Q3 YTD/FY2024 Financial Results



Atsushi Kitamura Chief Financial Officer (CFO) Astellas Pharma Inc. February 4, 2025

Cautionary Statement Regarding Forward-Looking Information

In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.



Agenda



Q3 YTD/FY2024 Consolidated Financial Results FY2024 Revised Forecast

Ш

Initiatives for Sustainable Growth



Q3 YTD/FY2024 Financial Results: Key Message

Revenue

- Increased significantly YoY (+22%)
- Strategic Brands: Expanded to over 240.0 bil. yen (+140.0 bil. yen YoY)

SG&A expenses*

SG&A ratio improved by 4.0ppt YoY, driven by robust progress of SMT (Sustainable Margin Transformation)

Core operating profit

Increased significantly YoY (+44%), driven by growth of XTANDI, Strategic Brands and SMT cost optimization

Revised full-year forecast

Upward revision of revenue (+100.0 bil. yen), core OP (+70.0 bil. yen) based on robust core business progress



Q3 YTD/FY2024 Financial Results

(billion yen)	Q3 YTD FY2023	Q3 YTD FY2024	Change	Change (%)	FY2024 Latest FCST	FX impact (YoY)
Revenue	1,189.1	1,453.0	+264.0	+22.2%	1,900.0	+66.3
Cost of sales	219.3	272.3	+53.1	+24.2%	345.0	+7.6
SG&A expenses	547.0	631.7	+84.8	+15.5%	845.0	+31.7
US XTANDI co-pro fee	146.2	200.1	+53.9	+36.8%	255.0	+12.1
SG&A excl. the above	400.7	431.6	+30.9	+7.7%	590.0	+19.6
(SG&A ratio*)	33.7%	29.7%	-4.0ppt	717 70	31.1%	
R&D expenses	216.3	251.4	+35.1	+16.2%	340.0	+9.9
(R&D ratio)	18.2%	17.3%	-0.9ppt	-	17.9%	
Core operating profit**	206.5	297.5	+91.0	+44.1%	370.0	+17.1
(Core OP margin)	17.4%	20.5%	+3.1ppt	70	19.5%	
<full basis=""></full>						
Amortisation of intangible assets	66.2	104.2	+38.0	+57.5%		Note) Amortisation of IZERVAY's intangible assets started from Q2/FY2023
Other income	8.5	4.4	-4.1	-47.9%		Other expenses (booked in Q3)
Other expenses	84.0	220.6	+136.6	+162.7%		Impairment losses on intangible assets: 180.5
Operating profit	74.1	-22.5	-96.6	-	11.0	Major impairment losses include: IZERVAY (Ex-US): 115.1,
Profit before tax	73.6	-29.3	-102.9	-	1.0	AT466: 51.8, iota: 8.0
Profit	50.3	-24.1	-74.5	-	14.0	



Q3 YTD/FY2024 Financial Results: XTANDI and Strategic Brands

XTANDI: US performance exceeded expectations, while other regions expanded as expected

(billion yen)	Q3 YTD/FY2024	YoY	FY2024 FCST*	
Xtandi	703.1	+143.1 (+26%)	909.9	 ✓ Strong US growth driven by EMBARK impact (M0 CSPC) ✓ Upward revision of FCST based on Q3 overperformance, despite the anticipated negative impact from US IRA Medicare Part D redesign in Q4

Strategic Brands: On track to achieve total FCST of over 340.0 bil. yen, building confidence towards FY2025 target 500.0 bil. yen

(billion yen)	Q3 YTD/FY2024	YoY	FY2024 FCST*	
Strategic Brands Total	243.8	+138.1 (+131%)	344.9	✓ Significant contribution to profit growth✓ Expect further growth in FY2025 and beyond
PADCEV.	117.0	+61.4 (+110%)	165.2	 ✓ Continues to demonstrate strong global growth ✓ Expect steady growth moving forward, primarily driven by ex-US 1L mUC
izervay **	44.4	+39.2 (+743%)	71.5	 ✓ Label update resubmission accepted by FDA (PDUFA date: Feb 26) ✓ Expect growth to accelerate after approval
VEOZAH™	24.4	+20.9 (+586%)	32.5	 ✓ Steady global sales growth, in line with expectations ✓ Expect steady linear growth moving forward
YYLOY	4.9	+4.9	9.5	 ✓ Uptake in Japan, US and Europe exceeded expectations Aided by higher-than-expected rates of CLDN18.2 testing ✓ Upward revision of FCST reflecting strong performance
XOSPATA	53.1	+11.8 (+29%)	66.2	 ✓ Sales expanded in all regions, led by the US performance ✓ Expect continued moderate growth moving forward



Business Update: PADCEV, IZERVAY, VYLOY



Global sales driven by 1L mUC

- Strong quarterly global growth driven by ex-US, while maintaining steady growth in the US (QoQ growth: Global +12%, outside US +29%)
- Ex-US 1L mUC demonstrating strong uptake
- 1L mUC approval countries increased to 16 (+5 countries from Q2)
 Expect increase in approval and reimbursement
- US 1L mUC share continues to be at a high level, with both new patient start and market share approaching 55%
- Overall sales growth expected to be driven by ex-US performance, while moderate growth trend expected to continue in the US
- Expect continued solid global growth in FY2025
- Next potential growth opportunity is MIBC with TLR expected in FY2025



US business entering a robust growth phase

- Q3 sales affected by temporary impact from CRL and changes in inventory levels
- High level share maintained even before label update. Continues to be the #1 chosen treatment option for new patient start (Oct-Nov)
 - ✓ New patient start share: ~60%
 - ✓ Market share: ~40%
- Over 210K vials* shipped since launch as of Q3
- Available in ~1,800 Retina accounts
- Post-marketing safety profile remains consistent with clinical trial results
- DTC campaign progressing on track, expect market growth to accelerate moving forward
- Label update resubmission accepted by the FDA (PDUFA date: Feb 26)
- · Expect growth to accelerate after approval



Encouraging uptake, expect further growth

- Approved in 38 countries, launched in 9 countries (as of Q3)
 - ✓ Launched in the US in Oct, Germany in Nov
 - ✓ Approved in China in Dec
- Uptake exceeded expectations, primarily driven by Japan and US performance
- Higher-than-expected rates of CLDN18.2 testing
- Listed as preferred recommendation in major treatment guidelines
 - ✓ US: NCCN Guidelines (Category 1)
 - Japan: Gastric cancer treatment guideline (Preferred)
- For FY2025, expect further growth in Japan, US and Europe, as well as contribution from China
- Expect substantial sales contribution as one of the key growth drivers



Q3 YTD/FY2024 Financial Results: SG&A and R&D Expenses

- Robust progress of SMT initiatives toward the FY2024 target of 40.0 bil. yen in cost optimization
- SG&A ratio improved to 29.7% (-4.0ppt YoY)

Core basis: YoY comparison and ratio to revenue

Cost Items	YoY change	Ratio to Revenue	(billion yen)
SG&A expenses excl. US XTANDI co-pro fee	+7.7% (+2.8% excl. FX impact)	SG&A ratio: 29.7%	 ✓ Global organizational restructuring (approx12.0 YoY) ✓ Reduction of mature products-related expenses (approx8.0 YoY) ✓ Enhance company-wide efficiency with AI and digital (approx4.0 YoY) Allocate generated resources to Strategic Brands investment
R&D expenses	+16.2% (+11.6% excl. FX impact)	R&D ratio: 17.3%	 ✓ PF, Strategic Brands LCM and enhanced R&D functions (approx. +16.0 YoY) ✓ One-time co-development cost payments in Q1 ✓ Steady progress in outsourcing reduction through strengthening in-house capabilities



FY2024 Revised Forecast

- Core basis: Upward revision based on robust progress of revenue and SMT
- Full basis: Downward revision of profit mainly due to impairment losses on IZERVAY (Ex-US) and AT466
- No change in dividend forecast of 74 yen

Exchange rates for Latest forecast: 153 yen/USD, 164 yen/EUR (Forecast rates Q4: 155 yen/USD, 163 yen/EUR)

	FY2023		FY2024			
(billion yen)	Actual	Previous FCST	Latest FCST	Change	Main items of revision	
Revenue	1,603.7	1,800.0	1,900.0	+100.0	XTANDI: approx. +30.0FX impact: approx. +45.0	
SG&A expenses	740.1	823.0	845.0	+22.0		
US XTANDI co-pro fee	194.9	229.0	255.0	+26.0	Incorporate robust progress of SMT	
SG&A excl. the above	545.2	594.0	590.0	-4.0		
(SG&A ratio*)	34.0%	33.0%	31.1%	-1.9ppt		
R&D expenses	294.2	341.0	340.0	-1.0	No significant change	
(R&D ratio)	18.3%	18.9%	17.9%	-1.0ppt	140 Significant change	
Core operating profit**	276.9	300.0	370.0	+70.0	FX impact: approx. +10.0	
(Core OP margin)	17.3%	16.7%	19.5%	+2.8ppt	T A Impact. approx. 110.0	
<full basis=""></full>						
Operating profit	25.5	80.0	11.0	-69.0	 Impairment loss: approx180.0 (Ex-US IZERVAY: -120.0, AT466: -50.0, iota: -10 Release of impairment loss risk and other expenses incorporated in initial FCST 	



Agenda



Q3 YTD/FY2024 Consolidated Financial Results FY2024 Revised Forecast

Ш

Initiatives for Sustainable Growth



XTANDI and Strategic Brands: FY2024 Key Expected Events

(Blue: Updates since the last financial results announcement)

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
enzalutamide/ XTANDI	Jun	Approval (M1 CSPC; China)			
enfortumab vedotin/ PADCEV			; China, 1L mUC; Europe Approval (1L mUC; Japar		; China)
zolbetuximab/ VYLOY	Resub May ackno	mission wledgment (US) Sep	Approval Oct (US) Dec Approval (Europe) Dec	Interim analysis (Pancreatic) final (expe	recommended continuation to analysis ected in 2H/FY2025*)
avacincaptad pegol/ IZERVAY		Complete (Label up Withdrawa MAA (Euro	response Apple Resubmis acknowled to the policy of the pol	Jan Ssion Feb edgment Filing (Japan)	te



avacincaptad pegol / IZERVAY: Latest Status

Regulatory activities are in progress globally to maximize product potential



Revised sNDA for label update accepted in Jan

PDUFA date: Feb 26



Individual discussions with regulatory authorities in major countries ongoing



Japan

NDA submission for Conditional Approval based on overseas clinical study results planned in Feb



Regulatory applications completed in 9 countries (UK, Canada, Australia, etc.) and additional submissions being planned



Modality Small molecule

Antibody Gene Cell

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
	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing
	Bispecific immune cell engager	★ ASP2138	Anti-CLDN18.2 and anti-CD3	Phase 1 study ongoing
Immuno-	bispecific infinitione cell engager	ASP1002	Anti-CLDN4 and anti-CD137	Phase 1 study ongoing
Oncology	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	Phase 1 study ongoing
	Cancer cell therapy	ASP2802	CD20 convertible CAR-T (autologous)	Terminated
Targeted Protein	Drotain degradation	★ASP3082	KRAS G12D degrader	Phase 1 study ongoing
Degradation	Protein degradation	ASP4396	KRAS G12D degrader	Phase 1 study ongoing
Genetic	natio	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
Regulation	Gene replacement (AAV)	★ AT845	GAA gene	Phase 1 study ongoing
		ASP2016	FXN gene	Terminated
Blindness & Regeneration	Cell replacement	★ ASP7317 ●	RPE cells	Phase 1b study ongoing
Others (Non-PF)	Long-acting abiraterone prodrug	ASP5541 (PRL-02)	CYP17 lyase inhibitor	Phase 1 study ongoing
(14011-11)	Immune modulation*	ASP5502	STING inhibitor	Phase 1 study ongoing

^{*}PF Candidate Immune Homeostasis dissolved

★: Flagship program (See slides 30-31 for overview)



Improvement of R&D Productivity

Strategically reviewed R&D portfolio with discipline to allocate resource to prioritized assets

Strategic review of R&D portfolio

In-depth analysis to assess

probability of success and

programs across PFs/PF

Dissolved PF Candidate

Immune Homeostasis

future value potential

Terminated 7 R&D

Increased investment in PF flagship programs* after PoC

Prioritized investment

judgement

- Lifecycle management of Strategic Brands**
- Business development for late-stage/de-risked assets

Sustainable growth

Focus on prioritized PFs for long-term growth

Expand near-to-mid term revenue potential

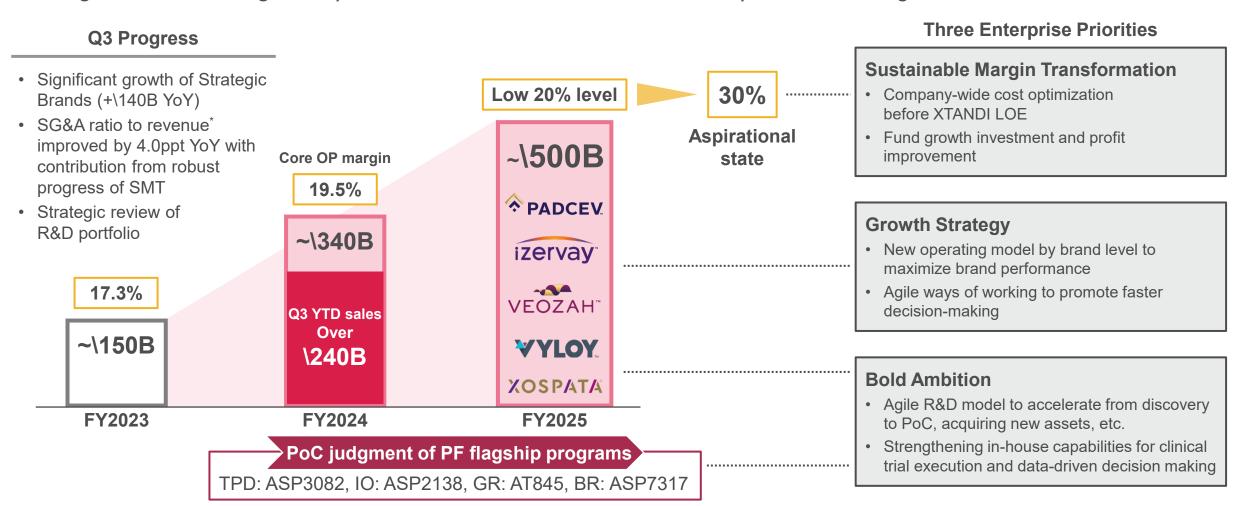
Candidate

^{*}Targeted Protein Degradation: ASP3082, Immuno-Oncology: ASP2138, Genetic Regulation: AT845, Blindness & Regeneration: ASP7317. See slides 30-31 for overview.

^{**}See slide 29 for details of LCM activities.

Progress in Q3 YTD/FY2024 and Latest Outlook

Entering a fundamental growth phase to overcome XTANDI LOE and pursue further growth







Upcoming Event

Sustainability Meeting 2024

> Feb 21st 2025, 10:00-11:30 (JST)





XTANDI and Strategic Brands: Potential Peak Sales (as of Feb 2025)

Brand	Potential Peak Sales (Global, billions of yen)
XTANDI (enzalutamide)	over 700.0
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



Q3 YTD/FY2024 Actual: FX Rate

Average rate for the period

Cur	rency	Q3 YTD/FY2023	Q3 YTD/FY2024	Change
USI	D	143 yen	152 yen	+9 yen
EUI	3	155 yen	165 yen	+9 yen

<Impact of exchange rate on financial results>

• Revenue: +66.3 billion yen

• Core OP: +17.1 billion yen



FY2024 Forecast: FX Rate & FX Sensitivity

Exchange rate Average for the period	FY2024 Previous FCST	FY2024 Latest FCST	Change
USD	149 yen	153 yen	+4 yen
EUR	160 yen	164 yen	+4 yen

Forecast rates for Q4: 155 yen/USD, 163 yen/EUR

Estimated FX sensitivity for Q4 (Jan-Mar 2025) of FY2024 latest forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption				
	Revenue	Core OP			
USD	Approx. +1.8 bil. yen	Approx. +0.3 bil. yen			
EUR	Approx. +0.8 bil. yen	Approx. +0.4 bil. yen			



Balance Sheet & Cash Flow Highlights

(billion yen)	FY2023 end	Dec 31, 2024
Total assets	3,569.6	3,451.6
Cash and cash equivalents	335.7	179.9
Total equity attributable to owners of the parent Equity ratio (%)	1,596.0 44.7%	1,493.8 43.3%
(billion yen)	Q3 YTD/FY2023	Q3 YTD/FY2024
Cash flows from operating activities	100.5	93.4
Cash flows from investing activities	-823.6	-86.5
Free cash flows	-723.1	7.0
Cash flows from financing activities	583.1	-170.6
Increase/decrease in short-term borrowings and commercial papers	263.2	-175.6
Proceeds from issuance of bonds and long-term borrowings	471.6	200.0
Redemption of bonds and repayments of long-term borrowings	-6.7	-32.7
Dividends paid	-116.7	-129.0



Balance of Bonds and Borrowings Highlights

(billion yen)	Sep 30, 2024	Dec 31, 2024
Balance of bonds and borrowings	927.5	915.4
Non-current liabilities Bonds Long-term borrowings	620.2 350.0 270.2	585.5 320.0 265.5
Current liabilities Commercial papers Short-term borrowings Current portion of long-term borrowings Current portion of bonds	307.3 164.8 91.8 50.6	329.9 179.8 67.2 52.9 30.0



Main Intangible Assets (as of Dec 31, 2024)

	Bil. yen	Foreign currency*
AT132	17.1	\$109M
AT845	11.4	\$73M
Gene therapy related technology**	69.0	\$439M
VEOZAH	91.0	€524M
VYLOY	61.0	€470M
IZERVAY (US)	687.0	\$4,371M
IZERVAY (Ex-US)	54.2	\$345M

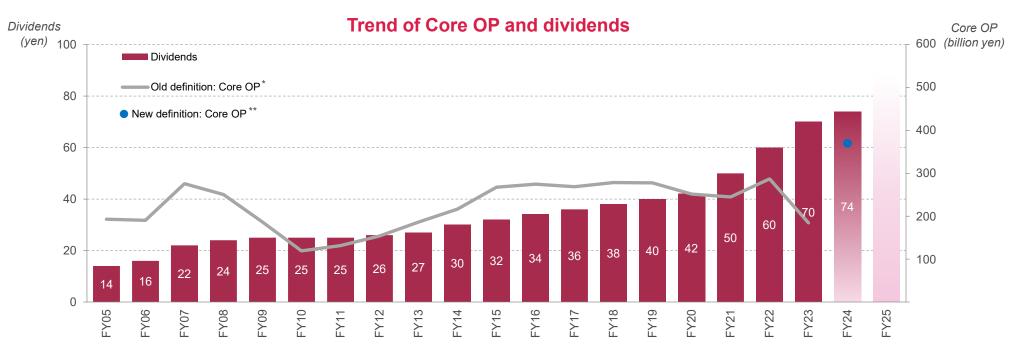


Capital Allocation

1 Top priority is investment for business growth

- Raise dividend level aligned with profit / cashflow plan and actual performance throughout CSP2021 period
- 3 Flexibly execute share buyback by excess cash

Aiming for higher level of dividends increase during CSP2021 aligned with the robust profit growth forecast



For illustrative purposes only



^{*}Prior to FY2012, operating profit is in accordance with J-GAAP

Core Basis Performance: Changes in Definitions and Context

Introduce New definition of core-based performance from FY2024

Financial Results (Full basis)

Revenue

Cost of sales

Gross profit

SG&A expenses

R&D expenses

Amortisation of Intangible assets

Gain on divestiture of Intangible assets

Share of profit (loss) of investments

accounted for using equity method

Other income

Other expenses

Operating profit

Finance income

Finance expenses

Profit before tax

Income tax expense

Profit

Financial Results (Old definition: Core basis)

Certain items reported in financial results on a full basis by the Company are excluded as non-core items from these financial results on a core basis. These adjusted items include impairment losses, gain/loss on sales of property, plant and equipment, restructuring costs, loss on disaster, a large amount of losses on compensation or settlement of litigations and other legal disputes

method' are newly excluded in the new definition Core operating profit

Adjustments to 'Finance income' and 'Finance expenses'

Financial Results

(New definition: Core basis)

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

Core profit

Core operating profit

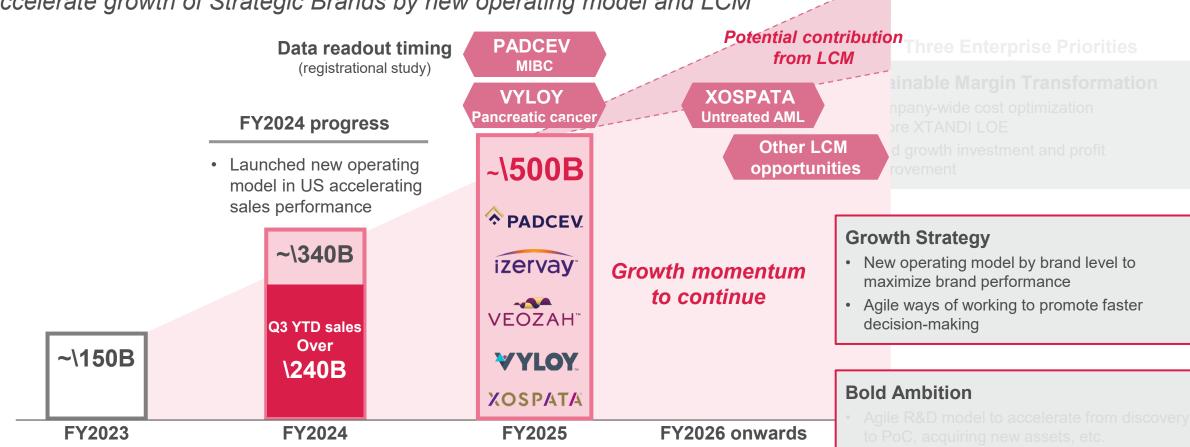
Adjustments to 'Finance income' and 'Finance expenses'

Core profit



Maximize Potential of Strategic Brands

Accelerate growth of Strategic Brands by new operating model and LCM



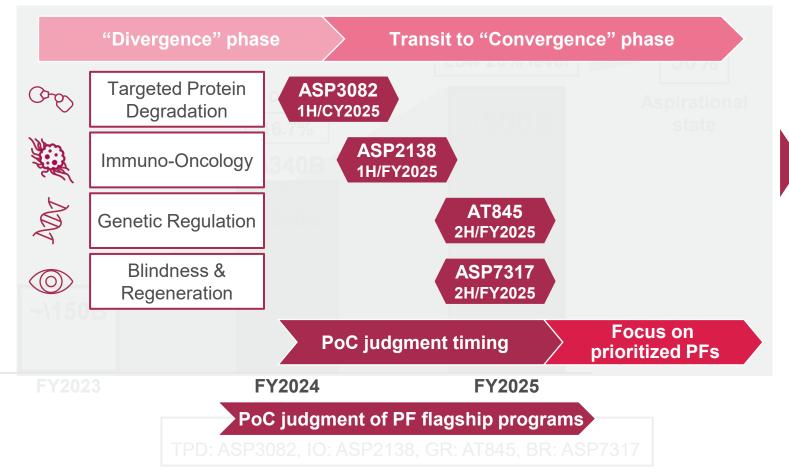
Expand new operating model globally to maximize brand potential

Strengthening in-house capabilities for clinical trial execution and data-driven decision making



Advance Focus Area Approach

- Focus on prioritized Primary Focuses and increase pipeline value based on PoC judgment of flagship programs
- Continue exploratory research at the frontier with discipline, to generate new programs for future growth



Sustainable Margin Transformation

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

Expect sales contribution in 2030's

- New operating model by brand level to maximize brand performance
- Agile ways of working to promote faster decision-making

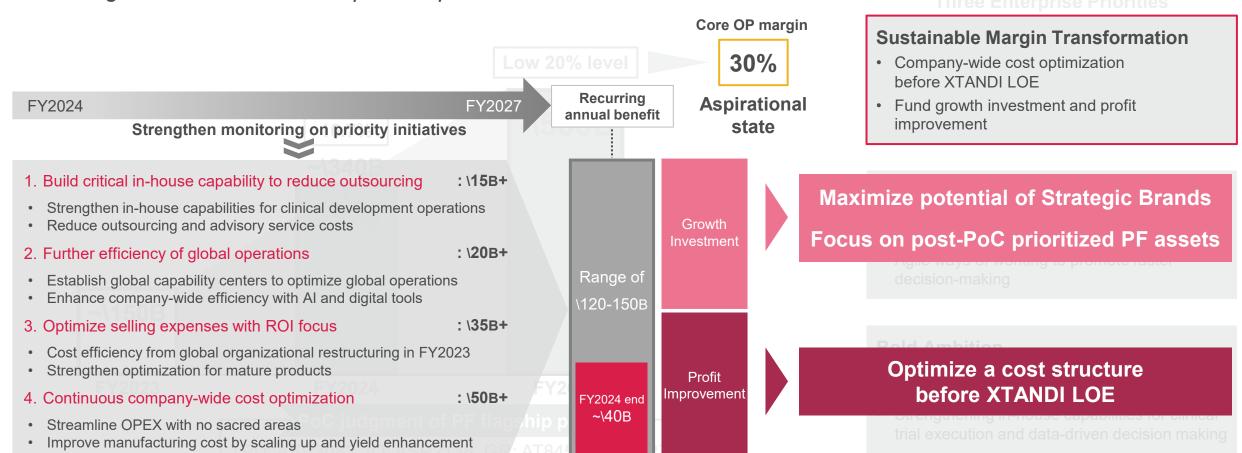
Bold Ambition

- Agile R&D model to accelerate from discovery to PoC, acquiring new assets, etc.
- Strengthening in-house capabilities for clinical trial execution and data-driven decision making



Sustainable Margin Transformation

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



Lifecycle Management of Strategic Brands (Blue: Updates since the last financial results announcement)

Product	Indication	Current status	Next milestone
	MIBC	Phase 3 EV-303 & EV-304 studies ongoing	TLR anticipated for FY2025
♦ PADCEV	NMIBC	Phase 1 EV-104 study ongoing	TLR anticipated for FY2025
enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	Head and neck cancer	2L+: Next step under discussion	(Under discussion)
	nead and neck cancer	1L: Phase 2 EV-202 study ongoing	TLR anticipated for FY2025
		Japan: NDA submission under preparation	NDA submission in Feb 2025
izervay (avacincaptad pegol	GA secondary to AMD	LCM opportunities under consideration (e.g. prefilled syringe, sustained release)	(Under discussion)
intravitreal solution) 2 mg	Stargardt disease	Phase 2 study ongoing	TLR anticipated for FY2025
VEOZAH™	VMS associated with menopause	Japan: Phase 3 STARLIGHT 2 & 3 studies ongoing	TLR anticipated for FY2026
(fezolinetant) tablets 45 mg	VMS in breast cancer women	Phase 3 HIGHLIGHT 1 study ongoing	TLR anticipated for FY2027
*YLOY	Gastric and GEJ cancer	Phase 3 study in combo with CPI and chemotherapy under preparation	Study start in Q1/FY2025
zolbetuximab for injection 100mg vial	Pancreatic cancer	Registrational Phase 2 GLEAM study ongoing	TLR anticipated for 2H/FY2025
XOSPATA® gilteritinib 40mg tablets	Newly diagnosed AML (HIC-eligible)	Phase 3 PASHA study ongoing	TLR anticipated for FY2026

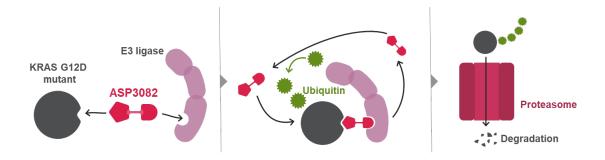


Overview of Primary Focus Flagship Programs (1/2)

ASP3082 (Targeted Protein Degradation)

Protein degrader targeting KRAS G12D mutant

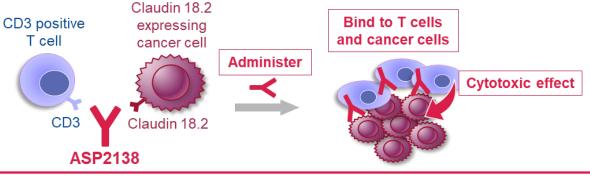
- Target disease: Cancers harboring KRAS G12D mutation
 - ✓ Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~15% in CRC, ~5% in non-squamous NSCLC¹
- Standard of care (metastatic PDAC): Chemotherapy
- Status: Phase 1 study ongoing (<u>NCT05382559</u>)
 - ✓ PDAC: 2L+ (monotherapy), 1L (combo with chemotherapy)
 - ✓ CRC: 2L+ (monotherapy, combo with cetuximab)
 - √ NSCLC: 2L+ (monotherapy)
- Anticipated PoC judgment timing: 1H/CY2025



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 adenocarcinoma² and ~60% in pancreatic adenocarcinoma³
- Standard of care (HER2-, advanced G/GEJ adenocarcinoma)
 - ✓ 1L: chemotherapy +/- checkpoint inhibitor
 - ✓ 2L+: paclitaxel + ramucirumab
- Status: Phase 1 study ongoing (<u>NCT05365581</u>)
 - ✓ G/GEJ adenocarcinoma, 1L & 2L, monotherapy & combo
- Anticipated PoC judgment timing: 1H/FY2025





Overview of Primary Focus Flagship Programs (2/2)

AT845 (Genetic Regulation)

Recombinant AAV8 expressing hGAA gene specially in muscle

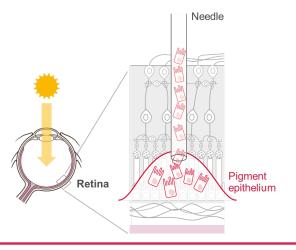
- Target disease: Pompe disease
 - ✓ Estimated incidence: 1 in ~40,000¹
- Standard of care: Enzyme replacement therapy (ERT)
 - ✓ Chronic, repeated infusions every 2 weeks
 - ✓ Secondary disease progression after 2-3 years on ERT^{2,3,4}
- Status: Phase 1/2 FORTIS study ongoing (<u>NCT04174105</u>)
 - ✓ Disease stability observed for up to 2 years while off ERT⁵
- 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 worldwide⁶
- Standard of care: Complement inhibitors
 - ✓ Slows progression, does not improve vision
- Status: Phase 1b study ongoing (<u>NCT03178149</u>)
- Anticipated PoC judgment timing: 2H/FY2025





Robust Pipeline of Astellas

Phase 1

enfortumab vedotin (NMIBC) ASP1570 ASP2138 ASP1002 ASP1012 ASP3082 ASP4396 zocaglusagene nuzaparvovec/ AT845 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)

Phase 3

enfortumab vedotin (MIBC)

ailteritinib

(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 CPI and chemotherapy)

mirabegron

(NDO, pediatric use (aged 6 months to less than 3 years): Europe)

roxadustat

(Anemia associated with CKD, pediatric use: Europe)

Strategic Brands

Programs with Focus Area approach

Others

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



Progress in Overall Pipeline

Phase 1 Entry to Approval Since the Last Financial Results Announcement

Phase 3 Entry Phase 2 Entry Phase 1 Entry Filing Approval enfortumab vedotin gilteritinib Newly diagnosed acute Locally advanced or myeloid leukemia metastatic urothelial cancer: (ineligible for high-intensity China chemotherapy) zolbetuximab Locally advanced unresectable or metastatic HER2-negative, claudin 18.2positive gastric or gastroesophageal junction adenocarcinoma: China

Discontinuation

ASP2802: B-cell lymphoma (Phase 1)

ASP2016: Cardiomyopathy associated with Friedreich ataxia (Phase 1)

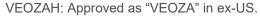
Note: Phase 1 entry and Phase transition are defined by first subject first treatment. Filing is defined as submission of application to health authorities.

Discontinuation is defined by the decision of company decision body.



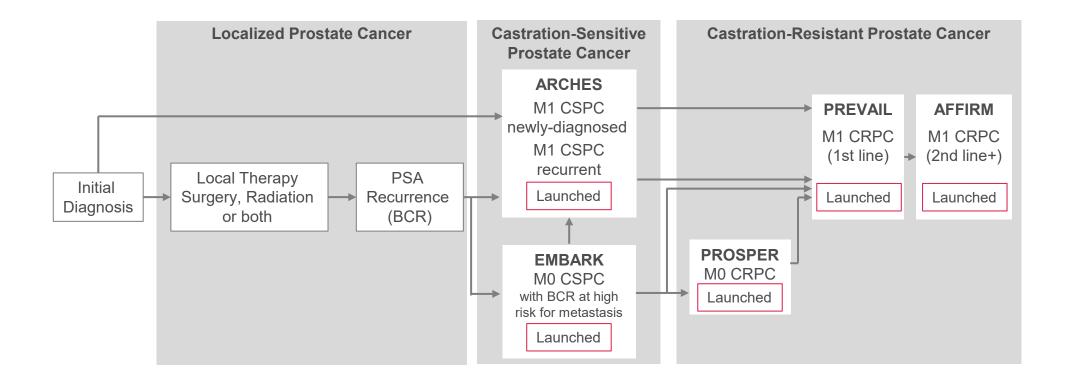
Strategic Brands: Status Update (Blue: Updates since the last financial results announcement)

Generic / Brand name	Indication	С	current status
	Metastatic urothelial cancer	•	Previously untreated (first line): Approved in China in Jan 2025
enfortumab vedotin /	Muscle-invasive bladder cancer	•	Phase 3 studies ongoing (enrollment completed)
PADCEV	Non-muscle-invasive bladder cancer	•	Phase 1 study ongoing (enrollment completed)
	Other solid tumors	•	Phase 2 study ongoing (enrollment completed)
	Relapsed and refractory AML	•	China: Phase 3 study stopped due to efficacy
	AML, post-HSCT maintenance	•	Development based on Phase 3 MORPHO study discontinued
gilteritinib/ XOSPATA	AML, newly diagnosed (HIC-eligible)	•	Phase 3 study ongoing (enrollment completed)
7,00171171	AML, newly diagnosed (HIC-ineligible)	•	Progressed to Phase 2
	AML, post-chemotherapy	•	Obtained topline results from Phase 2 GOSSAMER study
zolbetuximab/	Gastric and GEJ adenocarcinoma		Approved in China in Dec 2024 Phase 3 study in combo with CPI and chemotherapy under preparation to start in Q1/FY2025
VYLOY	Pancreatic adenocarcinoma	•	Phase 2 study ongoing (enrollment completed)
fezolinetant/	VMS due to menopause	•	China: Obtained topline results from Phase 3 MOONLIGHT 1 and MOONLIGHT 3 studies Japan: Phase 3 studies ongoing
VEOZAH	VMS in breast cancer patients on adjuvant endocrine therapy	•	Phase 3 study ongoing
avacincaptad pegol/	GA secondary to AMD	•	Revised sNDA for label update accepted in US in Jan 2025
IZERVAY	Stargardt disease	•	Phase 2b study ongoing





enzalutamide (1/2): Androgen Receptor Inhibitor







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

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

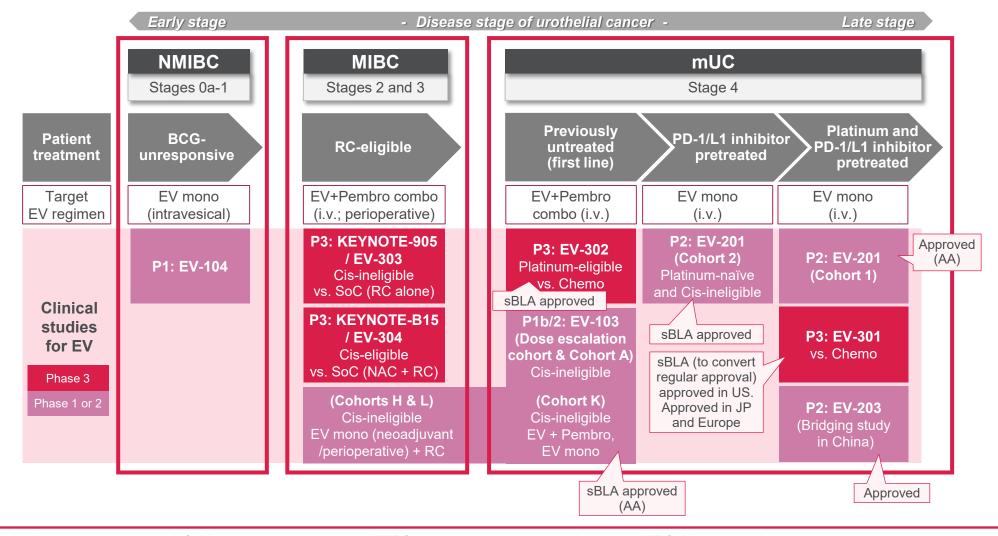
	Early stage			Late stage				
Disease stage	Castra	tion-sensitive (CSPC)	Castration-resistant (CRPC)				
- · · · · · · · · · · · · · · · · · · ·	МО	M1		МО	M1 (pre-chemo)	M1 (post-chemo)		
Phase 3 study	EMBARK	ARCHES	ENZAMET	PROSPER	PREVAIL	AFFIRM		
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	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





enfortumab vedotin (EV) (1/6): Nectin-4 Targeted ADC Overall UC Program







enfortumab vedotin (EV) (2/6): Clinical Studies

(Blue: Updates since the last financial results announcement)

For urothelial cancer

P3: EV-302	NCT04223856	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=886	Approved in US in Dec 2023, in Europe in Aug 2024, in Japan in Sep 2024, in China in Jan 2025
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=784	Enrollment completed
P1b/2: EV-103		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

For other solid tumors

P2: EV-202	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	IS tric	NSCLC, Non-squamous NSCLC, Head and neck astric and esophageal adenocarcinoma including GE inoma, Esophageal squamous cell carcinoma; EV m		n=329	Enrollment completed
------------	--	------------	--	--	-------	----------------------





enfortumab vedotin (EV) (3/6): Study Data by Disease Stage of UC

	Early stage							Late sta	age		
Diagona	MI	вс	mUC								
Disease stage	Surgery eligible		Pre	viously untreat	ed (first line)		PD-	·1/L1 inhibitor p	retreated		
3.7	Cis- eligible	Cis- ineligible	Platinum eligible				Platinum naïve & Cis-ineligible	Platinu	ım pretreated		
Study phase	Phase 3	Phase 3	Phase 3	Phase	e 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	784 (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 0.45 ✓ OS: HR 0.47	✓ 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 0.47 (31.5 mos vs.16.1 mos)	(Ongoing)	√ (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 0.45 (12.5 mos vs.6.3 mos)	(Ongoing)	√ (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)	✓ 67.7% vs. 44.4% (CR 29.1% vs. 12.5%)	✓ 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)	(Ongoing)	(Ongoing)	√ 13.2 mos	√ 22.1 mos **	✓ 13.8 mos **	√ 7.6 mos	√ 7.4 mos vs. 8.1 mos *		

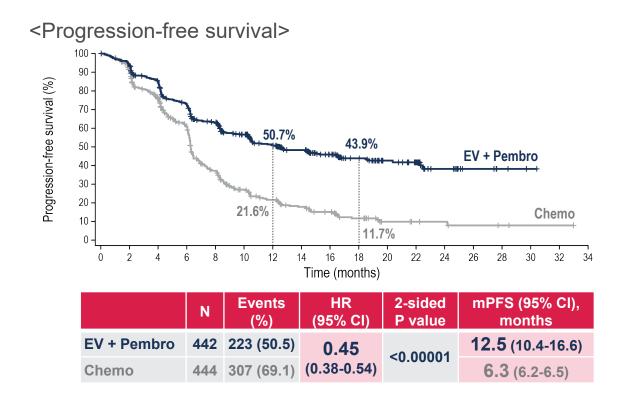
✓: Data obtained, *: Prespecified interim analysis, **: Updated data

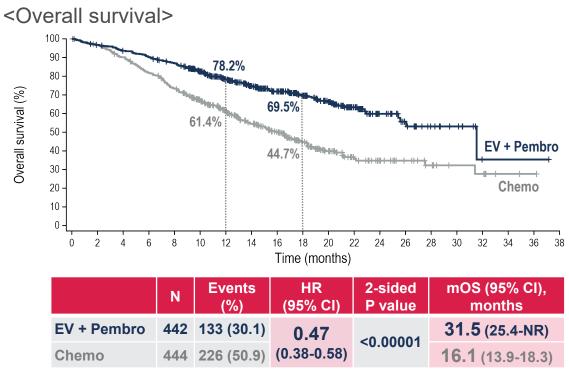




enfortumab vedotin (EV) (4/6): Study Data in 1L mUC (EV-302)

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





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





enfortumab vedotin (EV) (5/6): Study Data in Solid Tumors Other than UC (EV-202)

Cohort	Cancer type		ORR		
Conort	Cancer type	n	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%		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

enfortumab vedotin (EV) (6/6): Future Outlook

- 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 will provide further growth potential

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

Patie	ent 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**
IVIIDC	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 [AA in US]	87,000
2L+	PD-1/L1 inhibitor pretreated & Cis-ineligible	EV-201 Cohort 2 (monotherapy)	Approved	1,500 (US, Cis-ineligible)
mUC	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:

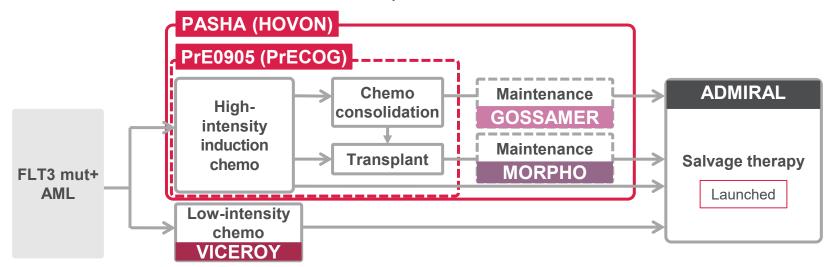
· Head and neck squamous cell carcinoma





gilteritinib: FLT3 Inhibitor

(Blue: Updates since the last financial results announcement)



Relapsed or refractory	P3: ADMIRAL	NCT02421939	Monotherapy vs. salvage chemo (2:1)	n=371	Launched in US, JP, and Europe
Nowly diagnood	P3: PASHA (HOVON)	NCT04027309	Combo with high intensity chemo	n=766	Enrollment completed (Sponsor: HOVON)
Newly diagnosed (HIC-eligible)	P2: PrE0905 (PrECOG)	NCT03836209	gilteritinib vs. midostaurin (1:1)	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 Progressed to Phase 2

China

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



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: SPOTLIGHT	NCT03504397		n=566	Approved in Japan in Mar 2024 in Europe in Sen
	P3: GLOW	NCT03653507	First line, Combo with CAPOX, DB, vs. placebo	n=507	2024, in US in Oct 2024, in China in Dec 2024
	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 pembrolizumab 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



fezolinetant: NK3 receptor antagonist

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 life¹

Women's Health Initiative (WHI) Study²

- 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)		FSFT: Mar 2024
		P3: STARLIGHT 3	NCT06206421	VMS associated with menopause; 52 weeks: DB, vs. placebo (1:1)	n=260	FSFT: Feb 2024
	China	P3: MOONLIGHT 1		Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg vs. placebo (1:1) The last 12 weeks: Active extension treatment period, 30 mg	n=302	Primary endpoints not met (12w DB period topline results)
		P3: MOONLIGHT 3	NCT04451226	VMS associated with menopause; open label, 30 mg for 52 weeks	n=150	Topline results obtained in Sep 2022

VMS in breast cancer women receiving adjuvant endocrine therapy

P3: HIGHLIGHT 1 NCT064	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
------------------------	---	-------	----------------



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 eye¹
- Approximately 75% of people living with GA in the US are believed to be undiagnosed²
- Without timely treatment, an estimated 66% of people with GA may become blind or severely visually impaired³

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	
		P3: GATHER2	NCT04435366	2 mg vs. Sham	n=448	accepted in US in Jan 2025
	Stargardt disease	P2b	NCT03364153	vs. Sham	n=121	FSFT: Jan 2018



On the forefront of healthcare change to turn innovative science into VALUE for patients

