Q3/FY2022 FINANCIAL RESULTS
ENDED DECEMBER 31, 2022

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Chief Financial Officer (CFO)
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February 6, 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 Q3/FY2022 Consolidated Financial Results

II Initiatives for Sustainable Growth

Q3/FY2022 FINANCIAL RESULTS: OVERVIEW

Revenue increased 17% YoY and was in line with full-year forecast revised in Q2

- Sales of XTANDI and Strategic products were on track globally
  - XTANDI: Sales in the US were in line with revised full-year forecast
  - Strategic products: Sales of PADCEV were in line with full-year forecast revised upward in Q2

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 6% YoY, in-line with full-year forecast
- Full basis was below full-year forecast due to foreign exchange loss caused by ruble depreciation and yen appreciation in Q3

Strategic products: PADCEV, XOSPATA, EVRENZO

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Q3/FY2022 FINANCIAL RESULTS

(billion yen)	Q3/FY21	Q3/FY22	Change	Change (%)	FY22 FCST*	Progress	FX impact
Revenue	**992.3**	**1,164.4**	**+172.1**	**+17.3%**	**1,529.0**	**76.2%**	+135.2 bil. yen
Cost of sales	194.1	226.1	+32.0	+16.5%			+13.3 bil. yen (Incl. the impact of elimination of unrealized profit remaining in Q3/FY21: +3.3 bil.yen)
% of revenue	19.6%	19.4%	-0.1 ppt				
SG&A expenses	406.4	471.0	+64.6	+15.9%	642.0	73.4%	+64.1 bil. yen
US XTANDI co-pro fee	108.7	138.2	+29.5	+27.2%	186.0	74.3%	
SG&A excl. the above	297.7	332.7	+35.0	+11.8%	456.0	73.0%	+38.4 bil. yen
R&D expenses	177.6	206.1	+28.4	+16.0%	278.0	74.1%	+23.0 bil. yen
Amortisation of intangible assets	20.2	29.2	+8.9	+44.1%			
Gain on divestiture of intangible assets	24.1	0.2	-23.9	-99.1%			
Core operating profit	**220.0**	**233.7**	**+13.6**	**+6.2%**	**290.0**	**80.6%**	+34.8 bil. yen
<Full basis>							**Ref. Other expenses** Impairment losses on intangible assets (AT702, AT751, AT753):23.2 bil. yen
Other income	4.2	2.5	-1.7	-40.2%			
Other expenses	54.9	54.9	+0.0	+0.0%			fezolinetant increased fair value of contingent consideration:13.4 bil. yen
Operating profit	**169.4**	**181.3**	**+11.9**	**+7.0%**	**269.0**	**67.4%**	Net foreign exchange losses:6.7 bil. yen (Net foreign exchange gains as of Q2：13.9 bil. yen)
Profit before tax	167.4	180.2	+12.8	+7.7%	267.0	67.5%	
Profit	**132.5**	**144.8**	**+12.3**	**+9.3%**	**208.0**	**69.6%**	Xyphos increased fair value of contingent consideration:4.0 bil. yen

*Announced in Oct 2022

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Q3/FY2022 FINANCIAL RESULTS & OUTLOOK: XTANDI

In line with full-year forecast revised in Q2, expect to achieve the full-year forecast of 670 billion yen

(billion yen)	Q3/FY2022 Act	YoY	FY2022 FCST*	Progress	
Xtandi (enzalutamide)	**511.9**	**+100.3 (+24%)** Excl. FX impact +32.5 (+8%)	**670.0** (YoY +25%)	**76%**	✓ Global sales are in line with the full-year forecast revised in Q2 ✓ Expect to meet the full-year forecast in all regions ✓ Near double digit growth even excluding FX impact, expect to achieve the full-year forecast in a global basis
US (Unit: $)	$1,972M	+30 (+2%)	$2,618M (+6%)	75%	✓ Performance in line with full-year forecast revised downward in Q2, Market conditions remains challenging • Levels of PAP ratio and generic competitor share continues to be high • New patient starts have not returned to pre COVID-19 levels ✓ TLR expected in Q4 for the future growth driver M0 CSPC indication (EMBARK), Expect to drive the growth trend after approval
Established Markets (Unit: €)	€1,067M	+101 (+11%)	€1,403M (+10%)	76%	✓ Performance in line with full-year forecast revised significantly upward in Q2 ✓ M1 CSPC continues to grow, especially in Germany, Italy, and Canada, contributing to strong demand increase (YoY +22%)
Japan	42.3	+5.8 (+16%)	55.4 (+17%)	76%	✓ Performance in line with full-year forecast revised upward in Q2 ✓ Market share expanded in all approved indications, maintaining No.1 share
Greater China	9.8	+4.3 (+79%)	12.3 (+56%)	80%	✓ Performance looks strong through Q3 due to shipment timing
International Markets	40.6	+12.9 (+47%)	48.0 (+34%)	85%	✓ Performance looks strong due to FX impact, actual business growth on track ✓ Expect to meet the full-year forecast excluding FX impact

* Revised in Oct 2022, FCST: Full-year forecast, PAP: Patient Assistance Program, TLR: Topline results, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive 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. (Commercial segment of Australia was changed from Established Markets to International Markets in Q3/FY2022. Disclosed numbers reflect this change)

Q3/FY2022 FINANCIAL RESULTS & OUTLOOK: STRATEGIC PRODUCTS

PADCEV and XOSPATA showed solid growth, expect to achieve the full-year forecast

(billion yen)	Q3/FY2022 Act	YoY	FY2022 FCST*	Progress	
PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	**33.1**	**+18.5 (+127%)** (Excl. FX impact +13.9 (+94%))	**45.4** (YoY +109%)	**73%**	✓ Global sales are in line with the full-year forecast revised upward in Q2 ✓ Strong performance in Europe is expected to offset the slightly underachieving performance of US, resulting to expectations to achieve the full-year forecast ✓ Expect significant growth after the anticipated approval of 1L mUC indication
US (Unit: $)	$161M	+35 (+28%)	$230M (+32%)	70%	✓ Revenue from clinical trial orders below expectations, actual demand in line with expectations ✓ Despite steady growth, anticipate to land slightly behind full-year forecast
Established Markets (Unit: €)	€33M	+33	€40M	83%	✓ Performance exceeding against full-year forecast revised upward in Q2, Market penetration exceeding expectations, led by Germany ✓ Launched in 20 countries and reimbursement started in 5 countries
Japan	6.3	+5.8	8.3 (+372%)	76%	✓ Progress in line with full-year forecast revised significantly upward in Q2 ✓ New patient start continues to show strong trend, market share expanding steadily
XOSPATA gilteritinib 40mg tablets	**36.3**	**+10.6 (+41%)** (Excl. FX impact +5.6 (+22%))	**45.8** (+34%)	**79%**	✓ Performance exceeding revised full-year forecast due to inventory burn ✓ Actual demand in line with expectations, expect to meet the full-year forecast
Evrenzo roxadustat	**2.4**	**+0.3 (+15%)**	**5.0** (+91%)	**48%**	✓ Performance below expectations even against downwardly revised full-year forecast ✓ Although launch and reimbursement are progressing in Europe, it is slower than expected. Obtained reimbursement in France (December), expect to obtain in Italy and Spain in the near future

* Revised in Oct 2022, FCST: Full-year forecast, 1L: First Line, mUC: Metastatic urothelial cancer
Established Markets: Europe, Canada (Commercial segment of Australia was changed from Established Markets to International Markets in Q3/FY2022. Disclosed numbers reflect this change)

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Q3/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 progress against FCST, for major cost items

Cost Items	YoY change	Ratio to Revenue	Progress against FCST	
Cost of sales	+16.5%	19.4% (-0.1ppt YoY)	-	✓ Cost of sales ratio was as expected
SG&A expenses **excl. US XTANDI co-pro fee**	+11.8% (-1.1% excl. FX impact)	28.6% (-1.4ppt YoY)	73.0%	✓ Optimization of commercial-related personnel globally (YoY approx. -8.0 bil. yen) ✓ Reduction of mature products-related costs (Approx. -6.0 bil. yen) ✓ Investment for new product launch readiness (Approx. +8.0 bil. yen) ✓ Cost reduction progressed as expected, actively making necessary investments ✓ As a result, SG&A expenses were in line with full-year forecast
R&D expenses	+16.0% (+3.1% excl. FX impact)	17.7% (-0.2ppt YoY)	74.1%	✓ Booked one-time expense for using PRV in Q1 for the application of fezolinetant (13.8 bil. yen) ✓ In line with full-year forecast, including the expense above

Full basis: Booked net foreign exchange losses of 6.7 bil. yen as "Other expenses" (Net foreign exchange gains as of Q2：13.9 bil. yen)
Major factors: Impact of RUB depreciation against EUR (Approx. 10.0 bil. yen), impact of JPY appreciation against USD (Approx. 9.0 bil. yen), etc.

PRV: Priority Review Voucher, RUB: Russian ruble

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OUTLOOK FOR FY2022

- Core basis: Revenue and Core OP are expected to be in line with full-year forecast
  Full-year forecast remain unchanged
  - ➢ Revenue: XTANDI and Strategic products are expected to be in line with full-year forecast
- Full basis: Downward revision
  - ➢ “Other expenses” booked in Q3
    - Net foreign exchange losses (6.7 billion yen) (Net foreign exchange gains as of Q2：13.9 billion yen)
    - Fair value increase of contingent consideration due to review of development plans for Xyphos-derived program (4.0 billion yen)
  - ➢ zolbetuximab met its primary endpoints in Phase 3 studies and planning to make decisions for regulatory submission globally. As a result, recognition of fair value increase of contingent consideration as “Other expenses” is expected in Q4 (over 40.0 billion yen), and full basis profit was revised downward

（billion yen）	FY22 FCST （announced in Oct 2022）	FY22 Latest FCST （announced in Feb 2023）	Change
Operating profit	269.0	195.0	-74.0
Profit	208.0	150.0	-58.0

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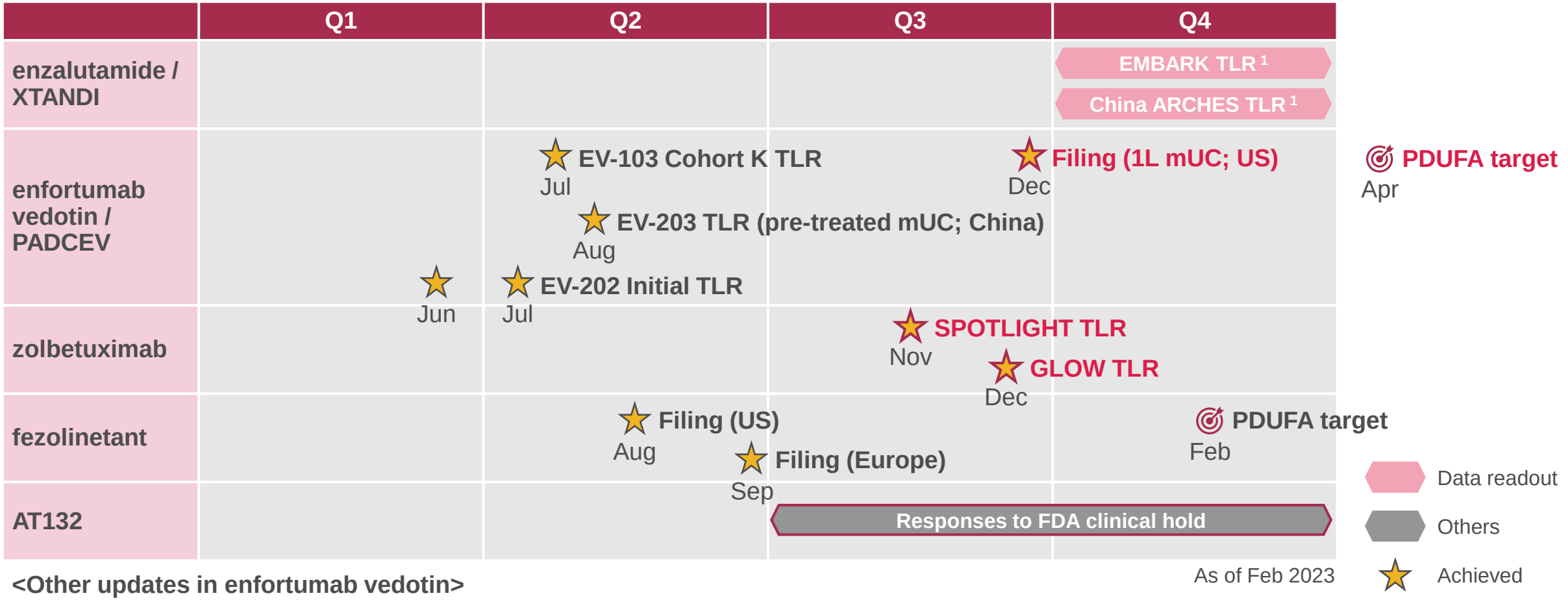
XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2022



<Other updates in enfortumab vedotin>

- EV-302 (1L mUC): Enrollment completed in Nov 2022, TLR[1] expected in 2023
- EV-202 (other solid tumors): Enrollment completed in Nov 2022, initial data expected to be disclosed in 1H 2023

1. The timeline of TLR is subject to shift due to its event-driven nature.
TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer, PDUFA: Prescription Drug User Fee Act, FDA: Food and Drug Administration

ZOLBETUXIMAB: LATEST STATUS

Achieved primary endpoints in two Phase 3 studies, aiming for global launch

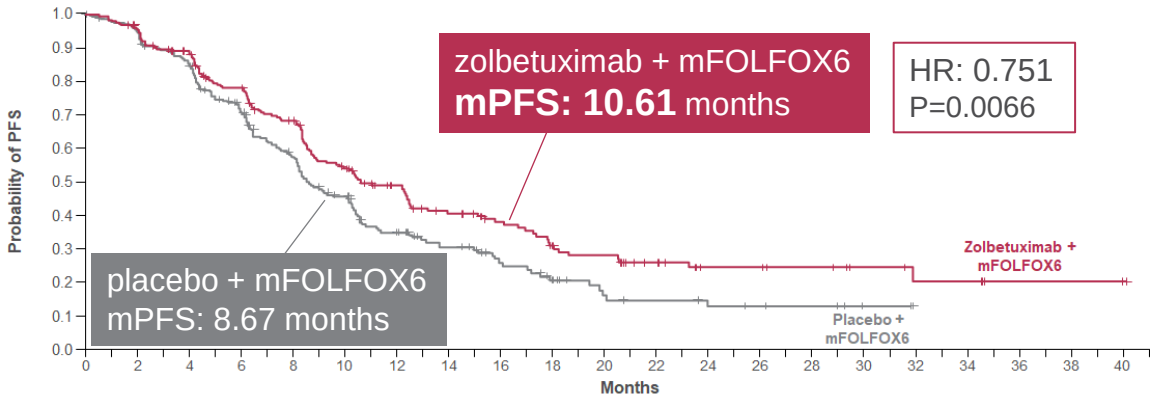
Clinical studies

- Topline results obtained in two Phase 3 studies
  - SPOTLIGHT: combo with mFOLFOX6 vs. placebo
  - GLOW: combo with CAPOX vs. placebo
- Met primary endpoint of PFS and key secondary endpoint of OS
- SPOTLIGHT study results presented at ASCO GI Cancers Symposium
  - Median OS longer than 18 months in zolbetuximab + mFOLFOX6

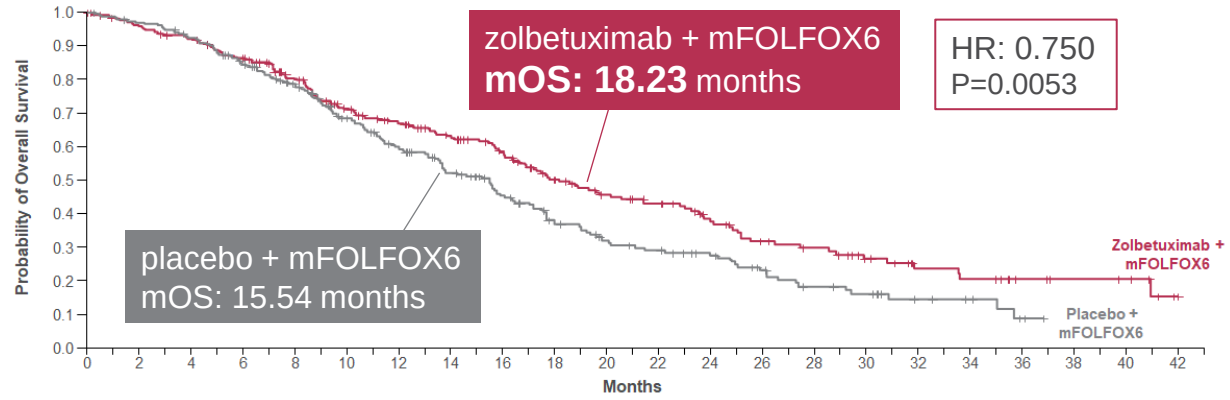
Activities toward launch

- Regulatory submission globally based on both studies
  - Target of first BLA submission: 1H FY2023
- Education and awareness activities for Claudin 18.2 ongoing
- Companion diagnostic to be marketed by Ventana Medical Systems/Roche

<Progression-free survival>



<Overall survival>



mFOLFOX6: 5-FU, leucovorin and oxaliplatin, CAPOX: Capecitabine and oxaliplatin, (m)PFS: (Median) Progression-free survival, (m)OS: (Median) Overall survival, ASCO GI Cancers Symposium: American Society of Clinical Oncology Gastrointestinal Cancers Symposium, BLA: Biologics License Application, HR: Hazard ratio

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PROGRESS IN FOCUS AREA APPROACH (1/3): CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

(Red: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology [1]	Project	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	**Clinical hold on FORTIS study lifted by FDA in Jan 2023**
	Gene regulation (AAV)		
Immuno-Oncology	Checkpoint	ASP1570	Phase 1 study ongoing
	Artificial adjuvant vector cell (aAVC)	ASP7517	Phase 2 study in R/R AML and MDS ongoing Phase 1 study in advanced solid tumors ongoing
		ASP0739	Phase 1 study ongoing
	Oncolytic virus (intratumoral)	ASP9801	Phase 1 study ongoing
	Oncolytic virus (systemic)		
	Bispecific immune cell engager	ASP2138	Phase 1 study ongoing
		ASP2074	Phase 1 study to start in Q4 FY2022
		ASP1002	**Phase 1 study to start in Q4 FY2022**
	Cancer cell therapy (UDC)		
Blindness & Regeneration	Cell replacement	ASP7317	Screening and enrollment in Phase 1b study restarted in Aug 2022
	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
	Mitochondrial stress	ASP8731	Phase 1 study ongoing
	Mitochondrial transfer		
Targeted Protein Degradation	Protein degradation	ASP3082	Phase 1 study ongoing
Primary Focus Candidate	Immune modulating/regulatory cells		
	Tissue-specific immune regulation		

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

1. Not exhaustively listed.
AAV: Adeno-associated virus, UDC: Universal donor cell, FDA: Food and Drug Administration, R/R: Relapsed and refractory, AML: Acute myeloid leukemia, MDS: Myelodysplastic syndrome, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

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PROGRESS IN FOCUS AREA APPROACH (2/3): CURRENT STATUS OF AT845 AND AT132

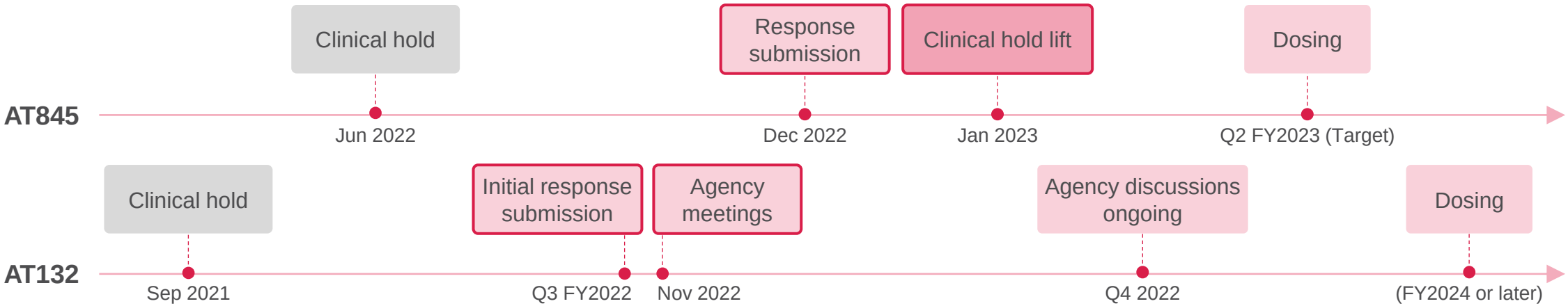
Activities ongoing toward resumption of clinical studies

AT845 (Target disease: Pompe disease)

- Clinical hold lifted by FDA in Jan 2023
  - ➢ Modified protocol
    - Exclusion of participants with history of or risk factors for neuropathy
    - Additional safety monitoring
- Target for resumption of dosing: Q2 FY2023

AT132 (Target disease: XLMTM)

- Initial clinical hold responses submitted in Q3 FY2022
- Productive Agency interactions
  - ➢ FDA Type B meeting (Nov 2022)
  - ➢ EMA PRIME meeting (Nov 2022)
- Ongoing Agency discussions scheduled in Q4 FY2022
- Plan will be updated based on Agency feedback



FDA: Food and Drug Administration, XLMTM: X-linked myotubular myopathy, EMA: European Medicines Agency, PRIME: PRIority MEdicines

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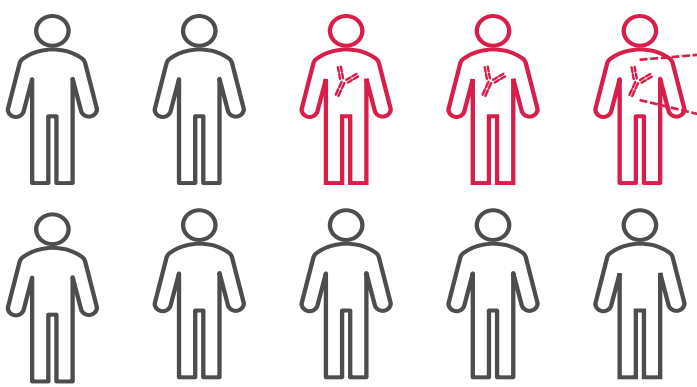
PROGRESS IN FOCUS AREA APPROACH (3/3): COLLABORATION WITH SELECTA BIOSCIENCES

Partnering for potential to bring AT845 to more patients

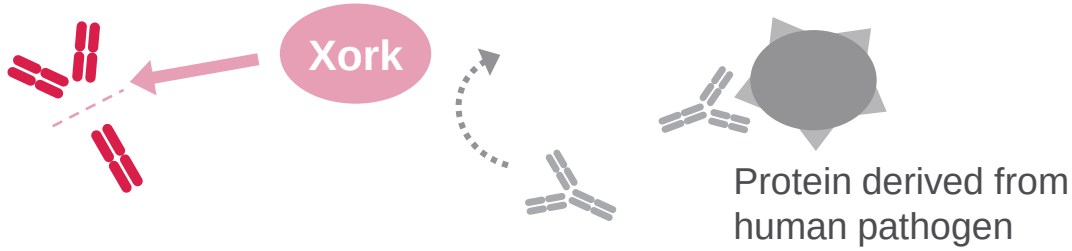
Pre-existing immunity (PEI)

- Patients with PEI have IgG antibodies against AAV and are not eligible for AAV-based gene therapy
- Up to 30% of LOPD patients may have PEI toward AAV8 [1]



IdeXork (Xork)

- Next generation IgG protease candidate which cleaves human IgG specifically and efficiently
- Derived from a non-human pathogen: low cross-reactivity to pre-existing antibodies in human serum which attenuate the efficacy



- Astellas would have the sole and exclusive right to commercialize Xork for use with investigational AT845 in Pompe disease

Selecta Biosciences

1. Hum Gene Ther Methods 24:59 (2013)
IgG: immunoglobulin G, AAV: Adeno-associated virus, LOPD: Late-onset Pompe disease

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PROGRESS TOWARD ACHIEVING CSP2021

Revenue, Pipeline Value

1 XTANDI and Strategic products:
≥ ¥1.2T in FY2025

- ✓ Sales in line with revised full-year forecast
- ✓ PADCEV: sBLA accepted for 1L mUC in the US
- ✓ zolbetuximab: Obtained topline results in two Phase 3 studies

2 Post-PoC projects from Primary Focuses

3 Multiple technology platforms

4 Focus Area projects:
≥ ¥0.5T in FY2030

- ✓ AT845: Clinical hold lifted
- ✓ Gene Therapy: Collaboration with Selecta
- ✓ ASP1002: Phase 1 entry

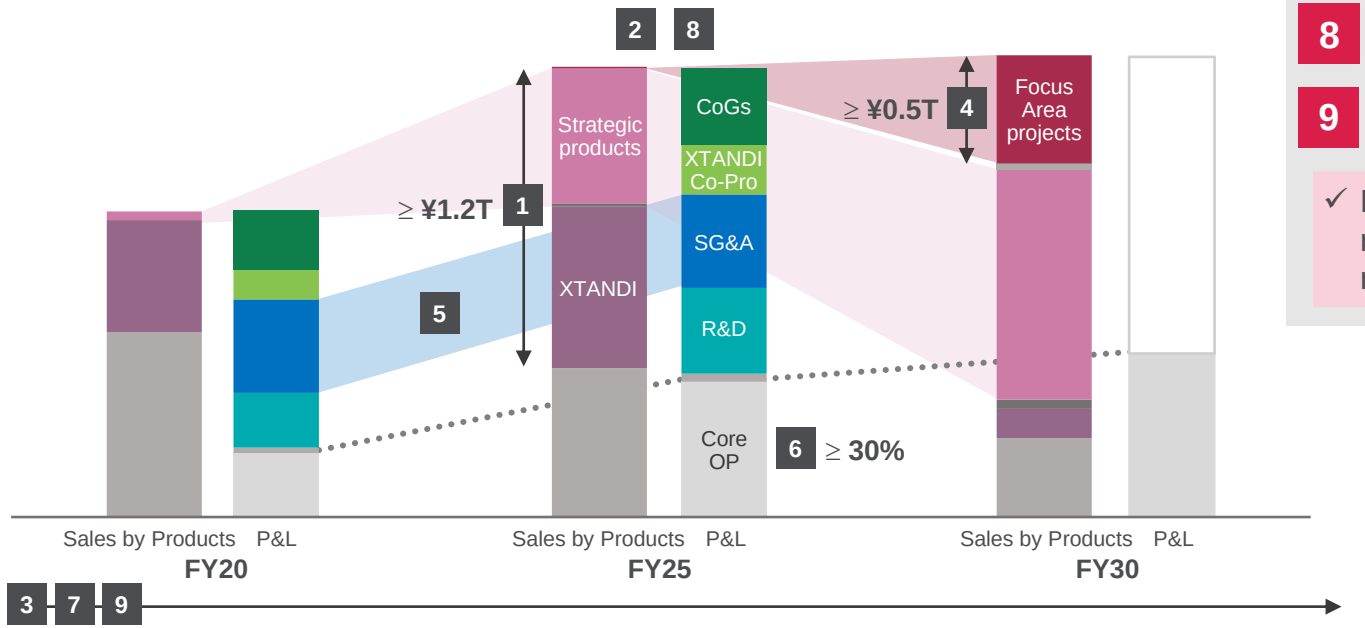
Core OP

5 Flat SG&A in absolute terms

6 Sufficient R&D investments
Core OP margin of ≥ 30% in FY2025

7 Steady increase in dividends

- ✓ SG&A expenses controlled in line with full-year forecast, decreased YoY when excluding FX impact



Future growth

8 Rx+: Breakeven by FY2025

9 Sustainability

- ✓ Received SBTi approval for revised GHG emissions reduction targets

Strategic products: PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132
CSP: Corporate Strategic Plan, sBLA: Supplemental Biologics License Application, 1L: First line, mUC: Metastatic urothelial cancer, SBTi: Science Based Targets initiative, GHG: Greenhouse gas

Sustainability Meeting

- February 17th 2023, 14:00-15:30 (JST)

fezolinetant Meeting

- March (planned)

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	Q3/FY21	Q3/FY22	Change (%)
Revenue	**326.1**	**325.5**	**340.6**	**303.9**	**381.8**	**380.4**	**402.2**	**992.3**	**1,164.4**	**+17.3%**
Cost of sales	61.0	63.2	66.6	54.5	76.1	75.5	74.4	190.8	226.1	+18.5%
% of revenue	18.7%	19.4%	19.6%	17.9%	19.9%	19.9%	18.5%	19.2%	19.4%	+0.2ppt
SG&A expenses	137.1	133.4	135.9	142.4	153.4	154.6	163.0	406.4	471.0	+15.9%
US XTANDI co-pro fee	34.5	36.6	37.6	30.6	43.1	46.5	48.6	108.7	138.2	+27.2%
SG&A excl. the above	102.6	96.8	98.3	111.8	110.3	108.0	114.4	297.7	332.8	+11.8%
R&D expenses	58.3	60.7	58.6	68.4	74.0	65.2	66.9	177.6	206.1	+16.0%
Amortisation of intangible assets	6.0	6.4	7.9	8.0	10.7	9.2	9.2	20.2	29.2	+44.1%
Gain on divestiture of intangible assets	-	-	24.1	0.1	0.2	0.0	0.0	24.1	0.2	-99.1%
Core operating profit	**64.1**	**61.8**	**97.5**	**29.2**	**68.1**	**77.3**	**88.3**	**223.4**	**233.7**	**+4.6%**
(Ref) Impact on Core OP*1	**+1.2**	**-0.7**	**+2.8**	**+4.5**	**+12.8*2**	**-12.8**	**-**	**+3.3**	**-**	**-**

*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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Q3/FY2022: REVENUE BY REGION

(billion yen)	Q3/FY21	Q3/FY22	Change (%)
Japan	203.2	204.5	+0.6%
United States	407.9	501.1	+22.8%
Established Markets	233.0	271.1	+16.4%
Greater China	50.3	65.2	+29.4%
International Markets	89.2	105.2	+18.0%

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 Q3/FY2022. Disclosed numbers reflect this change

Q3/FY2022: SALES OF MAIN PRODUCTS

(billion yen)	Q3/FY21	Q3/FY22	Change	CER growth	FY22 FCST*
XTANDI	411.6	511.9	+24.4%	+7.9%	670.0
PADCEV	14.6	33.1	+126.9%	+94.4%	45.4
XOSPATA	25.7	36.3	+41.1%	+21.7%	45.8
EVRENZO	2.1	2.4	+15.0%	+13.3%	5.0
mirabegron	126.9	141.0	+11.1%	-2.8%	195.0
Prograf	141.1	151.6	+7.5%	-2.3%	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

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Q3/FY2022 ACTUAL: FX RATE

Average rate for the period

Currency	Q3/FY21	Q3/FY22	Change
USD	111 yen	137 yen	-25 yen
EUR	131 yen	141 yen	-10 yen

Change in current rate from previous fiscal year end

Currency	Q3/FY21	Q3/FY22
USD	-4 yen	-9 yen
EUR	-1 yen	-6 yen

<Impact of exchange rate on financial results>

- 135.2 billion yen increase in revenue, 34.8 billion yen increase in core OP

FY2022 FCST: FX RATE & FX SENSITIVITY

Exchange rate Average for the period	FY2022 Initial FCST	FY2022 Revised FCST
USD	120 yen	137 yen
EUR	135 yen	139 yen

Forecast rates from Q3 onwards: 140 USD/yen, 140 EUR/yen

Estimated FX sensitivity (Q3 onwards) of FY2022 revised forecasts by 1 yen depreciation

Currency	Average rate 1 yen lower than assumption	
	Revenue	Core OP
USD	Approx. +3.1 bil. yen	Approx. +0.5 bil. yen
EUR	Approx. +1.4 bil. yen	Approx. +0.6 bil. yen

BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY21 end	FY22 Q3 end
Total assets	2,332.4	2,513.9
Cash and cash equivalents	316.0	381.8
Total equity attributable to owners of the parent	1,460.3	1,570.4
Equity ratio (%)	62.6%	62.5%

(billion yen)	Q3/FY21	Q3/FY22	FY21
Cash flows from operating activities	208.9	212.2	257.4
Cash flows from investing activities	-47.6	-61.8	-62.4
Free cash flows	161.3	150.4	195.0
Cash flows from financing activities	-141.3	-91.1	-216.3
Increase/decrease in short-term borrowings and CP	-40.0	-15.0	-30.0
Proceeds from issuance of bonds and long-term borrowings	-	50.0	-
Acquisition of treasury shares	-0.7	-10.6	-50.7
Dividends paid	-85.2	-100.4	-85.2

Balance of bonds (Incl. CP) and borrowings：175.0 billion yen

CP: Commercial Paper

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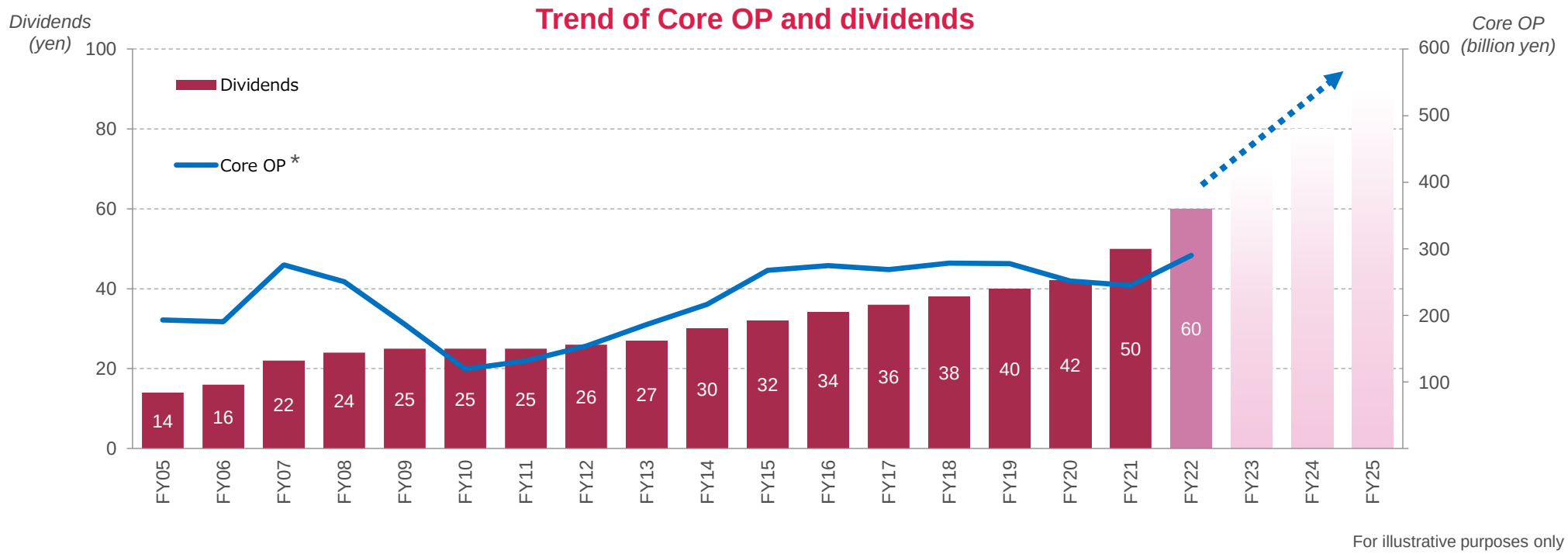
CAPITAL ALLOCATION

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)
- ASP9801
- ASP7517 (Solid tumors)
- ASP0739
- ASP1570
- ASP2138
- ASP2074
- ASP1002
- ASP7317
- bocidelpar/ASP0367 (Duchenne muscular dystrophy)
- ASP8731
- AT845
- ASP3082
- ASP0598
- ASP8062

Phase 2

- enfortumab vedotin (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- fezolinetant (VMS associated with menopause: Japan)
- resamirigene bilparvovec /AT132 (XLMTM)
- ASP7517 (AML and MDS)
- bocidelpar/ASP0367 (Primary mitochondrial myopathies)
- FX-322 (Sensorineural hearing loss)
- 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 associated with menopause: China)
- mirabegron (Pediatric use: Europe)

Submitted/Filed

- enfortumab vedotin (mUC previously untreated, Cis-ineligible: US)
- fezolinetant (VMS due to menopause: US, Europe)
- peficitinib (Rheumatoid arthritis: China)

XTANDI and Strategic products
(PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132)

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, MDS: Myelodysplastic syndrome, 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, Cis: Cisplatin

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PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since the Last Financial Results Announcement

ASP1002
Cancer

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

XTANDI & STRATEGIC PRODUCTS: STATUS UPDATE

(Red: Updates since the last financial results announcement)

Project / Product	Indication	Current status
enzalutamide / XTANDI	M1 CSPC	• **EU:** CHMP positive opinion received for label update to include the OS data in Mar 2022 • **China:** Phase 3 study ongoing (enrollment completed)
	M0 CSPC	• Phase 3 study ongoing (enrollment completed)
enfortumab vedotin / PADCEV	Metastatic urothelial cancer	• **Previously untreated (first line):** Phase 3 study ongoing **(enrollment completed)**. **sBLA accepted in US in Dec 2022** • **China:** Obtained topline results from Phase 2 bridging study in Aug 2022
	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	• Phase 3 study ongoing (enrollment completed)
	AML, newly diagnosed (HIC-eligible)	• Phase 3 study ongoing
	AML, newly diagnosed (HIC-ineligible)	• Phase 1 study under preparation to start in Q4 FY2022
	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 SPOTLIGHT study presented at ASCO GI in Jan 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) • **Asia:** LSLV in Phase 3 MOONLIGHT 1 study in Apr 2022. Obtained topline results from Phase 3 MOONLIGHT 3 study in Sep 2022 • **Japan: LSLV** in Phase 2b STARLIGHT **in Dec 2022**
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, CHMP: Committee for Medicinal Products for Human Use, OS: Overall survival, sBLA: Supplemental Biologics License Application, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, GEJ: Gastroesophageal junction, ASCO GI: American Society of Clinical Oncology Gastrointestinal Cancers Symposium, 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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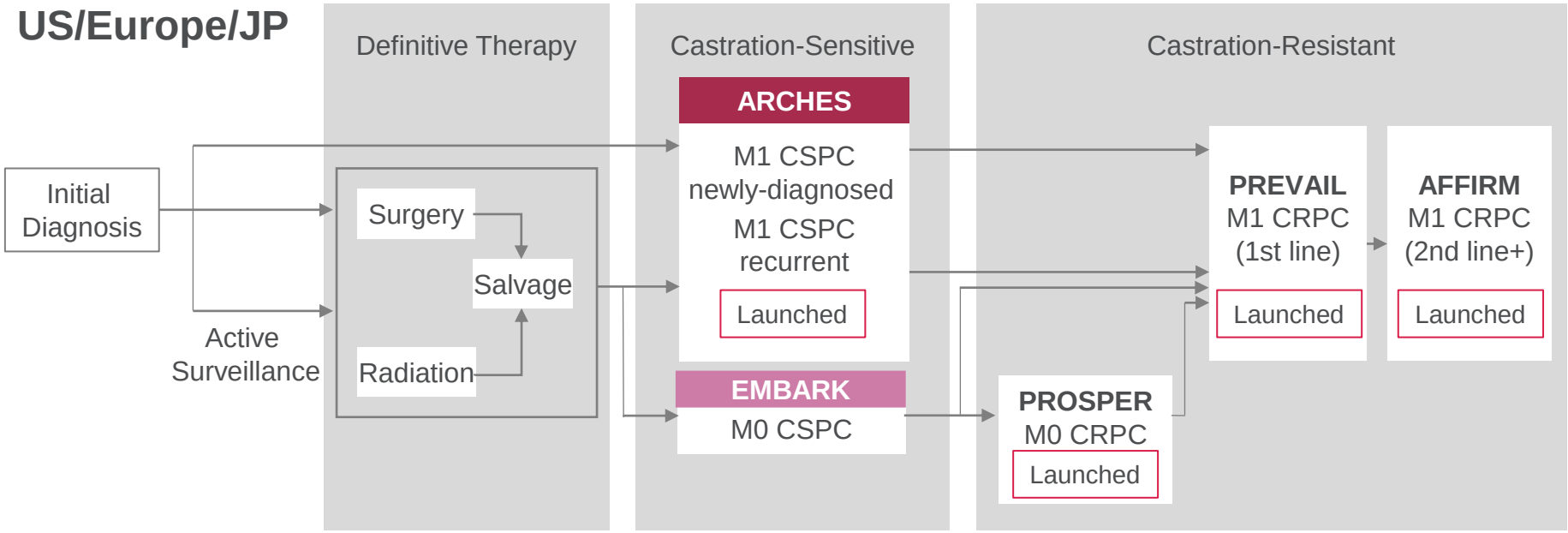
ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR



	P3: ARCHES	NCT02677896	**M1 CSPC**	Combo with ADT, vs. placebo	n=1,150	Approved in US in Dec 2019, in JP in May 2020, and in Europe in Apr 2021 Filed label update to include the OS data in US and Europe in Dec 2021; Approved in US in Sep 2022, CHMP positive opinion received in Mar 2022
	P3: EMBARK	NCT02319837	**M0 CSPC**	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

China

- **M1 CSPC:** Enrollment completed in Phase 3 China-ARCHES study (NCT04076059)

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy, OS: Overall survival, CHMP: Committee for Medicinal Products for Human Use

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

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

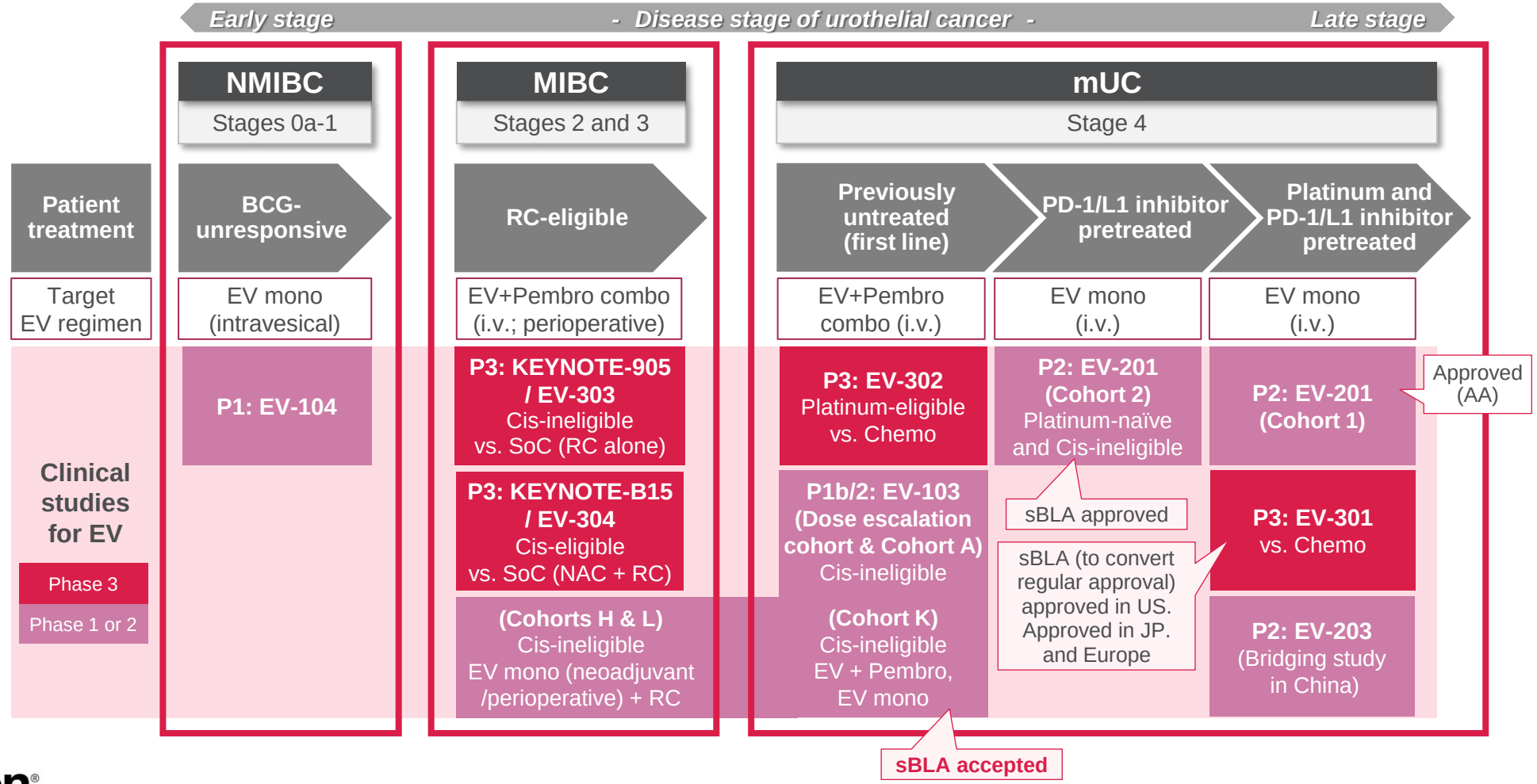
Disease stage	Early stage → Late stage					
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	**EMBARK**	**ARCHES**	**ENZAMET**	**PROSPER**	**PREVAIL**	**AFFIRM**
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary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



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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

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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=457	Cohort K and other cohorts: **sBLA accepted in US in Dec 2022** **Enrollment completed**
	P2: EV-203	NCT04995419	<Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono	n=40	Topline results obtained in Aug 2022
	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

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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

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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 *

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✔: 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

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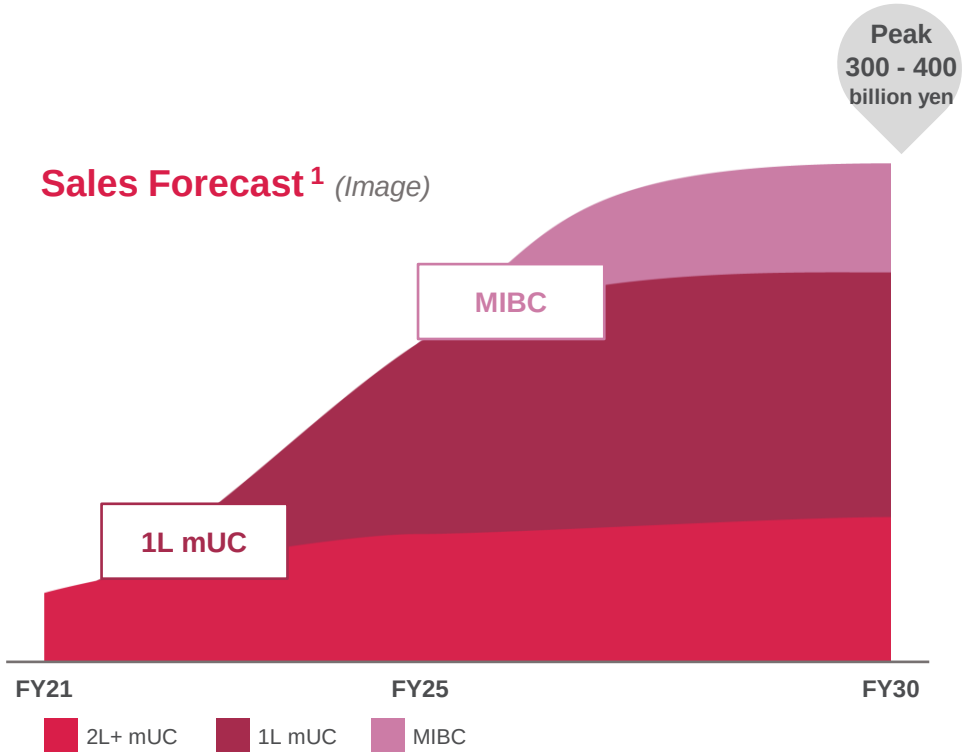
ENFORTUMAB VEDOTIN (EV) (4/4): FUTURE OUTLOOK

- *The most significant growth driver is 1L mUC indication, which is expected to account for more than half of total sales in the future*
- *Success in NMIBC and other solid tumors will provide further growth potential*

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 Filed** [AA in US]	**76,000** (incl. US, Cis-ineligible: **8,000**)
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

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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

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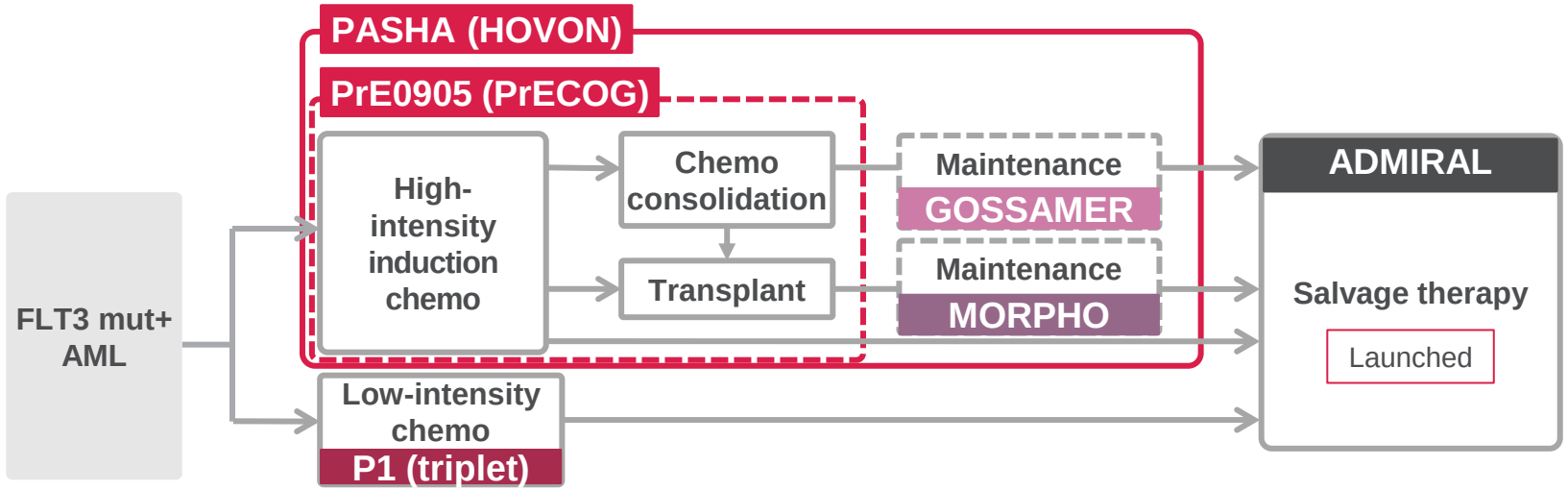
GILTERITINIB: FLT3 INHIBITOR



	Relapsed or refractory	**P3: ADMIRAL**	NCT02421939	Monotherapy vs. salvage chemo (2:1)	n=371	Launched in US, JP, and Europe
	Newly diagnosed (HIC-eligible)	**P3: PASHA (HOVON)**	NCT04027309	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=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	Enrollment completed 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	To start in Q4 FY2022

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

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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	**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) LSLV: Apr 2022
	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	**LSLV: Dec 2022**

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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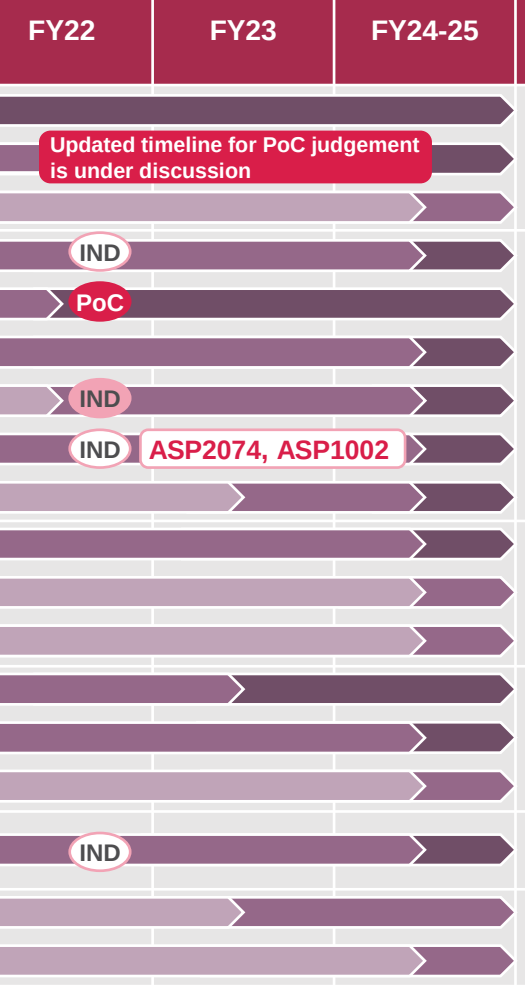
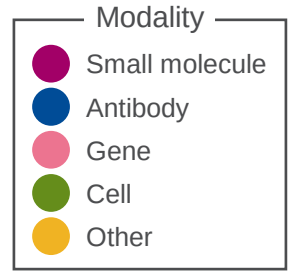
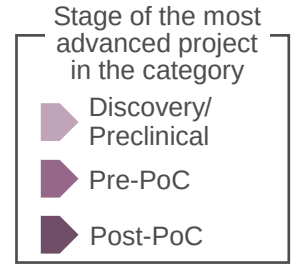
FOCUS AREA APPROACH:
CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS

Primary Focus	Biology/Modality/Technology [1]	Lead project	No. of projects aiming for PoC by end FY25 [2]
Genetic regulation	Gene replacement (AAV)	AT132	4
		AT845	
	Gene regulation (AAV)		
Immuno-Oncology	Checkpoint	ASP1570	12
	Artificial adjuvant vector cell (aAVC)	ASP7517	
	Oncolytic virus (intratumoral)	ASP9801	
	Oncolytic virus (systemic)		
	Bispecific immune cell engager	ASP2138	
	Cancer cell therapy (UDC)		
Blindness & Regeneration	Cell replacement	ASP7317	3
	Cell replacement (UDC)		
	Gene regulation (AAV)		
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	4
	Mitochondrial stress	ASP8731	
	Mitochondrial transfer		
Targeted protein degradation	Protein degradation	ASP3082	1
Primary Focus Candidates	Immune modulating/regulatory cells		-
	Tissue-specific immune regulation		
		Total	24







POC PoC judgement

IND Phase 1 entry of lead project

IND Phase 1 entry of follow-on project

1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Feb 2023)
PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell, IND: Investigational New Drug

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ON THE FOREFRONT OF HEALTHCARE CHANGE