Q1/FY2023 FINANCIAL RESULTS
ENDED JUNE 30, 2023

Naoki Okamura
President and CEO
Astellas Pharma Inc.
August 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 Q1/FY2023 Consolidated Financial Results

II Initiatives for Sustainable Growth

Q1/FY2023 FINANCIAL RESULTS: OVERVIEW

Revenue

- Revenue decreased 2% YoY, due to the impact of Lexiscan generic
- XTANDI and XOSPATA expanded as expected, while PADCEV exceeded expectations
- VEOZAH's initial uptake in line with expectations

Cost items

- SG&A and R&D expenses were on track

Operating profit

- Core OP increased 17% YoY (incl. FX impact)

Revenue and core operating profit were behind expectations due to the impact of Lexiscan generic

On the other hand, core business that will contribute to future growth were on track

Q1/FY2023 FINANCIAL RESULTS

(billion yen)	Q1/FY22	Q1/FY23	Change	Change (%)	FY23 FCST*	Progress	FX impact** (YoY)
Revenue	**381.8**	**375.0**	**-6.8**	**-1.8%**	**1,520.0**	**24.7%**	+17.5 bil. yen
Cost of sales	88.9	68.9	-19.9	-22.4%			-11.1 bil. yen
% of revenue	23.3%	18.4%	-4.9ppt				
SG&A expenses	153.4	168.2	+14.8	+9.6%	661.0	25.4%	+8.0 bil. yen
US XTANDI co-pro fee	43.1	44.6	+1.4	+3.4%	176.0	25.3%	
SG&A excl. the above	110.3	123.6	+13.3	+12.1%	485.0	25.5%	+5.5 bil. yen
R&D expenses	74.0	64.6	-9.4	-12.7%	251.0	25.7%	+2.4 bil. yen
Amortisation of intangible assets	10.7	9.1	-1.7	-15.6%			
Gain on divestiture of intangible assets	0.2	0.1	-0.1	-68.5%			
Core operating profit	**55.3**	**64.9**	**+9.6**	**+17.4%**	**290.0**	**22.4%**	+18.2 bil. yen
＜Full base＞							
Other income	16.3	3.9	-12.4	-76.0%			Other expenses • Fair value increase contingent consideration due to FX impact (zolbetuximab): 7.6 bil. yen • Impairment loss on the transfer of the Meppel plant: 7.3 bil. yen
Other expenses	38.4	23.1	-15.4	-40.0%			
Operating profit	**33.1**	**45.8**	**+12.6**	**+38.2%**	**288.0**	**15.9%**	
Profit before tax	31.7	46.8	+15.2	+47.9%	289.0	16.2%	
Profit	**24.8**	**33.1**	**+8.3**	**+33.5%**	**227.0**	**14.6%**	

* Exchange rates for initial FY2023 FCST: 130 USD/yen,140 EUR/yen

** Incl. the impact of elimination of unrealized profit remaining in Q1/FY22 (12.8 bil.yen). FX impact on core operating profit excluding this impact: +5.4 bil. yen

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Q1/FY2023 FINANCIAL RESULTS: MAIN PRODUCTS

XTANDI and XOSPATA are in line, PADCEV exceeded expectations. VEOZAH's uptake on track

(billion yen)	Q1/FY2023 Act	YoY	FY2023 FCST*	
Xtandi (enzalutamide)	174.1	+11.7 (+7%)	669.9	✓ Global sales are in line with expectations Ex-US performance are above/in line offsetting the US underperformance ✓ US: Progress below expectations due to higher-than-expected PAP ratio Demand excluding PAP showed steady growth (YoY +4%) Potential positive impact expected from M0 CSPC after approval ✓ EM: Growth of M1 CSPC led to strong demand increase (YoY +17%)
PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	15.2	+4.7 (+44%)	66.7	✓ Global sales exceeding expectations Progressive quarterly growth expected throughout FY23 ✓ US: Market penetration exceeding expectations for the 1L mUC additional indication, expect further sales contribution ✓ EM: Expect countries with reimbursement to increase from Q2 onward
XOSPATA gilteritinib 40mg tablets	13.0	+2.5 (+24%)	49.3	✓ Global sales are in line with expectations ✓ Sales expanded in all regions
VEOZAH™ (fezolinetant) tablets 45 mg	0.6	+0.6	49.3	✓ Launched in May, sales force activities started in June Initial uptake is on track with expectations ✓ Expect substantial growth from Q3 onward

* Exchange rates for initial FY2023 FCST: 130 USD/yen,140 EUR/yen, Sales by regions for XTANDI and PADCEV are on slides 21-22
PAP: Patient Assistance Program, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, 1L: First line, mUC: Metastatic urothelial cancer
EM (Established Markets): Europe, Canada, etc.

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VEOZAH: BUSINESS UPDATE

VEOZAH™ (fezolinetant) tablets 45 mg

Launched in May, sales force activities started in June, with inclusion in treatment guideline as recommended drug
Overall progress is in line with expectations, substantial sales growth expected from Q3 onward

	Q1 Progress	Outlook for Q3 onward
Market Access	✓ Commercial insurance coverage on track (Approx. 15% of lives) ✓ Payer discussions proceeding above expectations ✓ Broad range of patient support programs offered	**Expect widespread commercial insurance coverage** Expect majority of commercial insurance plans to add VEOZAH for coverage by the end of FY23
HCP	✓ 40K HCPs reached in-person ✓ 70K bottles of sample distributed ✓ 40K HCPs accessed VEOZAH website	**Fully branded DTC activities to start, including TV commercials**
Patient	No major DTC activities	

Focus on activities for HCP through Q2

Build patient experience through patient support programs until coverage expansion

Expect substantial sales growth from Q3 driven by widespread insurance coverage and full DTC activities

Aim to achieve the FY23 forecast of 49.3 bil. yen

Data as of end of Jun 2023
HCP: Healthcare professional, DTC: Direct-to-consumer

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Q1/FY2023 FINANCIAL RESULTS: COST ITEMS

Cost of sales ratio was as expected
SG&A and R&D expenses were on track

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	-22.4%	18.4% (-4.9ppt YoY)	-	✓ Main factor for the decreased YoY was the impact of foreign exchange related to the elimination of unrealized profits in Q1/FY2022 (12.8 bil. yen) ✓ Cost of sales ratio was as expected
SG&A expenses **excl. US XTANDI co-pro fee**	+12.1% （+7.1% excl. FX impact）	33.0% (+4.1ppt YoY)	25.5%	✓ Increase in VEOZAH-related costs (approx. +5.0 bil. yen) ✓ Reduction of mature products-related costs (approx. -1.0 bil. yen) ✓ Cost reduction progressed as expected, actively making necessary investments ✓ As a result, in line with initial full-year forecast
R&D expenses	-12.7% （-16.0% excl. FX impact）	17.2% (-2.2ppt YoY)	25.7%	✓ Booked one-time expense for using PRV in Q1/FY2022 for the application of VEOZAH（13.1 bil. yen) ✓ In line with initial full-year forecast

PRV: Priority Review Voucher

FY2023 REVISED FORECAST

- *No changes have been made to Core basis FY2023 forecast*
  - ✓ Plan to reassess in Q2, considering the impact of the Iveric Bio acquisition

- *Downward revision of Full basis profit*
  - ✓ Planned one-time expenses related to organizational restructuring on a global scale, including the review of Japan commercial structure: approx. 20.0 billion yen
  - ✓ Impairment loss related to the Meppel plant business transfer: approx. 7.0 billion yen

(billion yen)	Initial Forecast	Revised Forecast	Change
Operating profit	**288.0**	**259.0**	**-29.0**
Profit	**227.0**	**204.0**	**-23.0**

Organizational restructuring: Subject to Works Council, consultative, and legal requirements

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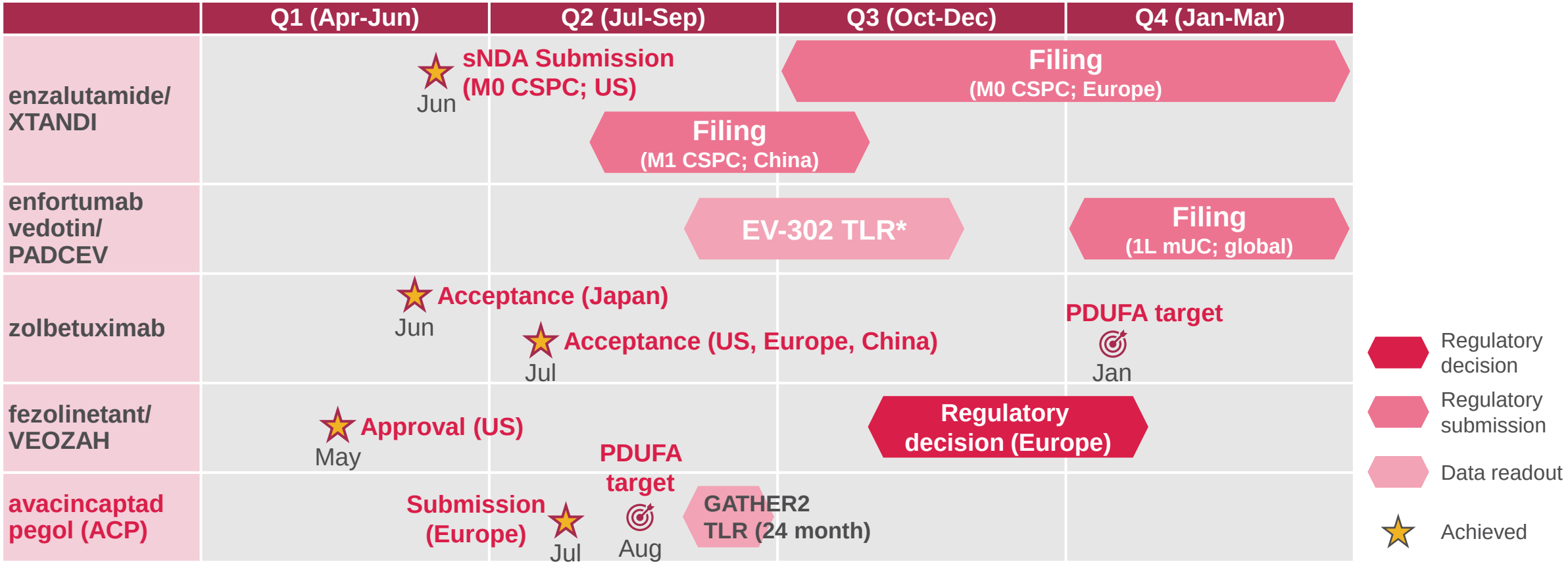
XTANDI AND STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2023



As of Jul 2023

<Other updates>

- enzalutamide/XTANDI: Phase 3 EMBARK study data presented at AUA in Apr 2023
- enfortumab vedotin/PADCEV: Initial data from Phase 2 EV-202 and Phase 1 EV-104 studies presented at ASCO in Jun 2023
- fezolinetant/VEOZAH: TLR obtained in Phase 3b DAYLIGHT study in Jun 2023
- gilteritinib/XOSPATA: Phase 3 MORPHO study data presented at EHA in Jun 2023

* The timeline of TLR is subject to shift due to its event-driven nature. sNDA: Supplemental New Drug Application, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, M1: Metastatic, TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer, PDUFA: Prescription Drug User Fee Act, AUA: American Urological Association, ASCO: American Society of Clinical Oncology, EHA: European Hematology Association

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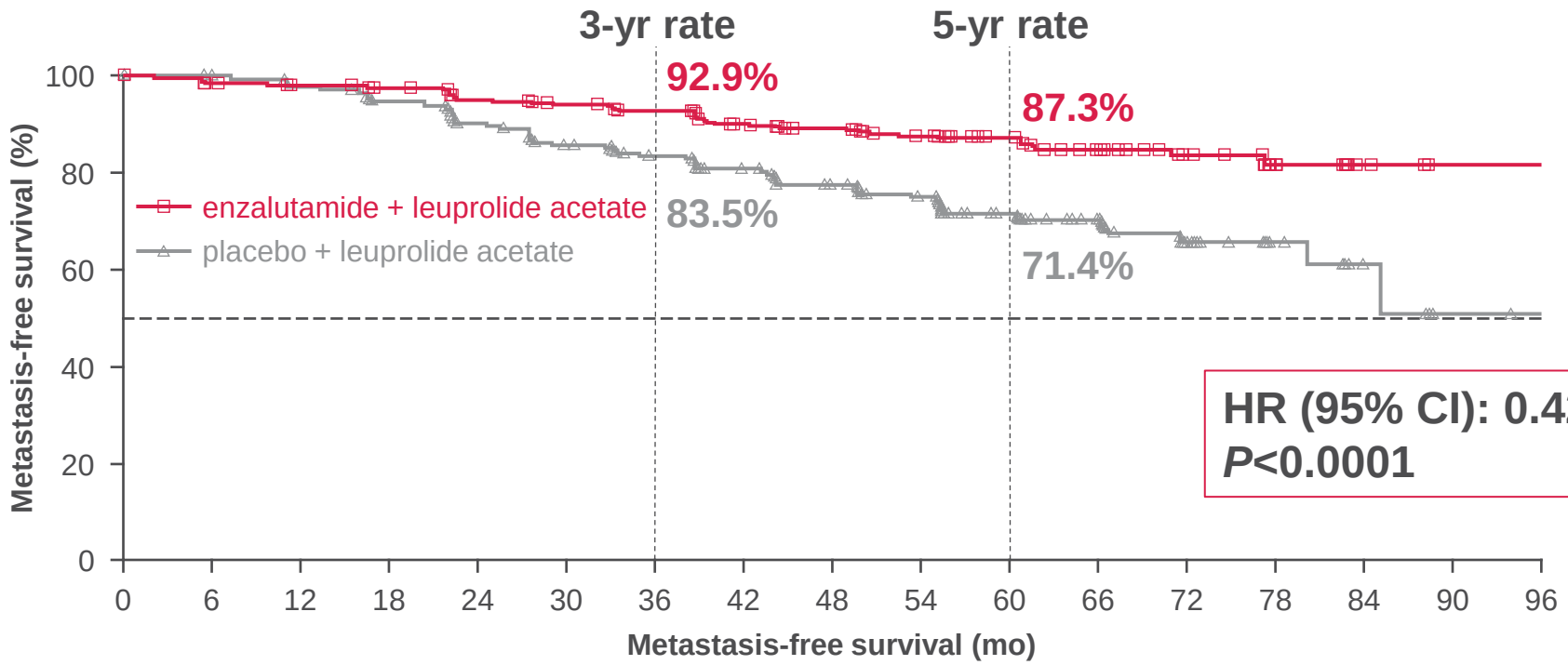
ENZALUTAMIDE / XTANDI: LATEST DATA

EMBARK study data presented at AUA 2023, demonstrating consistent benefit of enzalutamide even in early-stage prostate cancer



HR (95% CI): 0.42 (0.31–0.61)
***P*<0.0001**

Patients at risk

enzalutamide + LEU	355	331	324	318	304	292	281	265	251	234	180	116	60	24	6	0	0
placebo + LEU	358	335	321	303	280	259	238	221	203	183	138	88	32	15	6	1	0

Patient population:
M0 CSPC with high-risk BCR

AUA: American Urological Association, HR: Hazard ratio, CI: Confidence interval, LEU: Leuprolide, M0 CSPC: Non-metastatic castration-sensitive prostate cancer, BCR: Biochemical recurrence

ENFORTUMAB VEDOTIN / PADCEV: LATEST DATA

EV-202 study data presented at ASCO 2023, demonstrating promising efficacy in head and neck cancers

Head and neck cancers

- The sixth most common cancer worldwide [1]; estimated 932,000 new cases and 467,000 deaths globally in 2020 [2]
- Five-year overall survival rate: 40-50% [3]
- Second-line treatment in advanced cancer: PD-1/L1 inhibitors approved, previously reported ORR 13-18% [4]
- Nectin-4 expression found in 59-86% of head and neck cancers [5]

EV-202 study Cohort 5

- Study design

Patient population	Patients with previously treated advanced head and neck cancer (n=46)
Regimen	EV monotherapy on days 1, 8 and 15 of each 28-day cycle

- Results

ORR [95% CI]	23.9% [12.6-38.8]
Safety	No new safety signals noted

Next steps

- Second or later line: Future direction under discussion
- First line: New cohort (combo w/ pembrolizumab) to be added to EV-202 study

1. Nat Rev Dis Primers 6:92 (2020)
2. Global cancer observatory: CANCER TODAY. Published 2020. https://gco.iarc.fr/today
3. J Glob Oncol 5:1 (2019)
4. CheckMate 141: N Engl J Med 375:1856 (2016); KEYNOTE-012: J Clin Oncol 34:3838 (2016)
5. Cancer Res 76:3003 (2016); Oncotarget 13:1166 (2022)

ASCO: American Society of Clinical Oncology, ORR: Objective response rate, EV: Enfortumab Vedotin, CI: Confidence interval

ACQUISITION OF IVERIC BIO

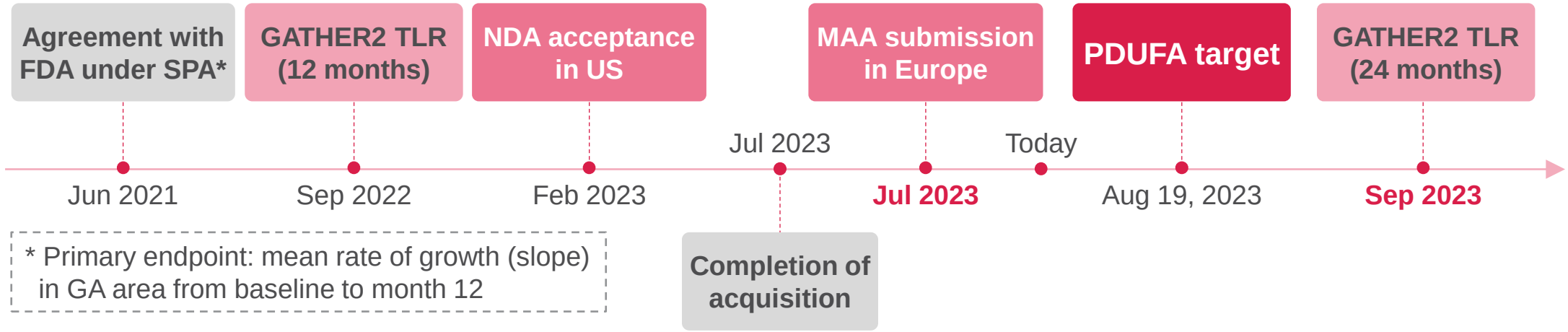
President: Pravin U. Dugel, MD

- Principal investigator in 100+ multicenter clinical trials
- Chair of SAB for multiple global pharma companies, consulted for 50+ companies
- Member of the board of directors of the largest retina society in US [1] and Europe [2]

Organization

- Iveric Bio leads ACP-related activities incl. regulatory, manufacturing, commercial and market access
- Senior team with significant ophthalmology experience
- Fully operationalized infrastructure and expertise across all core commercial functions
  - ✓ Field commercial team to deploy with goal of covering 100% of retina accounts and their local referral networks upon approval

<Key events for ACP>



* Primary endpoint: mean rate of growth (slope) in GA area from baseline to month 12

Careers listed include past experience. 1. ASRS (American Society of Retina Specialists), 2. EURETINA (European Society of Retina Specialists)
SAB: Scientific Advisory Board, ACP: avacincaptad pegol, FDA: Food and Drug Administration, SPA: Special Protocol Assessment, TLR: Topline results, NDA: New Drug Application, MAA: Market Authorization Application, PDUFA: Prescription Drug User Fee Act, GA: Geographic atrophy

PROGRESS IN FOCUS AREA APPROACH (1/2): 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	Activities to restart FORTIS study commenced in Feb 2023
	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 **Orphan drug designation granted by FDA in May 2023 (gastric/GEJ cancer)**
		ASP2074	Undisclosed	Phase 1 study ongoing
		ASP1002	Undisclosed	Phase 1 study ongoing
	Oncolytic virus (systemic)			
	Cancer cell therapy (UDC)			
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells	**First 2 patients dosed in Jun 2023 after restart of Phase 1b study**
	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
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, GEJ: Gastroesophageal junction, 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

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PROGRESS IN FOCUS AREA APPROACH (2/2): COLLABORATIONS IN PF TARGETED PROTEIN DEGRADATION

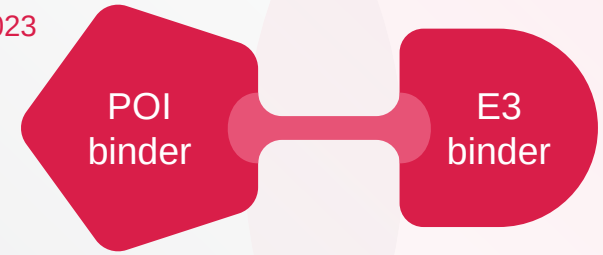
PeptiDream's PDPS technology platform

- Discover multiple novel protein degraders targeting diverse targets

Target expandability

PeptiDream NEW Jul 2023

POI binder: proprietary binders for historical undruggables



Functional enhancement

FIMECS

E3 binder: for specificity, longer-action, and patentability

FIMECS provides access to RaPPIDS™

- Efficient synthesis platform for protein degraders
- Discovery of cancer-specific E3 ligase binders

cullgen NEW Jun 2023

Cullgen's uSMITE™ targeted protein degradation platform

- Develop targeted protein degraders against multiple targets including a cell cycle protein
- Leverage uSMITE platform featuring novel E3 ligands to create next-generation protein degraders

PF: Primary Focus, POI: protein of interest, PDPS: Peptide Discovery Platform System, RaPPIDS: Rapid Protein Proteolysis Inducer Discovery System, uSMITE: Ubiquitin-mediated, small molecule induced target elimination

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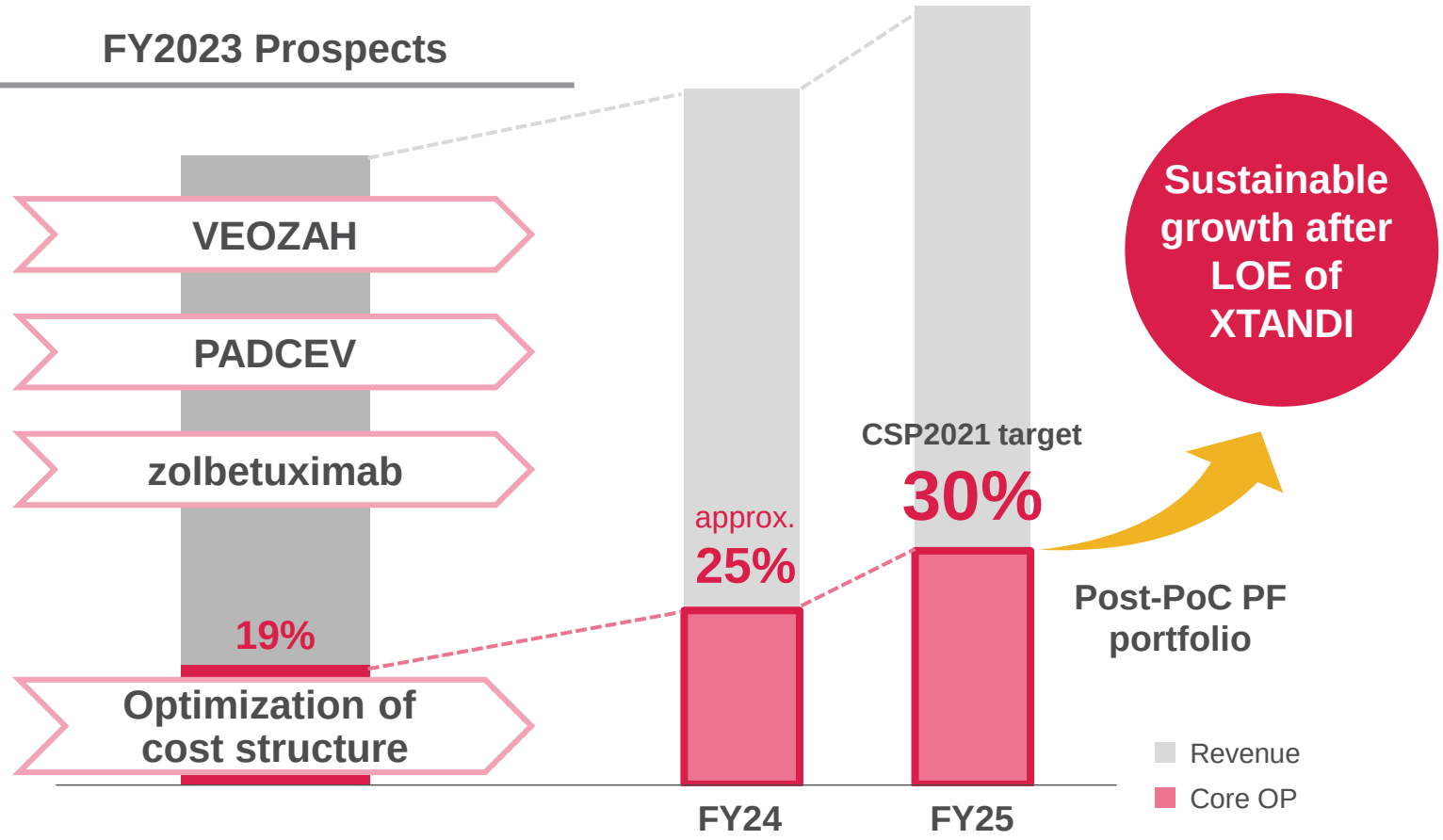
TOWARD ACHIEVEMENT OF CSP2021

- *Continue commitment to CSP2021*
- *FY2023 is the turning point to ensure growth from FY2024 onwards*

Q1/FY2023 Progress

- VEOZAH launch, initial uptake in line with expectations
- XTANDI and XOSPATA as expected, while PADCEV exceeded
- zolbetuximab regulatory filings
- Iveric Bio acquisition
- Collaborations in Primary Focus Targeted Protein Degradation
- Initiatives for optimization of cost structure proceeding on track

FY2023 Prospects



Impact of the acquisition of Iveric Bio on prospects for FY2023 onwards is not included.
CSP: Corporate Strategic Plan, LOE: Loss of exclusivity, PoC: Proof of concept, PF: Primary Focus

APPENDIX

CHANGE EXCHANGE RATES USED FOR ELIMINATION OF UNREALIZED PROFIT ON INVENTORIES（PRO FORMA FIGURES）

- Pro forma figures when calculating the cost of sales at exchange rate after the change (average rate) is as shown in red font in the table below

(billion yen)	Quarterly				
	FY2022				FY2023
	Q1	Q2	Q3	Q4	Q1
Revenue	**381.8**	**380.4**	**402.2**	**354.3**	**375.0**
Cost of sales	76.1	75.5	74.4	62.3	68.9
% of revenue	19.9%	19.9%	18.5%	17.6%	18.4%
SG&A expenses	153.4	154.6	163.0	159.3	168.2
US XTANDI co-pro fee	43.1	46.5	48.6	37.3	44.6
SG&A excl. the above	110.3	108.0	114.4	122.0	123.6
R&D expenses	74.0	65.2	66.9	70.1	64.6
Amortisation of intangible assets	10.7	9.2	9.2	9.3	9.1
Gain on divestiture of intangible assets	0.2	0.0	0.0	0.0	0.1
Core operating profit	**68.1**	**77.3**	**88.3**	**53.2**	**64.9**
(Ref) Impact on Core OP*	**+12.8**	**-12.8**	**-**	**-**	**-**

* Impact on Core OP when this change is applied

Q1/FY2023: REVENUE BY REGION

(billion yen)	1Q/FY2022	1Q/FY2023	Change (%)
Japan	66.8	68.3	+2.2%
United States	160.9	150.0	-6.8%
Established Markets	86.6	96.8	+11.8%
Greater China	23.2	22.5	-2.7%
International Markets	33.9	34.7	+2.4%

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.

Q1/FY2023 FINANCIAL RESULTS: XTANDI (REGION)

(billion yen)	Q1/FY2023 Act	YoY	FY2023 FCST
Global Sales	**174.1**	**+11.7 (+7%)** Excl. FX impact 〔 +1.9 (+1%) 〕	**669.9** (YoY +1%)
US (Unit: $)	$632M	$-15M (-2%)	$2,635M (+4%)
Established Markets (Unit: €)	€365M	€+26M (+8%)	€1,419M (+1%)
Japan	14.4	+0.3 (+2%)	58.2 (+6%)
Greater China	4.4	+0.8 (+23%)	14.5 (+31%)
International Markets	13.8	-0.1 (-1%)	55.9 (+1%)

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.

Q1/FY2023 FINANCIAL RESULTS: PADCEV (REGION)

PADCEV
enfortumab vedotin
Injection for IV infusion 20 mg & 30 mg vials

(billion yen)	Q1/FY2023 Act	YoY	FY2023 FCST
Global Sales	**15.2**	**+4.7 (+44%)** Excl. FX impact 〔+3.9 (+37%)〕	**66.7** (YoY +50%)
US (Unit: $)	$76M	$+20M (+35%)	$341M (+59%)
Established Markets (Unit: €)	€16M	€+7M (+79%)	€82M (+70%)
Japan	2.2	+0.3 (+13%)	9.9 (+18%)
International Markets	0.1	+0.1	0.9

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

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Q1/FY2023 ACTUAL: FX RATE

Average rate for the period

Currency	Q1/FY2022	Q1/FY2023	Change
USD	130 yen	137 yen	-8 yen
EUR	138 yen	150 yen	-11 yen

Change in current rate from previous fiscal year end

Currency	Q1/FY2022	Q/FY2023
USD	-14 yen	-12 yen
EUR	-8 yen	-14 yen

<Impact of exchange rate on financial results>

- 17.5 billion yen increase in revenue, 18.2 billion yen* increase in core OP

* Incl. the impact of elimination of unrealized profit remaining in Q1/FY2022: 12.8 bil.yen. FX impact on core operating profit excluding this impact: +5.4 bil. yen.

FY2023 FORECAST: FX RATE & FX SENSITIVITY

Exchange rate Average for the period	FY2022	FY2023 FCST	Change
USD	135 yen	130 yen	+5 yen
EUR	141 yen	140 yen	+1 yen

Estimated FX sensitivity of FY2023 forecasts by 1 yen appreciation

Currency	Average rate 1 yen higher than assumption	
	Revenue	Core OP
USD	Approx. -6.6 bil. yen	Approx. -2.8 bil. yen
EUR	Approx. -1.1 bil. yen	Approx. -1.2 bil. yen

BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY2022 end	Jun 30, 2023
Total assets	2,456.5	2,798.0
Cash and cash equivalents	376.8	561.5
Total equity attributable to owners of the parent	1,508.0	1,578.4
Equity ratio (%)	61.4%	56.4%

(billion yen)	Q1/FY2022	Q1/FY2023
Cash flows from operating activities	48.8	12.2
Cash flows from investing activities	-19.1	-12.3
Free cash flows	29.7	-0.1
Cash flows from financing activities	-46.6	165.0
Increase/decrease in short-term borrowings and CP	15.0	234.0
Acquisition of treasury shares	-10.6	-10.7
Dividends paid	-45.7	-53.9

As of end of June, Balance of bonds (Incl. CP) and borrowings: 359.0 billion yen

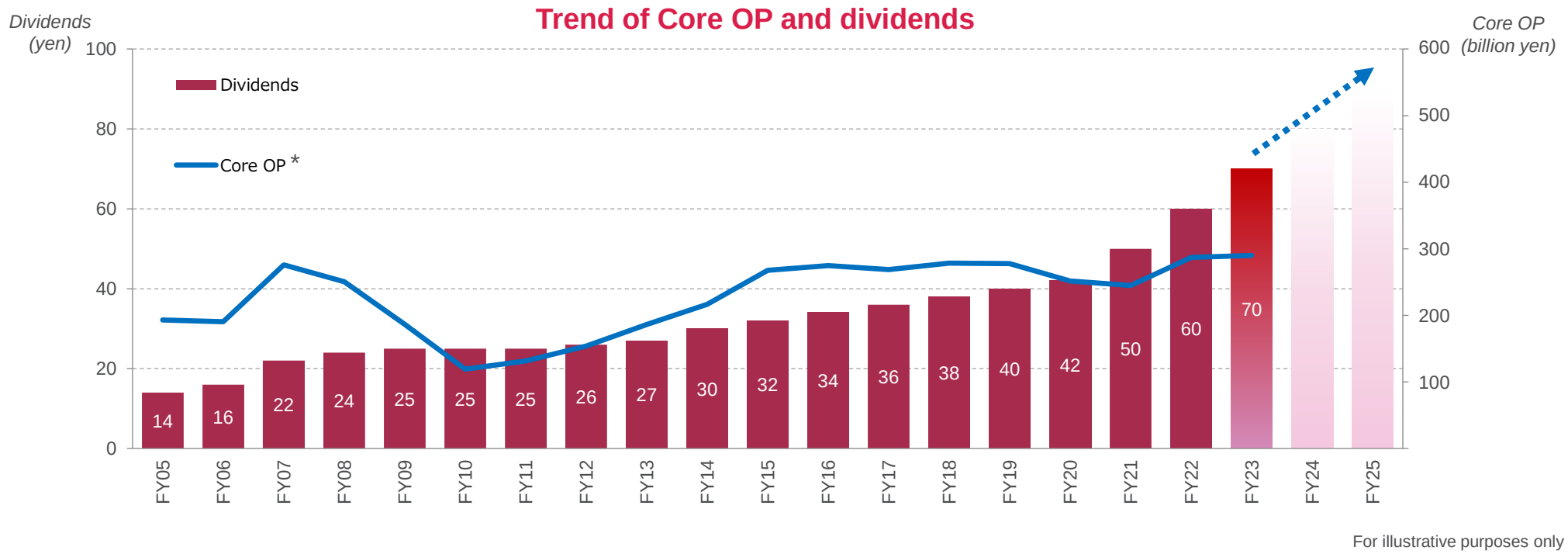
As of August 1st, Balance of bonds (Incl. CP) and borrowings: 969.0 billion yen

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
- ASP7317
- bocidelpar/ASP0367 (Duchenne muscular dystrophy)
- AT845
- ASP3082
- ASP8062

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

- enzalutamide (M0 CSPC: Europe, M1 CSPC: China)
- enfortumab vedotin (mUC previously untreated, MIBC)
- gilteritinib (Earlier-stage AML, pediatric use)
- fezolinetant (VMS due to menopause: China)
- mirabegron (Pediatric use: Europe)

Submitted/Filed

- enzalutamide (M0 CSPC: US)
- 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: US, 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.

NMIBC: Non-muscle-invasive bladder cancer, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, XLMTM: X-linked myotubular myopathy, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms, 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
			enzalutamide Non-metastatic castration-sensitive prostate cancer: US	**fezolinetant** Vasomotor symptoms associated with menopause: US
			zolbetuximab Gastric and gastroesophageal junction adenocarcinoma: Japan, US, Europe, China	
			isavuconazole Invasive aspergillosis and mucormycosis in pediatric patients: US	

Discontinuation

ASP0598: Chronic tympanic membrane perforation (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	• **China**: Obtained topline results from Phase 3 China ARCHES study in Mar 2023
	M0 CSPC	• **sNDA submitted in US in Jun 2023. Results from Phase 3 EMBARK study presented at AUA in Apr 2023**
enfortumab vedotin / PADCEV	Metastatic urothelial cancer	• **Previously untreated (first line):** Phase 3 study ongoing. sBLA approved (accelerated approval) in US in Apr 2023 (cisplatin-ineligible) • **Pretreated:** BLA accepted in China in Mar 2023
	Muscle-invasive bladder cancer	• Phase 3 studies ongoing
	Non-muscle-invasive bladder cancer	• Phase 1 study ongoing. **Initial data from Phase 1 EV-104 study presented at ASCO in Jun 2023**
	Other solid tumors	• Phase 2 study ongoing. **Initial data from Phase 2 EV-202 study presented at ASCO in Jun 2023**
gilteritinib / XOSPATA	Relapsed and refractory AML	• **China:** Phase 3 study stopped due to efficacy
	AML, post-HSCT maintenance	• **Results from Phase 3 MORPHO study presented at EHA in Jun 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**. MAA accepted in Europe in Sep 2022. **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	**GA secondary to AMD**	• **NDA accepted in US in Feb 2023. MAA submitted in Europe in Jul 2023**
	Stargardt disease	• **Phase 2b study ongoing**

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, (s)NDA: (Supplemental) New Drug Application, AUA: American Urological Association, (s)BLA: (Supplemental) Biologics License Application, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, GEJ: Gastroesophageal junction, ASCO: American Society of Clinical Oncology, EHA: European Hematology Association, VMS: Vasomotor symptoms, MAA: Marketing Authorization Application, LSLV: Last subject last visit, FDA: Food and Drug Administration, GA: Geographic atrophy, AMD: Age-related macular degeneration

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

Product	Potential Peak Sales *(Global, billions of yen)*
XTANDI (enzalutamide)	over 700
VEOZAH (fezolinetant)	300 - 500
PADCEV (enfortumab vedotin) [1]	300 - 400
XOSPATA (gilteritinib)	100 - 200
zolbetuximab	100 - 200
EVRENZO (roxadustat) [2]	under 50 [3]
AT132 (resamirigene bilparvovec)	under 50

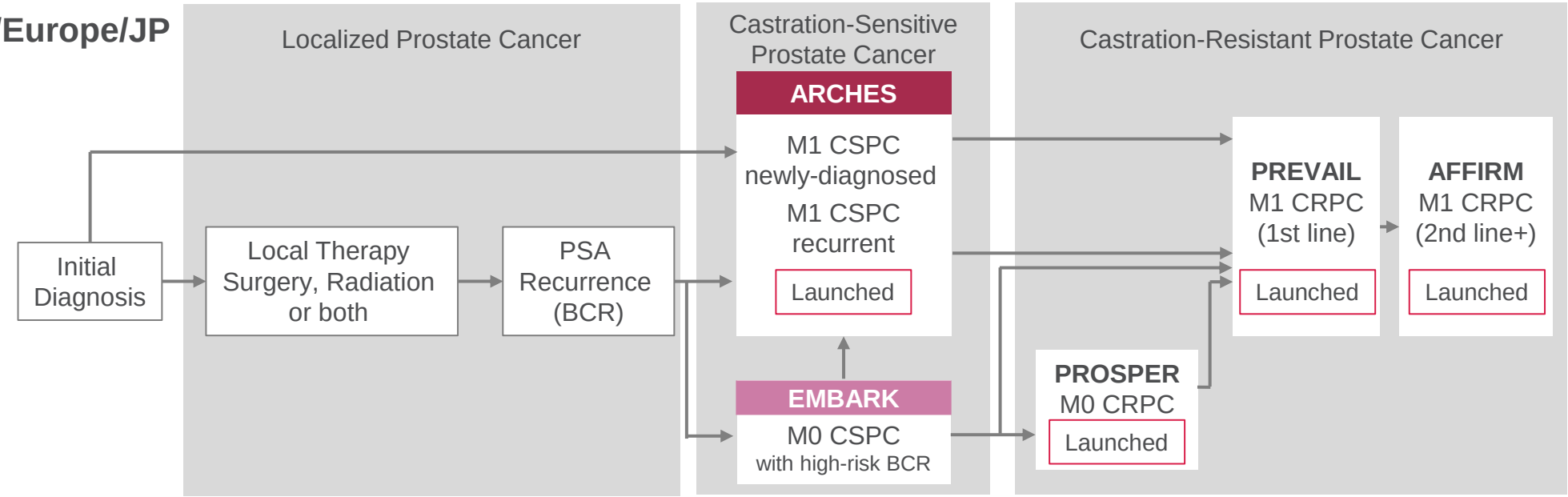
Note) Only indications undergoing pivotal studies are included for projection (as of July 2023)

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.
3. Previous potential peak sales: 50 - 100 billion yen (announced in May 2021)

ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

(Red: Updates since the last financial results announcement)

US/Europe/JP



P3: EMBARK	NCT02319837	**M0 CSPC**	ENZA + ADT vs. placebo + ADT vs. ENZA mono	n=1,068	**sNDA submitted in US in Jun 2023**

China

- **M1 CSPC:** Topline results obtained in Mar 2023 in Phase 3 China ARCHES study (NCT04076059)

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, sNDA: Supplemental New Drug Application

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

(Red: Updates since the last financial results announcement)

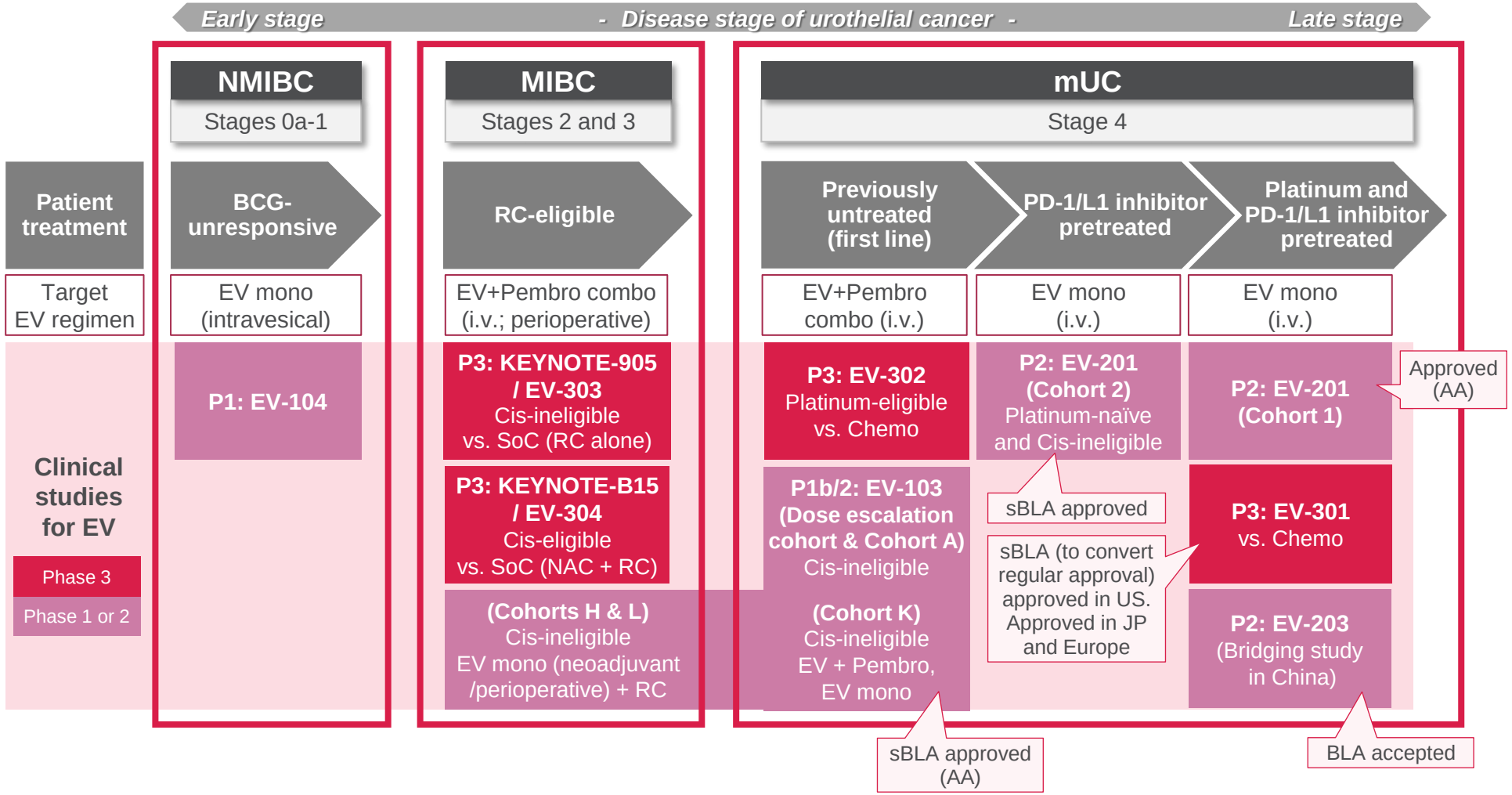
Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

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	Enrollment completed
	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 & OS	✓ 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)	(Ongoing)	(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)	(Ongoing)	(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)	(Ongoing)	✓ 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

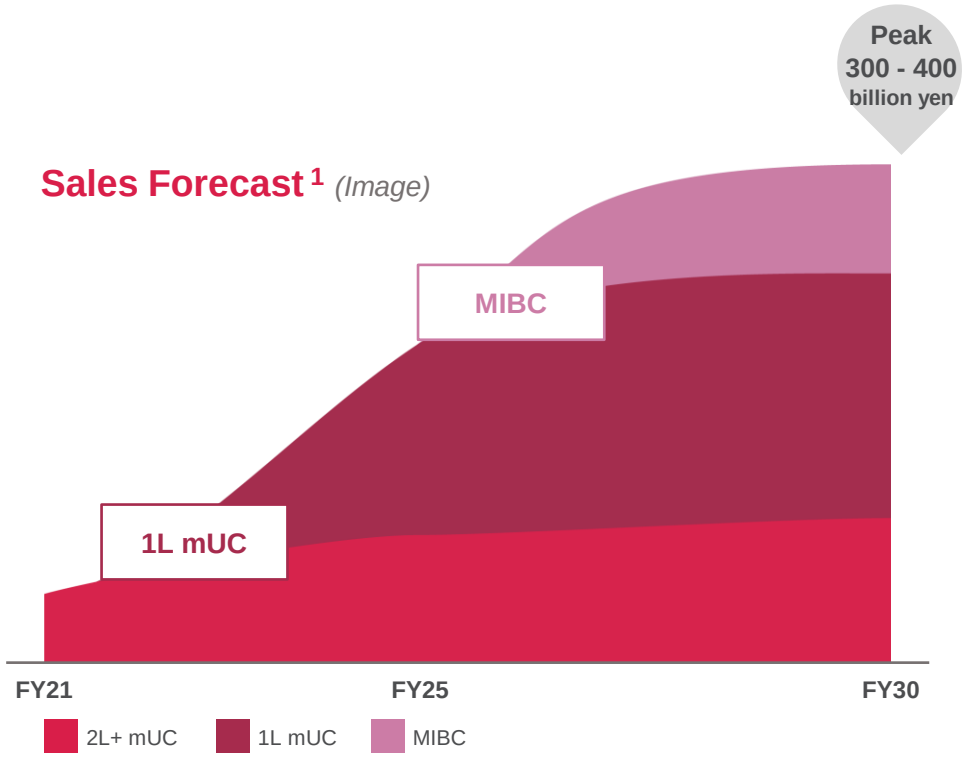
(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer, cis: Cisplatin, Pembro: Pembrolizumab, mono: Monotherapy, Chemo: Chemotherapy, pCR: Pathologic complete response, EFS: Event-free survival, ORR: Objective response rate, CR: Complete response, OS: Overall survival, HR: Hazard 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**
	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)	**FY2024 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)
	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

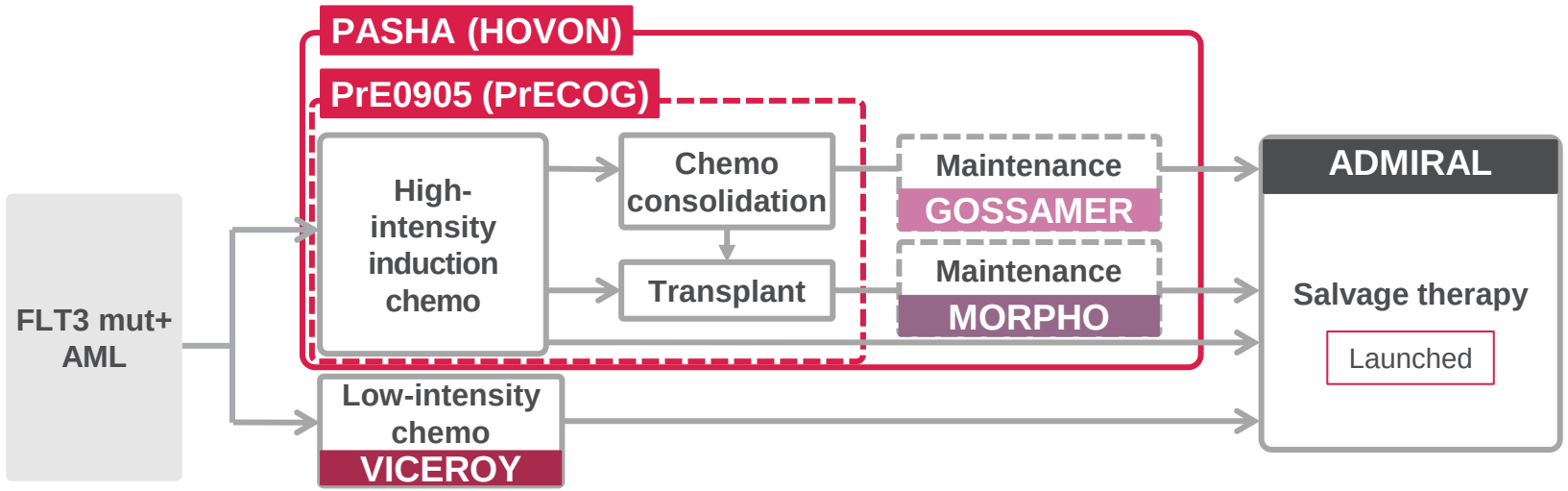
**Combo w/ Pembro:
Head and neck squamous cell carcinoma

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

(Red: Updates since the last financial results announcement)



	Relapsed or refractory	**P3: ADMIRAL**	NCT02421939	Monotherapy vs. salvage chemo (2:1)	n=371	Launched in US, JP, and Europe
	Newly diagnosed (HIC-eligible)	**P3: PASHA (HOVON)**	NCT04027309	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=768	**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

(Red: Updates since the last financial results announcement)

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
	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

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

Geographic atrophy (GA)

- Advanced form of dry age-related macular degeneration (AMD)
- ~1.6 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

- ACP inhibits complement C5, and slows inflammation and cell death associated with development and progression of GA
- Breakthrough Therapy designation granted by FDA in Nov 2022
- NDA filed under Priority Review with a PDUFA goal date of Aug 19, 2023

	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	NDA accepted in US in Feb 2023 **MAA submitted in Europe in Jul 2023**
		P3: GATHER2	NCT04435366	2 mg vs. Sham	n=448	
	Stargardt disease	**P2b**	NCT03364153	vs. Sham	n=120	FSFT: Jan 2018

1. Arch Ophthalmol. 129:75-80 (2011)

FDA: Food and Drug Administration, NDA: New Drug Application, PDUFA: Prescription Drug User Fee Act, MAA: Marketing Authorization Application

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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	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