Flagship Programs (2/2)

AT845 (Genetic Regulation)

Recombinant AAV8 continuously expressing hGAA gene specially in muscle

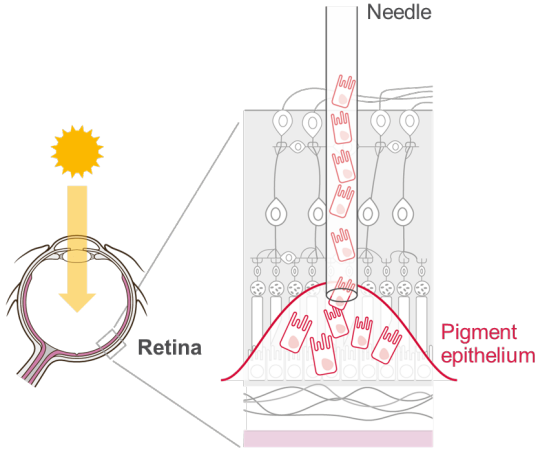
- Target disease: Pompe disease
  - ✓ Estimated incidence: 1 in ~40,000[1]
- Standard of care: Enzyme replacement therapy (ERT)
  - ✓ Chronic, repeated infusions every 2 weeks
  - ✓ Secondary disease progression after 2-3 years on ERT[2,3,4]
  - ✓ Substantial economic burden with high rates of healthcare resource utilization[5]
- Status: Phase 1/2 FORTIS study ongoing (NCT04174105)
  - ✓ Five of six participants have discontinued ERT, and remained clinically stable while off ERT for 1-3 years[6]
- Anticipated PoC judgment timing: 2H/FY2025



ASP7317 (Blindness & Regeneration)

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

- Target disease: Geographic atrophy secondary to AMD
  - ✓ Estimated Number of patients: ~5 million worldwide[7]
- Standard of care: Complement inhibitors
  - ✓ Slows progression, does not improve vision
  - ✓ Available only in limited countries
- Status: Phase 1b study ongoing (NCT03178149)
- Anticipated PoC judgment timing: 2H/FY2025



1. NORD (National Organization for Rare Disorders) at https://rarediseases.org/rare-diseases/pompe-disease/, 2. Neuromuscul Disord. 2021;31:91-100,
3. J Neurol. 2021;268:2482-2492, 4. Mol Genet Metab. 2012;106:301-309, 5. Mol Genet Metab. 2025;144:Article 108958, 6. WORLD*Symposium* 2025, 7. Retina. 2017;37:819-835
AAV: Adeno-associated virus, hGAA: Human acid alpha-glucosidase, PoC: Proof of concept, AMD: Age-related macular degeneration

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Robust Pipeline of Astellas

Phase 1

- enfortumab vedotin (NMIBC)
- ASP1570
- ASP2138
- ASP1002
- ASP1012
- ASP3082
- ASP4396
- ASP7317
- abiraterone decanoate/ ASP5541 (PRL-02)
- ASP5502

Phase 2

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

Phase 3

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

Submitted/Filed

- avacincaptad pegol (GA secondary to AMD; Japan)

Strategic Brands

Programs with Focus Area approach

Others

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

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

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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
	zocaglusagene nuzaparvovec/AT845 Pompe disease		**avacincaptad pegol** Geographic atrophy secondary to age-related macular degeneration: Japan	

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

Strategic Brands: Status Update

(Blue: Updates since the last financial results announcement)

Generic / Brand name	Indication	Current status
enfortumab vedotin/ PADCEV	Muscle-invasive bladder cancer	• Phase 3 studies ongoing (enrollment completed)
	Non-muscle-invasive bladder cancer	• Phase 1 study ongoing (enrollment completed)
	Other solid tumors	• Phase 2 study ongoing (enrollment completed)
avacincaptad pegol/ IZERVAY	GA secondary to AMD	• **Revised sNDA for label update approved in US in Feb 2025** • **NDA submitted in Japan in Feb 2025**
	Stargardt disease	• Phase 2b study ongoing (enrollment completed)
fezolinetant/ VEOZAH	VMS due to menopause	• Japan: Phase 3 studies ongoing • China: **Phase 2 study ongoing**
	VMS in breast cancer patients on adjuvant endocrine therapy	• Phase 3 study ongoing
zolbetuximab/ VYLOY	Gastric and GEJ adenocarcinoma	• Phase 3 study in combo with pembrolizumab and chemotherapy under preparation to start in Q1/FY2025
	Pancreatic adenocarcinoma	• Phase 2 study ongoing (enrollment completed)
gilteritinib/ XOSPATA	AML, post-HSCT maintenance	• Development based on Phase 3 MORPHO study discontinued
	AML, newly diagnosed (HIC-eligible)	• Phase 3 study ongoing (enrollment completed)
	AML, newly diagnosed (HIC-ineligible)	• Phase 2 study ongoing
	AML, post-chemotherapy	• Obtained topline results from Phase 2 GOSSAMER study

VEOZAH: Approved as “VEOZA” in ex-US.
GA: Geographic atrophy, AMD: Age-related macular degeneration, (s)NDA: (Supplemental) New Drug Application, VMS: Vasomotor symptoms, GEJ: Gastroesophageal junction, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy

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enfortumab vedotin (EV) (1/7): Nectin-4 Targeted ADC Overview of Development

- *The most significant growth driver is 1L mUC indication, which is expected to account for more than half of total sales in the future*
- *Success in NMIBC and other solid tumors may provide further growth potential*

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

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

<Early clinical phase> (Not included in potential peak sales)

Patient segment	Study (EV regimen)
NMIBC High-risk BCG-unresponsive	EV-104 [Phase 1] (monotherapy, intravesical)
Other solid tumors	EV-202 [Phase 2] (monotherapy* / combo w/ Pembro**)

*Monotherapy:
- HR+/HER2- breast cancer
- Triple-negative breast cancer
- Squamous non-small cell lung cancer
- Non-squamous non-small cell lung cancer
- Head and neck cancer
- Gastric and esophageal adenocarcinoma including GEJ adenocarcinoma
- Esophageal squamous cell carcinoma

**Combo w/ Pembro:
- Head and neck squamous cell carcinoma

*US, Germany, France, Italy, Spain, UK, Japan, China (based on internal estimates) **Excluding China. 1L: First line, mUC: Metastatic urothelial cancer, ADC: Antibody-drug conjugate, NMIBC: Non-muscle-invasive bladder cancer, MIBC: Muscle-invasive bladder cancer, 2L+: Second or later line, Cis: Cisplatin, Pembro: Pembrolizumab, AA: Accelerated Approval, BCG: Bacillus Calmette-Guerin, HR+: Hormone receptor positive, HER2-: HER2 negative, GEJ: Gastroesophageal junction

enfortumab vedotin (EV) (2/7): Clinical Studies

Urothelial cancer

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

Other solid tumors

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

MIBC: Muscle-invasive bladder cancer, Cis: Cisplatin, Pembro: Pembrolizumab, RC: Radical cystectomy, Chemo: Chemotherapy, mUC: Metastatic urothelial cancer, mono: Monotherapy, sBLA: Supplemental Biologics License Application, NMIBC: Non-muscle-invasive bladder cancer, BCG: Bacillus Calmette-Guerin, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer, GEJ: Gastroesophageal junction

enfortumab vedotin (EV) (3/7): Study Data by Disease Stage of UC

(Blue: Updates since the last financial results announcement)

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

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

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

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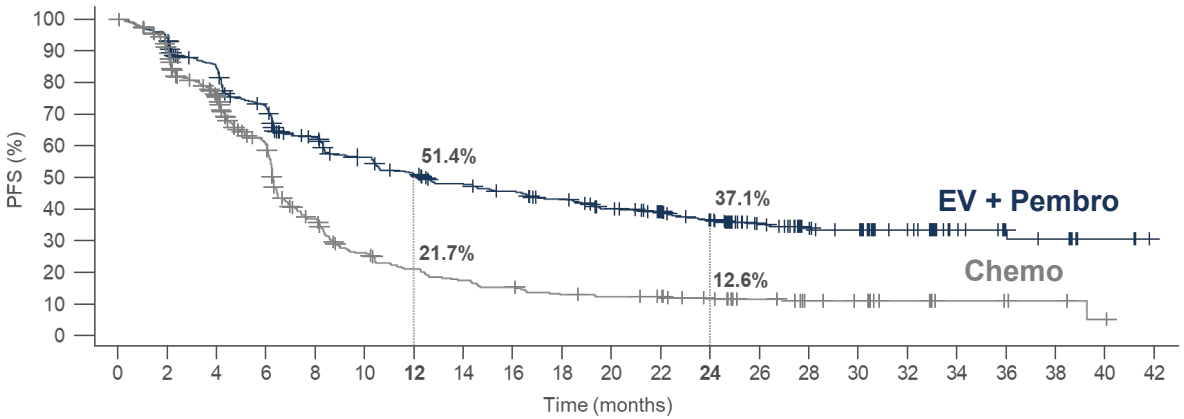
enfortumab vedotin (EV) (4/7): Study Data in 1L mUC (EV-302)

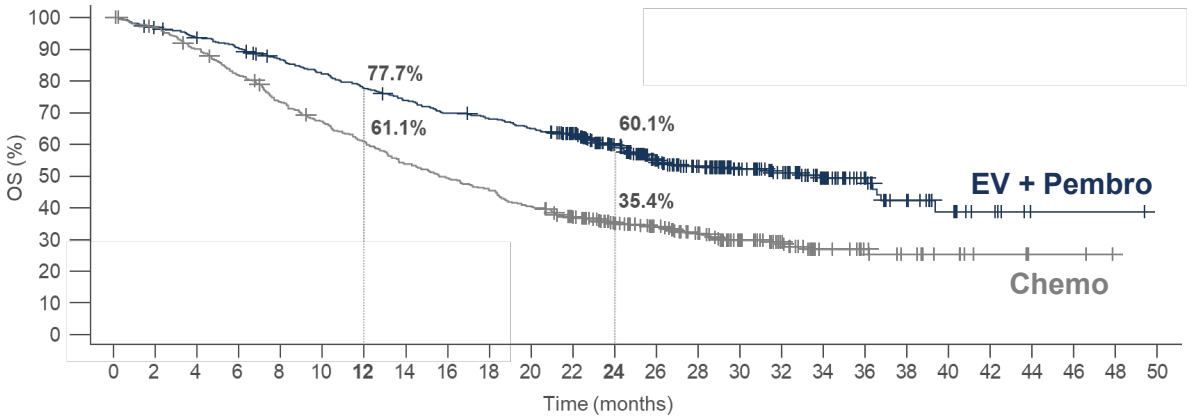
Statistically significant and clinically meaningful improvement over chemotherapy with nearly doubled mOS and mPFS

<Progression-free survival>



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

<Overall survival>



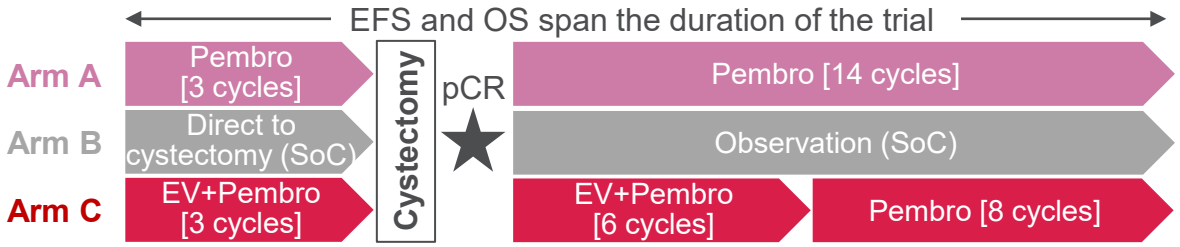
	N	Events	HR (95% CI)	2-sided P value	mOS (95% CI), months
EV + Pembro	442	203	0.51 (0.43, 0.61)	<0.00001	33.8 (26.1, 39.3)
Chemo	444	297			15.9 (13.6, 18.3)

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

Data cutoff: August 8, 2024
1L: First line, mUC: Metastatic urothelial cancer, (m)OS: (Median) Overall survival, PFS: Progression-free survival, Pembro: Pembrolizumab, Chemo: Chemotherapy, HR: Hazard ratio, CI: Confidence interval, NR: Not reached

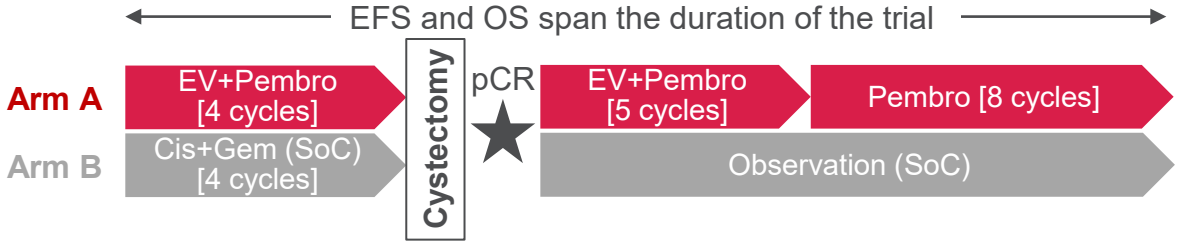
enfortumab vedotin (EV) (5/7): Development for Muscle-invasive bladder cancer (MIBC)

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



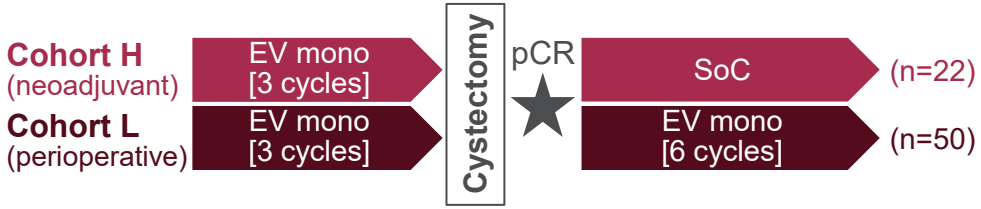
- Endpoints:
  - ✓ Primary: EFS
  - ✓ Key secondary: OS, pCR
- n=595, randomized 1:1:1
- Arm C added to the Merck-sponsored KEYNOTE-905 study

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



- To assess EV monotherapy in MIBC to support the EV+Pembro combo treatment outcome
- Primary endpoint: pCR

<Results>

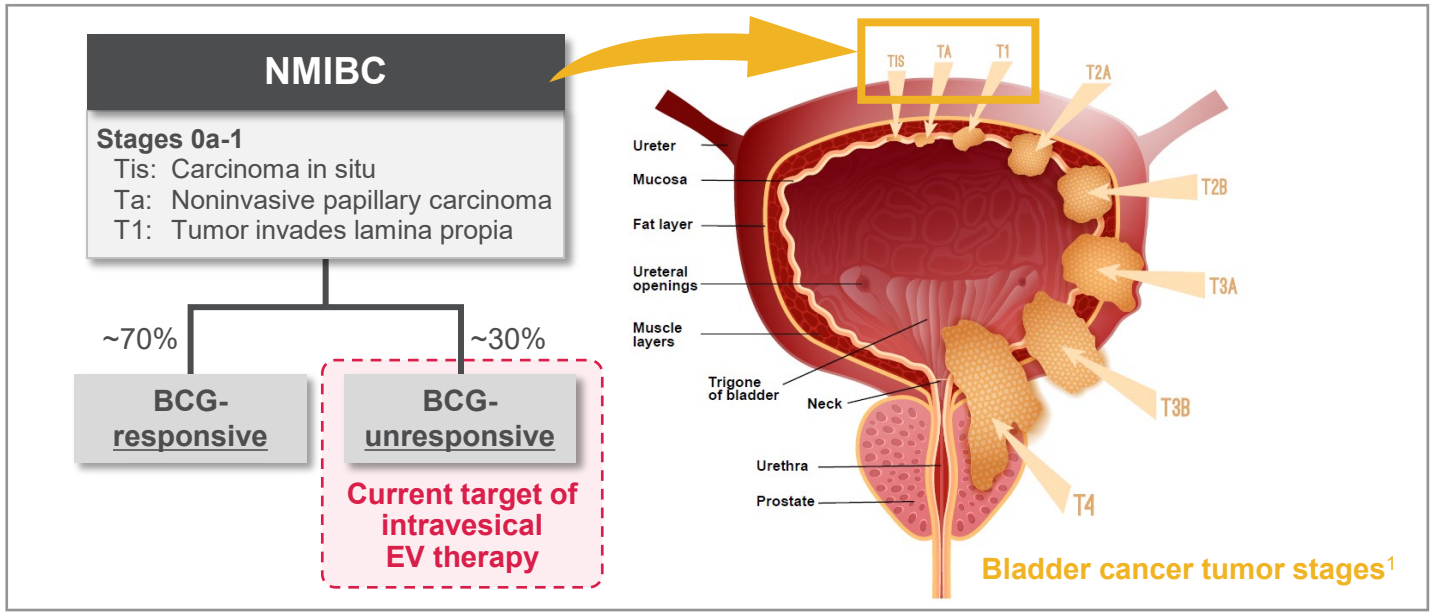
Cohort	pCR	pDS
H	36.4%	50.0%
L	34.0%	42.0%

1 cycle = 21 days

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

enfortumab vedotin (EV) (6/7): Development for Non-muscle-invasive bladder cancer (NMIBC)

Explore the activity of intravesical EV in earlier-stage urothelial cancer



SoC and UMNs

- The traditional SoC is TURBT followed by intravesical BCG therapy, reducing disease recurrence by about 70%
- Approx. 30% of patients are unresponsive to BCG, and recurrence and progression remain common
- Treatment options for BCG-unresponsive patients are limited

Clinical study

- Phase 1 EV-104 study with intravesical EV dosing in high-risk BCG-unresponsive NMIBC patients

1. NCCN Guideline for Patients - Bladder Cancer, Version 2019

SoC; Standard of care, UMN: Unmet medical need, BCG: Bacillus Calmette-Guerin, TURBT: Transurethral resection of the bladder tumor

enfortumab vedotin (EV) (7/7): Study Data in Solid Tumors Other than Urothelial Cancer (EV-202)

Cohort	Cancer type	n	ORR	
			Target*	Result
1	HR+/HER2- breast cancer	45	30%	**15.6%**
2	Triple-negative breast cancer	42	25%	**19.0%**
3	Squamous non-small cell lung cancer	23	17.5%	**4.3%**
4	Non-squamous non-small cell lung cancer	43	25%	**16.3%**
5	Head and neck cancer	46	17.5%	**23.9%**
7	Gastric and esophageal adenocarcinoma incl. GEJ adenocarcinoma	42	17.5%	**9.5%**
8	Esophageal squamous cell carcinoma	44	17.5%	**18.2%**
9	1L head and neck squamous cell carcinoma	Ongoing		

Cohorts 1-8: Second or later line, monotherapy
Cohort 9: First line, combo with pembrolizumab
*Minimum responders needed to declare promising antitumor activity

ORR: Objective response rate, HR+: Hormone receptor positive, HER2-: HER2 negative, GEJ: Gastroesophageal junction, 1L: First line

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

(Blue: Updates since the last financial results announcement)

Geographic atrophy (GA)

- Advanced form of dry age-related macular degeneration (AMD)
- Globally, approximately 5 million people are estimated to have GA at least in one eye[1]
- Approximately 75% of people living with GA in the US are believed to be undiagnosed[2]
- Without timely treatment, an estimated 66% of people with GA may become blind or severely visually impaired[3]

Characteristics of ACP

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

GA secondary to AMD	**P2/3: GATHER1**	NCT02686658	Part 1: 1 mg, 2 mg vs. Sham (n=77) Part 2: 2 mg, 4 mg vs. Sham (n=209)	n=286	**Revised sNDA for label update approved in US in Feb 2025. NDA submitted in Japan in Feb 2025**
	P3: GATHER2	NCT04435366	2 mg vs. Sham	n=448	
Stargardt disease	**P2b**	NCT03364153	vs. Sham	n=121	Enrollment completed

1. Retina. 2017;37:819-835, 2. IQVIA Medical Claims (DX) data Jan ’20-Dec ’21: 24 Months, 3. JAMA Ophthalmol. 2021;139:743-750
(s)NDA: (Supplemental) New Drug Application

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

VMS in breast cancer women receiving adjuvant endocrine therapy

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

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

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zolbetuximab: Anti-Claudin 18.2 Monoclonal Antibody

(Blue: Updates since the last financial results announcement)

Target: Claudin 18.2 (CLDN18.2)

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

Gastric and GEJ adenocarcinoma

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

Pancreatic adenocarcinoma

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

Gastric and GEJ adenocarcinoma	**P3: LUCERNA**	NCT06901531	**First line, combo with Pembro and chemo, DB, vs. placebo**	**n=500**	**Under preparation to start in Q1/FY2025**
	P2: ILUSTRO	NCT03505320	Cohort 1: Third or later line, zolbetuximab monotherapy Cohort 2: First line, combo with mFOLFOX6 Cohort 3: Third or later line, combo with Pembro Cohort 4: First line, combo with mFOLFOX6 and nivolumab Cohort 5: Perioperative, combo with FLOT	n=143	Enrollment completed
Pancreatic adenocarcinoma	**P2: GLEAM**	NCT03816163	First line, combo with nab-paclitaxel and gemcitabine, open	n=393	Enrollment completed

*CLDN18.2 positivity is defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining
GEJ: Gastroesophageal junction, Pembro: Pembrolizumab, chemo: Chemotherapy, DB: Double-blind, mFOLFOX6: 5-FU, leucovorin and oxaliplatin, FLOT: Fluorouracil, leucovorin, oxaliplatin and docetaxel

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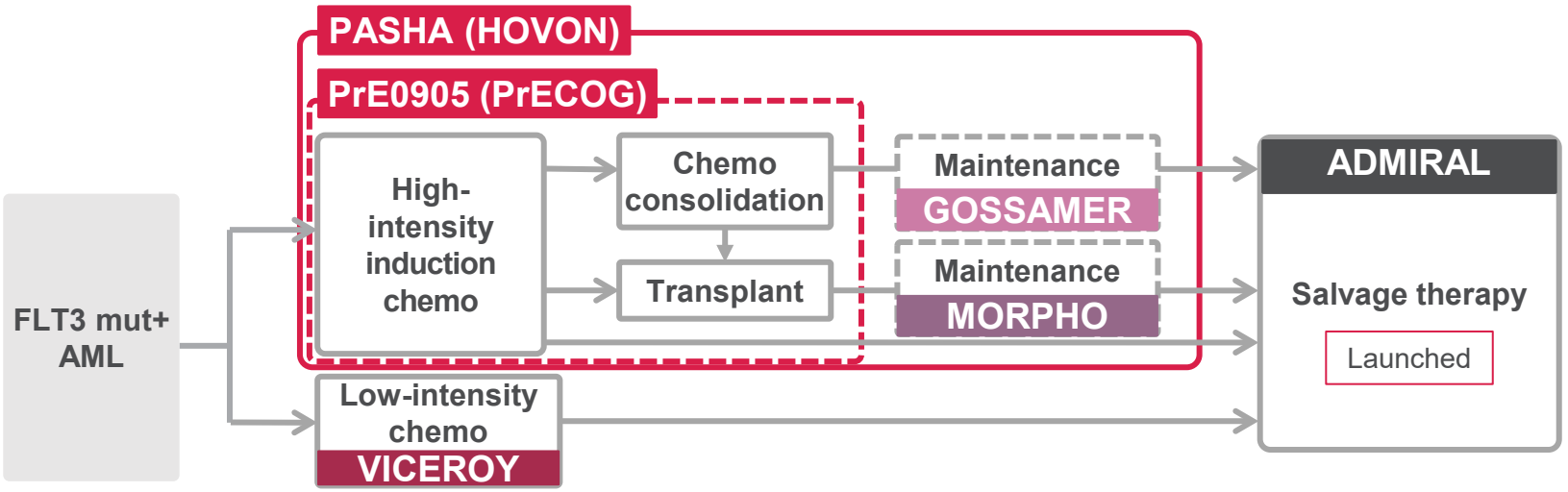
gilteritinib: FLT3 Inhibitor



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

China

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

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

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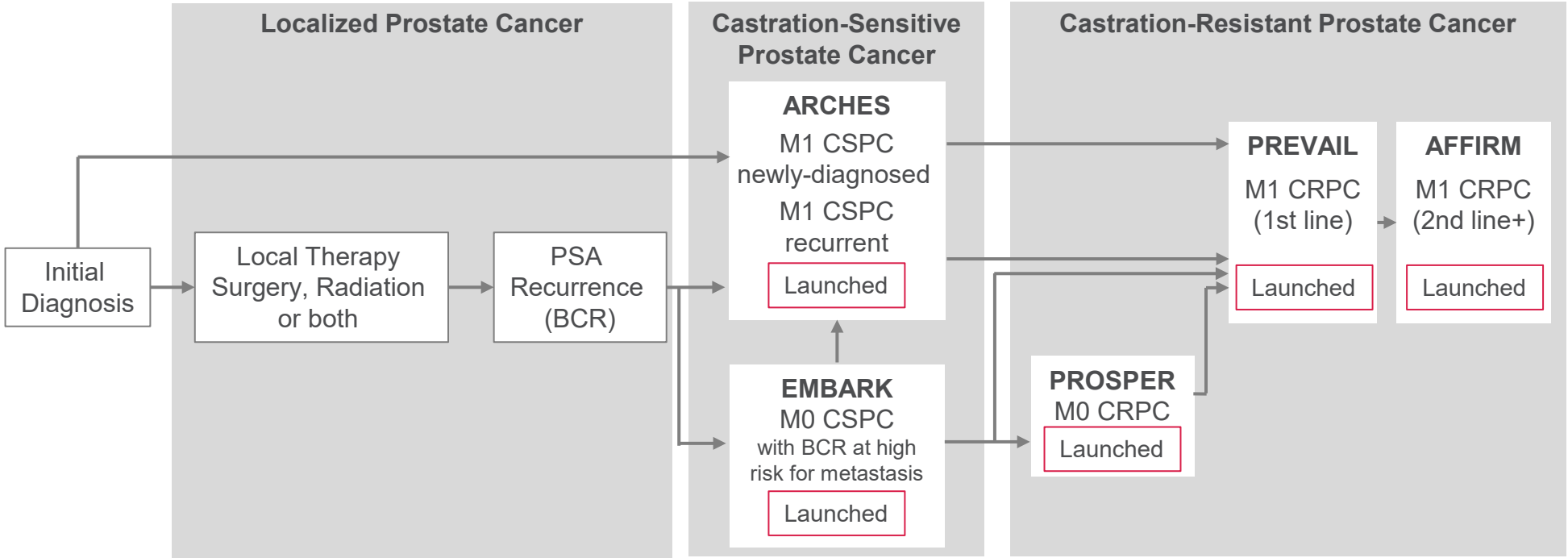
enzalutamide (1/2): Androgen Receptor Inhibitor



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

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

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

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

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

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

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