

FY2023 FINANCIAL RESULTS

ENDED MARCH 31, 2024



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President and CEO
Astellas Pharma Inc.
April 25, 2024

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FY2024 Forecast
CSP2021 Outlook

FY2023 FINANCIAL RESULTS: OVERVIEW

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Revenue increased YoY. Exceeded the revised full-year forecast

- XTANDI: Increased approx. +90.0 bil. yen YoY, contributed to the achievement of the full-year forecast
- PADCEV, XOSPATA, VEOZAH, IZERVAY: Increased approx. +70.0 bil. yen YoY,
Contributed to sales expansion as growth drivers

Cost items

- SG&A: Increased YoY mainly due to the impact of Iveric Bio acquisition and investments in growth drivers
Achieved more efficient cost management than expectation through timely assessment of resources
- R&D: On track

Core Operating profit

- Decreased YoY mainly due to the impact of Iveric Bio acquisition
- Exceeded the revised full-year forecast due to excess revenue and efficient cost management

FY2023 FINANCIAL RESULTS

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(billion yen)	FY2022	FY2023	Change	Change (%)	FY23 FCST	Achievement	FX impact (YoY)
Revenue	1,518.6	1,603.7	+85.1	+5.6%	1,562.0	102.7%	+96.3
Cost of sales	288.4	292.5	+4.1	+1.4%			+15.8
% of revenue	19.0%	18.2%	-0.7 ppt				
SG&A expenses	630.3	740.1	+109.8	+17.4%	731.0	101.2%	+44.3
US XTANDI co-pro fee	175.5	194.9	+19.4	+11.0%	187.0	104.3%	+12.2
SG&A excl. the above	454.8	545.2	+90.5	+19.9%	544.0	100.2%	+32.0
R&D expenses	276.1	294.2	+18.1	+6.5%	286.0	102.9%	+12.5
Amortisation of intangible assets	38.4	98.8	+60.4	+157.1%			Note) Amortisation of IZERVAY's intangible assets started from Q2
Gain on divestiture of intangible assets	0.2	9.7	+9.5	-			
Core operating profit	286.9	184.6	-102.3	-35.6%	164.0	112.6%	+19.1
< Full basis >							
Other income	3.6	8.7	+5.0	+138.7%			Other expenses (booked in Q4)
Other expenses	157.5	167.8	+10.3	+6.5%			
Operating profit	133.0	25.5	-107.5	-80.8%	13.0	196.3%	• Impairment loss for intangible assets : 56.3 (AT808: 39.9, EVRENZO: 16.4) • Fair value increase of contingent consideration (zolbetuximab)*: 8.0
Profit before tax	132.4	25.0	-107.4	-81.1%	12.0	208.1%	
Profit	98.7	17.0	-81.7	-82.7%	3.0	568.2%	

Full-year forecast revised in Feb 2024, full basis forecast revised on 12th Apr 2024. The Exchange rate assumption: 140 yen/USD, 152 yen/EUR

Actual exchange rates for FY2023: 145 yen/USD, 157 yen/EUR

*Booked due to updates to the clinical development plan for pancreatic cancer and FX impact

FY2023 FINANCIAL RESULTS: MAIN PRODUCTS

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Significant contribution to revenue expansion as growth drivers

(billion yen)	FY2023 Act	YoY	FY2023 FCST*	Achievement against FCST	
 Xtandi® (enzalutamide)	750.5	+89.3 (+14%)	719.8	104%	✓ Global sales exceeded the FCST revised upward in Q2 ✓ Sales expanded in all regions, despite 10+ years on the market ✓ ~6% growth even excluding FX impact
 PADCEV® enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	85.4	+40.9 (+92%)	85.2	100%	✓ Global sales exceeded FCST revised significantly upward in Q2 ✓ US: More than doubled demand driven largely by the launch and penetration of 1L mUC (YoY +103%)
 XOSPATA® gilteritinib 40mg tablets	55.1	+8.5 (+18%)	55.2	100%	✓ Global sales expanded in line with the FCST revised upward in Q2 ✓ Sales expanded in all regions
 VEOZAH™ (fezolinetant) tablets 45 mg	7.3	+7.3	7.1	102%	✓ Progress in line with FCST revised in Q3 ✓ While commercial lives covered (payer coverage) expanded to 50% as planned, HCP's perception of VEOZAH access and affordability remains low
 izervay™ (avacincaptad pegol intravitreal solution) 2 mg	12.1	+12.1	11.0	110%	✓ Sales exceeded expectations driven by accelerated momentum with vial demand doubling from Q3 to Q4 ✓ Estimate market share in the Q4 period (Jan-Mar) to be ~25% ✓ 50,000+ vials shipped since launch, available in ~1,000 Retina accounts

*XTANDI, PADCEV, XOSPATA: Revised in Nov 2023 (upward revision), VEOZAH: Revised in Feb 2024 (downward revision),
 IZERVAY: Announced in Nov 2023 (no revision since announcement), Actual exchange rates for FY2023: 145 yen/USD, 157 yen/EUR
 1L: First line, mUC: Metastatic urothelial cancer, VEOZAH: Approved as "VEOZA" in Europe Details for the main products are on slide 24-27

FY2023 FINANCIAL RESULTS: COST ITEMS

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- *SG&A: Increased YoY mainly due to the impact of Iveric Bio acquisition and investments in growth drivers*
Achieved more efficient cost management than expectation through timely assessment of resources (excl. FX impact)
- *R&D: On track*

Core basis: YoY comparison, ratio to revenue, and achievement against FCST, for major cost items

Cost Items	YoY change	Ratio to Revenue	Achievement against FCST	
Cost of sales	+1.4%	18.2% (-0.7 ppt YoY)	-	Cost of sales ratio was improved mainly due to changes in product mix
SG&A expenses excl. US XTANDI co-pro fee	+19.9% (+12.8% excl. FX impact)	34.0% (+4.1 ppt YoY)	100.2%	YoY increase excl. FX impact: approx. +58.0 ✓ Impact of Iveric Bio acquisition (approx. +31.0 YoY) ✓ Increase in VEOZAH-related costs (approx. +40.0 YoY) ✓ Reduction of mature products-related costs (approx. -8.0 YoY)
R&D expenses	+6.5% (+2.0% excl. FX impact)	18.3% (+0.2 ppt YoY)	102.9%	YoY Increase mainly due to FX impact and Iveric Bio acquisition

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INITIATIVES FOR SUSTAINABLE GROWTH: OVERVIEW OF QUARTERLY UPDATES

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XTANDI and Strategic products

- enzalutamide / XTANDI : Approval for M0 CSPC* indication (Europe)
- enfortumab vedotin / PADCEV : Acceptance of application for 1L mUC (China)
- zolbetuximab / VYLOY : Approval (Japan)
- fezolinetant / VEOZAH : Phase 3 studies initiated (Japan), Phase 3 study for additional indication under preparation
- avacincaptad pegol / IZERVAY: Acceptance of application for label update (US)

Focus Area approach

- Phase 1 entry : ASP2016 (Genetic Regulation), ASP2802 (Immuno-Oncology), ASP4396 (Targeted Protein Degradation)
- Progress of clinical study : ASP2138 dose expansion cohort in Phase 1 study initiated
- Project termination : ASP2074 (Immuno-Oncology), ASP0367 (Mitochondria)
- Dissolution of Primary Focus Mitochondria

Rx+ program

- BlueStar (Digital therapeutics for diabetes): Pivotal clinical study initiated (Japan)

VEOZAH: Approved as "VEOZA" in Europe

*with biochemical recurrence at high risk for metastasis.

M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, 1L: First line, mUC: Metastatic urothelial cancer

XTANDI AND STRATEGIC PRODUCTS: FY2023 KEY EVENTS

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Achieved regulatory approval for VYLOY, VEOZAH, IZERVAY and indication expansion for XTANDI and PADCEV

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)
enzalutamide/ XTANDI		Acceptance (M0 CSPC*; US) ★ Aug	Approval (M0 CSPC*; US) ★ Nov	Approval (M0 CSPC*; Europe) ★ Apr
enfortumab vedotin/ PADCEV		EV-302 TLR ★ Sep	Acceptance (1L mUC; US) ★ Nov	Approval (US) ★ Dec
zolbetuximab	Acceptance (Japan) ★ Jun	Acceptance (US, Europe, China) ★ Jul	Complete response (US) ★ Jan	Approval (Japan) ★ Mar
fezolinetant/ VEOZAH	Approval (US) ★ May		Approval (Europe) ★ Dec	
avacincaptad pegol/ IZERVAY	Approval (US) Acceptance (Europe) ★ Aug	GATHER2 TLR (24 month) ★ Sep		Acceptance (Label update; US) ★ Mar

<Other updates>

- fezolinetant / VEOZAH: FSFT in Phase 3 studies in Japan (STARLIGHT 2 / STARLIGHT 3) in Q4

Phase 3 study for induced VMS in breast cancer patients on adjuvant endocrine therapy to start in Q2/FY2024

As of Apr 2024, VEOZAH: Approved as "VEOZA" in Europe

*with biochemical recurrence at high risk for metastasis. M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, M1: Metastatic, TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer, FSFT: First subject first treatment, VMS: Vasomotor symptoms



PROGRESS IN FOCUS AREA APPROACH: CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

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Primary Focus	Biology/Modality/Technology	Project	Mechanism of Action	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	GAA gene	Phase 1 study ongoing
		ASP2016	FXN gene	Phase 1 study under preparation to start in Q3/FY2024
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing Dose expansion expected in 1H/FY2024
	Bispecific immune cell engager	ASP2138	Anti-Claudin 18.2 and anti-CD3	Phase 1 study ongoing, Dose expansion initiated
		ASP2074	Anti-TSPAN8 and anti-CD3	Terminated
		ASP1002	Undisclosed	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	Phase 1 study under preparation to start in Q1/FY2024
	Cancer cell therapy	ASP2802	CD20 convertible CAR-T (autologous)	Phase 1 study under preparation to start in Q1/FY2024
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells	Phase 1b study ongoing
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	PPARδ modulator	Terminated
Targeted Protein Degradation	Protein degradation	ASP3082	KRAS G12D degrader	Phase 1 study ongoing Dose expansion expected in 1H/FY2024
		ASP4396	KRAS G12D degrader	Phase 1 study ongoing
Others (Non-PF)	Long-acting abiraterone prodrug	PRL-02	CYP17 lyase inhibitor	Phase 1 study ongoing

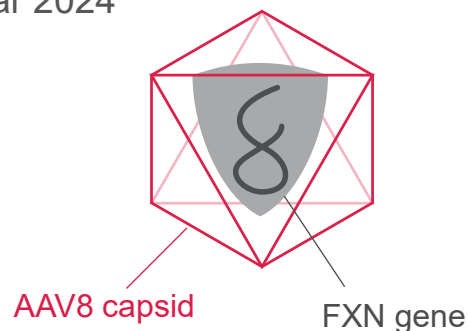
Modality	
●	Small molecule
●	Antibody
●	Gene
●	Cell

PF Mitochondria Dissolved

ASP2016

Recombinant AAV8 encoding human frataxin (FXN) gene

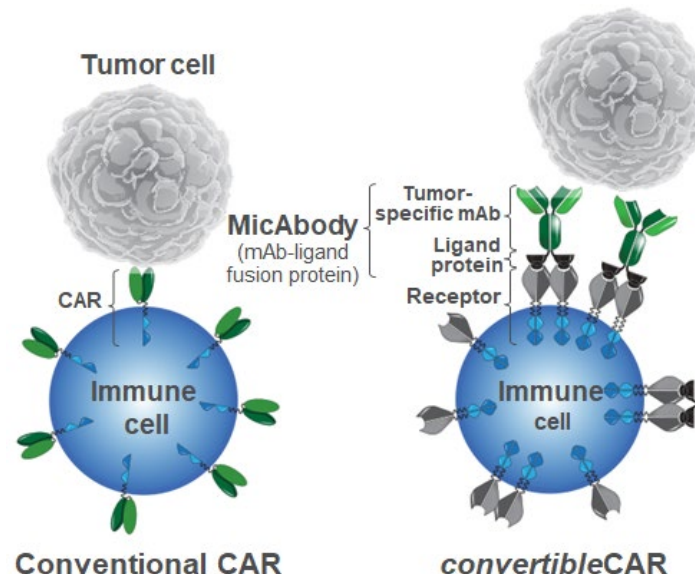
- Target disease: Cardiomyopathy associated with Friedreich ataxia (FA)
 - ✓ Progressive, neurodegenerative movement disorder caused by loss-of-function mutation in FXN
 - ✓ Estimated prevalence (US and EU5*): 1/50,000-1/100,000
 - ✓ Cardiomyopathy occurs in >60% of FA patients – leading cause of early death
- Fast Track designation granted by FDA in Mar 2024



ASP2802

*convertible*CAR-T comprised of autologous T cells and MicAbody directed to CD20

- Target disease: CD20+ B-cell lymphoma
- Activity control with MicAbody dose: Less long-term toxicity and prolonged response expected
- Will inform future allogenic CAR programs

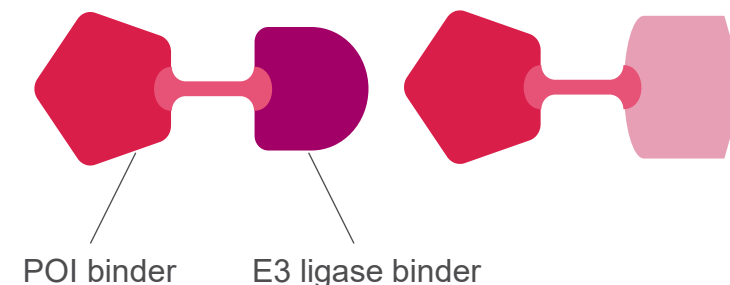


ASP4396

Protein degrader targeting KRAS G12D mutant

- Target disease: Cancers harboring KRAS G12D mutation
- Different E3 ligase binder vs. ASP3082
- FSFT in Phase 1 study in Apr 2024
- Expected to enhance the development of Targeted Protein Degradation platforms

<Image> Structures of ASP4396 & ASP3082



*Germany, France, Italy, Spain, UK

AAV: Adeno-associated virus, FDA: Food and Drug Administration, CAR: Chimeric antigen receptor, mAb: Monoclonal antibody, KRAS: Kirsten rat sarcoma viral oncogene homologue, POI: Protein of interest, FSFT: First subject first treatment

REVIEW OF CSP2021 SO FAR

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<i>Performance Goal</i>	<i>Progress / situation above or below original assumptions</i>	<i>Counteractions</i>
1. Revenue: XTANDI and Strategic products sales $\geq$ ¥1.2T in FY2025	● PADCEV EV-302 study ● VEOZAH uptake ● IRA Medicare Part D redesign	• Iveric Bio acquisition • Product value maximization through LCM (ex. PADCEV, VYLOY indication expansion)
2. Pipeline Value: Focus Area projects expected sales $\geq$ ¥0.5T in FY2030	● New Primary Focus (Targeted Protein Degradation) ● PoC not yet obtained in FA projects ● Setbacks in Potenza programs, aAVC programs, FX-322	• Reform of R&D organization/operation • Focused resource allocation to prioritized projects • Propella acquisition
3. Core OP Margin: $\geq$ 30% in FY2025	● Cost control (not enough to offset investments in new launch products) ● Earlier generic entry than anticipated	• Strict cost control while securing investment for future growth • Optimized operation through digital

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FY2024 FORECAST: BACKGROUND

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Balanced forecast between ambitious and achievable

- ✓ Updated VEOZAH's sales outlook
- ✓ Factored in the impact of US mirabegron generic entry
- ✓ Significant growth of Strategic products (+120.0 bil. yen YoY)
- ✓ Change the definition of core basis to adequately represent profitability
- ✓ Factored in impairment loss risk and other expenses* (full basis)

*Estimated based on other expenses booked in the past and the balance of intangible assets (No impairment indication as of April 2024)

FY2024 FORECAST: XTANDI, PADCEV, XOSPATA, VYLOY

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PADCEV: Expect further significant growth in FY2024 / VYLOY: Expect global launch

(billion yen)	FY2024 FCST	YoY (vs. FY2023)	
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757.0

+6.6 (+1%)

- ✓ Expect global sales to be at the same level as FY2023, with ex-US regions offsetting the impact of the US IRA
- ✓ US: Expect growth in M0 CSPC, however, expect overall sales to decline factoring in the impact of IRA Medicare Part D redesign scheduled to be effective Jan 2025 (\$50-70M impact)
- ✓ Ex-US: Expect continued growth driven by M1 CSPC



151.2

+65.9 (+77%)

- ✓ Expect progressive strong quarterly growth in FY2024
- ✓ US: Contribution to come from 1L mUC throughout FY2024 as a significant growth driver, expect positive impact from the NCCN guideline update (changed to Category 1)
- ✓ Ex-US: Anticipate potential approval of 1L mUC in Japan, EST and INT by the end of 2024, expect sales to accelerate after approval
- ✓ Expect continued launch and reimbursement of 2L+ mUC around the world



60.0

+4.9 (+9%)

- ✓ Expect continued growth in launched markets led by EST
- ✓ Expect increases in launched countries and reimbursement in INT



- Nominal sales factored into FY2024 forecast (few billion yen), focus on penetration of CLDN18.2 testing for the first year of launch
- Japan approval in March, expect launch in June. Anticipate potential approval in US, EST, INT and China from Q2 onward

FY2024 FORECAST: VEOZAH, IZERVAY

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VEOZAH: Peak sales updated by reviewing initial assumptions / IZERVAY: Expect significant growth in FY2024



FY2024 FCST YoY (vs. FY2023)

28.3 bil. yen **+21.0 (+288%)**

<US>

- ✓ Expect linear demand growth throughout the year
- ✓ Aim for over 80% of commercial lives covered by the end of FY2024
- ✓ Continue to increase patient and HCP activation through commercial investments; at the same time, optimize A&P as needed throughout the fiscal year focusing on ROI

Update of potential peak sales (global): **150 - 250 billion yen***

- ✓ Updated sales forecast by reviewing initial assumptions driven by learnings since launch and latest market research
- ✓ Downward revision largely driven by adjusting the following assumptions based on insights and data obtained since launch
 - **Access and Affordability:** updated to reflect actual payer coverage mix and patient copay (out-of-pocket) expenses
 - **Treatment rate:** adjusted treatment rate in the overall VMS market
 - **NK class share** (within VMS market): adjusted class share ramp



FY2024 FCST YoY (vs. FY2023)

46.4 bil. yen **+34.3 (+283%)**

<US>

- ✓ Expect progressive significant quarterly growth in FY2024 driven by;
 - Approval of permanent J-Code (effective Apr 1)
 - Anticipated approval of label update (PDUFA date: Nov 19)
- ✓ Signs of significant uplift since the approval of permanent J-Code, not just among existing IZERVAY utilizers, but also new HCPs who have been waiting for the permanent J-Code
- ✓ Aim for total patient share of ~40% by the end of FY2024

Future expectations

- ✓ Progress in line with the FY2025 outlook projected at launch (over 100.0 bil. yen)
- ✓ Expect profit contribution to significantly exceed IZERVAY-related expenses (SG&A and cost of sales) starting from FY2025

XTANDI AND STRATEGIC PRODUCTS: FY2024 KEY EXPECTED EVENTS

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	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)	
enzalutamide/ XTANDI			NMPA Decision (M1 CSPC; China)		
enfortumab vedotin/ PADCEV		NMPA Decision (2L+ mUC; China)	MHLW/EC Decision (1L mUC; Japan, Europe)		
zolbetuximab/ VYLOY	Resubmission (US)	FDA Decision (US)		NMPA Decision (China)	
			EC Decision (Europe)		
				TLR* (Pancreatic)	
avacincaptad pegol/ IZERVAY			PDUFA target (Label update; US) Nov		
			EC Decision (Europe)		

 Regulatory decision
 Regulatory submission
 Data readout

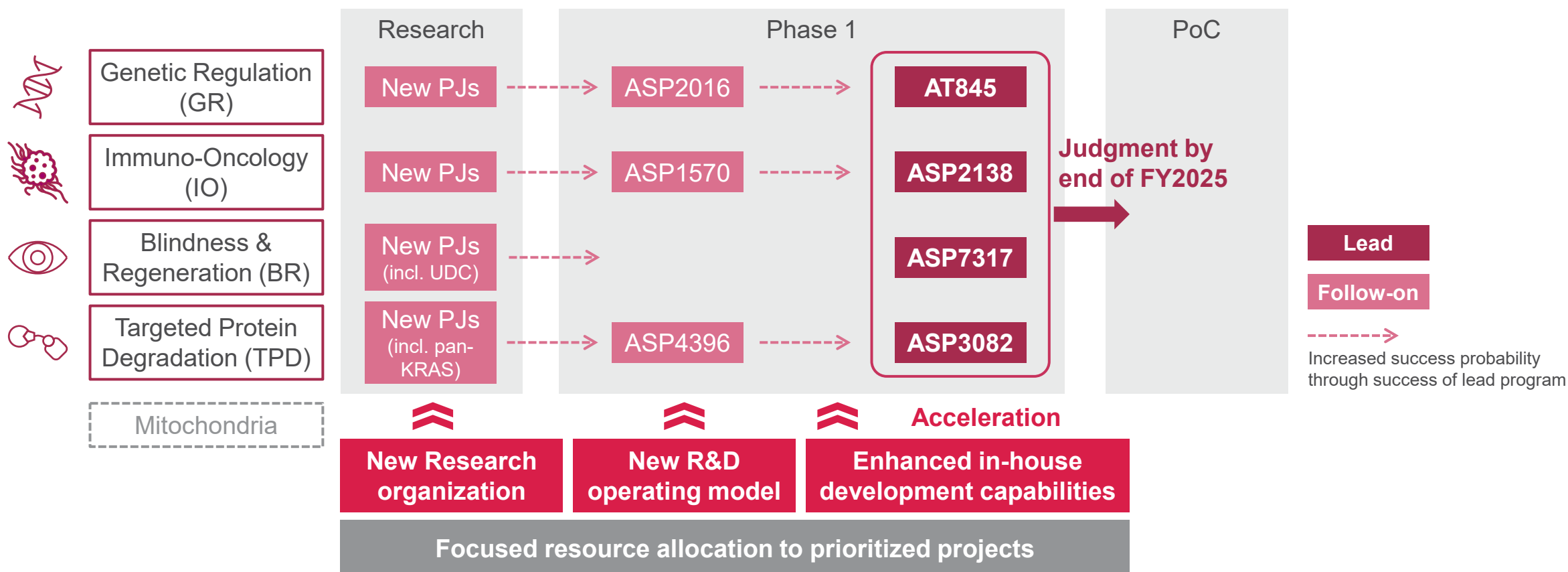
As of Apr 2024 *The timeline of TLR is subject to shift due to its event-driven nature.

NMPA: National Medical Products Administration, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, 2L+: Second or later line, mUC: Metastatic urothelial cancer, MHLW: Ministry of Health, Labour and Welfare, EC: European Commission, 1L: First line, FDA: Food and Drug Administration, TLR: Topline results, PDUFA: Prescription Drug User Fee Act

FOCUS AREA APPROACH: OUTLOOK

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- Expect PoC judgment in lead programs from each PF by end of FY2025 (GR: AT845, IO: ASP2138, BR: ASP7317, TPD: ASP3082)
- Success of lead programs will enhance expectation for success of follow-on programs
- Reform of R&D organization and operation will accelerate PoC judgment



CHANGE IN DEFINITION OF CORE BASIS FROM FY2024

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<Background>

- The acquisition of Iveric Bio (July 2023) made it difficult to adequately represent profitability under the old definition
- The new definition of core basis better represents profitability and ensures comparability with global pharmaceutical companies

<Changes>

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" have been newly excluded as new adjustment items

(billion yen)		FY2021 Actual	FY2022 Actual	FY2023 Actual	FY2024 FCST
Core Operating profit <Old definition>		244.7	286.9	184.6	110.0
New adjustment items	Amortisation of intangible assets (Ratio to Revenue)	28.3 (2.2%)	38.4 (2.5%)	98.8 (6.2%)	140.0 (8.5%)
	Gain on divestiture of intangible assets	24.2	0.2	9.7	-
	Share of profit (loss) of investments accounted for using equity method	0.5	1.3	-3.2	-
Core Operating profit <New definition>		248.3	323.9	276.9	250.0

FY2024 FORECAST

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- Increase in revenue, mainly driven by growth of PADCEV, VEOZAH and IZERVAY (approx. +120.0 bil. yen)
- Factored in the impact of US mirabegron generic entry, however, the decline in core OP margin is minimized to approx. 2 percentage points by thorough review of costs that will not contribute to future growth and value enhancement

(billion yen)	FY2023 Actual	2024 FCST	Change	Main factors for increase/decrease (YoY)
Revenue	1,603.7	1,650.0	+46.3	• PADCEV, VEOZAH, IZERVAY: approx. +120.0 • Impact of US mirabegron generic entry: approx. -80.0
SG&A expenses	740.1	757.0	+16.9	• Strategic products: approx. +35.0 • Reduction of mature products-related costs: approx. -9.0 • Global organizational restructuring implemented in FY2023: approx. -10.0
US XTANDI co-pro fee	194.9	189.0	-5.9	
SG&A excl. the above	545.2	568.0	+22.8	
R&D expenses	294.2	317.0	+22.8	• Investment to strengthen Primary Focus (mainly IO, TPD) and R&D functions: approx. +25.0 • Review of R&D portfolio: approx. -3.0
Core operating profit (New)	276.9	250.0	-26.9	
Core OP margin	17.3%	15.2%	-2.1 ppt	

< Full basis >

Operating profit	25.5	48.0	+22.5
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Main adjustments excluded on core basis

- Amortisation of intangible assets: 140.0
- Impairment loss risk and other expenses*: 60.0
(Estimated based on other expenses booked in the past and the balance of intangible assets)

In anticipation of growth from FY2024 onwards, dividend per share is forecasted at 74 yen, an increase of 4 yen

FY2024 exchange rate assumption: 145 yen/USD, 155 yen/EUR IO: Immuno-Oncology, TPD: Targeted Protein Degradation

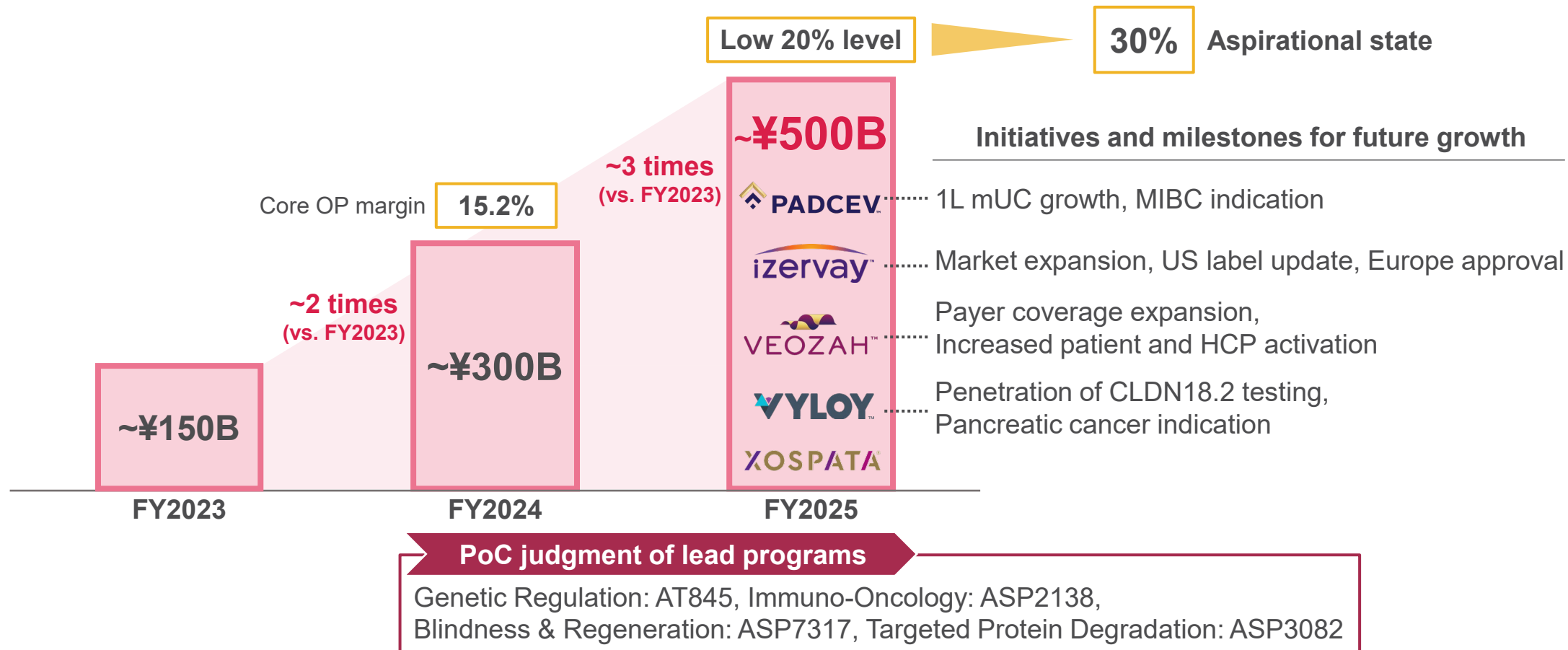
*No impairment indication as of April 2024



CSP2021: LATEST OUTLOOK

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*While Performance Goals are challenging to achieve in FY2025, establish a structure to overcome XTANDI LOE
Strategic products will significantly grow from FY2024 and contribute to profit expansion*



APPENDIX



XTANDI & XOSPATA: BUSINESS UPDATE

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FY2023 performance in line with FCST upwardly revised in Q2



FY2023 Act	YoY	FY2023 Revised FCST*
750.5 bil. yen	+89.3 (+14%)	719.8 104%**

- ✓ Global sales exceeded the FCST revised upward in Q2
- ✓ Sales expanded in all regions, despite 10+ years on the market
- ✓ ~6% growth even excluding FX impact
- ✓ US: Steady growth in demand excluding PAP (demand YoY +4%), driven by M0 CSPC indication based on EMBARK study

FY2023 Act	YoY	FY2023 Revised FCST*
55.1 bil. yen	+8.5 (+18%)	55.2 100%**

- ✓ Global sales expanded in line with the FCST revised upward in Q2
- ✓ Sales expanded in all regions



FY2024 FCST	YoY (vs. FY2023)
757.0 bil. yen	+6.6 (+1%)

- ✓ Expect global sales to be at the same level as FY2023, with ex-US regions offsetting the impact of the US IRA
- ✓ US: Expect growth in M0 CSPC, however, expect overall sales to decline factoring in the impact of IRA Medicare Part D redesign scheduled to be effective Jan 2025 (\$50-70M impact)
- ✓ Ex-US: Expect continued growth driven by M1 CSPC

FY2024 FCST	YoY (vs. FY2023)
60.0 bil. yen	+4.9 (+9%)

- ✓ Expect continued growth in launched markets led by EST
- ✓ Expect increases in launched countries and reimbursement in INT

*Announced in Nov 2023, **Achievement against FY2023 FCST, Actual exchange rates for FY2023: 145 yen/USD, 157 yen/EUR, Exchange rates assumptions for FY2024: 145 yen/USD, 155 yen/EUR

PAP: Patient Assistance Program, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, IRA: Inflation Reduction Act

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.

(Commercial segment of Taiwan changed from Greater China to International Markets from FY2024. Region title of Greater China changed to China from FY2024)



PADCEV & VYLOY: BUSINESS UPDATE

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PADCEV near double growth achieved, expect further significant growth in FY2024. Expect VYLOY to launch globally



FY2023 Act	YoY	FY2023 Revised FCST*
85.4 bil. yen	+40.9 (+92%)	85.2 100%**

- ✓ Global sales exceeded FCST revised significantly upward in Q2

<US>

- ✓ More than doubled demand driven largely by the launch and penetration of 1L mUC (YoY +103%)
- ✓ NCCN guideline updated in Mar, Category 2A recommendation changed to Category 1 preferred recommendation for 1L mUC treatment

<Ex-US>

- ✓ Launched countries increased to 36 (+14 countries in FY2023)

FY2024 FCST	YoY (vs. FY2023)
151.2 bil. yen	+65.9 (+77%)

- ✓ Expect progressive strong quarterly growth in FY2024

<US>

- ✓ Contribution to come from 1L mUC indication throughout FY2024 as a significant growth driver
- ✓ Expect positive impact from the NCCN guideline update (Category 1)

<Ex-US>

- ✓ Anticipate potential approval of 1L mUC in Japan, EST and INT by the end of 2024, expect sales to accelerate after approval
- ✓ Expect continued launch and reimbursement of 2L+ mUC around the world



- Nominal sales factored into FY2024 forecast (few billion yen), focus on penetration of CLDN18.2 testing for the first year of launch
- Japan approval in March, expect launch in June
- Anticipate potential approval in US, EST, INT and China from Q2 onward

*Announced in Nov 2023, **Achievement against FY2023 FCST, Actual exchange rates for FY2023: 145 yen/USD, 157 yen/EUR, Exchange rates assumptions for FY2024: 145 yen/USD, 155 yen/EUR

1L: First line, mUC: Metastatic urothelial cancer, NCCN: National Comprehensive Cancer Network, 2L+: Second or later line

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.

(Commercial segment of Taiwan changed from Greater China to International Markets from FY2024. Region title of Greater China changed to China from FY2024)



VEOZAH: BUSINESS UPDATE



26

Overall initiatives are progressing; however, demand trails expectations. Peak sales updated by reviewing initial assumptions

FY2023 Act	FY2023 Revised FCST*	
7.3 bil. yen	7.1	102%**

<US>

- ✓ Progress in line with FCST revised in Q3
- ✓ Steady increase in demand from Q3 to Q4 (Q3 vs. Q4: ~60% increase)
- ✓ Over 35K HCPs prescribed VEOZAH
- ✓ While commercial lives covered (payer coverage) expanded to 50% as planned, HCP's perception of VEOZAH access and affordability remains low

FY2024 FCST	YoY (vs. FY2023)
28.3 bil. yen	+21.0 (+288%)

<US>

- ✓ Expect steady demand growth throughout the year
- ✓ Aim for over 80% of commercial lives covered by the end of FY2024
- ✓ Continue to increase patient and HCP activation through commercial investments; At the same time, optimize A&P as needed throughout the fiscal year focusing on ROI

<Ex-US>

- ✓ Expect sales contribution from the increases in launched countries

Update of potential peak sales (global): 150 - 250 billion yen ***

- ✓ Updated sales forecast by reviewing initial assumptions driven by learnings since launch and latest market research
- ✓ Downward revision largely driven by adjusting the following assumptions based on insights and data obtained since launch
 - **Access and Affordability:** updated to reflect actual payer coverage and patient copay (out-of-pocket) expenses
 - **Treatment rate:** adjusted treatment rate in the overall VMS market
 - **NK class share** (within VMS market): adjusted class share ramp

*Announced in Feb 2024, **Achievement against FY2023 FCST, ***Previous peak sales forecast: 300-500 billion yen, VEOZAH: Approved as "VEOZA" in Europe
Actual exchange rates for FY2023: 145 yen/USD, 157 yen/EUR, Exchange rates assumptions for FY2024: 145 yen/USD, 155 yen/EUR
HCP: Healthcare professional, DTC: Direct-to-consumer, NK: Neurokinin, HRT: Hormone replacement therapy

IZERVAY: BUSINESS UPDATE (US)



27

Encouraging performance since launch with accelerated momentum. Expect significant growth in FY2024

FY2023 Act	FY2023 FCST*	
12.1 bil. yen	11.0	110%**

- ✓ Sales exceeded expectations driven by accelerated momentum with vial demand doubling from Q3 to Q4
- ✓ Estimate market share in the Q4 period (Jan-Mar) to be ~25% based on reported volume shipments and market research studies
- ✓ 50,000+ vials shipped since launch, available in ~1,000 Retina accounts
- ✓ Post-marketing safety profile consistent with clinical trial results

FY2024 FCST	YoY (vs. FY2023)
46.4 bil. yen	+34.3 (+283%)

- ✓ Expect progressive significant quarterly growth in FY2024 driven by;
 - Approval of permanent J-Code (effective Apr 1)
 - Anticipated approval of label update (PDUFA date: Nov 19)
- ✓ Signs of significant uplift since the approval of permanent J-Code, not just among existing IZERVAY utilizers, but also new HCPs who have been waiting for the permanent J-Code
- ✓ Aim for total patient share of ~40% by the end of FY2024

<Future expectations>

- Progress in line with the FY2025 outlook projected at launch (over 100.0 bil. yen)
- Expect profit contribution to significantly exceed IZERVAY-related expenses (SG&A and cost of sales) starting from FY2025

*Announced in Nov 2023 (no revision since announcement), **Achievement against FY2023 FCST

Actual exchange rates for FY2023: 145 yen/USD, 157 yen/EUR, Exchange rates assumptions for FY2024: 145 yen/USD, 155 yen/EUR

PDUFA: Prescription Drug User Fee Act, HCP: Healthcare professional



FY2023 ACTUAL: FX RATE

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Average rate for the period

Currency	FY2022	FY2023	Change
USD	135 yen	145 yen	+9 yen
EUR	141 yen	157 yen	+16 yen

<Impact of exchange rate on financial results>

- 96.3 billion yen increase in revenue, 19.1 billion yen increase in core OP

FY2024 FORECAST: FX RATE & FX SENSITIVITY

29

Exchange rate Average for the period	FY2023	FY2024 FCST	Change
USD	145 yen	145 yen	-
EUR	157 yen	155 yen	-2 yen

Estimated FX sensitivity of FY2024 forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption	
	Revenue	Core OP*
USD	Approx. +6.1 bil. yen	Approx. +0.3 bil. yen
EUR	Approx. +3.0 bil. yen	Approx. +1.2 bil. yen

*New Core definition

BALANCE SHEET & CASH FLOW HIGHLIGHTS

30

(billion yen)	FY2022 end	FY2023 end
Total assets	2,456.5	3,569.6
Cash and cash equivalents	376.8	335.7
Total equity attributable to owners of the parent	1,508.0	1,596.0
Equity ratio (%)	61.4%	44.7%
(billion yen)	FY2022	FY2023
Cash flows from operating activities	327.8	172.5
Cash flows from investing activities	-84.5	-845.8
Free cash flows	243.3	-673.3
Cash flows from financing activities	-195.6	614.1
Increase/decrease in short-term borrowings and CP	-15.0	324.3
Proceeds from issuance of bonds and long-term borrowings	50.0	472.3
Acquisition of treasury shares	-60.6	-10.7
Dividends paid	-100.4	-116.7

BALANCE OF BONDS AND BORROWINGS HIGHLIGHTS

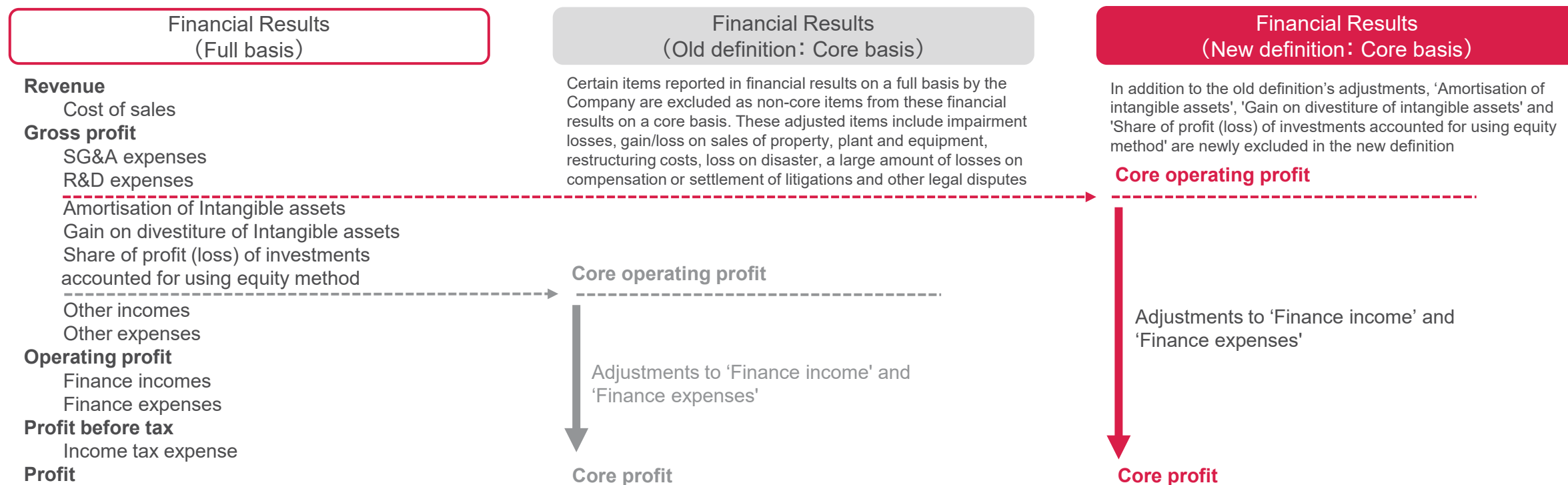
31

(billion yen)	FY2023 Dec end	FY2023end
Balance of bonds and borrowings	871.0	920.0
Non-current liabilities	463.8	447.7
Bonds	250.0	250.0
Long-term borrowings	213.8	197.7
Current liabilities	407.2	472.3
Commercial papers	357.0	285.0
Short-term borrowings	-	135.4
Current portion of long-term borrowings	50.2	51.9

CORE BASIS PERFORMANCE: CHANGES IN DEFINITIONS AND CONTEXT

32

Introduce New definition of core-based performance from FY2024



MAIN INTANGIBLE ASSETS (AS OF FY2023 END)

33

	Bil. yen	Foreign currency*
AT132	16.4	USD 109M
AT845	11.0	USD 73M
Other gene therapy related program**	57.5	USD 380M
Gene therapy related technology**	71.4	USD 472M
VEOZAH	94.1	EUR 556M
EVRENZO	4.3	-
VYLOY	64.0	EUR 493M
IZERVAY (US)	730.6	USD 4,828M
IZERVAY (Ex-US)	166.4	USD 1,100M

*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)

CAPITAL ALLOCATION

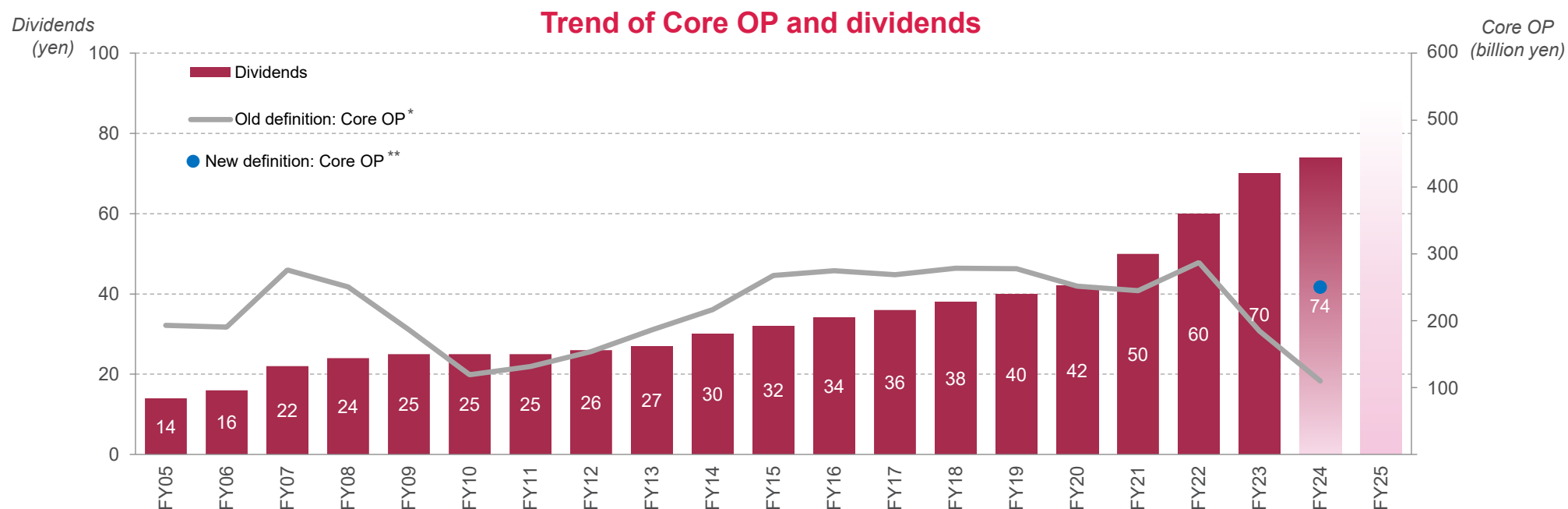
34

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

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



For illustrative purposes only

CSP: Corporate Strategic Plan

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

**Change in definition of core basis From FY2024



ROBUST PIPELINE OF ASTELLAS

35

Phase 1

enfortumab vedotin (NMIBC)
gilteritinib (Newly diagnosed AML, HIC-ineligible)
ASP1570
ASP2138
ASP1002
ASP1012
ASP2802
ASP7317
zocaglusagene nuzaparvovec/ AT845
ASP2016
ASP3082
ASP4396
abiraterone decanoate/ PRL-02/ASP5541

Phase 2

enfortumab vedotin (Other solid tumors)
zolbetuximab (Pancreatic adenocarcinoma)
resamirigene bilparvovec/ AT132 (XLMTM)
avacincaptad pegol (Stargardt disease)

Phase 3

enfortumab vedotin (MIBC)
gilteritinib (Earlier-stage AML, pediatric use)
fezolinetant (VMS due to menopause: China, Japan; Induced VMS in breast cancer patients on adjuvant endocrine therapy)
roxadustat (Anemia associated with CKD, pediatric use: Europe)
mirabegron (Neurogenic detrusor overactivity, pediatric use: Europe)

Submitted/Filed

enzalutamide (M1 CSPC: China)
enfortumab vedotin (mUC previously untreated: Europe, Japan, China; mUC pretreated: China)
zolbetuximab (Gastric and GEJ adenocarcinoma: US, Europe, China)
avacincaptad pegol (GA secondary to AMD: Europe)
peficitinib (Rheumatoid arthritis: China)

- XTANDI and Strategic products
- Projects with Focus Area approach
- Others

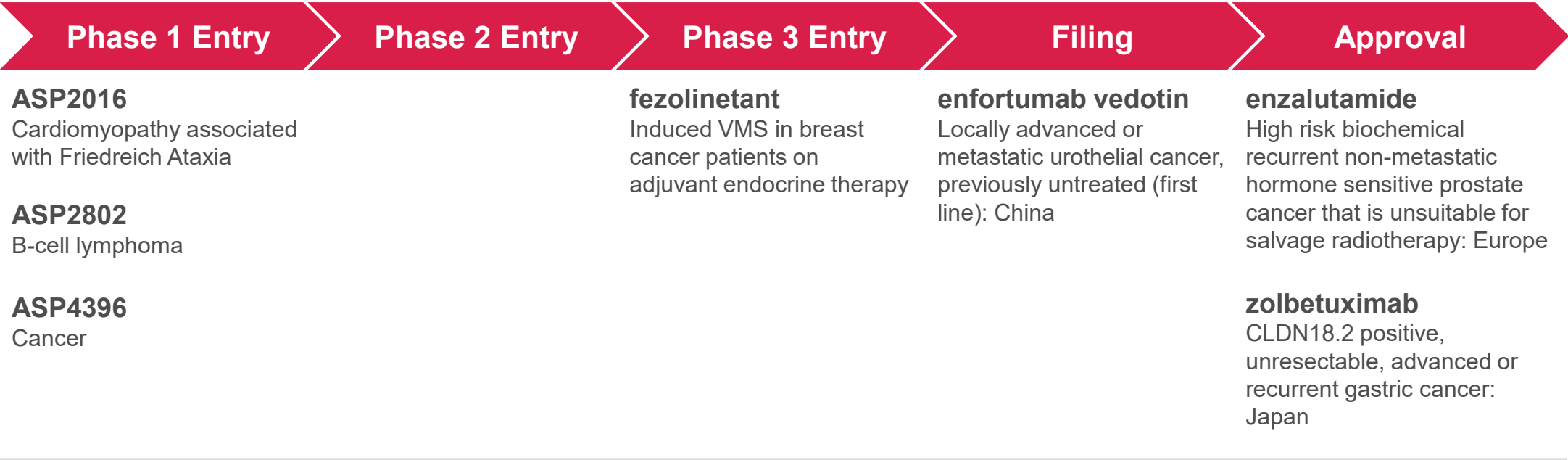
Please refer to R&D pipeline list for details including target disease.

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, CKD: Chronic kidney disease, M1: Metastatic, CSPC: Castration-sensitive prostate cancer,
mUC: Metastatic urothelial cancer, GEJ: Gastroesophageal junction, GA: Geographic atrophy, AMD: Age-related macular degeneration



PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since the Last Financial Results Announcement



Discontinuation

ASP2074: Cancer (Phase 1)
ASP0367: Primary mitochondrial myopathies (Phase 2), Duchenne muscular dystrophy (Phase 1)

Note: Phase 1 entry is defined as confirmation of IND open.
Phase transition is defined by approval of company decision body for entering to next clinical phase.
Filing is defined as submission of application to health authorities.
Discontinuation is defined by the decision of company decision body.

XTANDI AND STRATEGIC PRODUCTS: POTENTIAL PEAK SALES (AS OF APR 2024)

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Product	Potential Peak Sales (Global, billions of yen)
XTANDI (enzalutamide)	over 700.0
PADCEV (enfortumab vedotin) ¹	400.0 – 500.0
IZERVAY (avacincaptad pegol)	200.0 – 400.0
VEOZAH (fezolinetant)	150.0 – 250.0
XOSPATA (gilteritinib)	100.0 – 200.0
VYLOY (zolbetuximab)	100.0 – 200.0
EVRENZO (roxadustat) ²	under 50.0
AT132 (resamirigene bilparvovec)	under 50.0

Only indications undergoing pivotal studies are included for projection (as of Apr 2024)

1. Disclosed as “in-market sales,” not Astellas revenue. Sales for Americas are calculated based on the sales booked by Pfizer

2. Astellas territories only; Japan, Europe, the Commonwealth of Independent States, the Middle East, South Africa, etc.

XTANDI AND STRATEGIC PRODUCTS: STATUS UPDATE

(Red: Updates since the last financial results announcement)

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Project / Product	Indication	Current status
enzalutamide/ XTANDI	M1 CSPC	• NDA accepted in China in Sep 2023
	M0 CSPC with BCR at high risk for metastasis	• Approved in Europe in Apr 2024
enfortumab vedotin/ PADCEV	Metastatic urothelial cancer	• Previously untreated (first line): Type II variation/sNDA accepted in Europe/Japan in Jan 2024. sBLA accepted in China in Mar 2024
	Muscle-invasive bladder cancer	• Pretreated: BLA accepted in China in Mar 2023
	Non-muscle-invasive bladder cancer	• Phase 3 studies ongoing
	Other solid tumors	• Phase 1 study ongoing
gilteritinib/ XOSPATA	Relapsed and refractory AML	• Phase 2 study ongoing
	AML, post-HSCT maintenance	• China: Phase 3 study stopped due to efficacy
	AML, newly diagnosed (HIC-eligible)	• Development based on Phase 3 MORPHO study discontinued
	AML, newly diagnosed (HIC-ineligible)	• Phase 3 study ongoing (enrollment completed)
	AML, post-chemotherapy	• Phase 1 study ongoing
zolbetuximab/ VYLOY	Gastric & GEJ adenocarcinoma	• Obtained topline results from Phase 2 GOSSAMER study
	Pancreatic adenocarcinoma	• BLA/MAA accepted in Europe and China in Jul 2023. Received complete response letter in US in Jan 2024. Approved in Japan in Mar 2024
fezolinetant/ VEOZAH	VMS due to menopause	• Phase 2 study ongoing
	Induced VMS in breast cancer patients	• China: Obtained topline results from Phase 3 MOONLIGHT 1 and MOONLIGHT 3 studies
avacincaptad pegol/ IZERVAY	GA secondary to AMD	• Japan: FSFT in Phase 3 STARLIGHT 2 and STARLIGHT 3 studies in Mar and Feb 2024, respectively
	Stargardt disease	• Phase 3 study under preparation to start in Q2 FY2024
avacincaptad pegol/ IZERVAY	GA secondary to AMD	• MAA accepted in Europe in Aug 2023. sNDA for label update accepted in US in Mar 2024
	Stargardt disease	• Phase 2b study ongoing

VEOZAH: Approved as "VEOZA" in Europe. M1: Metastatic, CSPC: Castration-sensitive prostate cancer, M0: Non-metastatic, BCR: Biochemical recurrence, (s)NDA: (Supplemental) New Drug Application, BLA: Biologics License Application, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, GEJ: Gastroesophageal junction, MAA: Marketing Authorization Application, VMS: Vasomotor symptoms, FSFT: First subject first treatment, GA: Geographic atrophy, AMD: Age-related macular degeneration

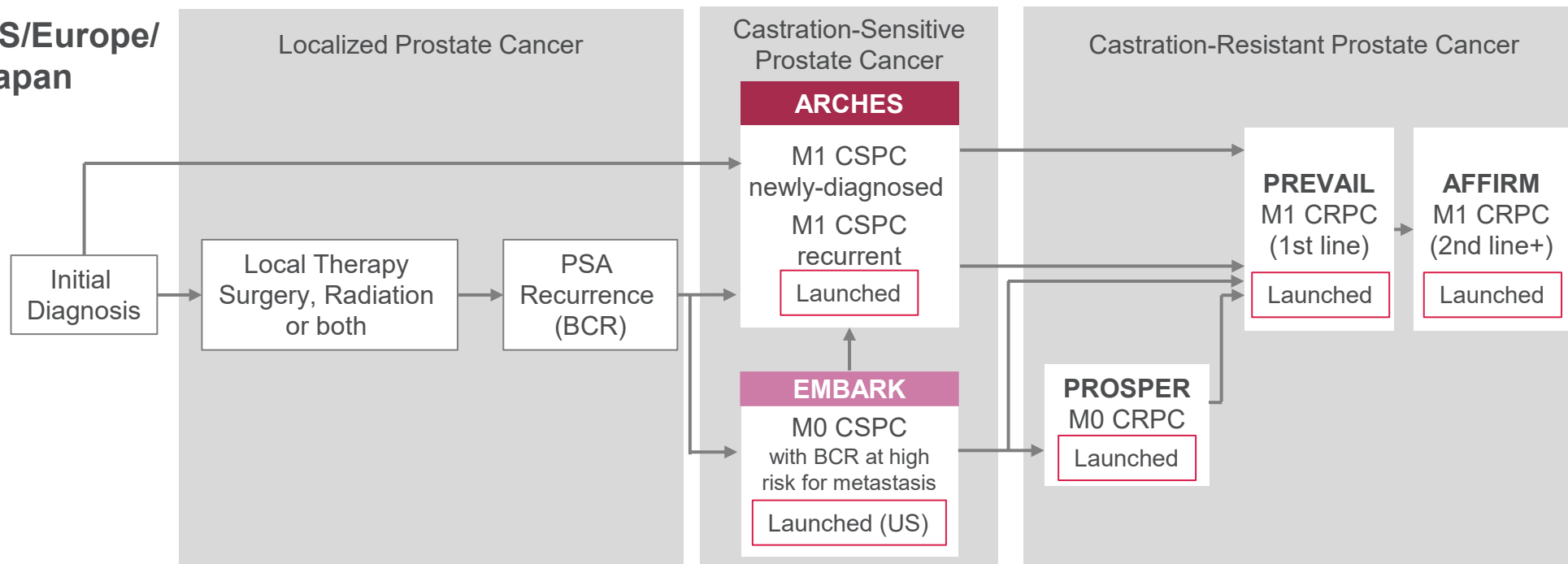


ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

(Red: Updates since the last financial results announcement)

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US/Europe/
Japan



P3: EMBARK

[NCT02319837](#)

M0 CSPC

ENZA + ADT vs. placebo + ADT vs. ENZA mono

n=1,068

Approved in US in Nov 2023.

Approved in Europe in Apr 2024

China

• M1 CSPC: NDA accepted in Sep 2023

ENZALUTAMIDE (2/2): PHASE 3 STUDY DATA BY DISEASE STAGE

40

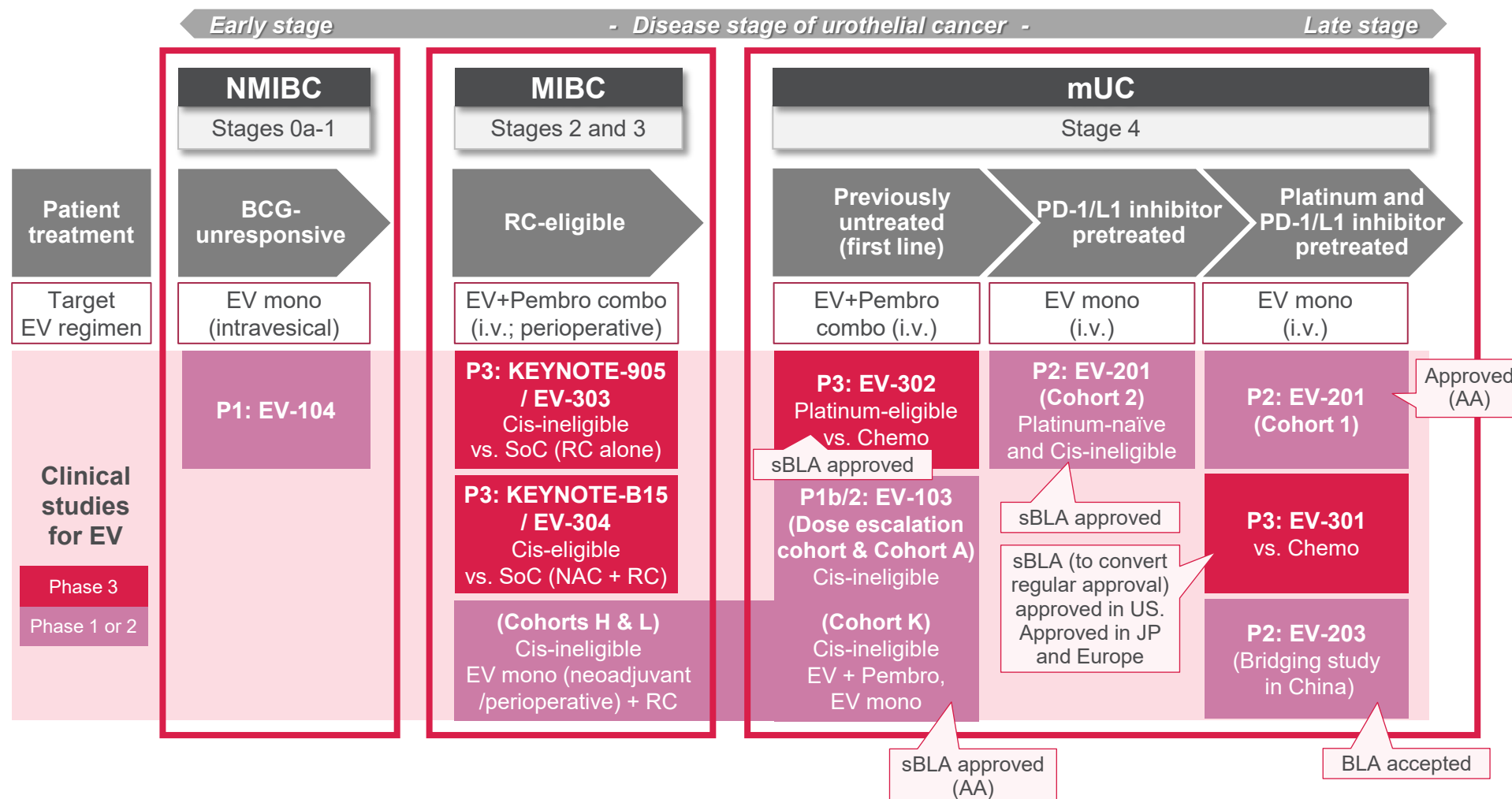
Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

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

ENFORTUMAB VEDOTIN (EV) (1/4): NECTIN-4 TARGETED ADC OVERALL UC PROGRAM

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ENFORTUMAB VEDOTIN (EV) (2/4): CLINICAL STUDIES

(Red: Updates since the last financial results announcement)

42

For urothelial cancer

P3: EV-301	NCT03474107	mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono vs. Chemo	n=608	sBLA (to convert regular approval) approved in US in Jul 2021. Approved in Japan in Sep 2021, in Europe in Apr 2022
P3: EV-302	NCT04223856	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=990	Approved in US in Dec 2023. Type II variation/sNDA accepted in Europe/Japan in Jan 2024. sBLA accepted in China in Mar 2024
P3: EV-303 /KEYNOTE-905	NCT03924895	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=857	FSFT in Pembro + EV arm: Dec 2020
P3: EV-304 /KEYNOTE-B15	NCT04700124	MIBC, Cis-eligible; EV + Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=784	Enrollment completed
P2: EV-201	NCT03219333	mUC, PD-1/L1 inhibitor pretreated; EV mono Cohort 1: Platinum pretreated Cohort 2: Platinum naïve and Cis-ineligible	n=219	Cohort 1: Approved (under the Accelerated Approval program) Cohort 2: sBLA approved in US in Jul 2021
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
P2: EV-203	NCT04995419	<Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono	n=40	BLA accepted in China in Mar 2023
P1: EV-104	NCT05014139	NMIBC, High-risk BCG-unresponsive; Intravesical EV mono	n=58	FSFT: Jan 2022

For 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=320	Enrollment completed for EV mono cohorts. Initial topline results obtained in Jun 2022
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ENFORTUMAB VEDOTIN (EV) (3/4): STUDY DATA BY DISEASE STAGE OF UC

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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	784 (2 arms)	857 (3 arms)	990 (2 arms)	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	pCR & EFS	pCR & 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) (4/4): FUTURE OUTLOOK

44

- 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)

Patient segment		Pivotal study (EV regimen)	Target filing timing	Number of eligible patients*
MIBC	Cis-ineligible	EV-303 (combo w/ Pembro)	FY2025 or later	10,000
	Cis-eligible	EV-304 (combo w/ Pembro)	FY2025 or later	37,000
1L mUC		EV-302 EV-103 Cohorts [Phase 1b/2 for AA in US] (combo w/ Pembro)	Approved Approved [AA in US]	76,000 (incl. US, Cis-ineligible: 8,000-9,000)
2L+ mUC	PD-1/L1 inhibitor pretreated & Cis-ineligible	EV-201 Cohort 2 (monotherapy)	Approved	1,600 (US, Cis-ineligible)
	Platinum & PD-1/L1 inhibitor pretreated	EV-301 EV-201 Cohort 1 [Phase 2 for AA in US] (monotherapy)	Approved	38,000

<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:

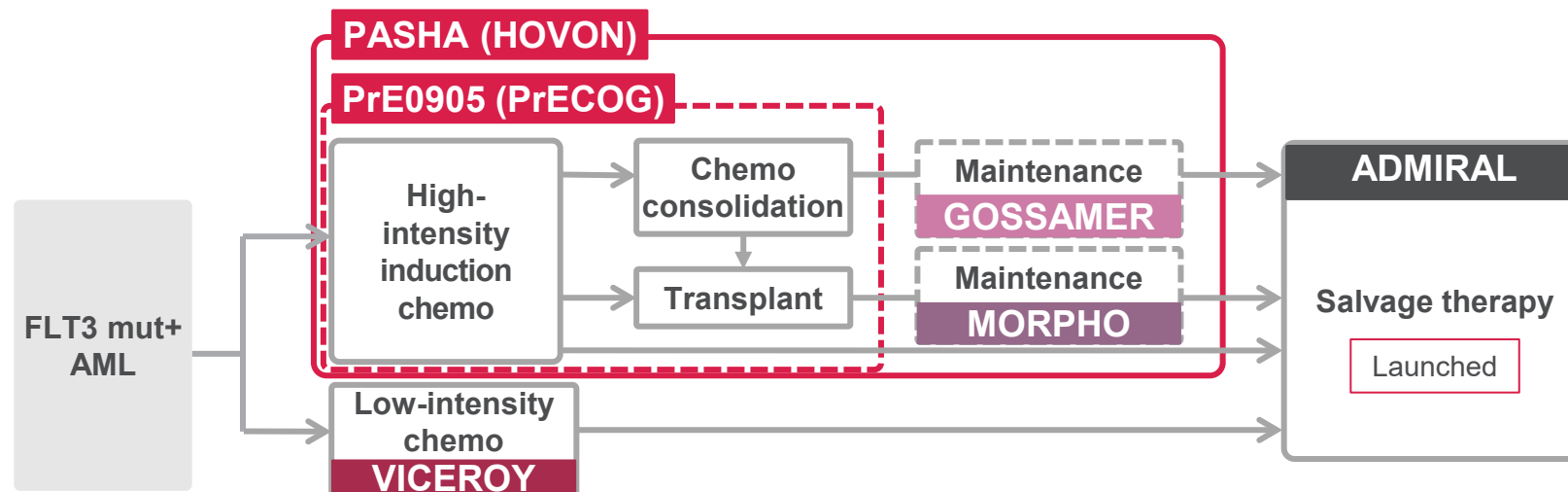
- HR+/HER2- breast cancer
- Triple-negative breast cancer
- Squamous NSCLC
- Non-squamous NSCLC
- Head and neck cancer
- Gastric and esophageal adenocarcinoma including GEJ adenocarcinoma
- Esophageal squamous cell carcinoma

**Combo w/ Pembro:

- Head and neck squamous cell carcinoma

GILTERITINIB: FLT3 INHIBITOR

45



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	n=766	Enrollment completed (Sponsor: HOVON)
	P2: PrE0905 (PrECOG)	NCT03836209	gilteritinib vs. midostaurin (1:1)	n=179	Enrollment completed (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 in Jan 2023

- 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

(Red: Updates since the last financial results announcement)

46

Target: Claudin 18.2

- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- 38% of patients had tumors that were Claudin 18.2+ in SPOTLIGHT and GLOW trials

Gastric and GEJ adenocarcinoma

- Target patient population: HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma
- Metastatic gastric cancer is an area of significant unmet need, especially in advanced stages with ~6% five-year survival rate at Stage IV and treatment options are limited

Gastric and GEJ adenocarcinoma	P3: SPOTLIGHT	NCT03504397	First line, Combo with mFOLFOX6, DB, vs. placebo	n=566	BLA/MAA accepted in Europe and China in Jul 2023. Received complete response letter in US in Jan 2024. Approved in Japan in Mar 2024
	P3: GLOW	NCT03653507	First line, Combo with CAPOX, DB, vs. placebo	n=507	
	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	FSFT: Sep 2018
Pancreatic adenocarcinoma	P2	NCT03816163	First line, Combo with nab-paclitaxel and gemcitabine, open	n=369	FSFT: May 2019

FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

(Red: Updates since the last financial results announcement)

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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

US and Europe

P3: SKYLIGHT 1	NCT04003155	Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)	n=527	Approved in US in May 2023, in Europe in Dec 2023
P3: SKYLIGHT 2	NCT04003142	The last 40 weeks: Active extension treatment period, 30 mg or 45 mg	n=501	
P3: SKYLIGHT 4	NCT04003389	VMS associated with menopause; 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)	n=1,831	
P3b: DAYLIGHT	NCT05033886	Moderate to severe VMS associated with menopause, unsuitable for HRT; 24 weeks, DB, 45 mg vs. placebo (1:1)	n=453	Topline results obtained in Jun 2023

China

P3: MOONLIGHT 1	NCT04234204	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

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
P3: STARLIGHT 3	NCT06206421	VMS associated with menopause; 52 weeks: DB, vs. placebo (1:1)	n=260	FSFT: Feb 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.

VMS: Vasomotor symptoms. QoL: Quality of life, HRT: Hormone replacement therapy, DB: Double-blind, FSFT: First subject first treatment

AVACINCAPTAD PEGOL (ACP): COMPLEMENT C5 INHIBITOR / PEGYLATED RNA APTAMER

(Red: Updates since the last financial results announcement)

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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	MAA accepted in Europe in Aug 2023. sNDA for label update accepted in US in Mar 2024
	P3: GATHER2	NCT04435366	2 mg vs. Sham	n=448	
Stargardt disease	P2b	NCT03364153	vs. Sham	n=120	FSFT: Jan 2018

1. Retina 37:819-835 (2017). 2. IQVIA Medical Claims (DX) data Jan '20-Dec '21: 24 Months. 3. JAMA Ophthalmol 139:743-750 (2021)

MAA: Marketing Authorization Application, sNDA: Supplemental New Drug Application, FSFT: First subject first treatment

ON THE FOREFRONT OF HEALTHCARE CHANGE

