FY2022 FINANCIAL RESULTS
ENDED MARCH 31, 2023

Naoki Okamura
President and CEO
Astellas Pharma Inc.
April 27, 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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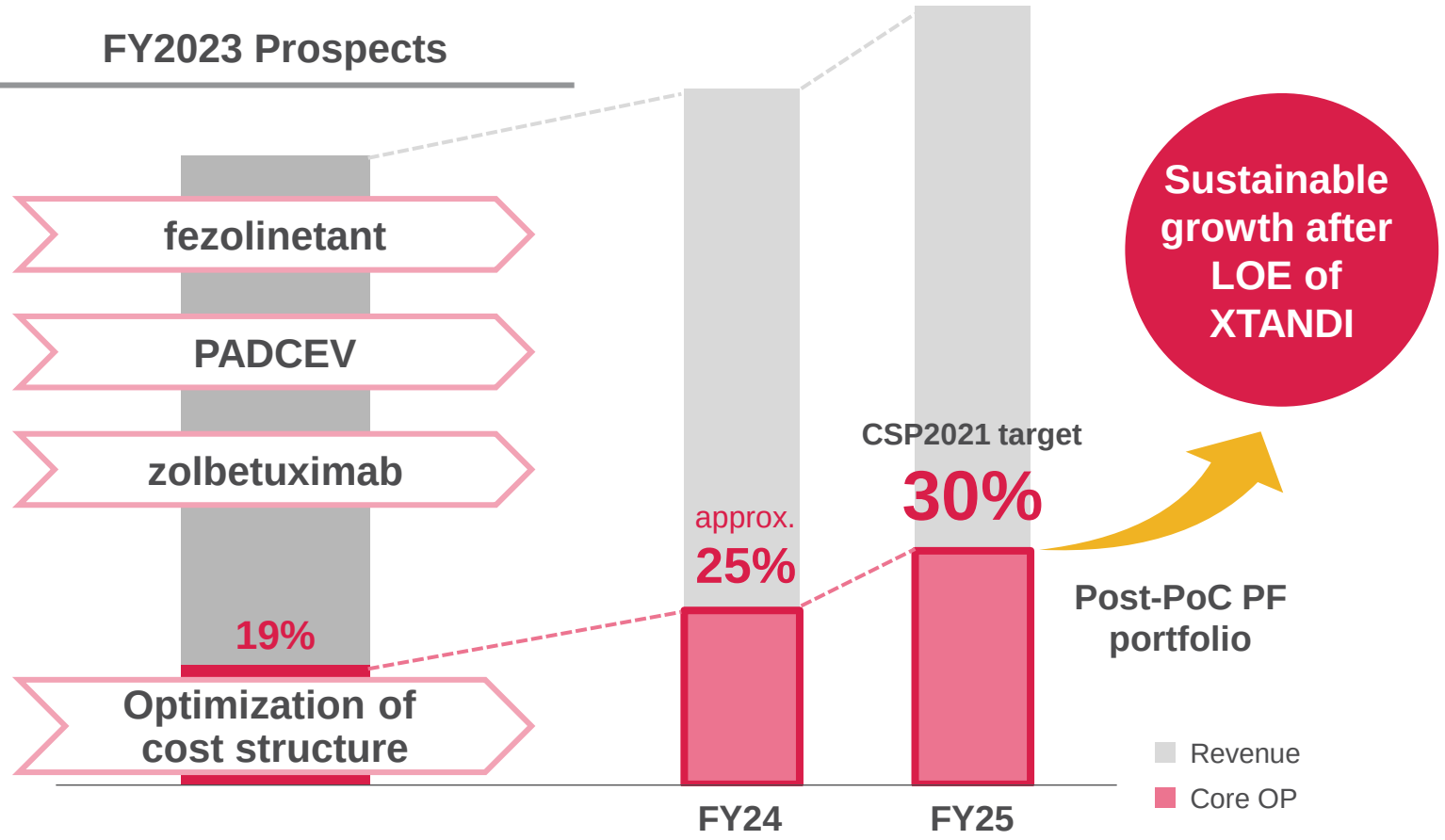
TOWARD ACHIEVEMENT OF CSP2021

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

FY2022 Review

- Core results in line with expectations, but slightly behind full-year forecast
- fezolinetant NDA, PADCEV sBLA, successful zolbetuximab Phase 3 studies
- Established new PF "Targeted Protein Degradation"
- No PoC obtained in FA projects

FY2023 Prospects



Approval of PADCEV sBLA for first-line metastatic urothelial cancer in US is Apr 2023.
CSP: Corporate Strategic Plan, NDA: New Drug Application, sBLA: Supplemental Biologics License Application, PF: Primary Focus, PoC: Proof of concept, FA: Focus Area, LOE: Loss of exclusivity

AGENDA

FY2022 FINANCIAL RESULTS: OVERVIEW

Revenue increased 17% YoY and was in line with expectations, but slightly behind full-year forecast
XTANDI, PADCEV and XOSPATA expanded as expected with full-year forecasts

Cost items

- Cost of sales ratio was as expected
- SG&A expenses were on track and decreased YoY when excluding FX impact
- R&D expenses were on track

Operating profit

- Core OP increased 17% YoY and was in line with expectations, but slightly behind full-year forecast

FY2022 FINANCIAL RESULTS

(billion yen)	FY2021	FY2022	Change	Change (%)	FY2022 FCST [1]	Achievement	FX impact (YoY)
Revenue	**1,296.2**	**1,518.6**	**+222.5**	**+17.2%**	**1,529.0**	**99.3%**	+164.4 bil. yen
Cost of sales	253.0	288.4	+35.3	+14.0%			+13.3 bil. yen (Incl. the impact of elimination of unrealized profit remaining in Q4/FY2021: +7.8 bil.yen)
% of revenue	19.5%	19.0%	-0.5 ppt				
SG&A expenses	548.8	630.3	+81.4	+14.8%	642.0	98.2%	+80.3 bil. yen
US XTANDI co-pro fee	139.3	175.5	+36.2	+26.0%	186.0	94.3%	
SG&A excl. the above	409.5	454.8	+45.3	+11.1%	456.0	99.7%	+50.4 bil. yen
R&D expenses	246.0	276.1	+30.1	+12.2%	278.0	99.3%	+27.5 bil. yen
Amortisation of intangible assets	28.3	38.4	+10.2	+35.9%			
Gain on divestiture of intangible assets	24.2	0.2	-24.0	-99.1%			
Core operating profit	**244.7**	**286.9**	**+42.2**	**+17.2%**	**290.0**	**98.9%**	+40.1 bil. yen
<Full basis>							
Other income	15.3	3.6	-11.6	-76.1%			
Other expenses	104.3	157.5	+53.2	+51.0%			
Operating profit	**155.7**	**133.0**	**-22.7**	**-14.6%**	**137.0**	**97.1%**	
Profit before tax	156.9	132.4	-24.5	-15.6%	135.0	98.0%	
Profit	**124.1**	**98.7**	**-25.4**	**-20.4%**	**105.0**	**94.0%**	

Ref. Other expenses (booked in Q4/FY2022)

- Fair value increase of contingent consideration(zolbetuximab) [2]:38.6 bil. yen
- Impairment losses on intangible assets :60.3 bil. yen(EVRENZO:47.1 bil. yen, FX-322:8.6 bil. yen, Adaptimmune:4.6 bil. yen)

1. FY22 FCST were announced in Oct 2022, provided that full basis is the revised forecast announced on April 11, 2023.
2. Booked in Q4/FY2022 due to internal decision-making to submit for approval of zolbetuximab

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FY2022 FINANCIAL RESULTS: MAIN PRODUCTS

XTANDI, PADCEV, XOSPATA showed solid growth in line with full-year forecast

(billion yen)	FY2022 Act	YoY	FY2022 FCST*	Achievement against FCST	
Xtandi® (enzalutamide)	661.1	+126.8 (+24%) Excl. FX impact 〔 +45.4 (+9%) 〕	670.0	99%	✓ Global sales showed growth in line with FCST ✓ US: Total demand growth offset by affordability challenges including fluctuating PAP rates and generic competitor share Despite the challenging environment, XTANDI continues to be the leading branded NHT across all indications ✓ Europe: Strong demand increase, achieved the upwardly revised FCST
PADCEV® enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	44.4	+22.7 (+104%) 〔 +17.2 (+79%) 〕	45.4	98%	✓ Global sales expanded significantly, driven by Europe and Japan ✓ US: Despite steady growth in actual demand, revenue from clinical orders was below expectations, resulting in underachieving the FCST ✓ Europe: Launched countries increased to 21 and obtained reimbursement in 7 countries
XOSPATA® gilteritinib 40mg tablets	46.6	+12.5 (+37%) 〔 +6.6 (+19%) 〕	45.8	102%	✓ Global sales achieved FCST ✓ Sales expanded in all regions, performance in line with expectations ✓ High market share in US, Europe and Japan
Evrenzo® roxadustat	3.2	+0.6 (+23%)	5.0	64%	✓ Progress was significantly behind FCST ✓ Japan: Market share was lower than expected due to competitive pressure ✓ Europe: Launched with reimbursement in Italy in Q4

* Announced in Oct 2022
FCST: Full-year forecast, PAP: Patient Assistance Program, NHT: Novel Hormonal Therapy

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FY2022 FINANCIAL RESULTS: COST ITEMS

Cost of sales ratio was as expected
SG&A expenses were on track and decreased YoY when excluding FX impact
R&D expenses were on track

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

Cost Items	YoY change	Ratio to Revenue	Achievement against FCST	
Cost of sales	+14.0%	19.0% (-0.5ppt YoY)	-	✓ Cost of sales ratio was as expected
SG&A expenses **excl. US XTANDI co-pro fee**	+11.1% (-1.3% excl. FX impact)	29.9% (-1.6ppt YoY)	99.7%	✓ Optimization of commercial-related personnel globally (YoY approx. -8.0 bil. yen) ✓ Reduction of mature products-related costs (approx. -8.0 bil. yen) ✓ Investment for new product launch readiness (approx. +12.0 bil. yen) ✓ Cost reduction progressed as expected, actively making necessary investments ✓ As a result, SG&A expenses were on track
R&D expenses	+12.2% (+1.1% excl. FX impact)	18.2% (-0.8ppt YoY)	99.3%	✓ Booked one-time expense for using PRV in Q1 for the application of fezolinetant (13.7 bil. yen) ✓ In line with full-year forecast, including the expense above

PRV: Priority Review Voucher

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AGENDA

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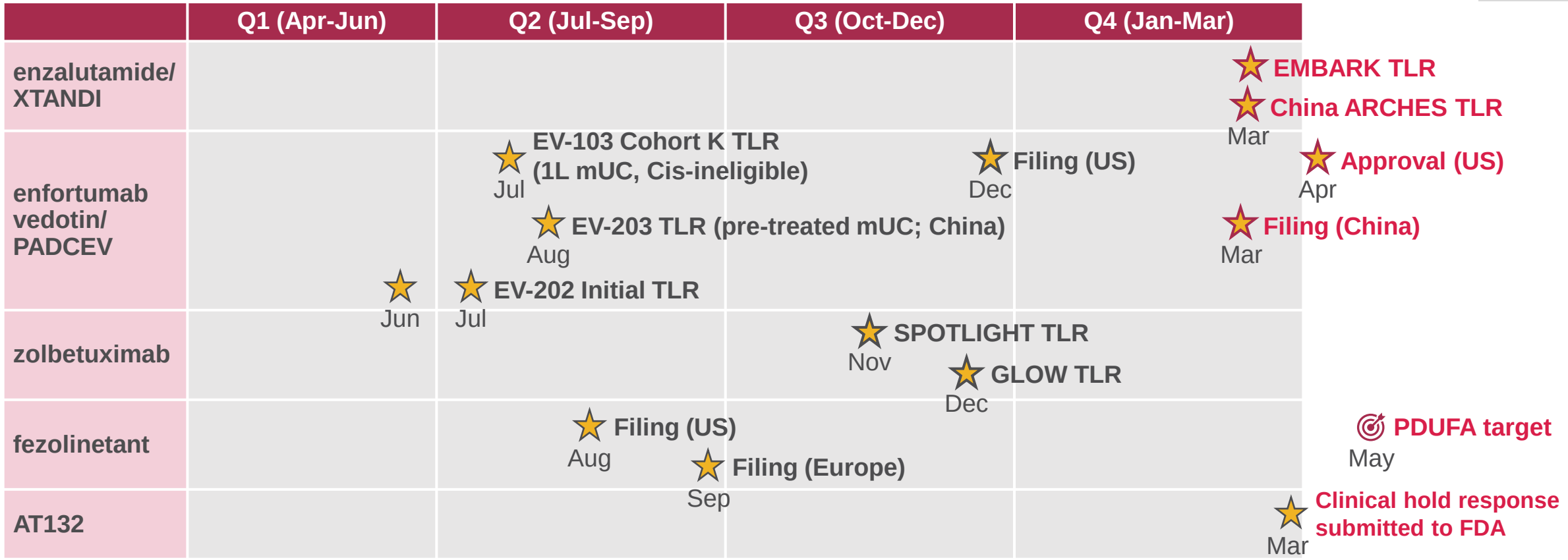
II Initiatives for Sustainable Growth

III FY2023 Forecasts and
Key Expected Events

XTANDI & STRATEGIC PRODUCTS: KEY EVENTS IN FY2022



<Other updates>

- zolbetuximab: SPOTLIGHT study results published in The Lancet in Apr 2023
- fezolinetant: SKYLIGHT 1 study results published in The Lancet in Mar 2023
  TLR obtained in STARLIGHT (Japan Phase 2b) study in Mar 2023
- gilteritinib/XOSPATA: TLR obtained in MORPHO study (Post-HSCT maintenance) in Mar 2023

TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer, Cis: Cisplatin, PDUFA: Prescription Drug User Fee Act, FDA: Food and Drug Administration, HSCT: Hematopoietic stem cell transplant

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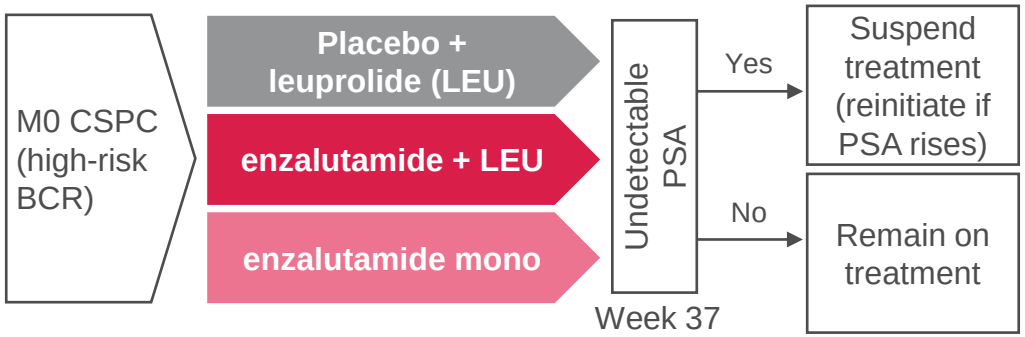
ENZALUTAMIDE/XTANDI: LATEST STATUS

- *Aiming for regulatory submission in US as well as Europe, based on the positive topline results from EMBARK study*
- *Revised potential peak sales upward to 700 billion yen*

EMBARK study

- Study design



- Topline results
  - ➢ Met primary endpoint of MFS (enzalutamide + LEU vs. placebo + LEU)
  - ➢ Positive trend in key secondary endpoint of OS (not yet mature)
  - ➢ Met other key secondary endpoints
    - MFS (enzalutamide mono vs. placebo + LEU)
    - Time to PSA progression
    - Time to first use of new antineoplastic therapy

Future plan

- EMBARK data presentation: AUA 2023 on Apr 29
- Regulatory submission: targeting mid-2023 in US and 2H FY2023 in Europe

Update of sales forecast

- Updated sales forecast by incorporating sales trend so far, M0 CSPC submission plan in Europe and FX rate trend
- Potential peak sales: over 700 billion yen*
  - ➢ Sales contribution from M0 CSPC：40-50 billion yen

* Previous forecast: 600-700 billion yen

M0 CSPC: Non-metastatic castration-sensitive prostate cancer, BCR: Biochemical recurrence, PSA: Prostate-specific antigen, MFS: Metastasis-free survival, OS: Overall survival, AUA: American Urological Association

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 [1]	Project	Current status	No. of projects aiming PoC by end FY25 [2]
Genetic Regulation	Gene replacement (AAV)	AT132	ASPIRO study put on clinical hold by FDA in Sep 2021	2
		AT845	**Activities to restart FORTIS study commenced in Feb 2023** **Preliminary data from FORTIS study presented at WORLD*Symposium* in Feb 2023**	
	Gene regulation (AAV)			
Immuno-Oncology	Checkpoint	ASP1570	Phase 1 study ongoing	7
	Artificial adjuvant vector cell (aAVC)	ASP7517	**Terminated**	
		ASP0739	**Terminated**	
	Oncolytic virus (intratumoral)	ASP9801	**Terminated**	
	Oncolytic virus (systemic)			
	Bispecific immune cell engager	ASP2138	Phase 1 study ongoing	
		ASP2074	**FSFT in Phase 1 study in Mar 2023**	
		ASP1002	**FSFT in Phase 1 study in Mar 2023**	
	Cancer cell therapy (UDC)			
Blindness & Regeneration	Cell replacement	ASP7317	Screening and enrollment in Phase 1b study restarted in Aug 2022	3
	Cell replacement (UDC)			
	Gene regulation (AAV)			
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD terminated due to operational reasons	3
	Mitochondrial stress	ASP8731	**Terminated**	
	Mitochondrial transfer			
Targeted Protein Degradation	Protein degradation	ASP3082	Phase 1 study ongoing. **Fast Track Designation granted by FDA in Feb 2023 (pancreatic adenocarcinoma)**	1
Primary Focus Candidate	Immune modulating/regulatory cells			-
	Tissue-specific immune regulation			
			Total	**24 → 16**

Modality
- Small molecule
- Antibody
- Gene
- Cell
- Other

1. Not exhaustively listed.
2. Estimated based on standard development timelines, assuming 100% probability of success (as of Apr 2023). Total number indicates change from Apr 2022.

AAV: Adeno-associated virus, UDC: Universal donor cell, FDA: Food and Drug Administration, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

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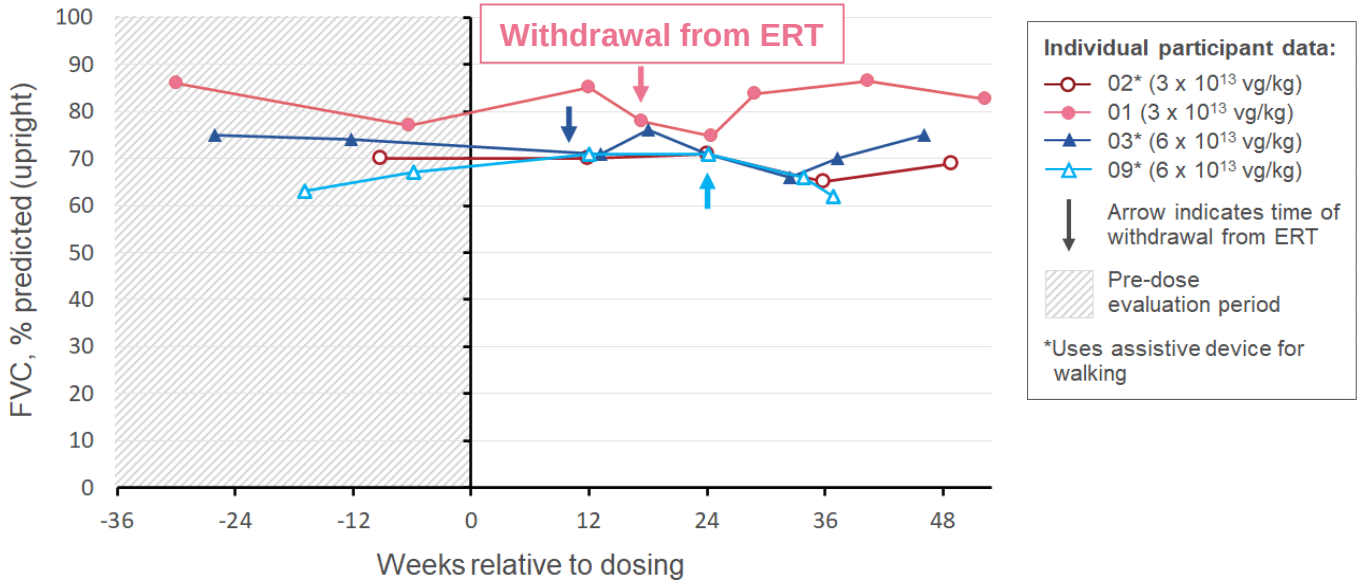
PROGRESS IN FOCUS AREA APPROACH (2/2): AT845 PRELIMINARY DATA FROM FORTIS STUDY

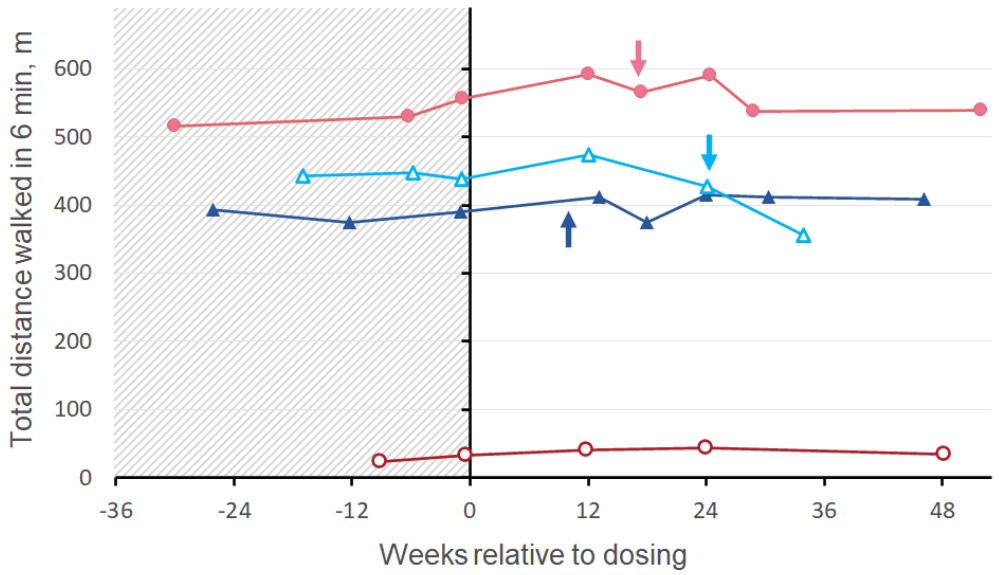
- *Three of four participants have discontinued enzyme replacement therapy (ERT)* following administration of AT845* [1]
- *Their measured functional outcomes have been stable while off ERT*

*ERT: only approved treatment for Pompe disease; a chronic treatment delivered in bi-weekly infusions

<Forced vital capacity (FVC)>



<6-minute walk test>



Note: The last two time points for Participant 09 (△) occurred after the development of peripheral polyneuropathy

- Activities to restart FORTIS study commenced in Feb 2023, with dosing anticipated to resume in Q2 FY2023

1. As of Sep 15, 2022

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PROGRESS IN Rx+ PROGRAM: SUMMARY OF FY2022

(Red: Updates since the last financial results announcement)

Key events expected in FY2022 (announced in Apr 2022)

Category	Program	Event	Progress
Digital health Other services	EG Holter	Initiation of pilot marketing	Jun 2022: Initiated sales pilot
Digital therapeutics	BlueStar	Initiation of clinical study (Japan)	Jan 2023: Partnership agreement with Roche Diabetes Care Japan, aiming for approval as a combined medical product with a blood glucose monitoring system Initiation of clinical study in Japan planned in FY2023
Drug-device combination	pudexacianinium chloride (ASP5354)	FSFT in Phase 3 study	Jan 2023: Collaboration on exclusive commercialization in US with Stryker, a medical device company with strengths in surgical visualization technology Preparation to initiate Phase 3 trials in FY2023

FSFT: First subject first treatment

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FY2023 FORECAST: OVERVIEW

- *Revenue to be the same level as previous fiscal year*
  Sales contributions of fezolinetant and PADCEV offsetting decrease in sales of Lexiscan
  - ✓ *SG&A expenses to increase YoY mainly due to investment in fezolinetant and zolbetuximab*
  - ✓ *Implementation of continued pursuit of operational excellence to achieve Core OP margin of 30% in FY2025*
  - ✓ *R&D expenses to decrease YoY due to decrease in development costs for Strategic products while continued investment to be made in Primary Focus*
- *As a result, Core OP to be the same level as previous fiscal year*
- *In anticipation of our growth from FY2024 onwards, dividend per share is forecasted at 70 yen, an increase of 10 yen*

FY2023 FORECAST

(billion yen)	FY2022 actual	FY2023 forecast	Change (%)
Revenue	**1,518.6**	**1,520.0**	**+0.1%**
SG&A expenses	630.3	661.0	+4.9%
US XTANDI co-pro fee	175.5	176.0	+0.3%
SG&A excl. the above	454.8	485.0	+6.6%
R&D expenses	276.1	251.0	-9.1%
Core operating profit	**286.9**	**290.0**	**+1.1%**
<Full basis>			
Operating profit	**133.0**	**288.0**	**+116.5%**
Profit	**98.7**	**227.0**	**+130.0%**

FY2023 FCST (FX rate)
USD: 130 yen
EUR: 140 yen

FX impact: -40.8 bil. yen

FX impact: -8.7 bil. yen

FY2023 FORECAST: MAIN PRODUCTS

Expect continued growth led by PADCEV, with sales contribution from fezolinetant

(billion yen)	FY2023 FCST	YoY	Main growth factors
Xtandi® (enzalutamide)	669.9	+8.8 (+1%) Excl. FX impact* [+30.7 (+5%)]	✓ US: Expect continued growth within the current indication; and potential approval of M0 CSPC additional indication by the end of FY2023 ✓ Japan: Expect sales growth driven by M1 CSPC ✓ China: Reimbursement for M0 CRPC additional indication started in Mar 2023
PADCEV® enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	66.7	+22.3 (+50%) [+23.5 (+54%)]	✓ US: Expect substantial growth driven by the additional indication of 1L mUC ✓ Europe: Expect increases in countries with reimbursement ✓ Japan: Expect continued growth within the current indication
XOSPATA® gilteritinib 40mg tablets	49.3	+2.7 (+6%) [+4.3 (+10%)]	✓ US and Europe: Expect continued growth in the large markets ✓ International Markets: Expect sales to expand from the increase of launched countries and reimbursement start

- fezolinetant: Factored into FY2023 forecast (40-50 billion yen), detailed guidance will be provided after approval

Regional forecasts for XTANDI and PADCEV are on slides 31-32, * Aligning the exchange rate to FY2023 forecast exchange rate
M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer 1L: First Line, mUC: Metastatic urothelial cancer,
International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc

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FY2023 FORECAST: COST ITEMS

Allocate limited resources in a disciplined manner to drive sustainable growth from FY2024 onwards

FY2024 and beyond
Accelerating future growth,
Optimize cost structure

Main factors for increase/decrease (YoY)

SG&A expenses
(excl. US XTANDI co-pro fee)
485.0 billion yen (+30.2 billion yen YoY)
Ratio to revenue: 31.9%

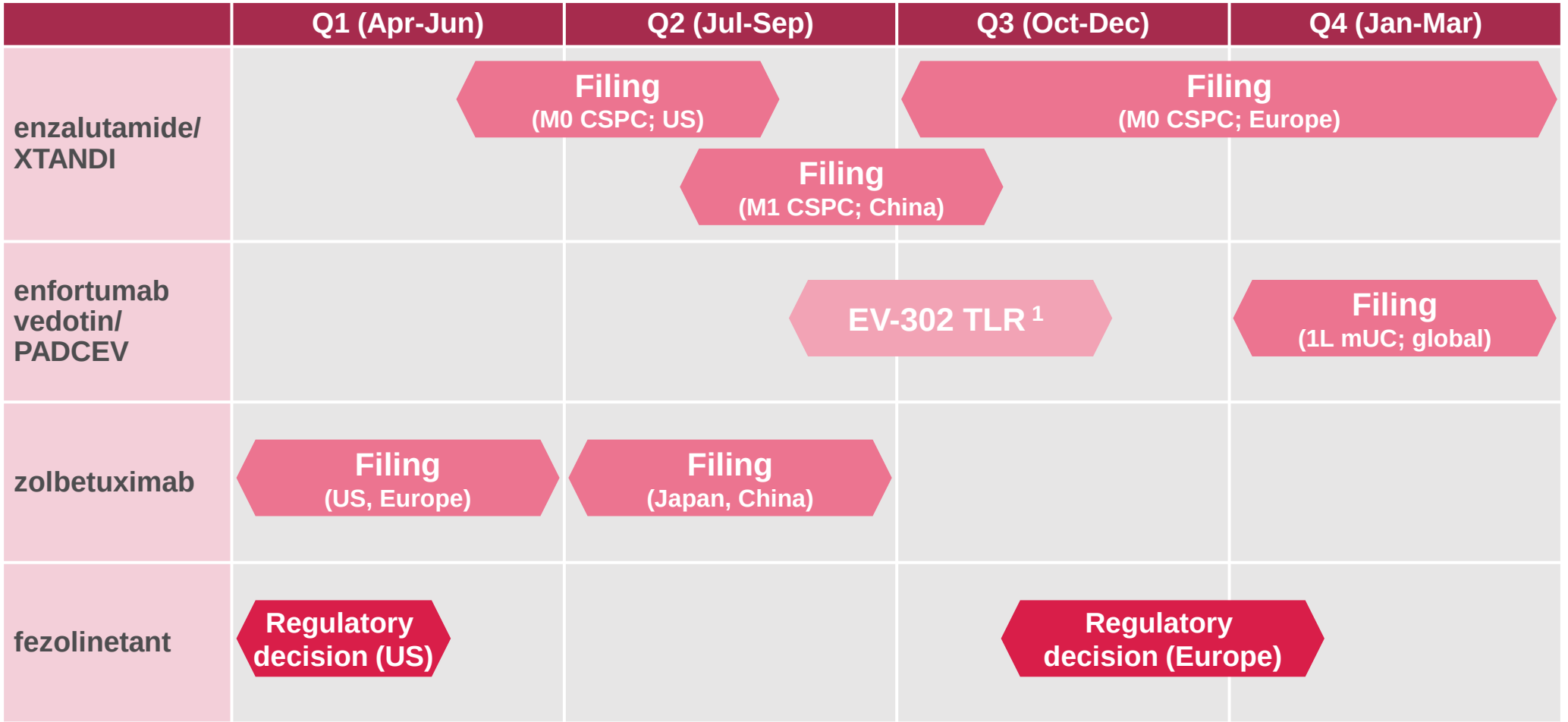
- Investments in fezolinetant and zolbetuximab (approx. +50.0 bil. yen)
- Reduction of mature products-related costs (approx. -8.0 bil. yen)

Continued pursuit of operational excellence

R&D expenses
251.0 billion yen (-25.1 billion yen YoY)
Ratio to revenue: 16.5%

- Increase in Primary Focus-related costs (approx. +8.0 bil. yen)
- One-time expense for PRV in FY22 (-13.7 bil. yen)
- Decrease in development costs for Strategic products (approx. -6.0 bil. yen)

XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2023



As of Apr 2023

1. The timeline of TLR is subject to shift due to its event-driven nature.
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, M1: Metastatic, TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer

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 [1]	Dosing resumption
Genetic Regulation	1 project		AT845
Immuno-Oncology	2 projects	ASP1570 ASP2138	
Blindness & Regeneration			ASP7317
Targeted Protein Degradation	1 project (pan-KRAS)	ASP3082	

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

NEW R&D OPERATING MODEL

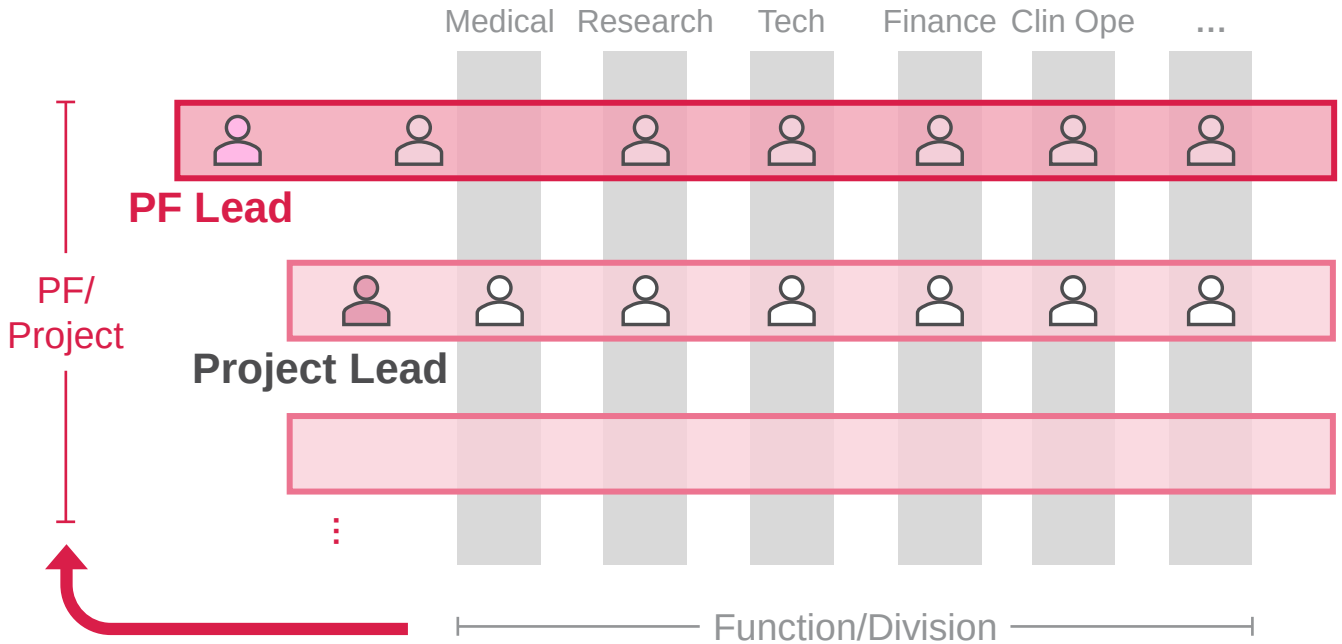
To achieve meaningful PoC as early as possible, enable agile decision making by empowering projects and Primary Focuses throughout the project lifecycle

Kachi Committee

- Cross-Primary Focus (PF) / cross-project prioritization
- Decision making focusing on key development milestones

Chaired by CXOs

Empower projects and PFs



PF Leadership Team

- PF strategy development & execution
- Budget management in place of divisions

Project Team

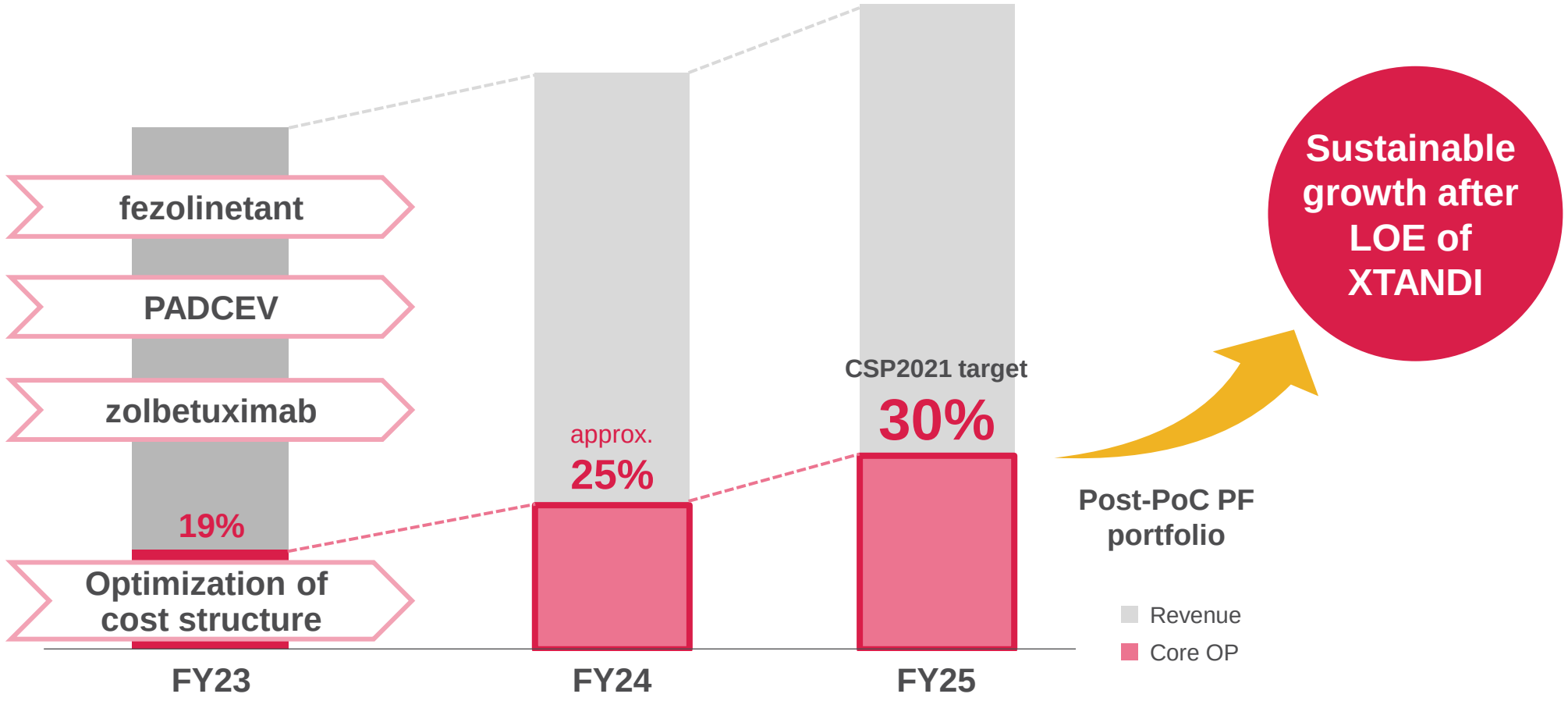
- Project strategy development & execution
- Day-to-day decisions within project

Agile decision making

PoC: Proof of concept

TOWARD ACHIEVEMENT OF CSP2021

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



CSP: Corporate Strategic Plan, PoC: Proof of concept, PF: Primary Focus, LOE: Loss of exclusivity

fezolinetant Meeting

- To be held after approval
  (Details will be delivered later)

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								Year to Date		
	Q1/FY21	Q2/FY21	Q3/FY21	Q4/FY21	Q1/FY22	Q2/FY22	Q3/FY22	Q4/FY22	FY21	FY22	Change (%)
Revenue	**326.1**	**325.5**	**340.6**	**303.9**	**381.8**	**380.4**	**402.2**	**354.3**	**1,296.2**	**1,518.6**	**+17.2%**
Cost of sales	61.0	63.2	66.6	54.5	76.1	75.5	74.4	62.3	245.2	288.4	+17.6%
% of revenue	18.7%	19.4%	19.6%	17.9%	19.9%	19.9%	18.5%	17.6%	18.9%	19.0%	+0.0ppt
SG&A expenses	137.1	133.4	135.9	142.4	153.4	154.6	163.0	159.3	548.8	630.3	+14.8%
US XTANDI co-pro fee	34.5	36.6	37.6	30.6	43.1	46.5	48.6	37.3	139.3	175.5	+26.0%
SG&A excl. the above	102.6	96.8	98.3	111.8	110.3	108.0	114.4	122.0	409.5	454.8	+11.1%
R&D expenses	58.3	60.7	58.6	68.4	74.0	65.2	66.9	70.1	246.0	276.1	+12.2%
Amortisation of intangible assets	6.0	6.4	7.9	8.0	10.7	9.2	9.2	9.3	28.3	38.4	+35.9%
Gain on divestiture of intangible assets	-	-	24.1	0.1	0.2	0.0	0.0	0.0	24.2	0.2	-99.1%
Core operating profit	**64.1**	**61.8**	**97.5**	**29.2**	**68.1**	**77.3**	**88.3**	**53.2**	**252.5**	**286.9**	**+13.6%**
(Ref) Impact on Core OP*1	**+1.2**	**-0.7**	**+2.8**	**+4.5**	**+12.8*2**	**-12.8**	**-**	**-**	**+7.8**	**-**	**-**

*1: Impact on Core OP when this change is applied
*2: The impact of elimination of unrealized profit, which was disclosed as 13.3 billion yen in Q1/FY22 financial results, was 12.8 billion yen after careful examination

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FY2022: REVENUE BY REGION

(billion yen)	FY2021	FY2022	Change (%)
Japan	258.8	262.3	+1.4%
United States	537.5	652.4	+21.4%
Established Markets	306.5	358.4	+16.9%
Greater China	66.3	80.0	+20.7%
International Markets	118.7	144.7	+21.9%

Established Markets: Europe, Canada Greater China: China, Hong Kong, Taiwan
International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc.
Commercial segment of Australia was changed from Established Markets to International Markets in FY2022. Disclosed numbers reflect this change

FY2022: SALES OF MAIN PRODUCTS

(billion yen)	FY2021	FY2022	Change	CER growth	FY2022 FCST*
XTANDI	534.3	661.1	+23.7%	+8.5%	670.0
PADCEV	21.7	44.4	+104.4%	+79.2%	45.4
XOSPATA	34.1	46.6	+36.7%	+19.3%	45.8
EVRENZO	2.6	3.2	+23.0%	+20.8%	5.0
mirabegron	172.3	188.6	+9.5%	-3.4%	195.0
Prograf	185.4	198.8	+7.2%	-1.7%	200.3

PADCEV (US): Co-promotion revenue from Seagen
mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL

* Announced in Oct 2022

FY2022 ACTUAL: FX RATE

Average rate for the period

Currency	FY2021	FY2022	Change
USD	112 yen	135 yen	-23 yen
EUR	131 yen	141 yen	-10 yen

Change in current rate from previous fiscal year end

Currency	FY2021	FY2022
USD	-11 yen	-11 yen
EUR	-5 yen	-9 yen

<Impact of exchange rate on financial results>

- 164.4 billion yen increase in revenue, 40.1 billion yen increase in core OP

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

FY2023 FORECAST: XTANDI (REGION)

(billion yen)	FY2023 FCST	YoY	Main growth factors
Xtandi® (enzalutamide)	**669.9**	**+8.8 (+1%)** Excl. FX impact* (+30.7 (+5%))	✓ Expect continued growth globally in actual business excluding FX impact ✓ Expect sales growth in all regions
US (Unit: $)	$2,635M	+112 (+4%)	✓ Despite the challenging conditions of PAP and generic competitor, expect continued growth within the current indication with a mid-single-digit growth in demand ✓ Expect approval of future growth driver M0 CSPC additional indication by the end of FY2023
Established Markets (Unit: €)	€1,419M	+14 (+1%)	✓ Expect mid-single-digit growth in demand driven by the growth of M1 CSPC indication ✓ On the other hand, expect negative impact from increased competitive and pricing pressure
Japan	58.2	+3.5 (+6%)	✓ Expect sales to expand mainly driven by the growth of M1 CSPC indication, despite anticipated impact of increased competitive pressure
Greater China	14.5	+3.4 (+31%)	✓ Reimbursement for M0 CRPC additional indication started in Mar 2023, expect sales contribution
International Markets	55.9	+0.3 (+0%)	✓ Expect double-digit growth excluding FX impact from the increase in countries with approval and reimbursement start for the additional indication of M1 CSPC

* Aligning the exchange rate to FY2023 forecast exchange rate

M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, Established Markets: Europe, Canada, Greater China: China, Hong Kong, Taiwan, International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc

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FY2023 FORECAST: PADCEV (REGION)

(billion yen)	FY2023 FCST	YoY	Main growth factors
PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	**66.7**	**+22.3 (+50%)** Excl. FX impact* [+23.5 (+54%)]	✓ Expect strong growth, driven by the contribution of 1L mUC indication in the US ✓ Sales growth in all regions
US (Unit: $)	$341M	+126 (+59%)	✓ Obtained approval for 1L mUC additional indication in Apr 2023, Expect significant contribution as a growth driver
Established Markets (Unit: €)	€82M	+34 (+70%)	✓ Anticipate obtaining reimbursement in large markets such as Germany, France, Italy and Spain
Japan	9.9	+1.5 (+18%)	✓ Expect continued growth within the current indication
International Markets	0.9	+0.8 (+887%)	✓ Expect sales contribution from the increase of launched countries and reimbursement start

* Aligning the exchange rate to FY2023 forecast exchange rate, 1L: First Line, mUC: Metastatic urothelial cancer
Established Markets: Europe, Canada, Greater China: China, Hong Kong, Taiwan,
International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc.

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BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY2021 end	FY2022 end
Total assets	2,332.4	2,456.5
Cash and cash equivalents	316.0	376.8
Total equity attributable to owners of the parent	1,460.3	1,508.0
Equity ratio (%)	62.6%	61.4%

(billion yen)	FY2021	FY2022
Cash flows from operating activities	257.4	327.8
Cash flows from investing activities	-62.4	-84.5
Free cash flows	195.0	243.3
Cash flows from financing activities	-216.3	-195.6
Increase/decrease in short-term borrowings and CP	-30.0	-15.0
Proceeds from issuance of bonds and long-term borrowings	-	50.0
Redemption of bonds and repayments of long-term borrowings	-30.0	-50.0
Acquisition of treasury shares	-50.7	-60.6
Dividends paid	-85.2	-100.4

Balance of bonds (Incl. CP) and borrowings：125.0 billion yen

CP: Commercial Paper

CAPITAL ALLOCATION

1. Top priority is investment for business growth

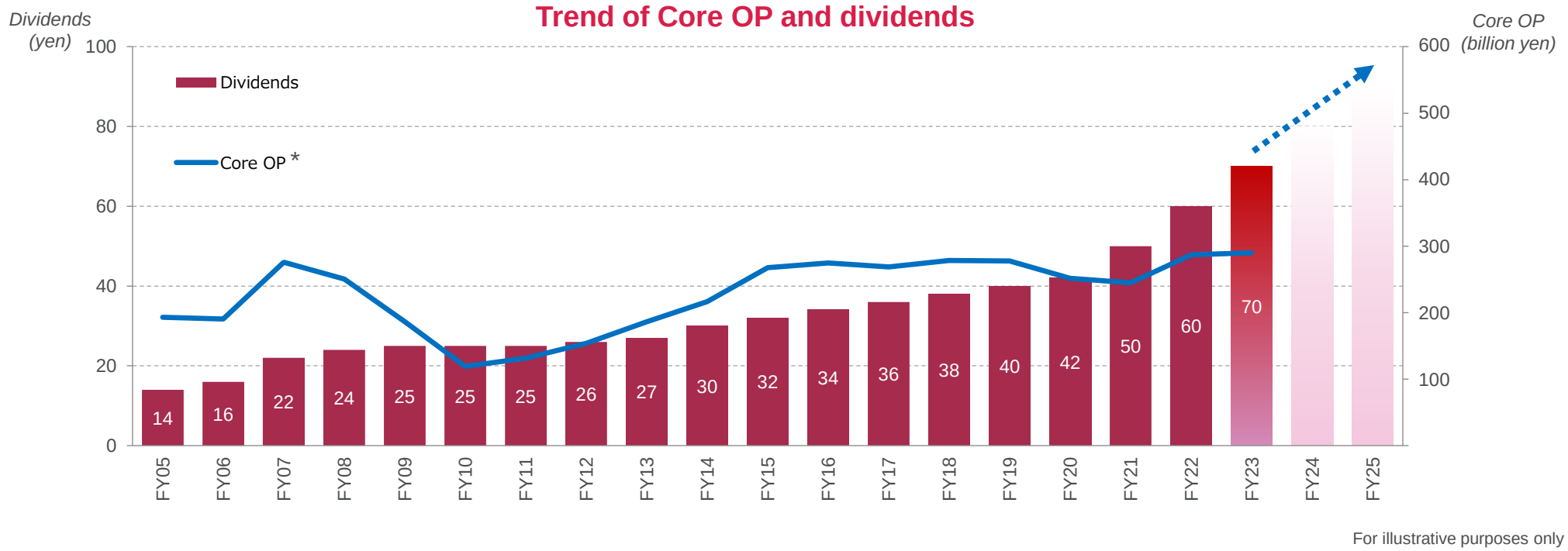
2. Raise dividend level aligned with profit / cashflow plan and actual performance throughout CSP2021 period

3. Flexibly execute share buyback by excess cash

Acquisition of own shares announced in Feb. 2023

- From Feb 7 to Mar 15, 2023
- 26.18 million shares
- 50.0 billion yen

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
- ASP0598
- ASP8062

Phase 2

- enfortumab vedotin (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- fezolinetant (VMS due to menopause: Japan)
- resamirigene bilparvovec /AT132 (XLMTM)
- bocidelpar/ASP0367 (Primary mitochondrial myopathies)
- isavuconazole (Pediatric use: US)

Phase 3

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

Submitted/Filed

- enfortumab vedotin (mUC pretreated: China)
- fezolinetant (VMS due to menopause: US, Europe)
- peficitinib (Rheumatoid arthritis: China)

XTANDI and Strategic products

Projects with Focus Area approach

Others

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

NMIBC: Non-muscle-invasive bladder cancer, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, XLMTM: X-linked myotubular myopathy, 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

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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
			enfortumab vedotin Locally advanced or metastatic urothelial cancer who received prior treatment with a PD-1/L1 inhibitor and platinum-based chemotherapy: China	**enfortumab vedotin** Locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy: US

Discontinuation

ASP9801: Cancer (Phase 1)
ASP7517: Acute myeloid leukemia and myelodysplastic syndrome (Phase 2), solid tumor (Phase 1)
ASP0739: Cancer (Phase 1)
ASP8731: Sickle cell disease (Phase 1)
FX-322: Sensorineural hearing loss (Phase 2)

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 & STRATEGIC PRODUCTS: STATUS UPDATE

(Red: Updates since the last financial results announcement)

Project / Product	Indication	Current status
enzalutamide / XTANDI	M1 CSPC	• **Europe: Label update to include the OS data approved in Mar 2023** • **China: Obtained topline results from Phase 3 China ARCHES study in Mar 2023**
	M0 CSPC	• **Obtained topline results from Phase 3 EMBARK study in Mar 2023. Results to be presented at AUA in Apr 2023**
enfortumab vedotin / PADCEV	Metastatic urothelial cancer	• **Previously untreated (first line):** Phase 3 study ongoing (enrollment completed). **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
	Other solid tumors	• Phase 2 study ongoing (enrollment completed)
gilteritinib / XOSPATA	Relapsed and refractory AML	• **China:** Phase 3 study stopped due to efficacy
	AML, post-HSCT maintenance	• **Obtained topline results from Phase 3 MORPHO study in Mar 2023**
	AML, newly diagnosed (HIC-eligible)	• Phase 3 study ongoing
	AML, newly diagnosed (HIC-ineligible)	• Phase 1 study ongoing
	AML, post-chemotherapy	• Obtained topline results from Phase 2 GOSSAMER study
zolbetuximab	Gastric & GEJ adenocarcinoma	• Obtained topline results from Phase 3 SPOTLIGHT and GLOW studies in Nov 2022 and Dec 2022, respectively. **Results from GLOW study presented at ASCO Plenary Series in Mar 2023. Results from SPOTLIGHT study published in The Lancet in Apr 2023**
	Pancreatic adenocarcinoma	• Phase 2 study ongoing
fezolinetant	VMS due to menopause	• **US & Europe**: NDA accepted in US in Aug 2022. MAA accepted in Europe in Sep 2022. Phase 3b DAYLIGHT study ongoing (enrollment completed). **Results from Phase 3 SKYLIGHT 1 study published in The Lancet in Mar 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**
AT132 (resamirigene bilparvovec)	X-linked myotubular myopathy	• ASPIRO study put on clinical hold by FDA due to a serious adverse event

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, OS: Overall survival, 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, VMS: Vasomotor symptoms, NDA: New Drug Application, MAA: Marketing Authorization Application, LSLV: Last subject last visit, FDA: Food and Drug Administration

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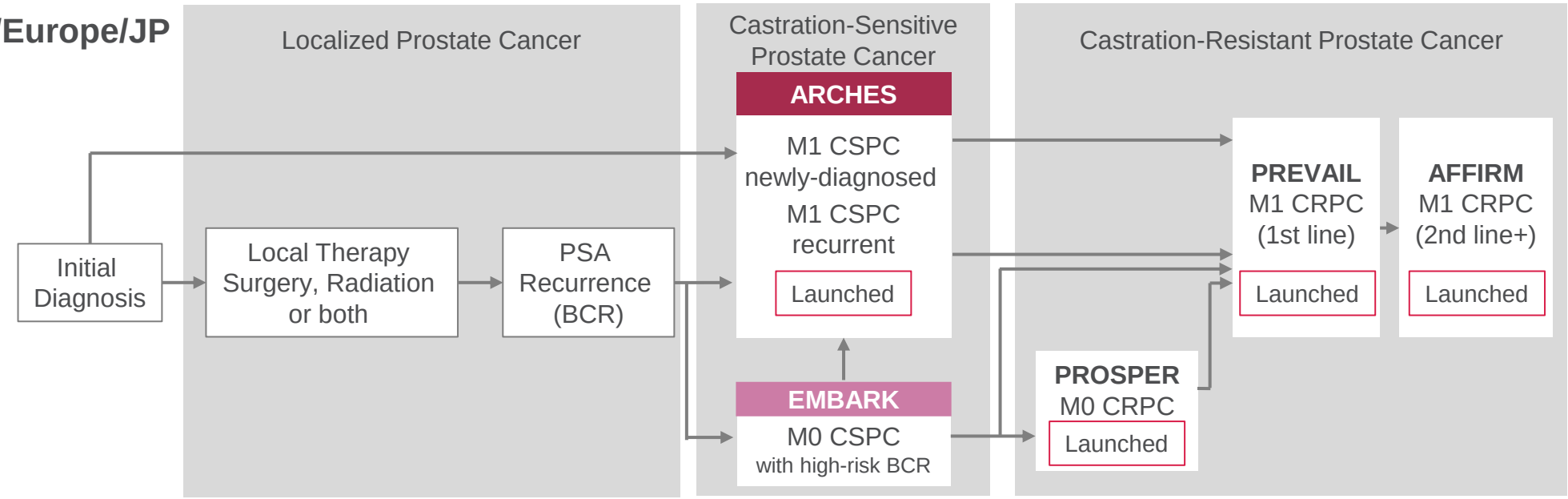
ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

(Red: Updates since the last financial results announcement)

US/Europe/JP



P3: ARCHES	NCT02677896	**M1 CSPC**	ENZA + ADT vs. placebo + ADT	n=1,150	Approved in US in Dec 2019, in JP in May 2020, and in Europe in Apr 2021 Label update to include the OS data approved in US in Sep 2022, CHMP positive opinion received in Mar 2022 and **approved in Europe in Mar 2023**
P3: EMBARK	NCT02319837	**M0 CSPC**	ENZA + ADT vs. placebo + ADT vs. ENZA mono	n=1,068	**Topline results obtained in Mar 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, OS: Overall survival, CHMP: Committee for Medicinal Products for Human Use, mono: Monotherapy

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

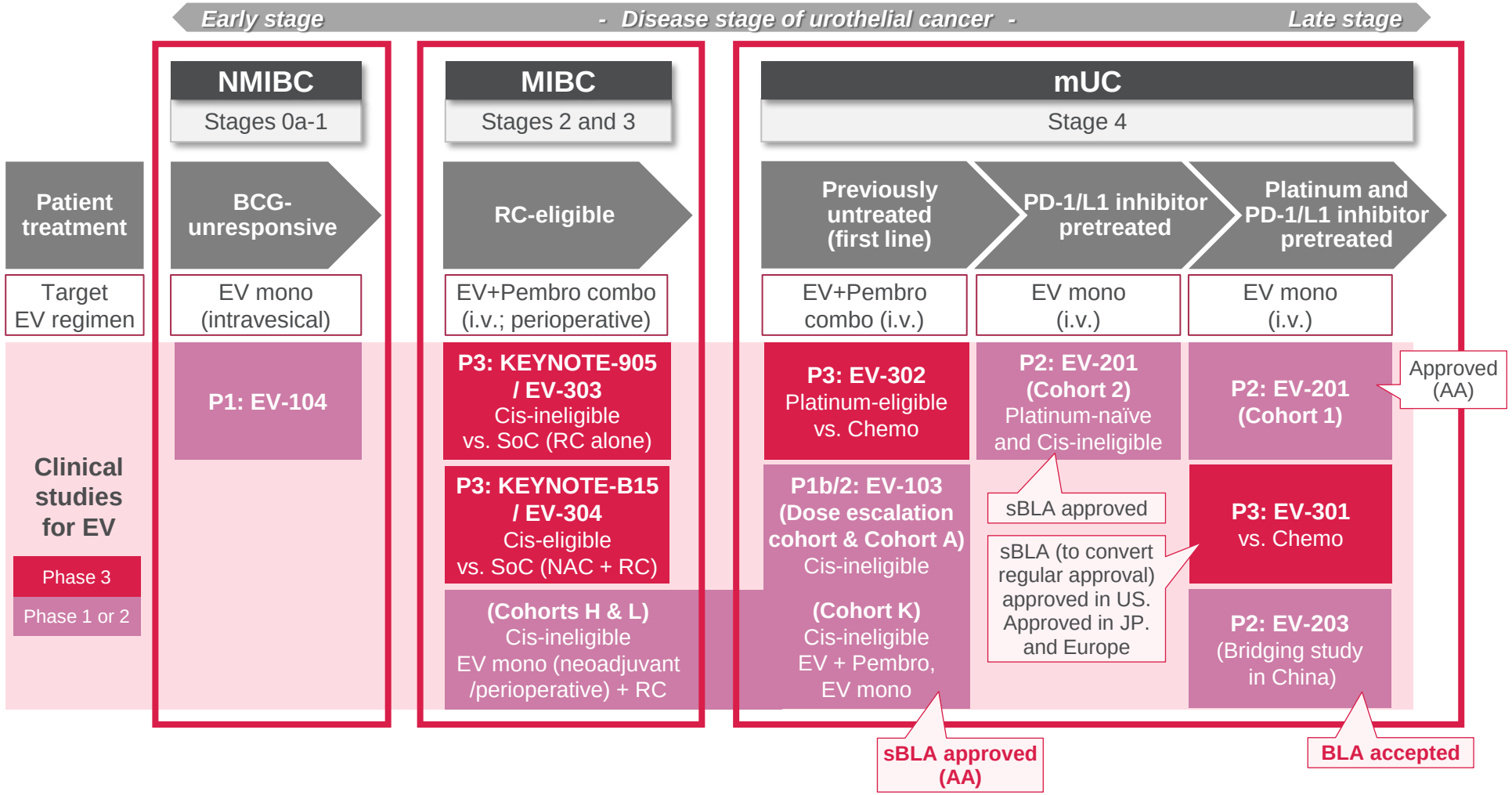
Disease stage	Early stage → Late stage					
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	**EMBARK**	**ARCHES**	**ENZAMET**	**PROSPER**	**PREVAIL**	**AFFIRM**
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary endpoint	✓ MFS	✓ 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	(Ongoing)	✓ 40.2 months	✓ 29.5 months	✓ 33.9 months	✓ 17.5 months	✓ 8.3 months

✓: Data obtained, *: Prespecified interim analysis

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

(Red: Updates since the last financial results announcement)



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 JP 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 (accelerated approval) 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	n=280	Enrollment completed Initial topline results obtained in Jun 2022

mUC: Metastatic urothelial cancer, mono: Monotherapy, Chemo: Chemotherapy, sBLA: Supplemental Biologics License Application, Pembro: Pembrolizumab, FSFT: First subject first treatment, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, RC: Radical cystectomy, 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

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	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)	(Ongoing)	✓ (26.1 mos **)	✓ (14.7 mos)	✓ (12.4 mos **)	✓ HR 0.70 * (12.9 mos vs.9.0 mos)
PFS	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	✓ (12.3 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	✓ 25.6 mos **	✓ 13.8 mos **	✓ 7.6 mos	✓ 7.4 mos vs. 8.1 mos *

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

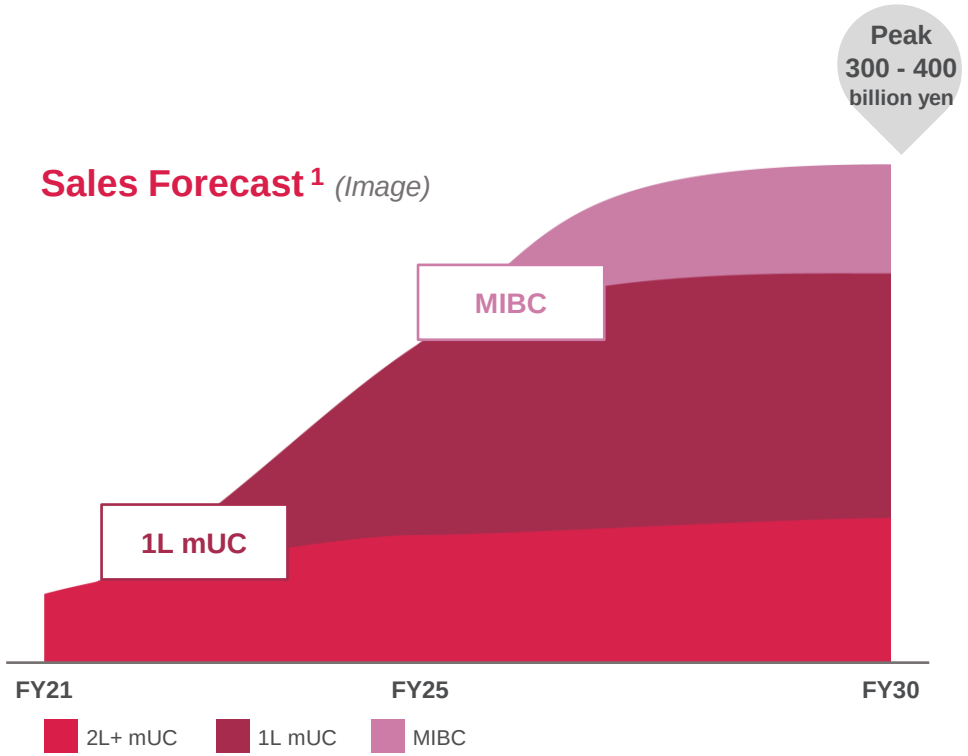
(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer, cis: Cisplatin, Pembro: Pembrolizumab, mono: Monotherapy, Chemo: Chemotherapy, pCR: Pathologic complete response, EFS: Event-free survival, ORR: Objective response rate, CR: Complete response, OS: Overall survival, HR: Hazard 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 (PADCEV 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 (PADCEV regimen)
NMIBC High-risk BCG-unresponsive	**EV-104** [Phase 1] (monotherapy, intravesical)
Other solid tumors	**EV-202** [Phase 2]* (monotherapy)

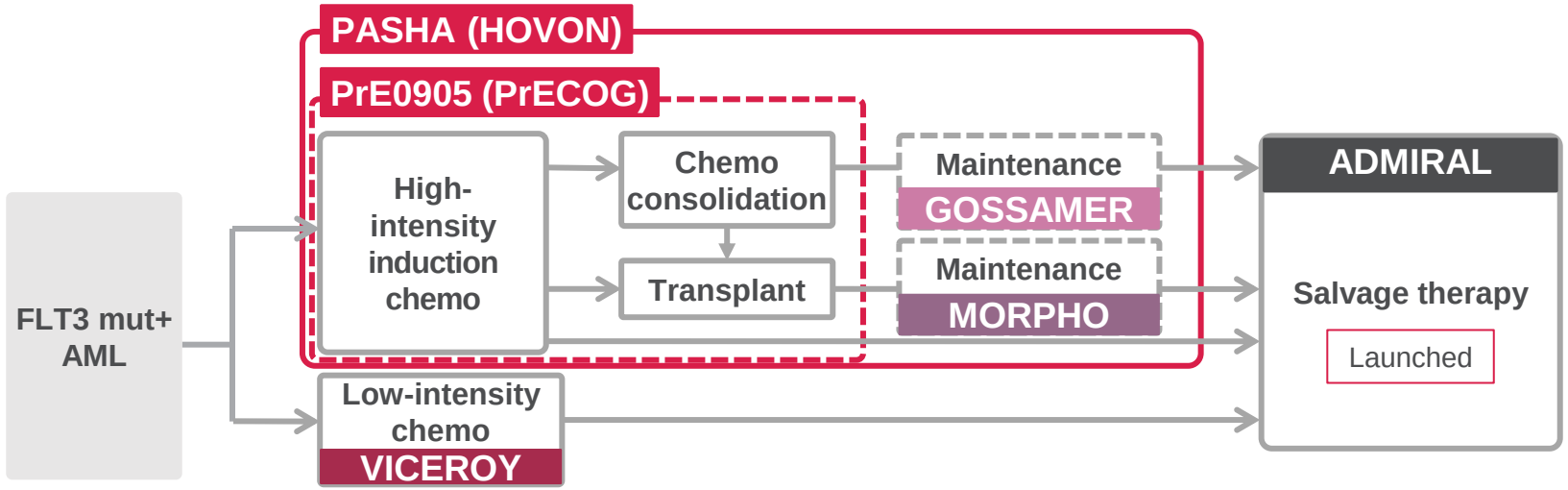
* HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric adenocarcinoma or esophageal adenocarcinoma or GEJ adenocarcinoma, Esophageal squamous cell carcinoma

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	FSFT: Dec 2019 (Sponsor: HOVON)
		P2: PrE0905 (PrECOG)	NCT03836209		n=179	FSFT: Dec 2019 (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	Topline results obtained in Nov 2022
		P3: GLOW	NCT03653507	First line, Combo with CAPOX, DB, vs. placebo	n=507	Topline results obtained in Dec 2022
		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, 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	NDA accepted in US in Aug 2022 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	Enrollment completed

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, NDA: New Drug Application, MAA: Marketing Authorization Application, LSLV: Last subject last visit

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AT132 (RESAMIRIGENE BILPARVOVEC): rAAV8-Des-hMTM1

Characteristics of AT132

- Delivers a functional copy of human MTM1 gene by AAV8 to transfect and express myotubularin in skeletal muscle cells
- Regulatory designations granted:
  - ✓ <US> RMAT, Rare Pediatric Disease, Fast Track, and Orphan Drug designations
  - ✓ <Europe> PRIME and Orphan Drug designations

X-linked myotubular myopathy (XLMTM)

- Rare neuromuscular disease with X-linked, loss of function mutations in MTM1 gene
  - ✓ Approximately 1 in 40,000 to 50,000 newborn males
  - ✓ Estimated 50% mortality by 18 months
  - ✓ Up to 24 hours of invasive mechanical ventilation, 60% of patients require tracheostomy
  - ✓ > 80% require gastrostomy tube placement
  - ✓ Motor milestones substantially delayed
  - ✓ No treatment available; supportive care only

ASPIRO (clinical study for registration in XLMTM patients)	NCT03199469	n=26	Study put on clinical hold by FDA due to a serious adverse event. Investigation on the event ongoing

(r)AAV: (recombinant) Adeno-associated virus, Des: Desmin promoter, hMTM1: Human myotubularin gene, RMAT: Regenerative Medicine Advanced Therapy, PRIME: PRIority MEdicines, FDA: Food and Drug Administration

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ON THE FOREFRONT OF HEALTHCARE CHANGE