Q2/FY2023 FINANCIAL RESULTS
ENDED SEPTEMBER 30, 2023

Naoki Okamura
President and CEO
Astellas Pharma Inc.
November 1, 2023

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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

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AGENDA

I Q2/FY2023 Consolidated Financial Results
FY2023 Revised Forecasts

II Initiatives for Sustainable Growth

Q2/FY2023 FINANCIAL RESULTS: OVERVIEW

Disclosing the consolidated financial results reflecting the impact of the acquisition of Iveric Bio starting from Q2/FY2023

Revenue increased YoY (when excl. the FX impact, revenue decreased due to the impact of LEXISCAN generic)

- Oncology products (XTANDI, PADCEV, XOSPATA) exceeded expectations, full-year forecast revised upward
- VEOZAH underperformed vs. forecast, will review full-year forecast in accordance with Q3 progress
- IZERVAY's initial uptake was in line with expectations

Cost items

- SG&A expenses were on track and R&D expenses were above full-year forecast
  (when excl. the effect of FX impact and the acquisition of Iveric Bio)

Operating profit

- Core OP decreased by 25% YoY due to the impact of LEXISCAN generic and the acquisition of Iveric Bio
  Taking these factors into account, full-year forecast revised downward

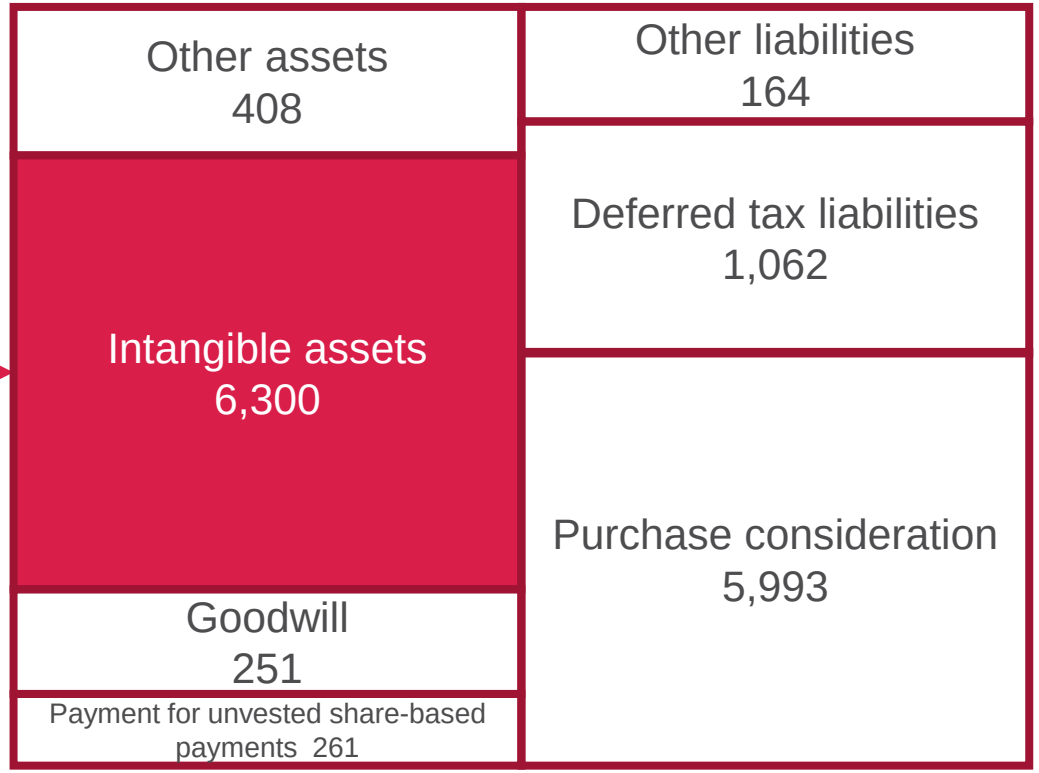
ACCOUNTING TREATMENT OF BUSINESS COMBINATION WITH IVERIC BIO

Booked intangible assets of $6,300M and goodwill of $251M

<Opening balance sheet as of July 11, 2023*>

($ million)

- IZERVAY US
  $5,200M
  →Amortisation started from Q2/FY2023
- IZERVAY Outside of US
  $1,100M
  →To be amortised after launches



*Parts of figures might be changed because the fair value of assets acquired and liabilities assumed is being measured

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Q2/FY2023 FINANCIAL RESULTS

(billion yen)	Q2/FY22	Q2/FY23	Change	Change (%)	FY23 Initial FCST*	Progress	FX impact (YoY)
Revenue	**762.2**	**767.1**	**+5.0**	**+0.6%**	**1,520.0**	**50.5%**	+37.8 bil. yen
Cost of sales	151.7	143.4	-8.3	-5.5%			+6.5 bil. yen
% of revenue	19.9%	18.7%	-1.2 ppt				
SG&A expenses	308.0	347.5	+39.5	+12.8%	661.0	52.6%	+16.1 bil. yen
US XTANDI co-pro fee	89.7	93.0	+3.4	+3.8%	176.0	52.8%	
SG&A excl. the above	218.3	254.4	+36.1	+16.5%	485.0	52.5%	+11.6 bil. yen
R&D expenses	139.2	141.9	+2.8	+2.0%	251.0	56.5%	+4.5 bil. yen
Amortisation of intangible assets	20.0	33.7	+13.8	+68.9%			
Gain on divestiture of intangible assets	0.2	9.4	+9.2	-			
Core operating profit	**145.4**	**109.8**	**-35.6**	**-24.5%**	**290.0**	**37.9%**	+11.0 bil. yen
＜Full basis＞							
Other income	16.2	7.1	-9.2	-56.4%			
Other expenses	41.7	65.9	+24.1	+57.8%			
Operating profit	**119.9**	**51.0**	**-68.9**	**-57.4%**	**259.0**	**19.7%**	
Profit before tax	120.5	52.2	-68.3	-56.7%	260.0	20.1%	
Profit	**96.4**	**31.7**	**-64.8**	**-67.2%**	**204.0**	**15.5%**	

Other expenses

- Payment for Iveric Bio's unvested share-based payments: 36.7 bil. yen
- Fair value increase contingent consideration due to FX impact (zolbetuximab): 8.8 bil. yen

* Exchange rates for initial FCST: 130 yen/USD, 140 yen/EUR, Core basis: disclosed on Apr 27, Full basis: revised on Aug 1

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XTANDI, PADCEV, XOSPATA: BUSINESS UPDATE

Oncology products exceeding expectations. Upward revision of FCST for each product, total of approx. +18.0 bil yen (excl. FX impact)

(billion yen)	Q2/FY2023 Act	YoY	FY2023 Initial FCST	FY2023 Revised FCST	
Xtandi (enzalutamide)	360.9	+28.9 (+9%)	669.9	719.8 (Approx. +3.0 when excl. FX impact)	✓ Global sales are in line with expectations Ex-US performance are offsetting the US performance ✓ US: PAP ratio continues to be high, however, demand excluding PAP showed steady growth (demand YoY +3%) ✓ Ex-US: EM and INT are above expectations, mainly from M1 CSPC growth ✓ Upward revision of FCST as Ex-US expected to outweigh the downside of US
PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	32.7	+11.9 (+57%)	66.7	85.2 (Approx. +13.0 when excl. FX impact)	✓ Global sales exceeding expectations, expect continued growth in 2H of FY23 ✓ US: Penetration of 1L mUC (cis-ineligible) continues to exceed expectations, expect further sales acceleration. In addition, expect approval of additional 1L mUC indication (cis-eligible) based on EV-302 within FY23 ✓ EM: Reimbursement started in Germany and Italy, expect sales growth from Q3 ✓ Significant upward revision of FCST, reflecting the strong US outlook
XOSPATA gilteritinib 40mg tablets	26.3	+2.8 (+12%)	49.3	55.2 (Approx. +2.0 when excl. FX impact)	✓ Global sales exceeding expectations ✓ Demand increased due to higher-than-expected new patient starts ✓ Upward revision of FCST, reflecting the strong global performance

Exchange rates for initial FCST: 130 yen/USD,140 yen/EUR, Exchange rates for revised FCST: 140 yen/USD,152 yen/EUR (FCST rates Q3 onwards: 140 yen/USD,150 yen/EUR)
PAP: Patient Assistance Program, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, 1L: First line, mUC: Metastatic urothelial cancer
EM (Established Markets): Europe, Canada, etc., INT (International Markets): Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Korea, Australia, Export sales, etc.

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VEOZAH: BUSINESS UPDATE

Overall activities are on track, however, Q2 sales underperformed due to overestimation of demand prior to DTC launch

Fully branded DTC activities including TV commercial started as planned, impact will be assessed going forward

(billion yen)	Q2/FY2023 Act	FY2023 FCST	
VEOZAH™ (fezolinetant) tablets 45 mg	**1.3**	Initial FCST will be reviewed in Q3	✓ Q2 sales underperformed vs. FCST due to overestimation of demand prior to DTC launch As a result, expect to miss initial FCST, however, remain confident in peak sales outlook ✓ Expect sales growth from Q3 onward, will review FCST in accordance with progress

<Status through Q2>

Market Access

- ✓ Commercial insurance coverage on track (Approx. 20% of lives)
- ✓ Payer discussions progressing as expected
- ✓ Takes about 6 months to review new drugs for coverage, expect coverage to increase over the course of FY23

HCP

- ✓ 70K HCPs reached in-person
- ✓ HCP awareness increased as expected ~40% (Jul) vs. ~50% (Sep)*

Patient

- ✓ Total of 9K patients with filled prescriptions

TV commercial started in the US on October 9

<Future outlook>

- ✓ Expect positive impact from DTC activities including TV commercial to come from December onward
- ✓ FY2023 full-year FCST will be reviewed after assessing the impact of DTC activities and progress of insurance coverage
- ✓ No change in peak sales outlook

*Market Research September 2023, DTC: Direct-to-consumer, HCP: Healthcare professional

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IZERVAY: BUSINESS UPDATE

Launched in September, initial uptake is on track. Expect breakeven in FY2025 and peak sales of 200.0 - 400.0 bil. yen

(billion yen)	Q2/FY2023 Act	FY2023 FCST
izervay (avacincaptad pegol intravitreal solution) 2 mg	1.2	11.0

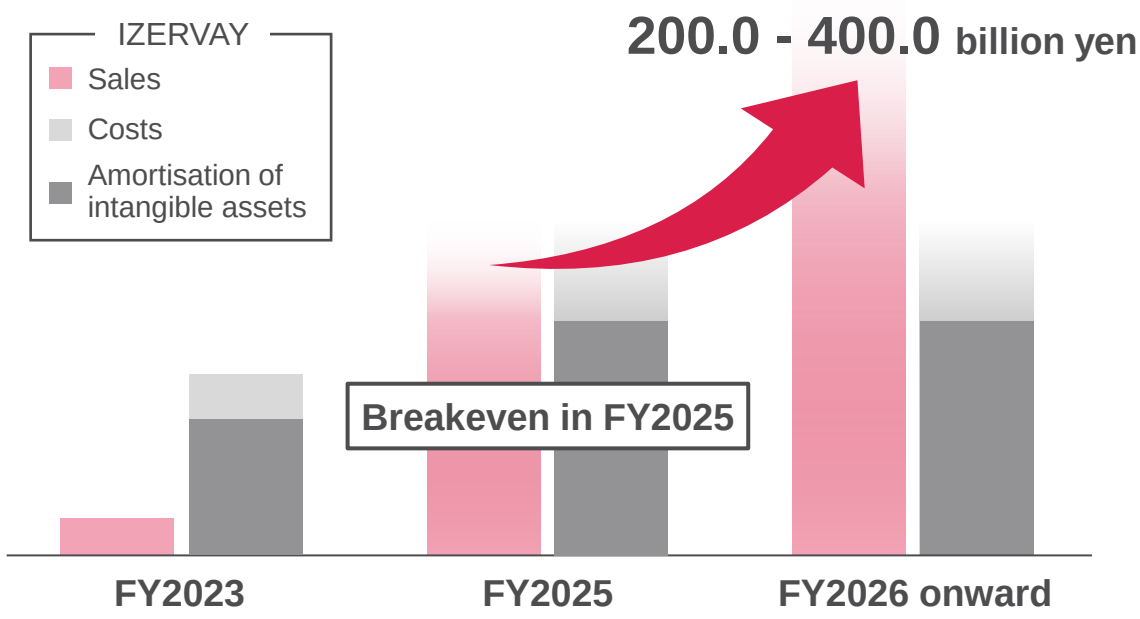
<Q2 Progress>

- ✓ US approval in August, launched in September
- ✓ Initial uptake is on track
- ✓ Over 10K units distributed
- ✓ Available in 500 Retina accounts

<Market Access>

- ✓ Anticipate mainly Medicare Part B
- ✓ Submitted application for permanent J-Code (expected Apr 2024)

<Sales forecast (image)>



<Amortisation of intangible assets>

- ✓ FY2023: Approx. 60.0 billion yen
- ✓ FY2024 onward: Approx. 80.0 - 100.0 billion yen (Fluctuates mainly due to FX rate)

J-Code: Permanent reimbursement codes used by government payers and commercial insurers to facilitate billing of Medicare Part B treatments, which must be administered by a healthcare professional. J-codes simplify and streamline the billing and reimbursement processes, allowing for efficient claims processing

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Q2/FY2023 FINANCIAL RESULTS: COST ITEMS

Cost of sales ratio was as expected

SG&A expenses were on track and R&D expenses were above full-year forecast (when excl. FX impact and the acquisition of Iveric Bio)

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

Cost Items	YoY change	Ratio to Revenue	Progress against FCST	
Cost of sales	-5.5%	18.7% (-1.2 ppt YoY)	-	✓ Cost of sales ratio was as expected
SG&A expenses **excl. US XTANDI co-pro fee**	+16.5% (+11.2% excl. FX impact)	33.2% (+4.5 ppt YoY)	52.5%	✓ Increase in VEOZAH-related costs (approx. +13.0 bil. yen YoY) ✓ Reduction of mature products-related costs (approx. -4.0 bil. yen YoY) ✓ Impact of acquisition of Iveric Bio: approx. +10.0 bil. yen
R&D expenses	+2.0% (-1.2% excl. FX impact)	18.5% (+0.2 ppt YoY)	56.5%	✓ zolbetuximab development costs above full-year forecast ✓ Impact of acquisitions of Iveric Bio: approx. +4.0 bil. yen

FY2023 REVISED FORECAST

- *Revenue: Upward revision*
  - ✓ *Reflect positive FX impact. Upward revision in XTANDI, PADCEV, XOSPATA, Downward revision in LEXISCAN*
- *Core OP: Downward revision*
  - ✓ *Downward revision due to the impact of LEXISCAN and Iveric Bio acquisition*

Exchange rates for revised forecast:
140 yen/USD, 152 yen/EUR
(Forecast rates Q3/2023 onwards:
140 yen/USD, 150 yen/EUR)

(billion yen)	FY2023 Initial FCST*	Main items of revision (excl. the impact of Iveric Bio acquisition)	FY2023 Revised FCST (excl. the impact of the acquisition)	The impact of the acquisition	FY2023 Revised FCST
Revenue	**1,520.0**	FX impact: approx. +90.0 XTANDI, PADCEV, XOSPATA: total approx. +18.0 LEXISCAN: approx. -26.0	**1,597.0**	IZERVAY: +11.0	**1,608.0**
SG&A expenses	661.0		699.0	Approx. +38.0	737.0
US XTANDI co-pro fee	176.0	Mainly FX impact	187.0	(incl. one-time costs associated with acquisitions)	187.0
SG&A excl. the above	485.0		512.0		550.0
R&D expenses	251.0	FX impact zolbetuximab development cost	271.0	Approx. +19.0	290.0
				IZERVAY amortisation: approx.+60.0	
Core operating profit	**290.0**	FX impact: approx. +19.0	**302.0**		**199.0**
<Full basis>					
Operating profit	**259.0**	Fair value increase contingent consideration due to changing exchange rates (zolbetuximab): approx. +7.0	**263.0**	Payment for unvested share-based payments: approx. +37.0	**123.0**

* Exchange rates for initial FCST: 130 yen/USD, 140 yen/EUR, Core basis: disclosed on Apr 27, Full basis: revised on Aug 1

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INITIATIVES FOR SUSTAINABLE GROWTH: OVERVIEW OF UPDATES

XTANDI and Strategic products

- enzalutamide / XTANDI : Acceptance of regulatory filing for M0 CSPC* in US and Europe
- enfortumab vedotin / PADCEV : Topline results from EV-302 study, presentation at ESMO
- fezolinetant / VEOZAH : CHMP positive opinion
- avacincaptad pegol / IZERVAY : Approval in US, Topline results from GATHER2 24-month data

Focus Area approach

- Genetic Regulation : AT845 first subject dosed after restart of FORTIS study
- Immuno-Oncology : New Phase 1 program entry (ASP1012: systemic oncolytic virus)

Rx+ program

- pudexacianinium chloride (ASP5354): First subject first treatment in Phase 3 study

VEOZAH: Under regulatory review as “VEOZA” in Europe
* High-risk biochemical recurrence
M0 CSPC: Non-metastatic castration-sensitive prostate cancer, ESMO: European Society for Medical Oncology, CHMP: Committee for Medicinal Products for Human Use

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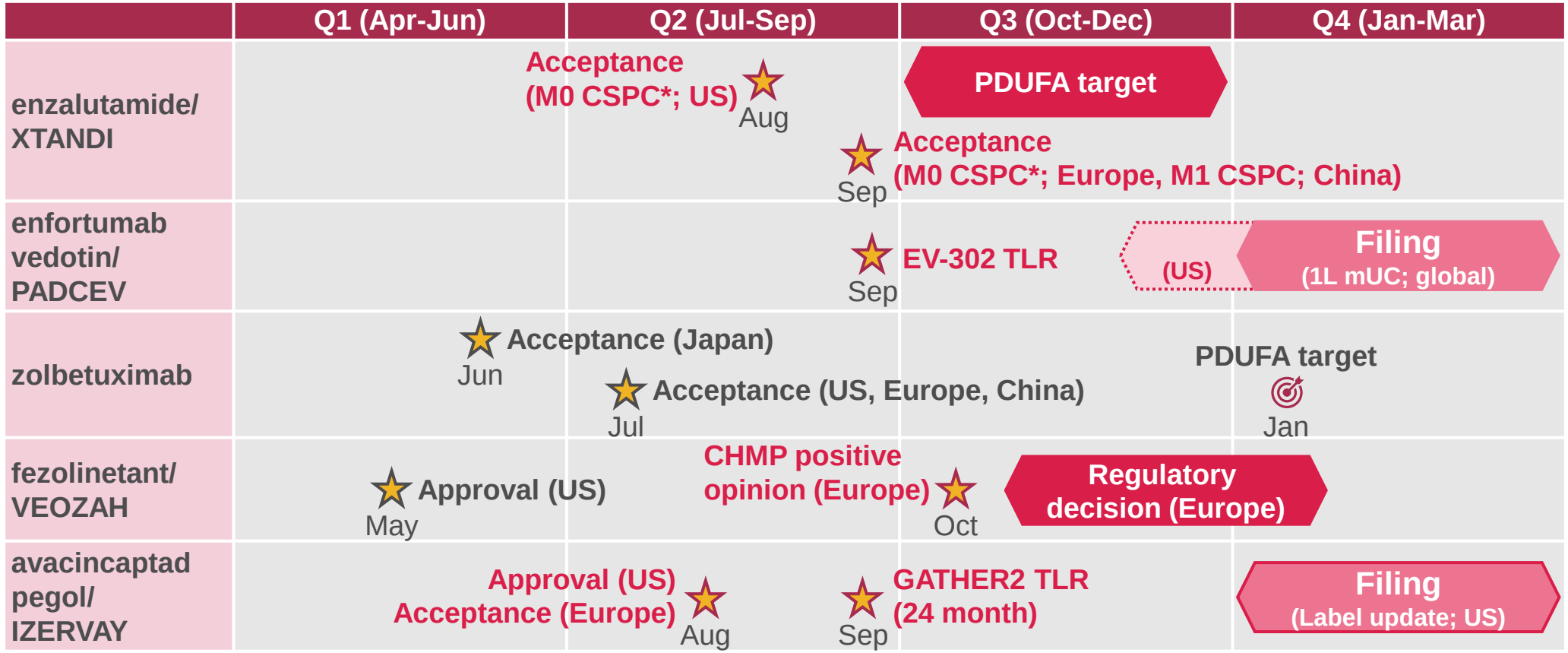
XTANDI AND STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2023



As of Oct 2023

<Other updates>

- enzalutamide / XTANDI: EMBARK study data published in NEJM in Oct 2023
- enfortumab vedotin / PADCEV: Data from EV-103 study Cohort L and EV-302 study presented at ESMO in Oct 2023
- zolbetuximab: Follow-up data from SPOTLIGHT and GLOW studies presented at ESMO in Oct 2023
- avacincaptad pegol / IZERVAY: GATHER2 study 12-month data published in The Lancet in Sep 2023

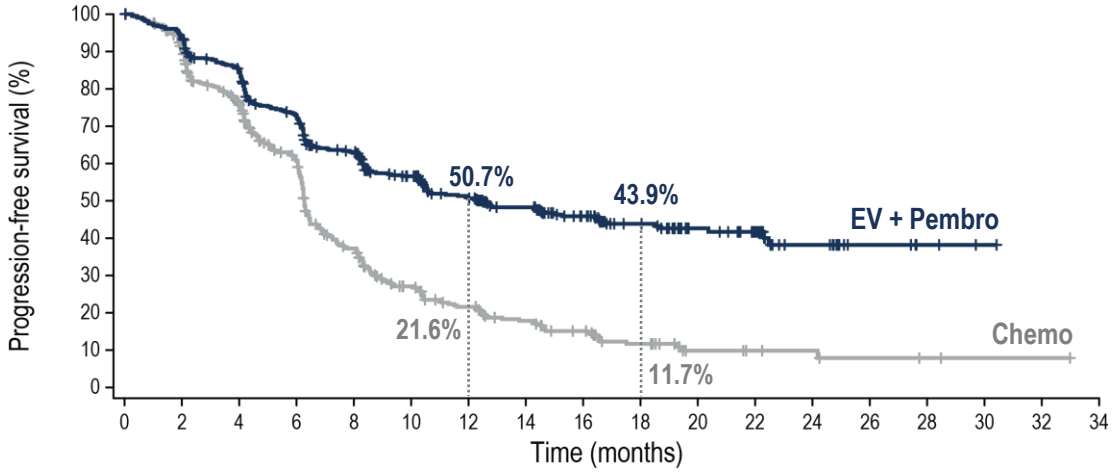
VEOZAH: Under regulatory review as “VEOZA” in Europe

* High-risk biochemical recurrence. M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, PDUFA: Prescription Drug User Fee Act, M1: Metastatic, TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer, CHMP: Committee for Medicinal Products for Human Use, NEJM: New England Journal of Medicine, ESMO: European Society for Medical Oncology

ENFORTUMAB VEDOTIN / PADCEV: EV-302 LATEST DATA

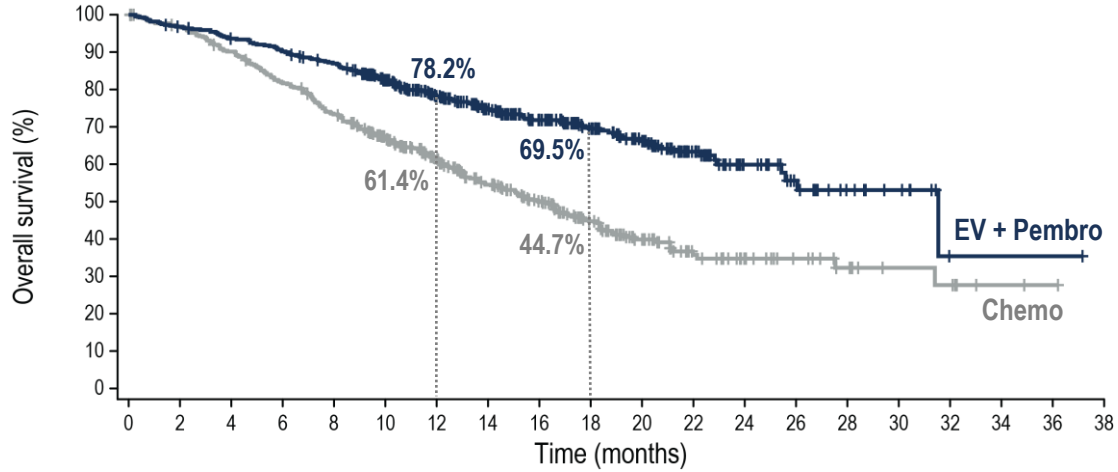
- *Statistically significant and clinically meaningful improvement over chemotherapy with nearly doubled mOS and mPFS*
- *Aiming for position as a new standard of care for 1L mUC*

<Progression-free survival>



	N	Events (%)	HR (95% CI)	2-sided P value	mPFS (95% CI), months
EV + Pembro	442	223 (50.5)	0.45 (0.38-0.54)	<0.00001	12.5 (10.4-16.6)
Chemo	444	307 (69.1)			6.3 (6.2-6.5)

<Overall survival>



	N	Events (%)	HR (95% CI)	2-sided P value	mOS (95% CI), months
EV + Pembro	442	133 (30.1)	0.47 (0.38-0.58)	<0.00001	31.5 (25.4-NR)
Chemo	444	226 (50.9)			16.1 (13.9-18.3)

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

<Future plan>

- Global regulatory submissions for 1L mUC in FY2023
- Upward revision of potential peak sales under consideration

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

ZOLBETUXIMAB: LATEST STATUS

Activities related to Claudin 18.2 as a first-in-class target are going well globally as planned toward launch

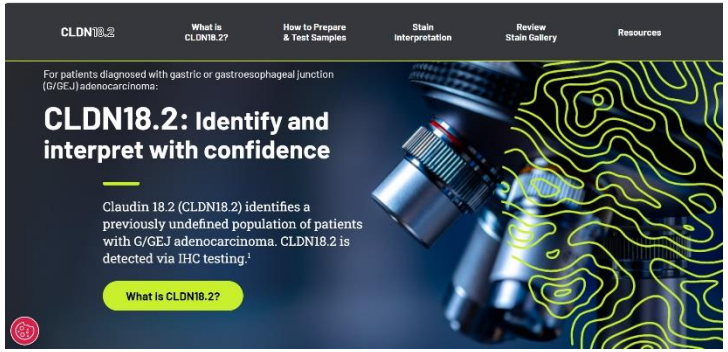
Activities toward launch

- Educational initiatives for HCPs (managing gastric cancer) and pathologists
  - ✓ Awareness improved by launching Claudin 18.2 awareness websites [1], approx. 80K visits as of Oct 2023
  - ✓ Conducted disease state and Claudin 18.2 education campaign in 11 conferences as of Sep 2023, planned for 6 conferences by the end of FY2023
- Roche is developing a companion diagnostic to identify patients whose gastric or GEJ adenocarcinoma tumors are Claudin 18.2-positive [2]
- Plan to initiate Early Access Program in approximately 20 countries to ensure patient access until its launch

ASCO 2023, Chicago

ESMO 2023, Madrid

ESMO GI 2023, Barcelona



zolbetuximab Meeting will be held after US approval, focusing on commercial strategy (Dec-Jan)

1. https://www.claudin182.com/, https://www.gastriccancerbiomarkers.com/
2. Claudin 18.2 positivity is defined as ≥ 75% tumor cells demonstrating moderate to strong membrane Claudin 18 staining using the VENTANA CLDN18 (43-14A) RxDx Assay.

ASCO: American Society of Clinical Oncology, ESMO: European Society for Medical Oncology, GI: Gastrointestinal Cancers, GEJ: Gastroesophageal junction, HCP: Healthcare professional

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

(Red: Updates since the last financial results announcement)

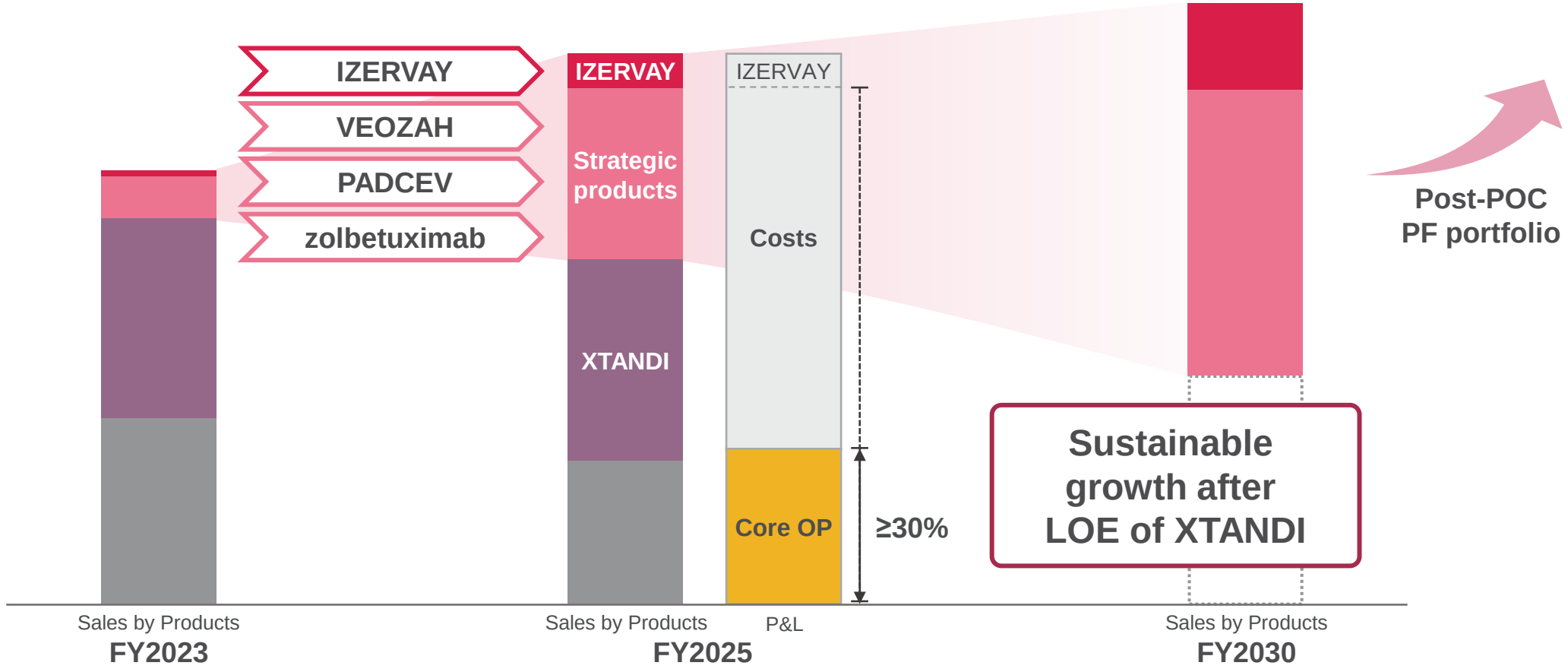
Primary Focus	Biology/Modality/Technology*	Project	Mechanism of Action	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	GAA gene	**First subject dosed in Sep 2023 after restart of FORTIS study**
	Gene regulation (AAV)			
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing
	Bispecific immune cell engager	ASP2138	Anti-Claudin 18.2 and anti-CD3	Phase 1 study ongoing
		ASP2074	**Anti-TSPAN8 and anti-CD3**	Phase 1 study ongoing
		ASP1002	Undisclosed	Phase 1 study ongoing
	Oncolytic virus (systemic)	**ASP1012**	**Leptin-IL-2**	**Phase 1 study under preparation to start in Q4/FY2023**
	Cancer cell therapy			
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells	Phase 1b study ongoing
	Cell replacement (UDC)			
	Gene regulation (AAV)			
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	PPARδ modulator	PMM: Phase 2/3 study ongoing DMD: Next step under discussion
Targeted Protein Degradation	Protein degradation	ASP3082	KRAS G12D degrader	Phase 1 study ongoing **Fast Track designation granted by FDA for CRC in Aug 2023 and for NSCLC in Sep 2023**
Primary Focus Candidate	Immune modulating/regulatory cells			
	Tissue-specific immune regulation			

Modality
- Small molecule
- Antibody
- Gene
- Cell

* Not exhaustively listed. AAV: Adeno-associated virus, MTM1: Myotubularin 1, FDA: Food and Drug Administration, GAA: Acid alpha-glucosidase, DGK: Diacylglycerol kinase, TSPAN8: Tetraspanin-8, IL-2: Interleukin-2, RPE: Retinal pigment epithelium, UDC: Universal donor cell, PPAR: Peroxisome proliferator-activated receptor, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy, KRAS: Kirsten rat sarcoma viral oncogene homologue, CRC: Colorectal cancer, NSCLC: Non-small cell lung cancer

TOWARD ACHIEVEMENT OF CSP2021

- *Continue to aim for achievement of original CSP2021, expect breakeven for IZERVAY in FY2025*
- *In addition to Strategic products, IZERVAY will also contribute to profits from FY2026 onwards, helping compensate for XTANDI LOE*



Strategic products: The definition on this slide follows that of CSP2021 announcement (May 2021)
CSP: Corporate Strategic Plan, LOE: Loss of exclusivity, PoC: Proof of concept, PF: Primary Focus

IZERVAY Meeting

✓ Nov 6th 2023 7:30am-8:15am (JST)

zolbetuximab Meeting

✓ To be held after anticipated US approval (Dec 2023 - Jan 2024)

Sustainability Meeting 2023

✓ Feb 21st 2024 10:00am-11:30am (JST)

APPENDIX

Q2/FY2023: REVENUE BY REGION

(billion yen)	Q2/FY2022	Q2/FY2023	Change (%)
Japan	133.3	137.6	+3.2%
United States	328.3	306.7	-6.6%
Established Markets	175.6	199.1	+13.4%
Greater China	45.0	44.9	-0.3%
International Markets	67.9	74.6	+10.0%

Established Markets: Europe, Canada, etc., Greater China: China, Hong Kong, Taiwan,
International Markets: Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Korea, Australia, Export sales, etc.

Q2/FY2023 ACTUAL: FX RATE

Average rate for the period

Currency	Q2/FY2022	Q2/FY2023	Change
USD	134 yen	141 yen	+7 yen
EUR	139 yen	153 yen	+15 yen

<Impact of exchange rate on financial results>

- 37.8 billion yen increase in revenue, 11.0 billion yen increase in core OP

FY2023 FORECAST: FX RATE & FX SENSITIVITY

Exchange rate Average for the period	FY2023 Initial FCST	FY2023 Revised FCST	Change
USD	130 yen	140 yen	+10 yen
EUR	140 yen	152 yen	+12 yen

Forecast rates Q3/FY2023 onwards: 140 yen/USD, 150 yen/EUR

Estimated FX sensitivity (Q3 onwards) of FY2023 revised forecasts by 1 yen depreciation

Currency	Average rate 1 yen lower than assumption	
	Revenue	Core OP
USD	Approx. +3.2 bil. yen	Approx. +0.1 bil. yen
EUR	Approx. +1.4 bil. yen	Approx. +0.6 bil. yen

BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY2022 end	Sep 30, 2023
Total assets	2,456.5	3,543.0
Cash and cash equivalents	376.8	334.0
Total equity attributable to owners of the parent	1,508.0	1,639.3
Equity ratio (%)	61.4%	46.3%

(billion yen)	Q2/FY2022	Q2/FY2023
Cash flows from operating activities	139.9	49.1
Cash flows from investing activities	-34.7	-783.3
Free cash flows	105.2	-734.3
Cash flows from financing activities	-81.4	670.2
Increase/decrease in short-term borrowings and CP	-15.0	274.9
Proceeds from issuance of bonds and long-term borrowings	-	470.5
Acquisition of treasury shares	-10.6	-10.7
Dividends paid	-45.7	-53.9

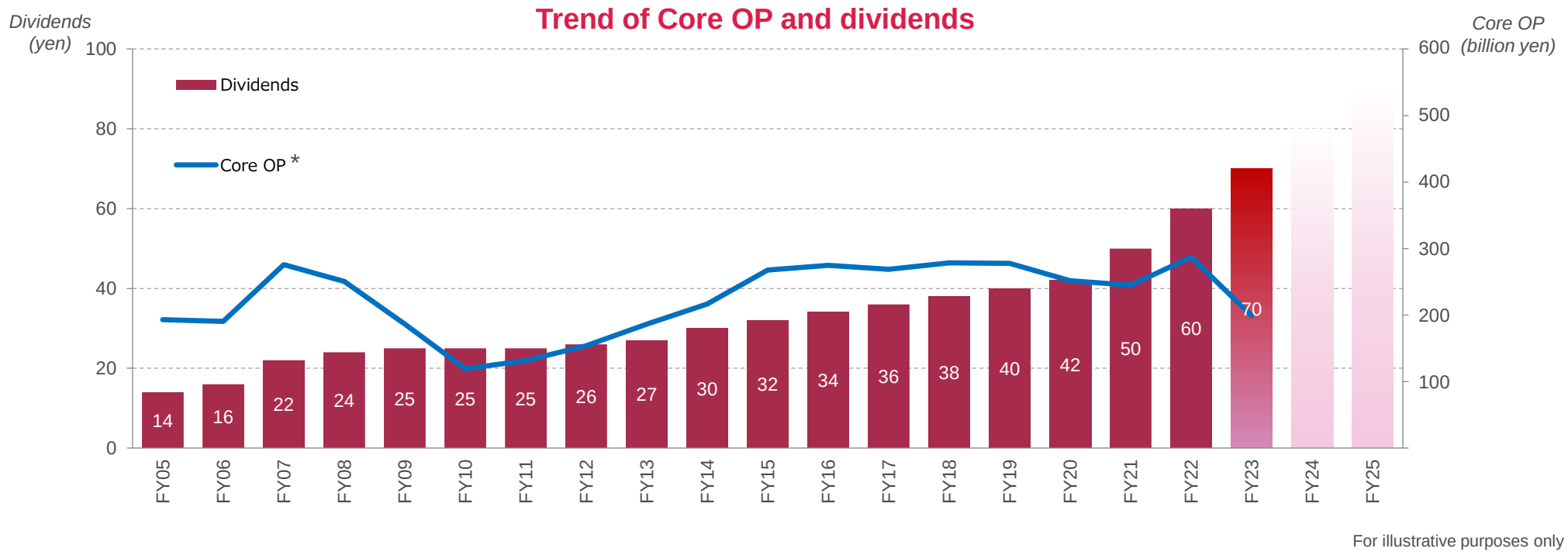
As of end of Sep, Balance of bonds (Incl. CP) and borrowings：889.6 billion yen

CP: Commercial Paper

CAPITAL ALLOCATION

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

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
CSP: Corporate Strategic Plan

ROBUST PIPELINE OF ASTELLAS

Phase 1

- enfortumab vedotin (NMIBC)
- gilteritinib (Newly diagnosed AML, HIC-ineligible)
- ASP1570
- ASP2138
- ASP2074
- ASP1002
- ASP1012
- ASP7317
- bocidelpar/ASP0367 (Duchenne muscular dystrophy)
- zocaglusagene nuzaparvovec /AT845
- ASP3082

Phase 2

- enfortumab vedotin (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- fezolinetant (VMS due to menopause: Japan)
- resamirigene bilparvovec /AT132 (XLMTM)
- avacincaptad pegol (Stargardt disease)
- bocidelpar/ASP0367 (Primary mitochondrial myopathies)

Phase 3

- enfortumab vedotin (mUC previously untreated, MIBC)
- gilteritinib (Earlier-stage AML, pediatric use)
- fezolinetant (VMS due to menopause: China)
- roxadustat (Anemia associated with CKD, pediatric use: Europe)
- mirabegron (Neurogenic detrusor overactivity, pediatric use: Europe)

Submitted/Filed

- enzalutamide (M0 CSPC*: US, Europe, M1 CSPC: China)
- enfortumab vedotin (mUC pretreated: China)
- zolbetuximab (Gastric and GEJ adenocarcinoma: Japan, US, Europe, China)
- fezolinetant (VMS due to menopause: Europe)
- avacincaptad pegol (GA secondary to AMD: Europe)
- peficitinib (Rheumatoid arthritis: China)
- isavuconazole (Pediatric use: US)

XTANDI and Strategic products

Projects with Focus Area approach

Others

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

* High-risk biochemical recurrence. NMIBC: Non-muscle-invasive bladder cancer, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, VMS: Vasomotor symptoms, XLMTM: X-linked myotubular myopathy, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, CKD: Chronic kidney disease, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, GEJ: Gastroesophageal junction, GA: Geographic atrophy, AMD: Age-related macular degeneration

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PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since the Last Financial Results Announcement

Phase 1 Entry	Phase 2 Entry	Phase 3 Entry	Filing	Approval
ASP1012 Cancer		**roxadustat** Anemia associated with chronic kidney disease in pediatric patients: Europe	**enzalutamide** Non-metastatic hormone-sensitive prostate cancer with high-risk biochemical recurrence: Europe, Metastatic hormone-sensitive prostate cancer: China	**avacincaptad pegol** Geographic atrophy secondary to age-related macular degeneration: US

Discontinuation

mirabegron: Overactive bladder in pediatric patients (Phase 3)
ASP8062: Alcohol use disorder (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.

IND: Investigational New Drug

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XTANDI AND STRATEGIC PRODUCTS: STATUS UPDATE

(Red: Updates since the last financial results announcement)

Project / Product	Indication	Current status
enzalutamide / XTANDI	M1 CSPC	• **NDA accepted in China in Sep 2023**
	M0 CSPC with high-risk BCR	• **sNDA accepted in US in Aug 2023. Type II variation accepted in Europe in Sep 2023. Results from Phase 3 EMBARK study published in NEJM in Oct 2023**
enfortumab vedotin / PADCEV	Metastatic urothelial cancer	• Previously untreated (first line): Approved in US in Apr 2023 (accelerated approval, cisplatin-ineligible). **Obtained topline results from Phase 3 EV-302 study in Sep 2023. Results presented at ESMO in Oct 2023** • Pretreated: BLA accepted in China in Mar 2023
	Muscle-invasive bladder cancer	• Phase 3 studies ongoing. **Data from Cohort L in EV-103 study presented at ESMO in Oct 2023**
	Non-muscle-invasive bladder cancer	• Phase 1 study ongoing
	Other solid tumors	• Phase 2 study ongoing
gilteritinib / XOSPATA	Relapsed and refractory AML	• China: Phase 3 study stopped due to efficacy
	AML, post-HSCT maintenance	• Topline results from Phase 3 MORPHO study obtained in Mar 2023
	AML, newly diagnosed (HIC-eligible)	• Phase 3 study ongoing (enrollment completed)
	AML, newly diagnosed (HIC-ineligible)	• Phase 1 study ongoing
	AML, post-chemotherapy	• Obtained topline results from Phase 2 GOSSAMER study
zolbetuximab	Gastric & GEJ adenocarcinoma	• NDA accepted in Japan in Jun 2023. BLA/MAA accepted in US, Europe and China in Jul 2023
	Pancreatic adenocarcinoma	• Phase 2 study ongoing
fezolinetant / VEOZAH	VMS due to menopause	• US & Europe: Approved in US in May 2023. **Received positive CHMP opinion in Europe in Oct 2023.** Obtained topline results from Phase 3b DAYLIGHT study in Jun 2023 • Asia: LSLV in Phase 3 MOONLIGHT 1 study in Apr 2022. Obtained topline results from Phase 3 MOONLIGHT 3 study in Sep 2022 • Japan: Obtained topline results from Phase 2b STARLIGHT study in Mar 2023
avacincaptad pegol / IZERVAY	GA secondary to AMD	• **Approved in US in Aug 2023. MAA accepted in Europe in Aug 2023. 12-month results from Phase 3 GATHER2 study published in The Lancet in Sep 2023. Obtained 24-month topline results from Phase 3 GATHER2 study in Sep 2023**
	Stargardt disease	• Phase 2b study ongoing

VEOZAH: Under regulatory review as “VEOZA” in Europe. M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, BCR: Biochemical recurrence, (s)NDA: (Supplemental) New Drug Application, NEJM: New England Journal of Medicine, ESMO: European Society for Medical Oncology, 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, CHMP: Committee for Medicinal Products for Human Use, LSLV: Last subject last visit, GA: Geographic atrophy, AMD: Age-related macular degeneration

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XTANDI AND STRATEGIC PRODUCTS: POTENTIAL PEAK SALES (AS OF OCT 2023)

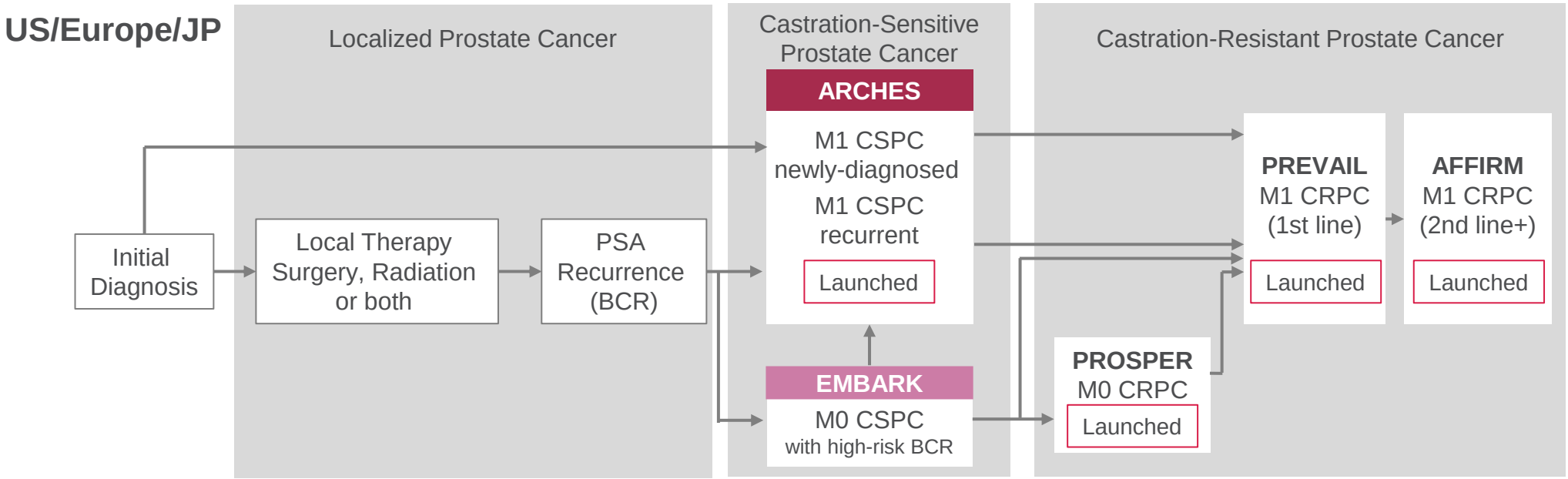
Product	Potential Peak Sales *(Global, billions of yen)*
XTANDI (enzalutamide)	over 700.0
VEOZAH (fezolinetant)	300.0 – 500.0
PADCEV (enfortumab vedotin) [1]	300.0 – 400.0
IZERVAY (avacincaptad pegol)	200.0 – 400.0
XOSPATA (gilteritinib)	100.0 – 200.0
zolbetuximab	100.0 – 200.0
EVRENZO (roxadustat) [2]	under 50.0
AT132 (resamirigene bilparvovec)	under 50.0

Only indications undergoing pivotal studies are included for projection (as of Oct 2023), IZERVAY included in Strategic products from Q2/FY2023

1. Sales for Americas are calculated based on the sales booked by Seagen,
2. Astellas territories only; Japan, Europe, the Commonwealth of Independent States, the Middle East, South Africa, etc.

ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

(Red: Updates since the last financial results announcement)



P3: EMBARK	NCT02319837	**M0 CSPC**	ENZA + ADT vs. placebo + ADT vs. ENZA mono	n=1,068	**sNDA accepted in US in Aug 2023. Type II variation accepted in Europe in Sep 2023**

China

- **M1 CSPC: NDA accepted in Sep 2023**

BCR: Biochemical recurrence, M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ENZA: enzalutamide, ADT: Androgen deprivation therapy, mono: Monotherapy, (s)NDA: (Supplemental) New Drug Application

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

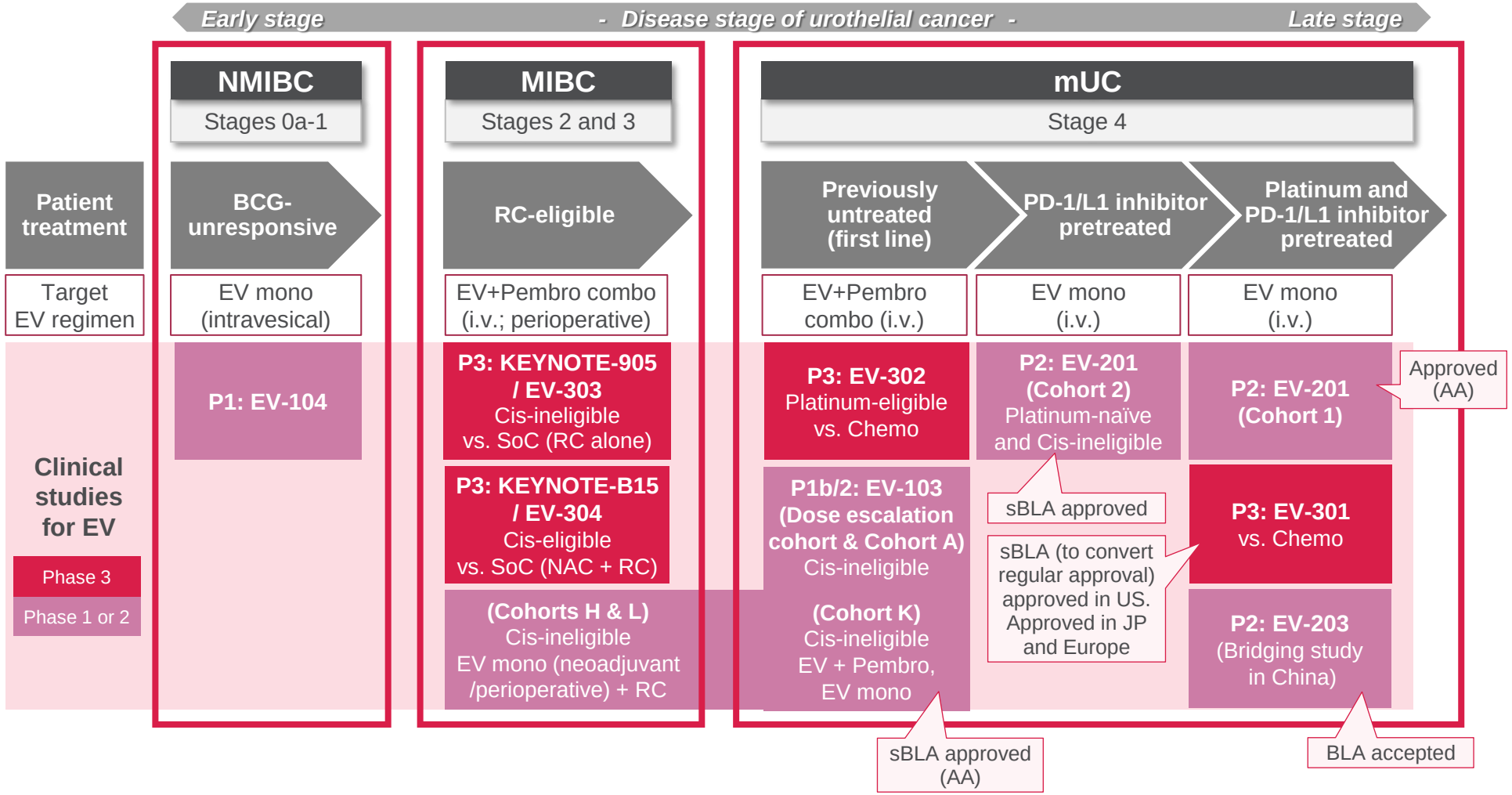
Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

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

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

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

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



ADC: Antibody-drug conjugate, mUC: Metastatic urothelial cancer, NMIBC: Non-muscle-invasive bladder cancer, MIBC: Muscle-invasive bladder cancer, BCG: Bacillus Calmette-Guerin, RC: Radical cystectomy, mono: Monotherapy, Pembro: Pembrolizumab, i.v.: Intravenous, Cis: Cisplatin, SoC; Standard of care, NAC: Neoadjuvant chemotherapy, Chemo: Chemotherapy, sBLA: Supplemental Biologics License Application, AA: Accelerated Approval

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

(Red: Updates since the last financial results announcement)

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	**Topline results obtained in Sep 2023**
	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	FSFT: May 2021
	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 adenocarcinoma or esophageal adenocarcinoma or 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

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

ENFORTUMAB VEDOTIN (EV) (3/4): STUDY DATA BY DISEASE STAGE OF UC

(Red: Updates since the last financial results announcement)

Disease stage	Early stage					Late stage			
	MIBC		mUC						
	Surgery eligible		Previously untreated (first line)				PD-1/L1 inhibitor pretreated		
	Cis-eligible	Cis-ineligible	Platinum eligible	Cis-ineligible			Platinum naïve & Cis-ineligible	Platinum pretreated	
Study phase	Phase 3	Phase 3	Phase 3	Phase 1b/2		Phase 1b/2	Phase 2	Phase 2	Phase 3
Study No.	**KN-B15 / EV-304**	**KN-905 / EV-303**	**EV-302**	**EV-103 Cohort K**		**EV-103 Cohort A & Others**	**EV-201 Cohort 2**	**EV-201 Cohort 1**	**EV-301**
No. of subjects	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

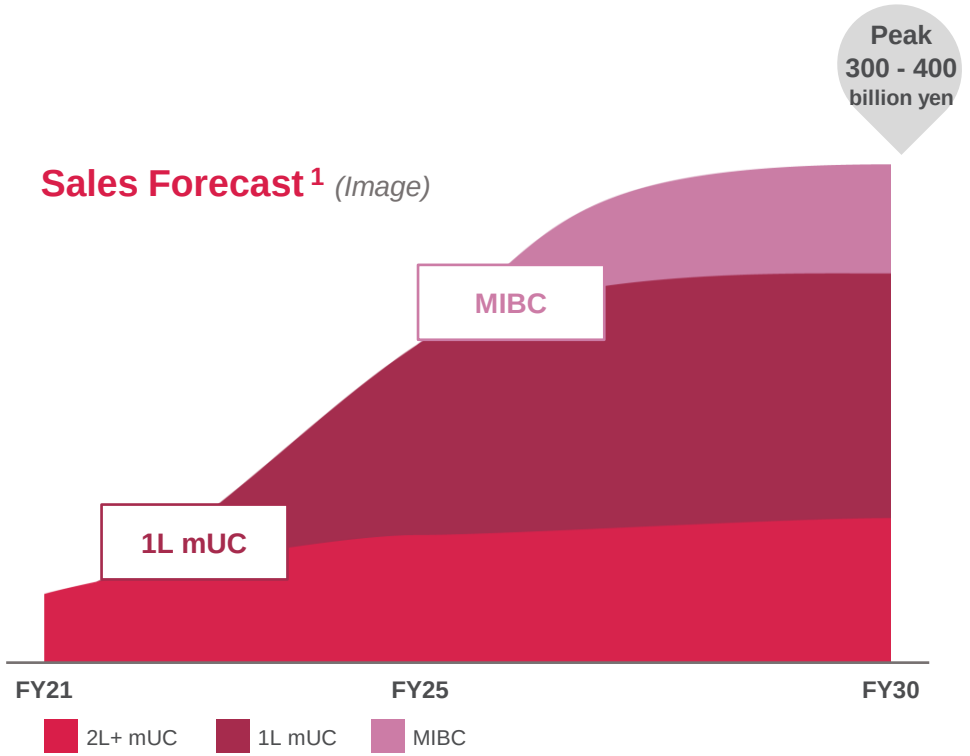
(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer, cis: Cisplatin, Pembro: Pembrolizumab, mono: Monotherapy, Chemo: Chemotherapy, pCR: Pathologic complete response, EFS: Event-free survival, ORR: Objective response rate, CR: Complete response, OS: Overall survival, HR: Hazard ratio, PFS: Progression-free survival, DoR: Duration of response

ENFORTUMAB VEDOTIN (EV) (4/4): FUTURE OUTLOOK

(Red: Updates since the last financial results announcement)

- *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*

Sales Forecast [1] *(Image)*



<Already approved / pivotal phase>

Patient segment		Pivotal study (EV regimen)	Target filing timing	Number of eligible patients [2]
MIBC	Cis-ineligible	EV-303 (combo w/ Pembro)	FY2025 or later	10,000
MIBC	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)	FY2023 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 [Phase 2] (monotherapy)	Approved	1,600 (US, Cis-ineligible)
2L+ mUC	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>

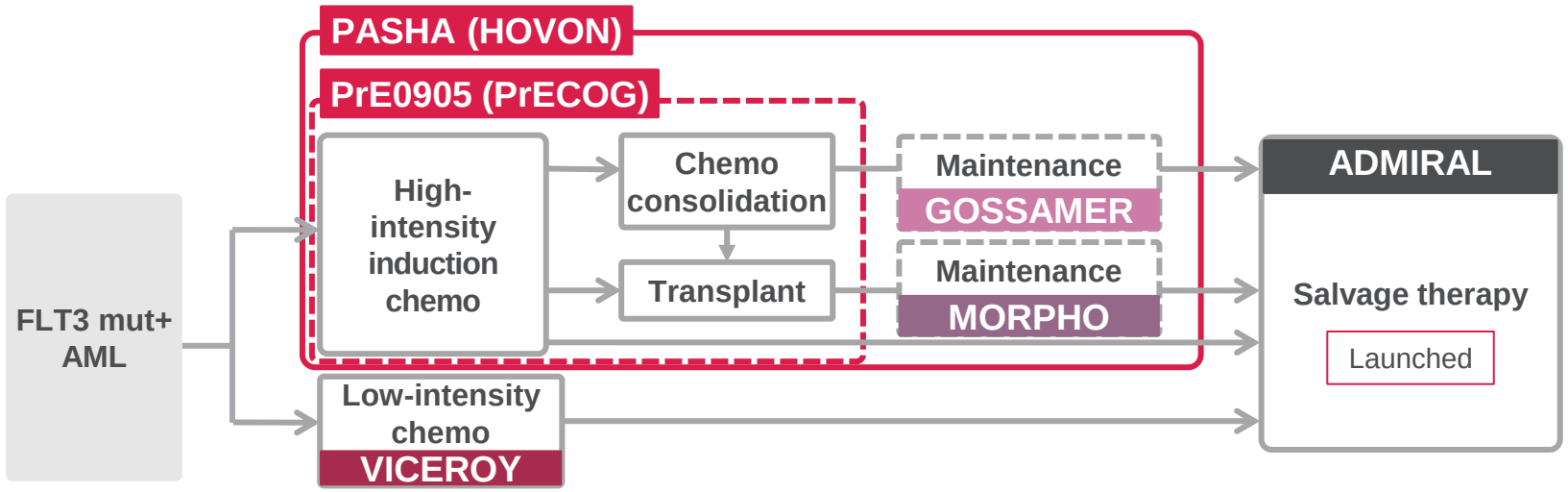
Patient segment	Study (EV regimen)
NMIBC High-risk BCG-unresponsive	EV-104 [Phase 1] (monotherapy, intravesical)
Other solid tumors	EV-202 [Phase 2] (monotherapy* / combo w/ Pembro**)

*Monotherapy:
HR+/HER2- breast cancer,
Triple-negative breast cancer,
Squamous NSCLC,
Non-squamous NSCLC,
Head and neck cancer,
Gastric adenocarcinoma or esophageal adenocarcinoma or GEJ adenocarcinoma,
Esophageal squamous cell carcinoma

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

1. Global. 2. Based on internal estimates
mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder, 1L: First line, 2L+: Second or later line, Cis: Cisplatin, Pembro: Pembrolizumab,
AA: Accelerated Approval, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer, GEJ: Gastroesophageal junction

GILTERITINIB: FLT3 INHIBITOR



	Relapsed or refractory	**P3: ADMIRAL**	NCT02421939	Monotherapy vs. salvage chemo (2:1)	n=371	Launched in US, JP, and Europe
	Newly diagnosed (HIC-eligible)	**P3: PASHA (HOVON)**	NCT04027309	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=766	Enrollment completed (Sponsor: HOVON)
		P2: PrE0905 (PrECOG)	NCT03836209		n=179	Enrollment completed (Sponsor: PrECOG, LLC.)
	Post-HSCT maintenance	**P3: MORPHO**	NCT02997202	Monotherapy vs. placebo (1:1)	n=356	Topline results obtained in Mar 2023 Collaborating with BMT-CTN
	Post-chemo maintenance	**P2: GOSSAMER**	NCT02927262	Monotherapy vs. placebo (2:1)	n=98	Topline results obtained in Aug 2021
	Newly diagnosed (HIC-ineligible)	**P1: 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

FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, FSFT: First subject first treatment, HSCT: Hematopoietic stem cell transplant, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands, BMT-CTN: Blood and Marrow Transplant - Clinical Trial Network, R/R: Relapsed or refractory

ZOLBETUXIMAB: ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

Target: Claudin 18.2

- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- Broadly expressed in various cancer types
  - ✓ Prevalence of patients with high expression of Claudin 18.2 is substantial: 38%
  - ✓ ~60% of primary pancreatic adenocarcinomas; ~20% of these meet the eligibility criteria for the ongoing Phase 2 study

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	NDA accepted in Japan in Jun 2023. BLA/MAA accepted in US, Europe and China in Jul 2023
		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	n=116	FSFT: Sep 2018
	Pancreatic adenocarcinoma	**P2**	NCT03816163	First line, Combo with nab-paclitaxel and gemcitabine, open	n=369	FSFT: May 2019

GEJ: Gastroesophageal junction, HER2-: HER2 negative, Claudin 18.2+: Claudin 18.2 positive, mFOLFOX6: 5-FU, leucovorin and oxaliplatin, DB: Double-blind,
CAPOX: Capecitabine and oxaliplatin, NDA: New Drug Application, BLA: Biologics License Application, MAA: Marketing Authorization Application, FSFT: First subject first treatment

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FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

(Red: Updates since the last financial results announcement)

VMS has a significant negative impact on QoL

- Physical symptoms include hot flashes and night sweats, which can impact sleep.
- Physical symptoms may lead to emotional impact including embarrassment, irritability, anxiety, and sadness
- Symptoms have a negative impact on multiple aspects of everyday life [1]

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

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

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) The last 40 weeks: Active extension treatment period, 30 mg or 45 mg	n=527	Approved in US in May 2023. MAA accepted in Europe in Sep 2022. **Positive CHMP opinion received in Oct 2023**
	P3: SKYLIGHT 2	NCT04003142		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

Asia (except for Japan)

	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

	P2b: STARLIGHT	NCT05034042	Peri- and post-menopausal patients with mild to severe VMS; 12 weeks: DB, 2 doses vs. placebo (1:1:1)	n=147	Topline results obtained in Mar 2023

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, MAA: Marketing Authorization Application,
CHMP: Committee for Medicinal Products for Human Use

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

(Red: Updates since the last financial results announcement)

Geographic atrophy (GA)

- Advanced form of dry age-related macular degeneration (AMD)
- ~1.5 million patients in the US [1]
- ~50% of patients are affected bilaterally
- ~40% of eyes with GA are blinded: leading cause of increasing irreversible blindness

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	**Approved in US in Aug 2023** **MAA accepted in Europe in Aug 2023** **GATHER2 24-month topline results obtained in Sep 2023**
		P3: GATHER2	NCT04435366	2 mg vs. Sham	n=448	
	Stargardt disease	**P2b**	NCT03364153	vs. Sham	n=120	FSFT: Jan 2018

1. Ophthalmology 128:576-586 (2021)

MAA: Marketing Authorization Application, FSFT: First subject first treatment

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FOCUS AREA APPROACH: KEY EVENTS EXPECTED IN FY2023

Expecting Phase 1 entry in 4 projects and several progress in Phase 1 studies toward PoC judgment

Primary Focus	IND	Phase 1	
		Early data readout*	Dosing resumption
Genetic Regulation	1 project		✓ AT845
Immuno-Oncology	2 projects (✓ ASP1012)	ASP1570 ASP2138	
Blindness & Regeneration			✓ ASP7317
Targeted Protein Degradation	1 project (pan-KRAS)	ASP3082	

✓: Achieved

* Dose escalation/monotherapy
PoC: Proof of concept, IND: Investigational New Drug

ON THE FOREFRONT OF HEALTHCARE CHANGE