Q1/FY2022 FINANCIAL RESULTS
ENDED JUNE 30, 2022

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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AGENDA

I Q1/FY2022 Consolidated Financial Results

II Initiatives for Sustainable Growth

Q1/FY2022 FINANCIAL RESULTS: FX IMPACT AND ONE-TIME FACTORS（FULL BASIS）

Affected the significant FX impact incl. elimination of unrealized profit due to the sharp depreciation of yen in Q1
Financial results were on track when excluding FX impact and one-time factors

(billion yen)	Q1/FY21	Q1/FY22	1. FX impact	Q1/FY22 (excl. 1)	2. One-time Factors	Q1/FY22 (excl. 1&2)
Revenue	**326.1**	**381.8**	**+35.5**	**346.3**		**346.3**
Cost of sales	62.2	88.9	+18.5*	70.4	XTANDI: Royalty payment adjustment for prior year (+1.8)	68.6
% of revenue	19.1%	23.3%		20.3%		19.8%
SG&A expenses	137.1	153.4	+16.7	136.7		136.7
US XTANDI co-pro fee	34.5	43.1	+6.7	36.4		36.4
SG&A excl. the above	102.6	110.3	+10.0	100.3		100.3
R&D expenses	58.3	74.0	+7.5	66.5	One-time expenses (+13.1)	53.4
Amort./Equity	5.7	10.4	+0.2	10.2		10.2
Gain on divestiture of intangible assets	-	0.2	-	0.2		0.2
Core OP	**62.8**	**55.3**	**-7.4**	**62.7**		**77.6**
Other income	0.4	16.3	+14.1	2.2		2.2
Other expenses	27.1	38.4	-	38.4	fezolinetant: Increased fair value of contingent consideration (+13.6)	24.8
Full OP	**36.1**	**33.1**	**+6.7**	**26.5**		**55.0**

No changes have been made to Full-year FCST as there are no items that are beyond expectations
Expect to have a positive FX impact for the full year

* Incl. FX impact on elimination of unrealized profit (+12.3)
Amort./Equity: Amortisation of intangible assets/ Share of profit (loss) of investments accounted for using equity method

Q1/FY2022 FINANCIAL RESULTS: OVERVIEW

Revenue increased 17% YoY and was on track when excluding FX impact

- Sales of XTANDI and Strategic products increased 26% YoY
- Cost of sales ratio increased YoY due to significant FX impact
- SG&A expenses were on track and decreased YoY when excluding FX impact
- R&D expenses were on track

Operating profit

- Core OP decreased YoY, same level as previous year when excluding FX impact, progress on track
- Full basis decreased YoY
  - Booked net foreign exchange gains as Other income (14.1 billion yen)
  - Booked impairment losses on intangible assets:
    Termination of research and development for AT702, AT751, AT753 (22.0 billion yen)
  - Booked fair value remeasurements on contingent consideration for fezolinetant US NDA submission as Other expenses (13.6 billion yen)

Strategic products: PADCEV, XOSPATA, EVRENZO
NDA: New Drug Application

Q1/FY2022 FINANCIAL RESULTS

(billion yen)	Q1/FY21	Q1/FY22	Change	Change (%)	FY22 Initial FCST	Progress	FX impact
Revenue	**326.1**	**381.8**	**+55.6**	**+17.1%**	**1,443.0**	**26.5%**	+35.5 bil. yen
Cost of sales	62.2	88.9	+26.6	+42.8%			+18.5 bil. yen*
% of revenue	19.1%	23.3%	+4.2 ppt				
SG&A expenses	137.1	153.4	+16.3	+11.9%	598.0	25.7%	+16.7 bil. yen
US XTANDI co-pro fee	34.5	43.1	+8.6	+25.1%			
SG&A excl. the above	102.6	110.3	+7.6	+7.4%	416.0	26.5%	+10.0 bil. yen
R&D expenses	58.3	74.0	+15.7	+26.9%	254.0	29.1%	+7.5 bil. yen
Amortisation of intangible assets	6.0	10.7	+4.8	+80.2%			
Gain on divestiture of intangible assets	-	0.2	+0.2	-			
Core operating profit	**62.8**	**55.3**	**-7.5**	**-12.0%**	**290.0**	**19.1%**	-7.4 bil. yen
<Full basis>							(Other income) Net foreign exchange gains: 14.1 bil. yen
Other income	0.4	16.3	+15.9	-			
Other expenses	27.1	38.4	+11.3	+41.7%			(Other expenses) Impairment losses on intangible assets (AT702,AT751,AT753): 22.0 bil. yen fezolinetant increased fair value of contingent consideration: 13.6 bil. yen
Operating profit	**36.1**	**33.1**	**-2.9**	**-8.2%**	**269.0**	**12.3%**	
Profit before tax	35.8	31.7	-4.2	-11.6%	267.0	11.9%	
Profit	**30.7**	**24.8**	**-5.9**	**-19.1%**	**208.0**	**11.9%**	

* Incl. FX impact on elimination of unrealized profit (+12.3 bil. yen)

Q1/FY2022 FINANCIAL RESULTS: XTANDI AND STRATEGIC PRODUCTS

Sales of XTANDI and Strategic products increased 26% YoY

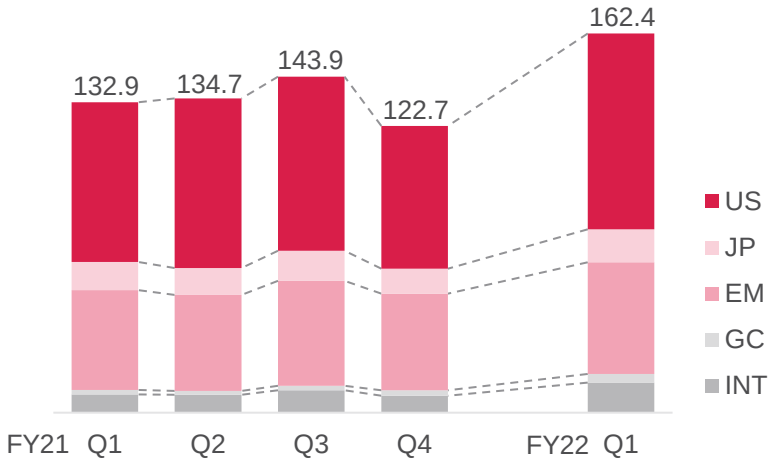
(billion yen)	Q1/FY2022 Act	YoY	FY2022 Initial FCST	Progress	
Xtandi (enzalutamide)	**162.4**	**+29.5 (+22%)**	**642.5**	**25%**	✓ Global sales are in line with expectations ✓ Signs of sales recovery in US from Q4 slowdown
PADCEV enfortumab vedotin-ejfv	**10.6**	**+6.4 (+152%)**	**36.5**	**29%**	✓ Global sales are above expectations • New patients starts far exceeded expectations in Japan • Clinical trial orders booked ahead of schedule in US ✓ Possibility of exceeding initial full-year forecast
XOSPATA gilteritinib	**10.5**	**+2.2 (+26%)**	**46.2**	**23%**	✓ Global sales are almost in line with expectations ✓ US performed below expectations due to inventory burn
Evrenzo roxadustat	**0.7**	**+0.1 (+19%)**	**9.9**	**7%**	✓ Sales in Japan and Europe are below expectations ✓ Expect reimbursement to start in European countries in 2H/FY2022

Strategic products: PADCEV, XOSPATA, EVRENZO
PADCEV (US): Co-promotion revenue from Seagen

Q1/FY2022 FINANCIAL RESULTS: BUSINESS UPDATE FOR XTANDI AND PADCEV

Xtandi (enzalutamide)

Revenue by Region (billion yen)



Global sales grew as expected, mainly from M1 CSPC contribution

<US> Performed below expectations, but showed signs of sales recovery

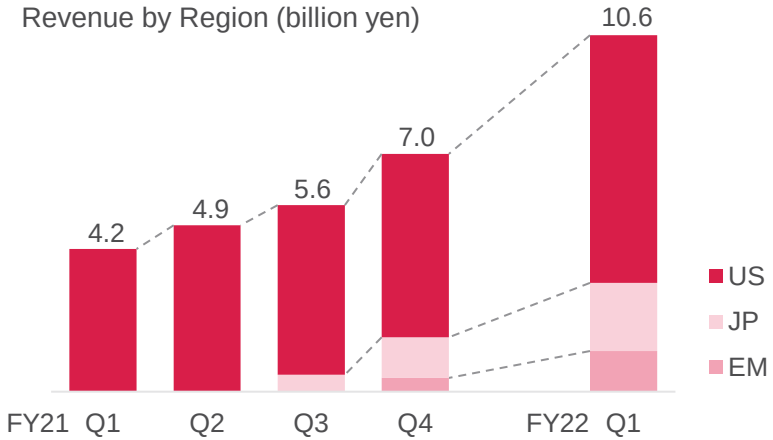
- Impact from generic competitor pressure continued, no significant expansion
- Signs of PAP rate settling, still slightly higher level than expected
- New patient starts are in upward trend, expect positive impact

<ex-US> Performed above expectations, especially contribution from Europe

- In Europe, M1 CSPC showed strong growth, and countries with reimbursement increased, contributing to demand increase
- Positive price impact, higher price than assumed was agreed upon (Germany)

PADCEV enfortumab vedotin-ejfv

Revenue by Region (billion yen)



Sales grew in all regions, global sales growth exceeding expectations

<US> Performed as expected, even excluding revenue from clinical trial orders

- Strong growth from cis-ineligible mUC 2L therapy

<JP> Market penetration far exceeding expectations since launched in Nov 2021

- Highly evaluated by physicians, new patient starts and market share higher than expected

<Europe> Approved in Apr 2022, currently launched in 8 countries, strong initial uptake

- Expect further increase in launch countries and reimbursement start

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EM (Established Market): Europe, Canada, Australia, GC (Greater China): China, Hong Kong, Taiwan, INT (International Market): Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea
M1: Metastatic, CSPC: Castration-sensitive prostate cancer, PAP: Patient Assistance Program, mUC: Metastatic urothelial cancer, 2L: Second line
PADCEV (US): Co-promotion revenue from Seagen

Q1/FY2022 FINANCIAL RESULTS: COST ITEMS

Cost of sales ratio increased YoY due to significant FX impact
SG&A expenses were on track and decreased YoY when excluding FX impact
R&D expenses were on track

Core basis: Main items for YoY and progress against FCST

Cost of sales
% of revenue

YoY: +4.2 ppt

- ✓ FX impact on elimination of unrealized profit: +3.2 ppt (+12.3 bil. yen)
- ✓ XTANDI royalty payment adjustment for prior year: +0.5 ppt (+1.8 bil. yen)

SG&A expenses
(excl. XTANDI US co-pro fee)

YoY: +7.4%
Progress
against FCST: 27%

- ✓ SG&A excl. FX impact: -2.4 bil. yen (YoY -2.3%)
- ✓ Global optimization of personnel aligned with transformation of product portfolio (Approx. -3.0 bil. yen)
- ✓ Reduction of mature products-related costs (Approx. -2.0 bil. yen)
- ✓ Investment for new product launch readiness (Approx. +2.0 bil. yen)

R&D expenses

YoY: +26.9%
Progress
against FCST: 29%

- ✓ FX impact (+7.5 bil. yen)
- ✓ Increase in one-time expenses that already factored into full-year FCST (+13.1 bil. yen)

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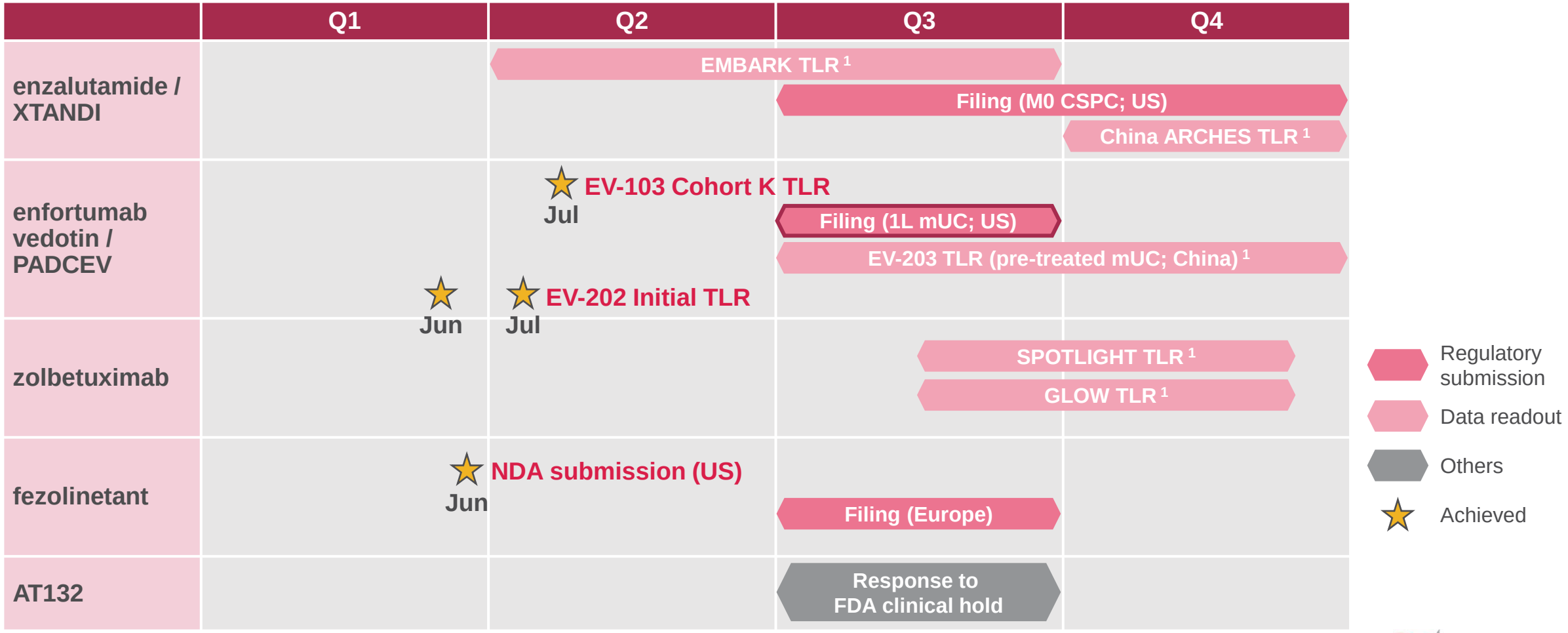
XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2022



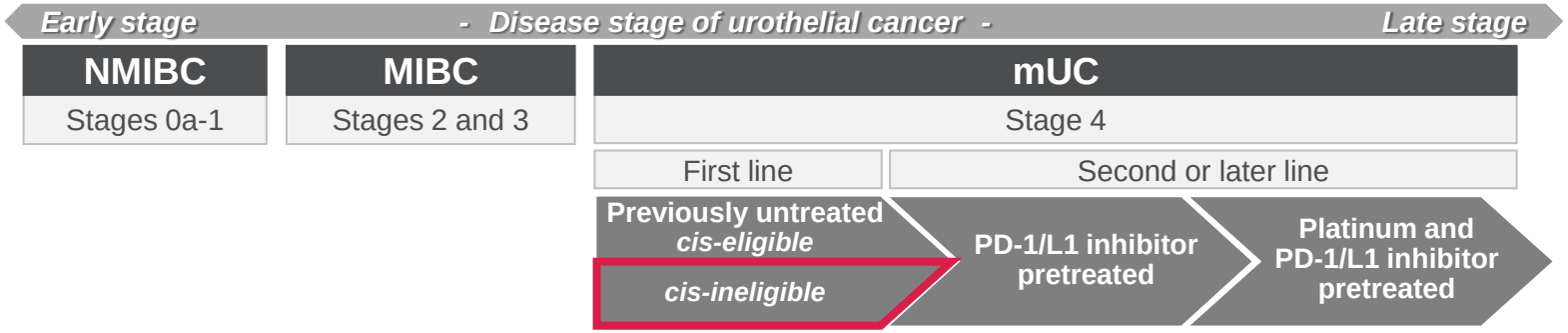
As of Jul 2022

1. The timeline of TLR is subject to shift due to its event-driven nature.
TLR: Topline results, M0 CSPC: Non-metastatic castration-sensitive prostate cancer, 1L: First line, mUC: Metastatic urothelial cancer, NDA: New Drug Application, FDA: Food and Drug Administration

ENFORTUMAB VEDOTIN (EV) (1/2): TOPLINE RESULTS FOR EV-103 STUDY COHORT K

Positive topline results obtained, showing consistent efficacy and safety with previous data [1]

- First-line treatment for advanced urothelial cancer (cis-ineligible, combination with pembrolizumab)
- Plan to discuss results with FDA aiming sBLA submission in 2022 under Accelerated Approval



<Cohort K in EV-103 study>

Patient segment	Patients with unresectable la/mUC who are unable to receive cisplatin-based chemotherapy in the first-line setting
Study arm	• EV + pembrolizumab combo (n=76) • EV monotherapy (n=73)
Primary endpoint	ORR (per BICR)
Secondary endpoint	DoR, PFS, OS, safety, etc.

<Topline results (Combo arm)>

ORR [95% CI]	64.5% [52.7 to 75.1]
DoR	Not reached (median cannot be calculated due to continued response in many subjects)
Safety	Tolerable and manageable, and no new safety concerns emerged

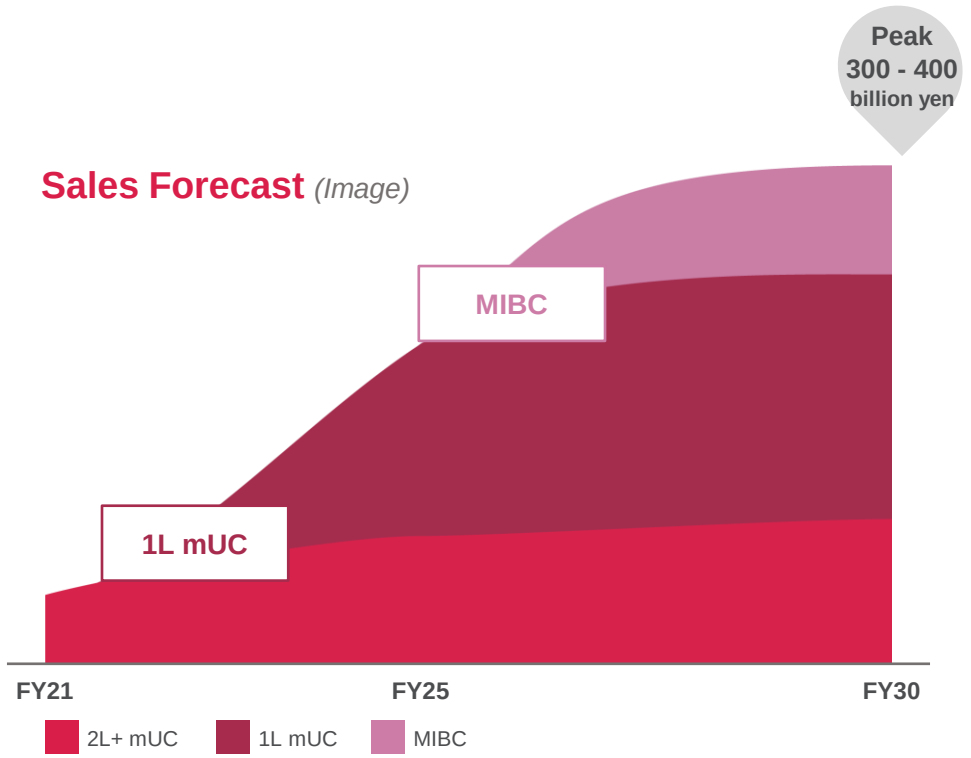
[Ref] Previously reported ORR data for gemcitabine + carboplatin treatment in first-line setting [2]: 42-46%

1. EV-103 dose-escalation cohort and expansion Cohort A. 2. IMvigor130: Galsky et al., AACR 2021 Abstract CT042; KEYNOTE-361: Powles et al., ASCO GU 2021 Abstract 450; DANUBE: Powles et al., EAU 2021
FDA: Food and Drug Administration, sBLA: Supplemental Biologics License Application, NMIBC: Non-muscle-invasive bladder cancer, MIBC: Muscle-invasive bladder cancer, cis: Cisplatin, la/mUC: Locally advanced or metastatic urothelial cancer, ORR: Objective response rate, BICR: Blinded independent central review, DoR: Duration of response, PFS: Progression-free survival, OS: Overall survival, CI: Confidence interval

ENFORTUMAB VEDOTIN (2/2): OVERVIEW

The most significant growth driver is 1L mUC indication, which is expected to account for more than half of total sales in the future

Sales Forecast *(Image)*



Patient segment		Pivotal study	Mono/ Combo [1]	OS	PFS	ORR	DoR	Target filing timing	Number of eligible patients [2]
MIBC	cis-ineligible	EV-303	Combo	(Ongoing)				FY2025 or later	10,000
	cis-eligible	EV-304	Combo	(Ongoing)				FY2025 or later	37,000
mUC, previously untreated (1L)		EV-302	Combo	(Ongoing)				FY2024	76,000
		EV-103 Cohort K	**Combo**	(Ongoing)		**64%**	**Not reached**	**2022 [3]**	**8,000** (US, cis-ineligible)
		EV-103 dose escalation cohort & Cohort A	Combo	26.1 mos	12.3 mos	73%	25.6 mos		
2L+ mUC	PD-1/L1 inhibitor pretreated	EV-201 Cohort 2	Mono	14.7 mos	5.8 mos	52%	13.8 mos	Approved	1,600 (US, cis-ineligible)
	Platinum & PD-1/L1 inhibitor pretreated	EV-301	Mono	12.9 mos	5.6 mos	41%	7.4 mos	Approved	38,000
		EV-201 Cohort 1	Mono	12.4 mos	5.8 mos	44%	7.6 mos		

Clinical studies in other patient segments are also ongoing:

- Non-muscle-invasive bladder cancer (NMIBC): EV-104 (Phase 1)
- Other solid tumors [4]: EV-202 (Phase 2)

1. Combination with pembrolizumab. 2. Based on internal estimates. 3. US 4. Hormone receptor positive/HER2 negative breast cancer, triple-negative breast cancer, squamous non-small cell lung cancer (NSCLC), non-squamous NSCLC, head and neck cancer, gastric adenocarcinoma or esophageal adenocarcinoma or gastroesophageal junction adenocarcinoma, esophageal squamous cell carcinoma. mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, 1L: First line, 2L+: Second or later line, cis: Cisplatin, mono: Monotherapy, OS: Overall survival, PFS: Progression-free survival, ORR: Objective response rate, DoR: Duration of response

FEZOLINETANT: LATEST STATUS

<Regulatory submission> NDA submitted to US FDA on June 22

<Data presentation> Latest data presented at ACOG and ENDO

- SKYLIGHT 1 study 12-w data: Consistent results with those of SKYLIGHT 2 study
- SKYLIGHT 2 study 52-w data:
  - ✓ Maintained improvement in VMS frequency and severity throughout 52 weeks
  - ✓ Reduction in VMS frequency and severity after re-randomization from placebo to fezolinetant
  - ✓ Consistent safety profile with that of 12-week placebo-controlled period

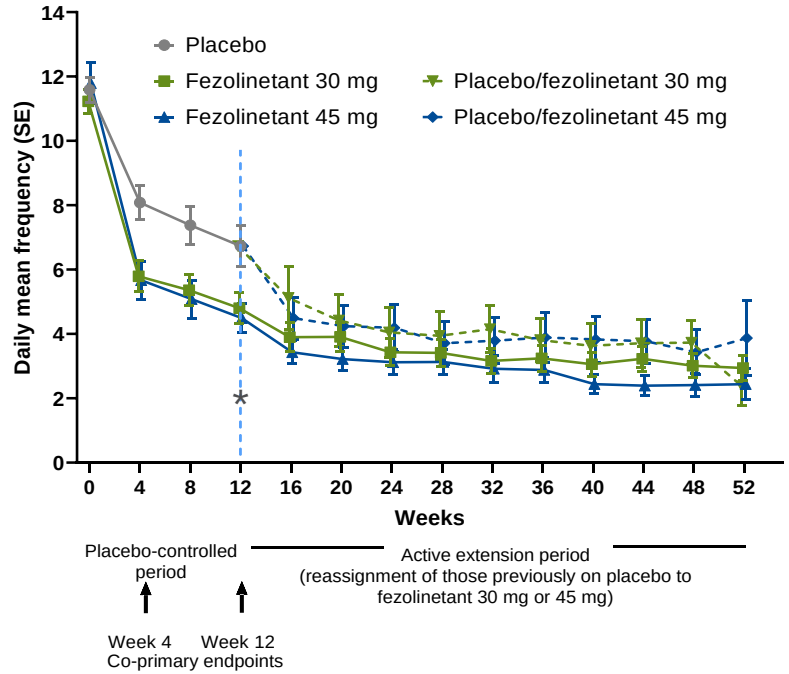
<VMS education and awareness activities (US)>

- HCP: Sequentially launched VMS educational/awareness website (KnowVMS.com) and omni-channel online and in-person approach
  - ✓ Reached 132k unique HCPs
- Consumer: Launching DSA (Disease State Awareness) campaign in August (TV from October)

<Upcoming events>

- SKYLIGHT 4 study 52-week data to be presented at NAMS in October
- Conference call after NAMS presentation will be held on October 17

SKYLIGHT 2 study 52-w data (VMS frequency)



SE: Standard error
*: Statistically significant for both fezolinetant doses vs. placebo

NDA: New Drug Application, FDA: Food and Drug Administration, ACOG: American College of Obstetricians and Gynecologists, ENDO: Endocrine Society, VMS: Vasomotor symptoms, HCP: Healthcare professional
NAMS: North American Menopause Society

PROGRESS IN FOCUS AREA APPROACH (1/4): CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

(Red: Updates since the last financial results announcement)

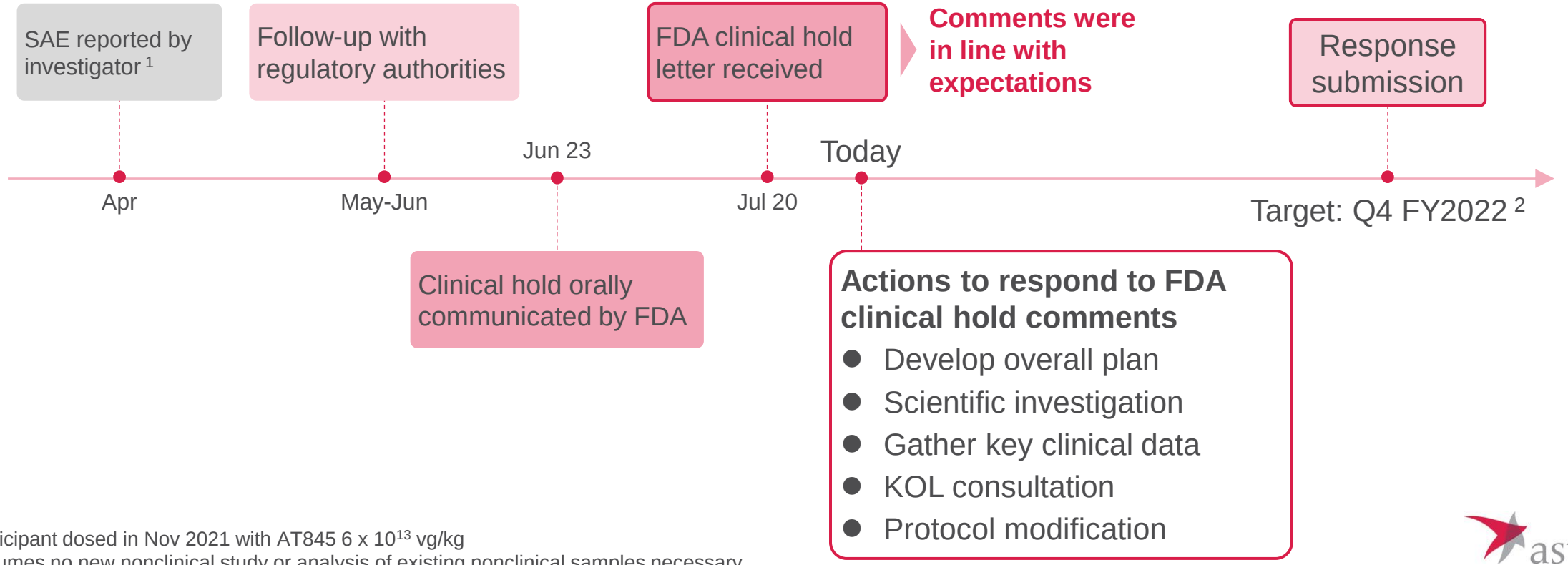
Primary Focus	Biology/Modality/Technology [1]	Project	Current status	No. of projects aiming PoC by end FY25 [2]
Genetic Regulation	Gene replacement (AAV)	AT132	ASPIRO study put on clinical hold by FDA in Sep 2021	4
		AT845	**FORTIS study put on clinical hold by FDA in Jun 2022**	
	Gene regulation (AAV)			
Immuno-Oncology	Checkpoint	ASP1570	Phase 1 study ongoing	12
	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	**FSFT in Phase 1 study in Jun 2022**	
	Cancer cell therapy (UDC)			
Blindness & Regeneration	Cell replacement	ASP7317	**Screening and enrollment in Phase 1b study anticipated to restart 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 ongoing	4
	Mitochondrial stress	ASP8731	Phase 1 study ongoing	
	Mitochondrial transfer			
Primary Focus Candidates	Immune modulating/regulatory cells			1
	Tissue-specific immune regulation			
	Targeted protein degradation	ASP3082	**FSFT in Phase 1 study in Jun 2022**	
			Total	**24**

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 Jul 2022)
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, FSFT: First subject first treatment, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

PROGRESS IN FOCUS AREA APPROACH (2/4): AT845

- FORTIS study placed on clinical hold by FDA, following the reporting of an SAE of peripheral sensory neuropathy
- Remain committed to the safe and effective development of AT845 for Pompe disease, and to gene therapy



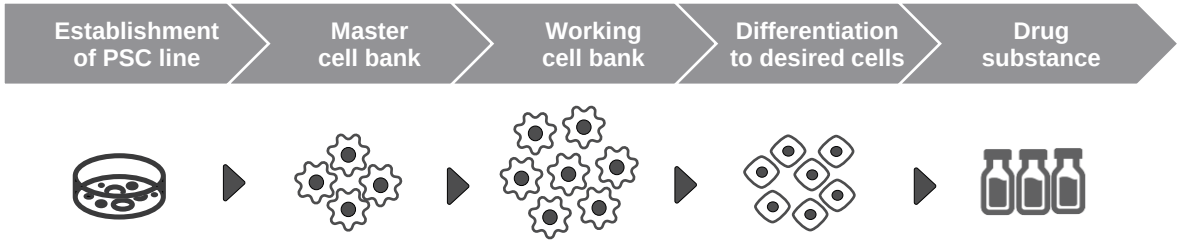
1. Participant dosed in Nov 2021 with AT845 6 x 10^{13} vg/kg
2. Assumes no new nonclinical study or analysis of existing nonclinical samples necessary

FDA: Food and Drug Administration, SAE: Serious adverse event, AE: Adverse event, KOL: Key opinion leader

PROGRESS IN FOCUS AREA APPROACH (3/4): ASP7317

Clinical study of ASP7317, the lead program of cell therapy, anticipated to restart

- ASP7317
  - ✓ Human embryonic stem cell-derived retinal pigment epithelial cells
  - ✓ Target disease: Geographic atrophy secondary to age-related macular degeneration, Stargardt disease
- The clinical study was voluntarily put on hold due to the manufacturing process changes and the introduction of new cutting-edge analytical methods for product release in accordance with technology advancements in a cell-therapy field
- Established capabilities enabling supply of cells that meet the high quality standard through activities for resumption



  - ✓ **Manufacturing**: Improving ratio of cells with desired characteristics
  - ✓ **Analysis**: Quality testing with high sensitivity and reproducibility
  - ✓ **Specification setting**: Building rationale based on multiple preclinical data
- Screening and enrollment anticipated to restart in Aug 2022
- Acceleration of research and development for subsequent cell therapy programs
  - ✓ Expected to be able to provide cells with higher quality for clinical studies without delay, by leveraging established capabilities

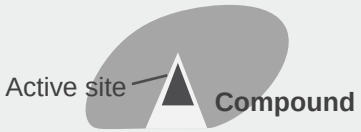
PSC: pluripotent stem cell

PROGRESS IN FOCUS AREA APPROACH (4/4): ASP3082

Potential first-in-class program from Focus Area approach entered clinical phase

Degradation of target protein with technology enabling access to “Undruggable target”

Conventional target

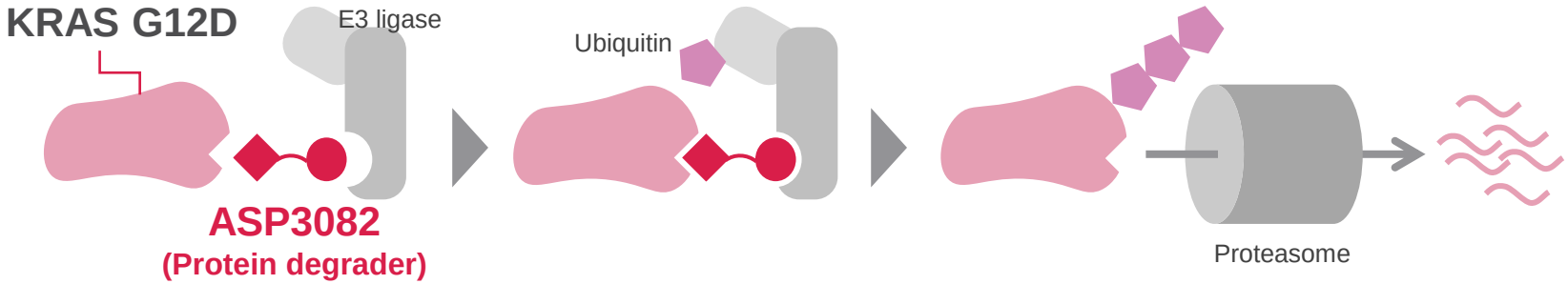


Able to control its function through binding to active site, conformational change, etc.

Undruggable target

Not able to sufficiently control its function by just binding, due to lack of apparent active sites, etc., considered hard to be a target of drug

Protein degrader: degrades target protein through intrinsic mechanism



Binding to target protein and E3 ligase, and bringing them adjacent to each other

Ubiquitylation of target protein by E2/E3 ligase complex

Degradation of ubiquitinated protein by proteasome

ASP3082 (Protein degrader)

- Target protein: KRAS G12D mutant
  - ✓ One of the most frequently mutated oncogenes in cancer, involved in cancer cell growth signaling
  - ✓ Have been considered an “Undruggable target” for which inhibitors are difficult to develop
- Target disease: Cancers harboring KRAS G12D mutation
- Primary Focus Candidate: Targeted Protein Degradation

Percentage with KRAS G12D mutation (%) [1]	
Pancreatic ductal adenocarcinoma	33.8
Rectum adenocarcinoma	12.0
Bile duct carcinoma	10.9
Colon adenocarcinoma	10.3
Endometrium carcinoma	5.3
Lung adenocarcinoma	3.6
Ovarian carcinoma	3.5

1. Nat Rev Cancer 18:767 (2018)
KRAS: Kirsten rat sarcoma viral oncogene homologue

PROGRESS IN Rx+ PROGRAM

Key events expected in FY2022 (announced in Apr 2022）

Category	Program	Event	Result
Digital health Other services	EG Holter/AI Software	Initiation of sales pilot	**Achieved (Jun 2022)**
Digital therapeutics	BlueStar	Initiation of clinical study (Japan)	
Drug-device combination	pudexacianinium chloride (ASP5354)	FSFT in Phase 3 study	

- Implantable medical devices (iota):
  Prepare for IDE submission in FY2022, toward initiation of clinical study in FY2023

AI: Artificial intelligence, IDE: Investigational Device Exemption, FSFT: First subject first treatment

PROGRESS TOWARD ACHIEVING CSP2021

Revenue, Pipeline Value

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

- ✓ Sales growth on track
- ✓ PADCEV: Obtained TLR from EV-103 Cohort K and EV-202
- ✓ fezolinetant: NDA submission in US, VMS education/awareness activities for HCP rolled out

2 Post-PoC projects from Primary Focuses

3 Multiple technology platforms

4 Focus Area projects:
≥ ¥0.5T in FY2030

- ✓ ASP7317: Phase 1b study anticipated to restart
- ✓ ASP2138, ASP3082: FSFT in Phase 1 study
- ✓ Gene therapy: Opening of new manufacturing facility in Sanford
- ✓ AT845: Clinical hold

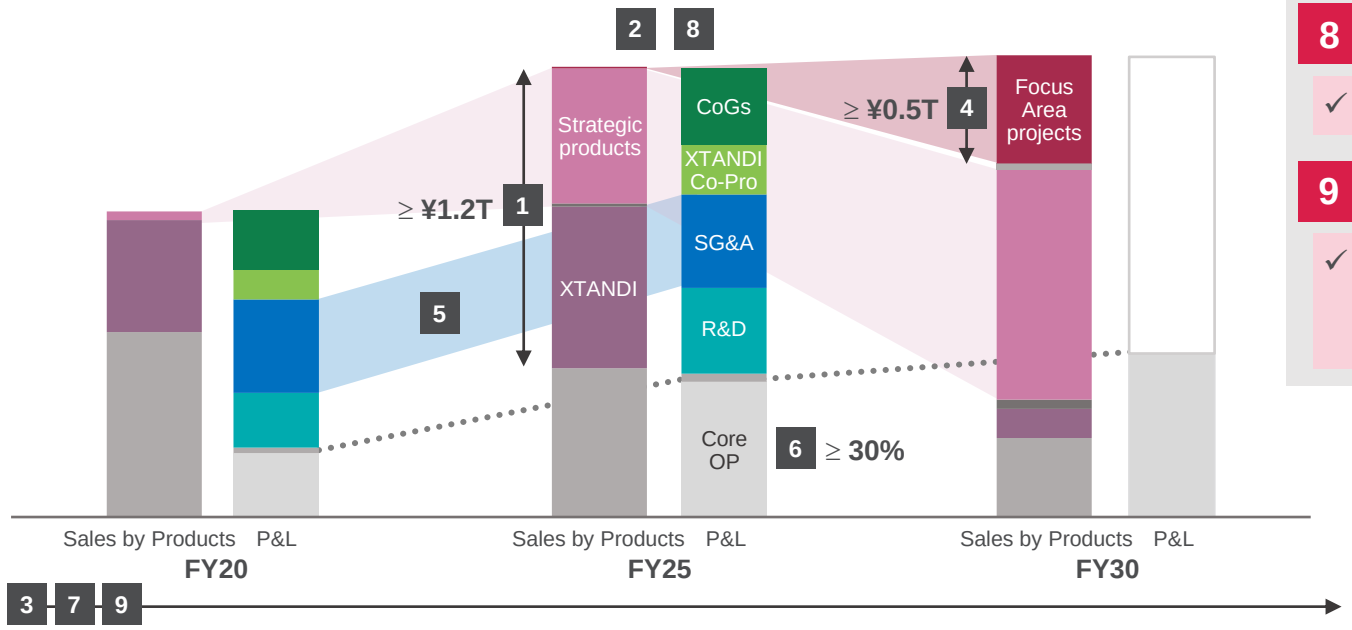
Core OP

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 decreased YoY when excluding FX impact



Future growth

8 Rx+: Breakeven by FY2025

- ✓ EG Holter: Initiation of sales pilot

9 Sustainability

- ✓ Selected for the FTSE4Good Index Series for 11 consecutive years

Strategic products: PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132
CSP: Corporate Strategic Plan, TLR: Topline results, NDA: New Drug Application, VMS: Vasomotor symptoms, HCP: Healthcare professionals, FSFT: First subject first treatment

UPCOMING IR EVENT
(SECURITIES ANALYSTS AND INSTITUTIONAL INVESTORS)

fezolinetant meeting

- Oct 17th 2022, 9:30-10:45 (JST)

Enfortumab Vedotin meeting (EV-103 Cohort K)

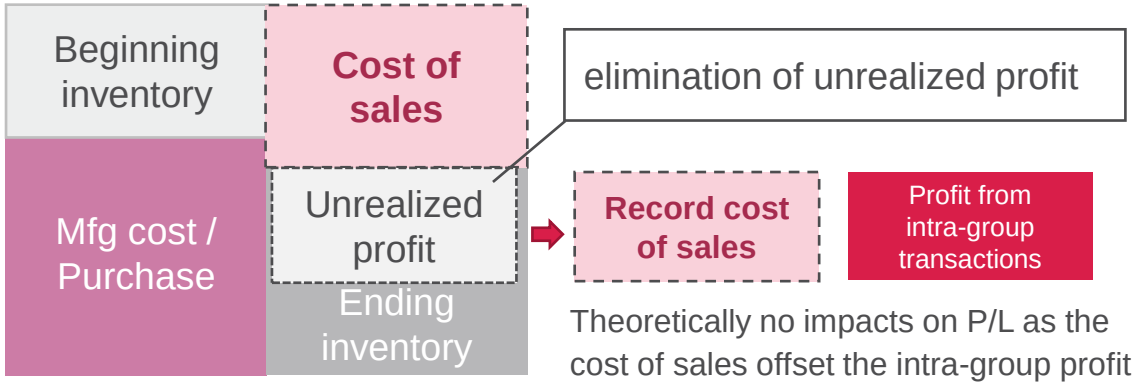
- To be announced

APPENDIX

FX IMPACTS ON ELIMINATION OF UNREALIZED PROFIT

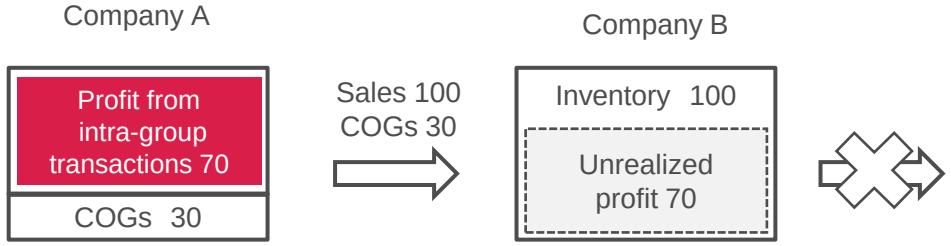
- In elimination of unrealized intercompany profit included in inventories as a part of the consolidation accounting process, FX fluctuation could cause impacts on cost of sales

Overview of cost of sales

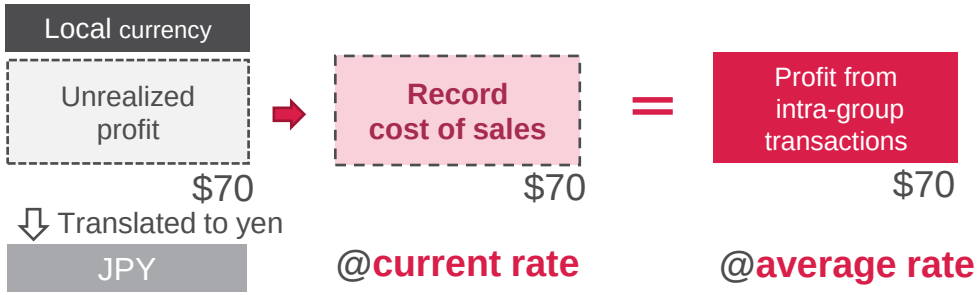


Theoretically no impacts on P/L as the cost of sales offset the intra-group profit

(example of unrealized intercompany profit) Co. A sold product to Co. B. At the year-end, the product had not yet been sold to 3rd parties.



FX impacts related to inventories held by foreign affiliates



(1) In case current rate (@120) is weaker than average rate (@110)

8,400 yen > 7,700 yen

Recorded COGs is larger
→ COGs +700 yen

(2) In case current rate (@100) is stronger than average rate (@110)

7,000 yen < 7,700 yen

Recorded COGs is smaller
→COGs -700 yen

Impacts on FY22Q1	Group consolidation (JPY)	:cost of sales +9.1 billion yen
	Sub-consolidation at ABV (euro)	:cost of sales +4.2 billion yen (mainly due to stronger RUB)

Mfg cost: Manufacturing cost

Q1/FY2022: REVENUE BY REGION

(billion yen)	Q1/FY21	Q1/FY22	Change (%)
Japan	67.5	66.8	-1.0%
United States	133.6	160.9	+20.4%
Established Markets	78.0	88.7	+13.7%
Greater China	16.4	23.2	+41.0%
International Markets	27.8	31.8	+14.5%

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

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Q1/FY2022: SALES OF MAIN PRODUCTS

(billion yen)	Q1/FY21	Q1/FY22	Change	CER growth	FY22 Initial FCST
XTANDI	132.9	162.4	+22.2%	+9.3%	642.5
PADCEV	4.2	10.6	+151.6%	+122.9%	36.5
XOSPATA	8.3	10.5	+26.3%	+12.1%	46.2
EVRENZO	0.6	0.7	+19.3%	+18.8%	9.9
mirabegron	44.0	47.9	+9.0%	-2.2%	178.7
Prograf	45.2	51.8	+14.6%	+5.8%	190.7

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

Q1/FY2022 ACTUAL: FX RATE

Average rate for the period

Currency	Q1/FY21	Q1/FY22	Change
USD	109 yen	130 yen	-20 yen
EUR	132 yen	138 yen	-6 yen

Change in closing rate from previous fiscal year end

Currency	Q1/FY21	Q1/FY22
USD	+0 yen	-14 yen
EUR	-2 yen	-8 yen

<Impact of exchange rate on financial results>

- 35.5 billion yen increase in revenue, 7.4 billion yen decrease in core OP
- FX impact on elimination of unrealized profit: COGs ratio +3.2 ppt

FY2022 FCST: FX RATE & FX SENSITIVITY

Average rate for the period

Currency	FY2021	FY2022 FCST	change
USD	112 yen	120 yen	+8 yen
EUR	131 yen	135 yen	+4 yen

Change in closing rate from the previous FY end

Currency	FY2021	FY2022 FCST
USD	+11 yen	-2 yen
EUR	+5 yen	+0 yen

Estimated FX sensitivity of FY2022 forecast by 1 yen depreciation

Currency	Average rate 1 yen lower than assumption		Year-end rate 1 yen lower than assumption
	Revenue	Core OP	Core OP
USD	Approx. +6.6 bil. yen	Approx. +1.1 bil. yen	Approx. -0.6 bil. yen
EUR	Approx. +2.8 bil. yen	Approx. +1.2 bil. yen	Approx. -0.2 bil. yen

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BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY21 end	Jun 30, 2022
Total assets	2,332.4	2,481.8
Cash and cash equivalents	316.0	313.0
Total equity attributable to owners of the parent	1,460.3	1,539.1
Equity ratio (%)	62.6%	62.0%

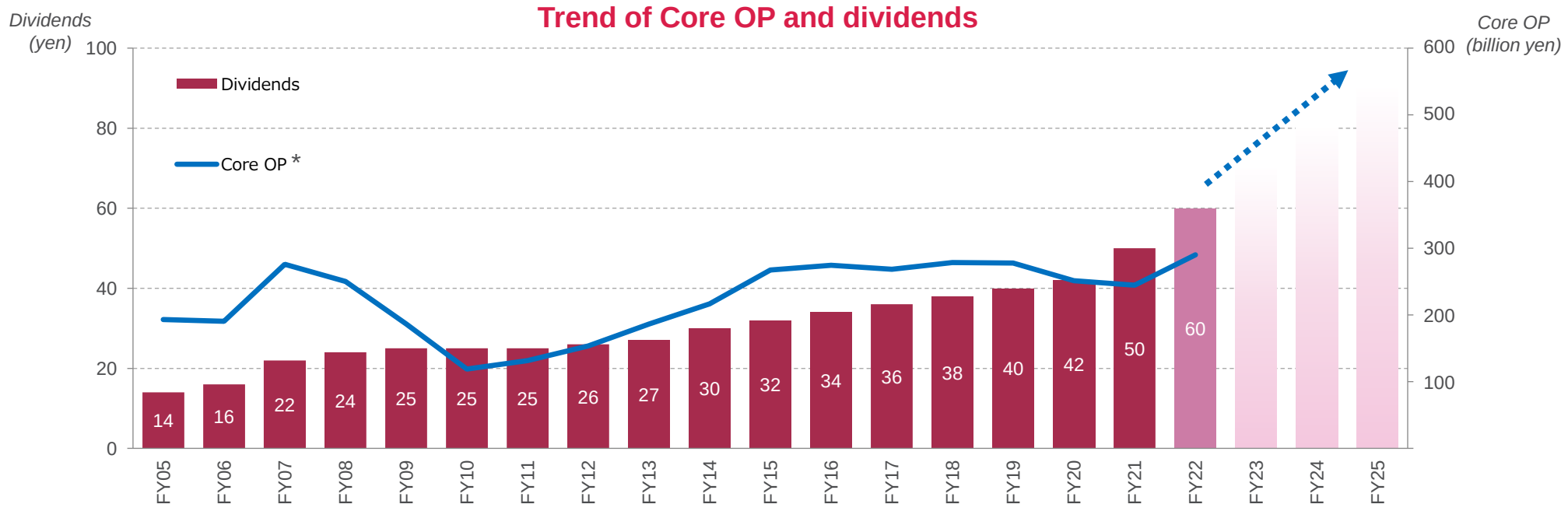
(billion yen)	Q1/FY21	Q1/FY22	FY21
Cash flows from operating activities	40.1	48.8	257.4
Cash flows from investing activities	-21.1	-19.1	-62.4
Free cash flows	19.0	29.7	195.0
Cash flows from financing activities	-44.7	-46.6	-216.3
Bonds and short-term borrowings	-	+15.0	-30.0
Acquisition of treasury shares	-0.7	-10.6	-50.7
Dividends paid	-38.9	-45.7	-85.2

Balance of bonds and borrowings：155.0 billion yen
(Increased by 15.0 billion yen from FY2021 end)

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
- ASP7317
- bocidelpar/ASP0367 (Duchenne muscular dystrophy)
- AT845
- ASP0598
- ASP1570
- ASP2138
- ASP8731
- ASP3082
- ASP8062

Phase 2

- enfortumab vedotin (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- roxadustat (Chemotherapy-induced anemia)
- 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: Europe, China)
- peficitinib (Rheumatoid arthritis: China)
- mirabegron (Pediatric use: Europe)

Submitted

- fezolinetant (VMS associated with menopause: US)

- 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

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
			fezolinetant Vasomotor symptoms associated with menopause: US	

Discontinuation

ASP8062: Opioid use disorder (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

XTANDI & STRATEGIC PRODUCTS: STATUS UPDATE

(Red: Updates since the last financial results announcement)

Project / Product	Indication	Current status
enzalutamide / XTANDI	M1 CSPC	• **US:** Filed label update to include the OS data in Dec 2021 • **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. **Obtained topline results from Cohort K in EV-103 study in Jul 2022** • **China:** Phase 2 bridging study ongoing (enrollment completed)
	Muscle-invasive bladder cancer	• Phase 3 studies ongoing
	Non-muscle-invasive bladder cancer	• Phase 1 study ongoing
	Other solid tumors	• Phase 2 study ongoing. **Obtained initial topline results in Jun 2022**
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	• Phase 3 studies ongoing (enrollment completed)
	Pancreatic adenocarcinoma	• Phase 2 study ongoing
roxadustat / EVRENZO	Chemotherapy-induced anemia	• Obtained topline results from Phase 2 study
fezolinetant	VMS associated with menopause	• **US & EU: NDA submitted in US in Jun 2022**. Phase 3b DAYLIGHT study ongoing. **12w data from Phase 3 SKYLIGHT 1 study presented at ACOG in May 2022. 52w data from Phase 3 SKYLIGHT 2 study presented at ENDO in Jun 2022. 52w data from Phase 3 SKYLIGHT 4 study to be presented at NAMS in Oct 2022** • **Asia:** LSLV in Phase 3 MOONLIGHT 1 study in Apr 2022. **LSLV in Phase 3 MOONLIGHT 3 study in Jun 2022** • **Japan:** Phase 2b STARLIGHT study ongoing
AT132 (resamirigene bilparvovec)	X-linked myotubular myopathy	• ASPIRO study put on clinical hold by FDA due to a serious adverse event

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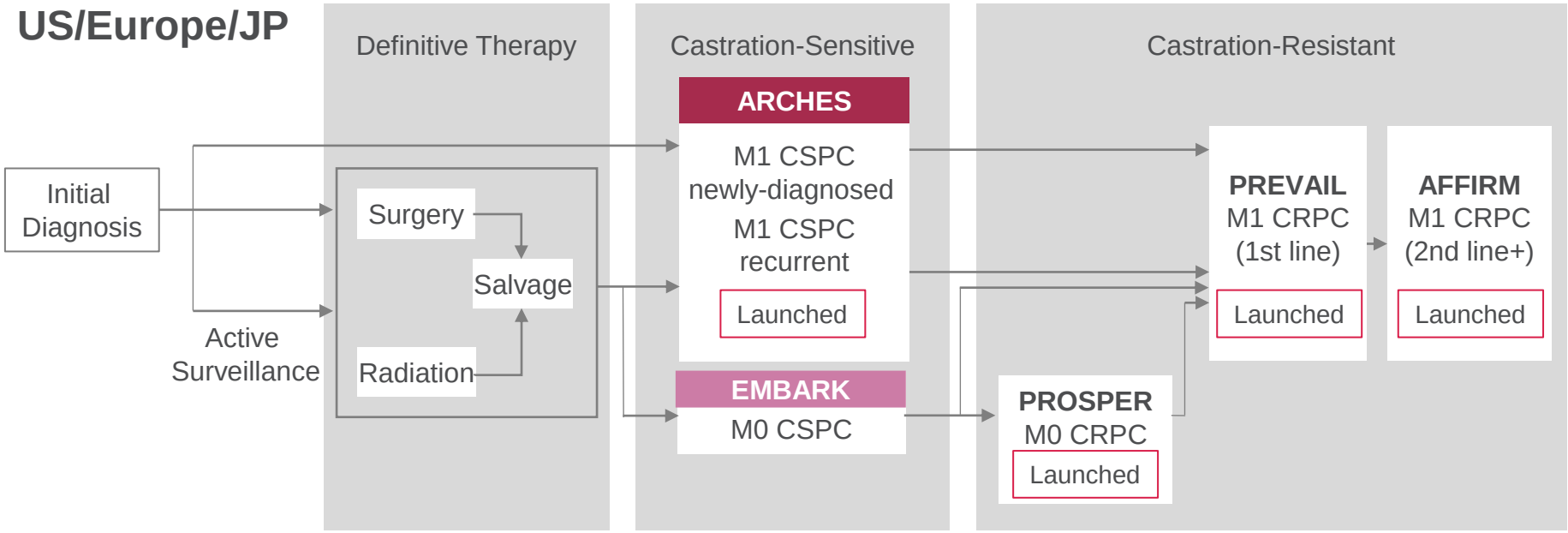
Strategic products: PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132. M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, OS: Overall survival, CHMP: Committee for Medicinal Products for Human Use, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, AACR: American Association for Cancer Research, GEJ: Gastroesophageal junction, NDA: New Drug Application, VMS: Vasomotor symptoms, ACOG: American College of Obstetricians and Gynecologists, ENDO: Endocrine Society, NAMS: North American Menopause Society, FDA: Food and Drug Administration

ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR



	P3: ARCHES	**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. CHMP positive opinion received in Mar 2022
	P3: EMBARK	**M0 CSPC**	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

China

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

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

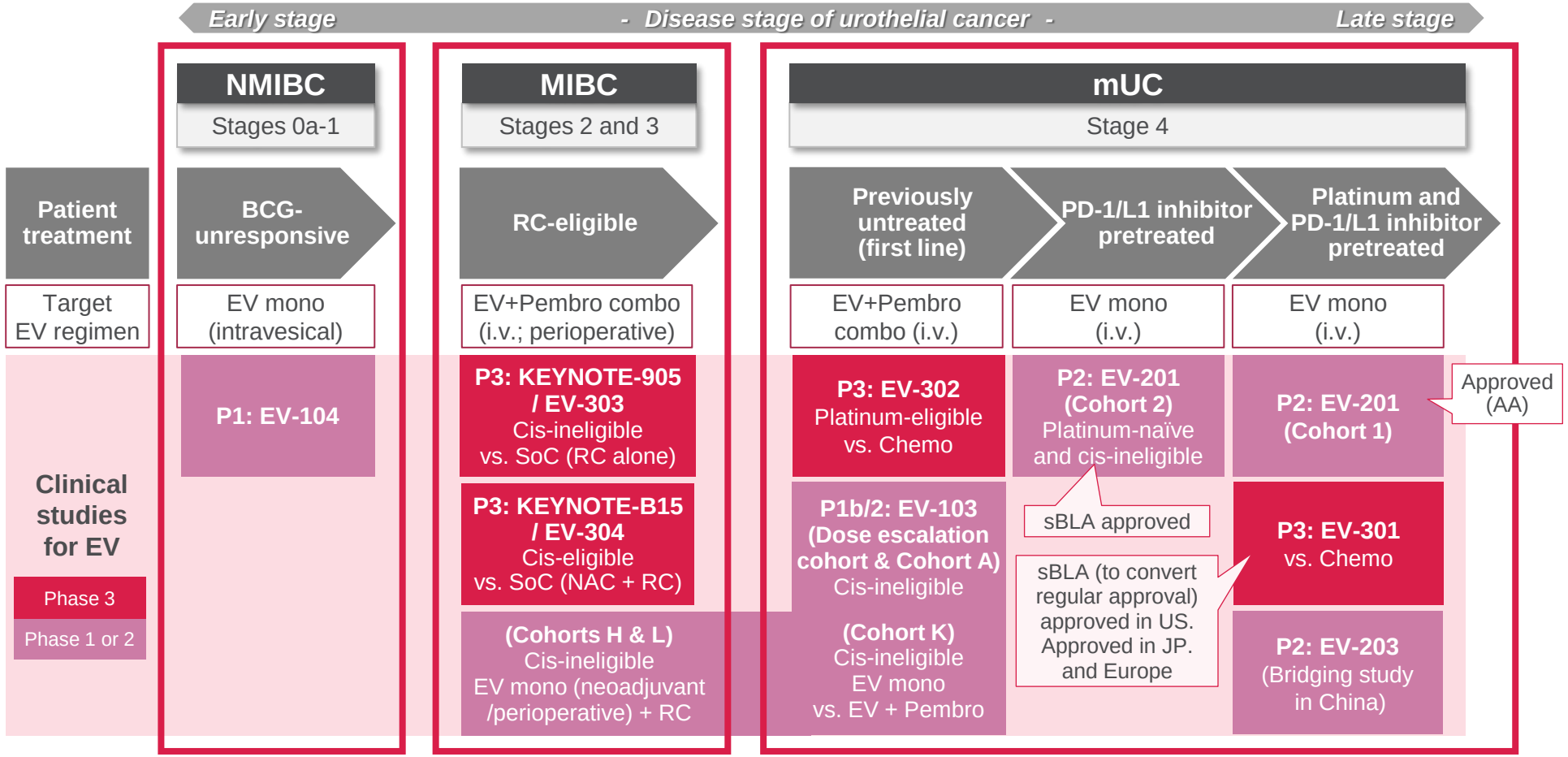
Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

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) (1/3): NECTIN-4 TARGETED ADC OVERALL UC PROGRAM



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

ENFORTUMAB VEDOTIN (EV) (2/3): CLINICAL STUDIES

(Red: Updates since the last financial results announcement)

For urothelial cancer

	P3: EV-301	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	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=860	FSFT: Apr 2020
	P3: EV-303 /KEYNOTE-905	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=836	FSFT in Pembro + EV arm: Dec 2020
	P3: EV-304 /KEYNOTE-B15	MIBC, Cis-eligible; EV+Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=784	FSFT: May 2021
	P2: EV-201	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	Cohorts A - G and K (mUC): A-G: Combo with Pembro and other chemo K: EV mono vs. 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: **Topline results obtained in Jul 2022** Cohort L: Enrollment ongoing Note) Data from Cohort K along with other cohorts evaluating EV + Pembro as first-line therapy for cis-ineligible patients could potentially support registration for Accelerated Approval in US
	P2: EV-203	<Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono	n=40	Enrollment completed in Jan 2022
	P1: EV-104	NMIBC, High-risk BCG-unresponsive; Intravesical EV mono	n=58	FSFT: Jan 2022

For other solid tumors

	P2: EV-202	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	FSFT: Mar 2020 **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

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

(Red: Updates since the last financial results announcement)

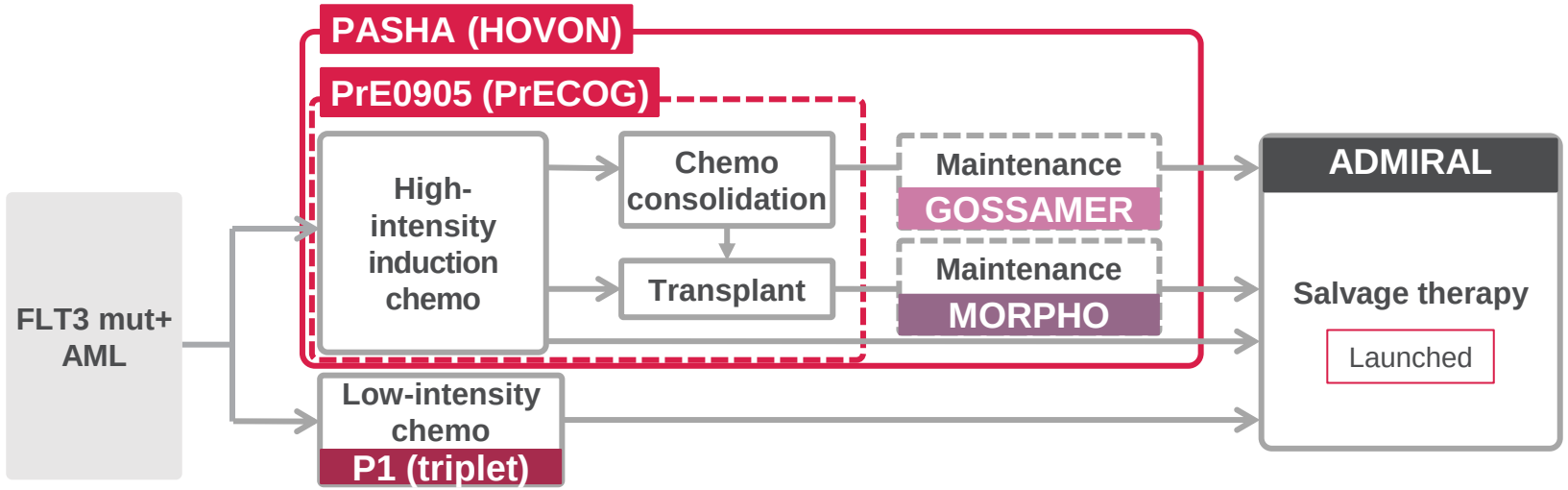
Disease stage	Early stage					Late stage		
	MIBC		mUC					
	Surgery eligible		Previously untreated (first line)			PD-1/L1 inhibitor pretreated		
	Cis-eligible	Cis-ineligible	Platinum eligible	Cis-ineligible		Platinum naïve & cis-ineligible	Platinum pretreated	
Study phase	Phase 3	Phase 3	Phase 3	Phase 1b/2	Phase 1b/2	Phase 2	Phase 2	Phase 3
Study No.	**KN-B15 / EV-304**	**KN-905 / EV-303**	**EV-302**	**EV-103 Cohort K**	**EV-103 Cohort A & Others**	**EV-201 Cohort 2**	**EV-201 Cohort 1**	**EV-301**
No. of subjects	784 (2 arms)	836 (3 arms)	860 (2 arms)	**149** (2 arms)	45	89	125	608 (2 arms)
EV regimen	Combo w/ Pembro (perioperative)	Combo w/ Pembro (perioperative)	Combo w/ Pembro	Mono vs. Combo w/ Pembro	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%**	✔ ORR 73% ** (CR 16% **)	✔ ORR 51% ** (CR 22% **)	✔ ORR 44% (CR 12%)	✔ OS HR 0.70 *
OS	(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)	✔ (12.3 mos **)	✔ (5.8 mos)	✔ (5.8 mos)	✔ HR 0.62 * (5.6 mos vs.3.7 mos)
ORR	(Ongoing)	(Ongoing)	(Ongoing)	**✔ 64%**	✔ 73% ** (CR 16% **)	✔ 52% (CR 20%)	✔ 44% (CR 12%)	✔41% vs.18% * (CR 4.9% vs.2.7%)
DoR	(Ongoing)	(Ongoing)	(Ongoing)	**Not reached**	✔ 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

GILTERITINIB: FLT3 INHIBITOR

(Red: Updates since the last financial results announcement)



	Relapsed or refractory	**P3: ADMIRAL**	Monotherapy vs. salvage chemo (2:1)	n=371	Launched in US, JP, and Europe
	Newly diagnosed (HIC-eligible)	**P3: PASHA (HOVON)**	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=768	FSFT: Dec 2019 (Sponsor: HOVON)
		P2: PrE0905 (PrECOG)		n=179	FSFT: Dec 2019 (Sponsor: PrECOG, LLC.)
	Post-HSCT maintenance	**P3: MORPHO**	Monotherapy vs. placebo (1:1)	n=346	Enrollment completed Collaborating with BMT-CTN
	Post-chemo maintenance	**P2: GOSSAMER**	Monotherapy vs. placebo (2:1)	n=98	Topline results obtained in Aug 2021
	Newly diagnosed (HIC-ineligible)	**P1**	Combo with venetoclax and azacitidine	TBD	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, AACR: American Association for Cancer Research, 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: 33% - 37%
  - ✓ ~60% of primary pancreatic adenocarcinomas; approx. 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 ~4% five-year survival rate at Stage IV and limited treatment options have been limited

	Gastric and GEJ adenocarcinoma	**P3: SPOTLIGHT**	First line, Combo with mFOLFOX6, DB, vs. placebo	n=550	Enrollment completed
		P3: GLOW	First line, Combo with CAPOX, DB, vs. placebo	n=500	Enrollment completed
		P2: ILUSTRO	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**	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

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 EU

P3: SKYLIGHT 1	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 submitted in US in Jun 2022**
P3: SKYLIGHT 2		n=501	
P3: SKYLIGHT 4	VMS associated with menopause; 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)	n=1,831	
P3b: DAYLIGHT	Moderate to severe VMS associated with menopause, unsuitable for HRT; 24 weeks, DB, 45 mg vs. placebo (1:1)	n=440	FSFT: Nov 2021

Asia (except for Japan)

P3: MOONLIGHT 1	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	VMS associated with menopause; open label, 30 mg for 52 weeks	n=150	**LSLV: Jun 2022**

Japan

P2b: STARLIGHT	Peri- and post-menopausal patients with mild to severe VMS; 12 weeks: DB, 2 doses vs. placebo (1:1:1)	n=135	FSFT: Nov 2021

1: DelveInsight, Epidemiology Forecast, Jun 2018, 2: Data Source - IMS NPA (2000-2016), IMS NSP (2000-2016). (3 HTs and SSRI) NAMS 2015 Position Statement.
VMS: Vasomotor symptoms, QoL: Quality of life, HRT: Hormone replacement therapy, DB: Double-blind , FSFT: First subject first treatment, LSLV: Last subject last visit

AT132 (RESAMIRIGENE BILPARVOVEC): rAAV8-Des-hMTM1

Characteristics of AT132

- Lead program in the gene therapy pipeline of Audentes Therapeutics, acquired by Astellas in Jan 2020
- Designed to deliver 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)	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

FOCUS AREA APPROACH: CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS

Expecting PoC judgement in 2 projects, Phase 1 entry in 5 projects (lead and follow-on projects)

Primary Focus	Biology/Modality/Technology [1]	Lead project	FY22	FY23	FY24-25	No. of projects aiming PoC by end FY25 [2]
Genetic regulation	Gene replacement (AAV)	AT132				4
		AT845		PoC		
	Gene regulation (AAV)					
Immuno-Oncology	Checkpoint	ASP1570		IND		12
	Artificial adjuvant vector cell (aAVC)	ASP7517		PoC		
	Oncolytic virus (intratumoral)	ASP9801				
	Oncolytic virus (systemic)			IND		
	Bispecific immune cell engager	ASP2138		IND		
	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					
Primary Focus Candidates	Immune modulating/regulatory cells					1
	Tissue-specific immune regulation					
	Targeted protein degradation	ASP3082		IND		
					Total	24

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

Stage of the most advanced project in the category
- Discovery/ Preclinical
- Pre-PoC
- Post-PoC

- POC: PoC judgement
- IND: Phase 1 entry of lead project
- IND: Phase 1 entry of follow-on project

Note
AT845: Updated timeline for PoC judgement is under discussion

1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Jul 2022)
PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

ON THE FOREFRONT OF HEALTHCARE CHANGE