Q2/FY2022 FINANCIAL RESULTS
ENDED SEPTEMBER 30, 2022

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October 31, 2022

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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

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AGENDA

I Q2/FY2022 Consolidated Financial Results

FY2022 Revised Forecasts

II Initiatives for Sustainable Growth

Q2/FY2022 FINANCIAL RESULTS: OVERVIEW

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

- XTANDI: Sales in the US were below initial full-year forecast. Strong performance in Europe and Japan covered the underachieving performance in the US
- Strategic products: Sales of PADCEV exceeded initial full-year forecast; strong performance mainly in Japan
- Cost of sales ratio was above initial full-year forecast due to changes in product mix
  Considering recent rapid exchange rate fluctuations, the exchange rate used for eliminating unrealized profit was changed from Q2 to exclude the impact on profit, based on the principle of materiality
  (see slides 20 and 21 for details)
- SG&A expenses were controlled in line with initial full-year forecast
- R&D expenses were on track

Operating profit

- Core OP increased 16% YoY, increased even excluding FX impact and was on track
- Full basis increased 33% YoY

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Strategic products: PADCEV, XOSPATA, EVRENZO

Q2/FY2022 FINANCIAL RESULTS

(billion yen)	Q2/FY21	Q2/FY22	Change	Change (%)	FY22 Initial FCST	Progress	FX impact
Revenue	**651.7**	**762.2**	**+110.5**	**+17.0%**	**1,443.0**	**52.8%**	+84.3 bil. yen
Cost of sales	124.7	151.7	+26.9	+21.6%			+12.5 bil. yen (Incl. the impact of elimination of unrealized profit remaining in Q2/FY21: +0.6 bil.yen
% of revenue	19.1%	19.9%	+0.8 ppt				
SG&A expenses	270.5	308.0	+37.4	+13.8%	598.0	51.5%	+40.2 bil. yen
US XTANDI co-pro fee	71.1	89.7	+18.6	+26.1%			
SG&A excl. the above	199.4	218.3	+18.9	+9.5%	416.0	52.5%	+24.0 bil. yen
R&D expenses	119.1	139.2	+20.1	+16.9%	254.0	54.8%	+15.1 bil. yen
Amortisation of intangible assets	12.4	20.0	+7.6	+61.3%			
Gain on divestiture of intangible assets	-	0.2	+0.2	-			
Core operating profit	**125.3**	**145.4**	**+20.1**	**+16.0%**	**290.0**	**50.1%**	+16.0 bil. yen
<Full basis>							**Ref.** (Other income) Net foreign exchange gains: 13.9 bil. yen (Other expenses) Booked in Q1 Impairment losses on intangible assets (AT702, AT751, AT753): 22.8 bil. yen fezolinetant increased fair value of contingent consideration: 13.7 bil. yen
Other income	2.8	16.2	+13.4	+470.7%			
Other expenses	38.0	41.7	+3.8	+9.9%			
Operating profit	**90.2**	**119.9**	**+29.7**	**+33.0%**	**269.0**	**44.6%**	
Profit before tax	89.1	120.5	+31.4	+35.2%	267.0	45.1%	
Profit	**71.6**	**96.4**	**+24.8**	**+34.7%**	**208.0**	**46.4%**	

Q2/FY2022 FINANCIAL RESULTS & OUTLOOK: XTANDI

Expect continued global growth despite the challenging market conditions in the US

(billion yen)	Q2/FY2022 Act	YoY	FY2022 Initial FCST	Progress	FY2022 Revised FCST	
Xtandi® (enzalutamide)	**332.0**	**+64.4 (+24%)** Excl. FX impact +22.8 (+9%)	**642.5**	**52%** Excl. FX impact 48%	**670.0** FX impact +55.8	✓ Global sales are in line with expectations up to Q2, as strong performance in Europe and JP covered the underachieving performance of the US ✓ In the US, sales are still expected to be challenging from Q3 onward considering the current market conditions. FCST has been revised downward excluding FX impact, yet near double-digit growth is expected in a global basis
US (Unit: $)	$1,304M	+19 (+1%)	$2,949M	44%	$2,618M	✓ Shifting to mature phase in current indications • Levels of PAP and generic competitor continue to be higher than expected • New patient starts are below expectations, not returned to pre COVID-19 levels ✓ Factors above are not expected to improve, downward revision of FCST (-$331M) ✓ Future growth driver is the anticipated additional indication of M0 CSPC, expect contribution after approval
Established Markets (Unit: €)	€715M	+74 (+12%)	€1,349M	53%	€1,429M	✓ M1 CSPC showed strong growth, contributing to demand increase (YoY +21%) ✓ Positive price impact from the agreement of higher price than assumed in Q1 (Germany), also contributed to the upward revision of FCST (+€80M)
Japan	27.5	+3.9 (+17%)	52.6	52%	55.4	✓ Maintained high market share. NHT market expansion higher than expected ✓ Factoring in the NHT market expansion, upward revision of FCST (+2.8 bil. yen)
Greater China	6.0	+2.4 (+66%)	13.3	45%	12.3	✓ Although demand expanded (YoY +34%), competitive pressure increased ✓ Expecting competitive pressure to continue, FCST has been revised downward
International Markets	24.4	+9.0 (+59%)	40.6	60%	44.3	✓ Continue to be growth market. Performance looks strong due to early shipment ✓ Outlook for full-year to be in line with initial FCST excluding FX impact

Exchange rates for initial FCST: 120 USD/yen,135 EUR/yen, Exchange rates for revised FCST: 137 USD/yen,139 EUR/yen (FCST rates Q3 onwards: 140 USD/yen,140 EUR/yen)
FCST: Full-year forecast, PAP: Patient Assistance Program, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, NHT: Novel Hormonal Therapy
Established Markets: Europe, Canada, Australia, Greater China: China, Hong Kong, Taiwan, International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Export sales, etc.

Q2/FY2022 FINANCIAL RESULTS & OUTLOOK: STRATEGIC PRODUCTS

Sales growth exceeding expectations for PADCEV, especially in Japan, upward revision of FCST

(billion yen)	Q2/FY2022 Act	YoY	FY2022 Initial FCST	Progress	FY2022 Revised FCST	
PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	**20.8**	**+11.7 (+128%)** (Excl. FX impact +8.9 (+98%))	**36.5**	**57%** (Excl. FX impact 53%)	**45.4** (FX impact +4.1)	✓ Global sales exceeding expectations ✓ Countries with approval expanded to 41 countries (as of Sep 2022) ✓ FCST has been revised upward, mainly factoring in the strong performance in JP
US (Unit: $)	$105M	+22 (+27%)	$230M	46%	$230M	✓ In line with initial FCST, FCST remains unchanged ✓ Expect significant growth after the anticipated approval of 1L mUC indication
Established Markets (Unit: €)	€19M	+19 (-)	€34M	56%	€40M	✓ Since the approval in Apr 2022, launched countries have increased Expect reimbursement to start in the near future ✓ Market penetration exceeding expectations, upward revision of FCST (+€6M)
Japan	4.0	+4.0 (-)	4.3	93%	8.3	✓ Continued from Q1, market penetration far exceeding expectations ✓ Significant upward revision of FCST (+4.0 bil. yen)
XOSPATA 40mg gilteritinib tablets	**23.5**	**+7.0 (+43%)** (+3.9 (+24%))	**46.2**	**51%** (47%)	**45.8** (+3.9)	✓ Global sales below expectations. Maintained high market share in US, the largest market, while market growth was lower than expected ✓ Factoring in the slowdown of the US market and increased competitive pressure in JP, FCST has been revised downward
Evrenzo roxadustat	**1.5**	**+0.1 (+9%)**	**9.9**	**15%**	**5.0**	✓ Sales in JP and Europe are below expectations. Continued to be impacted by competitive pressure in JP and low penetration of differentiation from standard of care in Europe ✓ Expect launch and reimbursement in France, Italy and Spain in 2H/FY22. However FCST has been revised downward factoring in the challenging situation up to Q2

Exchange rates for initial FCST: 120 USD/yen,135 EUR/yen, Exchange rates for revised FCST: 137 USD/yen,139 EUR/yen (FCST rates Q3 onwards: 140 USD/yen,140 EUR/yen)
FCST: Full-year forecast, 1L: First Line, mUC: Metastatic urothelial cancer, Established Markets: Europe, Canada, Australia

Q2/FY2022 FINANCIAL RESULTS: COST ITEMS

Cost of sales ratio increased YoY and was above full-year forecast
SG&A expenses were on track and decreased YoY when excluding FX impact
R&D expenses were on track when excluding FX impact

Core basis: Main items for YoY and progress against FCST

Cost of sales
% of revenue

YoY: +0.8 ppt

- ✓ Increase due to changes in product mix (mainly XTANDI (ex-US) and EVENITY) (+0.9 ppt)
- ✓ Cost of sales ratio was above forecast, mainly due to above factor

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

YoY: +9.5% (-2.6%)
Progress against FCST: 53% (50%)

- ✓ Global optimization of commercial-ralated personnel aligned with transformation of product portfolio (YoY approx. -6.0 bil. yen)
- ✓ Reduction of mature products-related costs (Approx. -4.0 bil. yen)
- ✓ Investment for new product launch readiness (Approx. +4.0 bil. yen)
- ✓ As a result of thoroughly reviewing costs that do not contribute to improving competitiveness and value, and actively making necessary investments, SG&A expenses were in line with initial forecast

R&D expenses

YoY: +16.9% (+4.2%)
Progress against FCST: 55% (52%)

- ✓ Booked one-time expenses for using PRV in Q1 for the application of fezolinetant
- ✓ In line with forecast, including the above expenses

( ) YoY change and forecast progress excluding FX impact

PRV: Priority Review Voucher

FY2022 REVISED FORECAST

- **Revenue: Upward revision**
  - ➢ XTANDI: Downward revision in US; Challenging market conditions to continue Q3 onwards.
    Upward revision in Europe and Japan
  - ➢ Reflect positive FX impact
- **Core OP: No Change**

(billion yen)	FY2022 Initial FCST	FY2022 Revised FCST	Change
Revenue	**1,434.0**	**1,529.0**	**+86.0**
SG&A expenses	598.0	642.0	+44.0
US XTANDI co-pro fee	182.0	186.0	+4.0
SG&A excl. the above	416.0	456.0	+40.0
R&D expenses	254.0	278.0	+24.0
Core operating profit (% of revenue)	**290.0** (20.1%)	**290.0** (19.0%)	**-**
<Full basis>			
Operating profit	**269.0**	**269.0**	**-**

Exchange rates for revised forecast:
137 USD/yen,139 EUR/yen
(Forecast rates Q3/FY2022 onwards:
140 USD/yen,140 EUR/yen)

FX impact: +115.5
XTANDI: US -39.7, ex-US +12.8,
PADCEV: +4.6, XOSPATA: -4.4, Evrenzo: -5.0

FX impact, decrease in US XTANDI co-pro fee

FX impact, increase in inventories related to commercial production of zolbetuximab:
Approx. +6.0

FX impact: +21.5
(Increase in cost of sales ratio and R&D expenses are factors for decrease in core operating profit margin)

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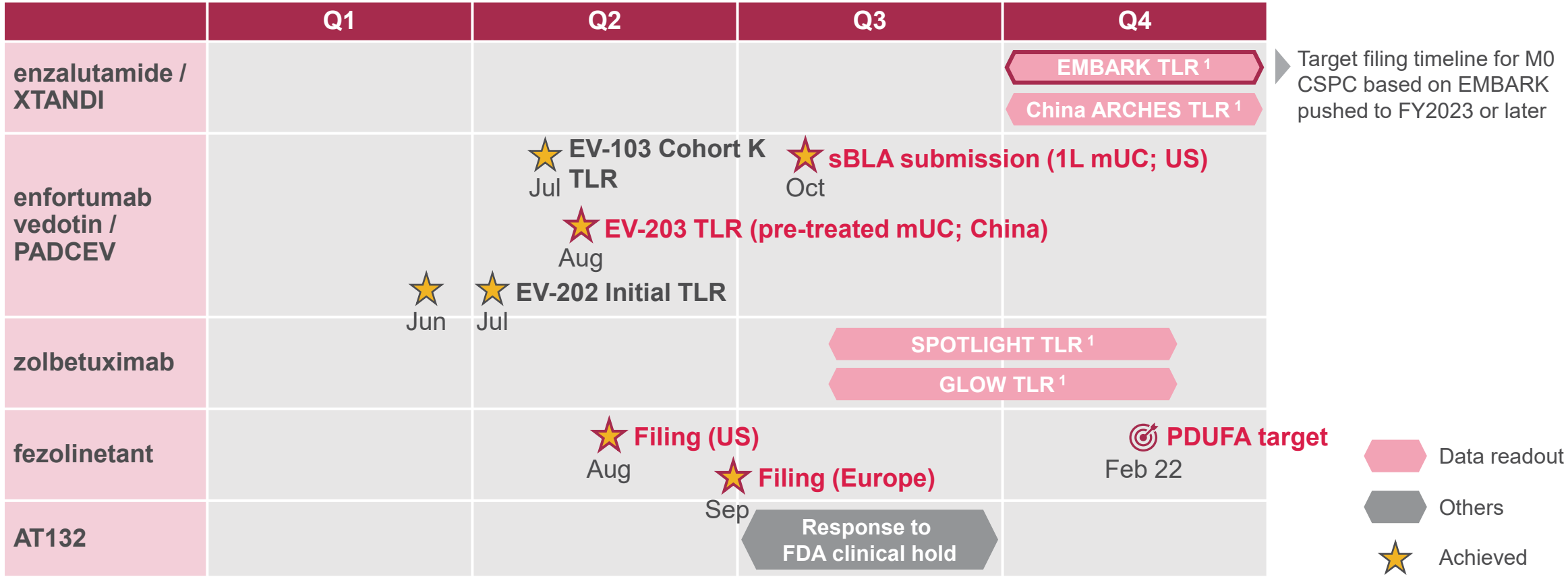
XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2022



As of Oct 2022

<Other updates>

- enzalutamide (M0 CSPC): Fast Track designation granted by FDA in Aug 2022
- zolbetuximab (gastric and GEJ adenocarcinoma): Fast Track designation granted by FDA in Sep 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, sBLA: Supplemental Biologics License Application, 1L: First line, mUC: Metastatic urothelial cancer, PDUFA: Prescription Drug User Fee Act, FDA: Food and Drug Administration, GEJ: Gastroesophageal junction

FEZOLINETANT: KEY SUCCESS FACTORS AND LATEST STATUS IN US AND EUROPE

Steady progress of development, important to approach different Key Success Factors in each region

US

Number of eligible patients[1]: ~10M

Key Success Factor[2]

- Women request new non-hormonal treatment from HCPs
- HCPs understand the profile of new non-hormonal treatment and recommend it to patients
- Ensure coverage from private insurance

Progress in development

- NDA accepted (Aug 2022)
- PDUFA target action date: Feb 22, 2023

Europe[3]

Number of eligible patients[1]: ~13M

Key Success Factor[2]

- Women recognize VMS as a treatable medical condition and consult their HCPs for help
- HCPs understand the profile of new non-hormonal treatment and prescribe it to patients
- Obtain reimbursement with the price reflecting the product value

Progress in development

- MAA accepted (Sep 2022)
- Enrollment completed in Phase 3b DAYLIGHT study (Oct 2022; faster than expected)

Common Key Success Factor: Enhance awareness of the burden of VMS and mechanism of action as a new non-hormonal treatment

1. Moderate to severe VMS associated with menopause, for 2030 (Source: Global impact of vasomotor symptoms 2020 VMS epidemiology). 2. Key success factors after approval. 3. Germany, France, Italy, Spain, UK.
HCP: Healthcare professional, VMS: Vasomotor symptoms, NDA: New Drug Application, PDUFA: Prescription Drug User Fee Act, MAA: Marketing Authorization Application

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	Phase 1 study ongoing	
		ASP2074	**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**	3
	Cell replacement (UDC)			
	Gene regulation (AAV)			
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	Phase 2/3 study in PMM ongoing **Additional screening activity discontinued in Phase 1b study in DMD**	4
	Mitochondrial stress	ASP8731	Phase 1 study ongoing. **Orphan drug designation granted by FDA in Sep 2022**	
	Mitochondrial transfer			
Targeted Protein Degradation	Protein degradation	ASP3082	Phase 1 study ongoing	1
Primary Focus Candidate	Immune modulating/regulatory cells			-
	Tissue-specific immune regulation			
			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 Oct 2022)
PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), 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

PROGRESS IN FOCUS AREA APPROACH (2/4): NEW PRIMARY FOCUS “TARGETED PROTEIN DEGRADATION” (1)

Primary Focus “Targeted Protein Degradation”

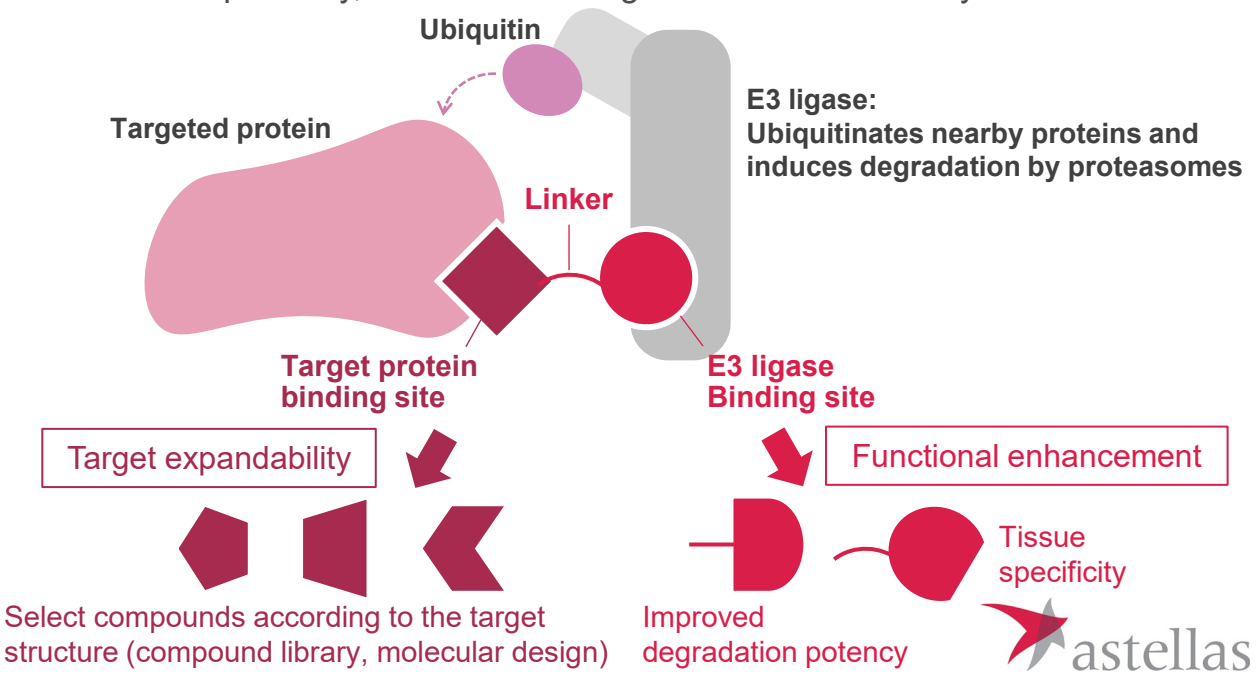
- Utilizes the ubiquitin-proteasome system, an intrinsic proteolytic mechanism, as an approach to access undruggable targets
- New modality consisting of three moieties, one that binds to the target protein and one that induces degradation, and a linker that bridges them (see right figure)
- Established a technology platform for creating protein degrader
- Created a lead program ASP3082 (KRAS G12D degrader) and advanced to clinical trial stage. Multiple follow-on programs under creation
- Proactively invest resources to the Primary Focus to continuously create programs in oncology and extend it into non-oncology fields

Advantages of technology

- Positioned as the most promising modality/technology at Astellas to approach intracellular undruggable targets
  - ➢ **Applicable to a wide range of targets:** Promotes degradation as a catalyst rather than inhibitory effect based on strong binding => Effective even with lower binding affinity than conventional molecules (fewer restrictions on binding sites)
  - ➢ **Retain advantages of small molecules:** Possibility of systemic administration (incl. oral), established manufacturing process and regulation, etc.

Applicability and expandability

- Applicable to various targets by conversion of target protein binding sites. Proteins without enzymatic activity (transcription factors, scaffold proteins, etc.) can be targeted
- Optimization including E3 ligase binding site and linker enables creation of compounds with enhanced functions such as degradation efficacy and tissue specificity, in addition to target molecule selectivity



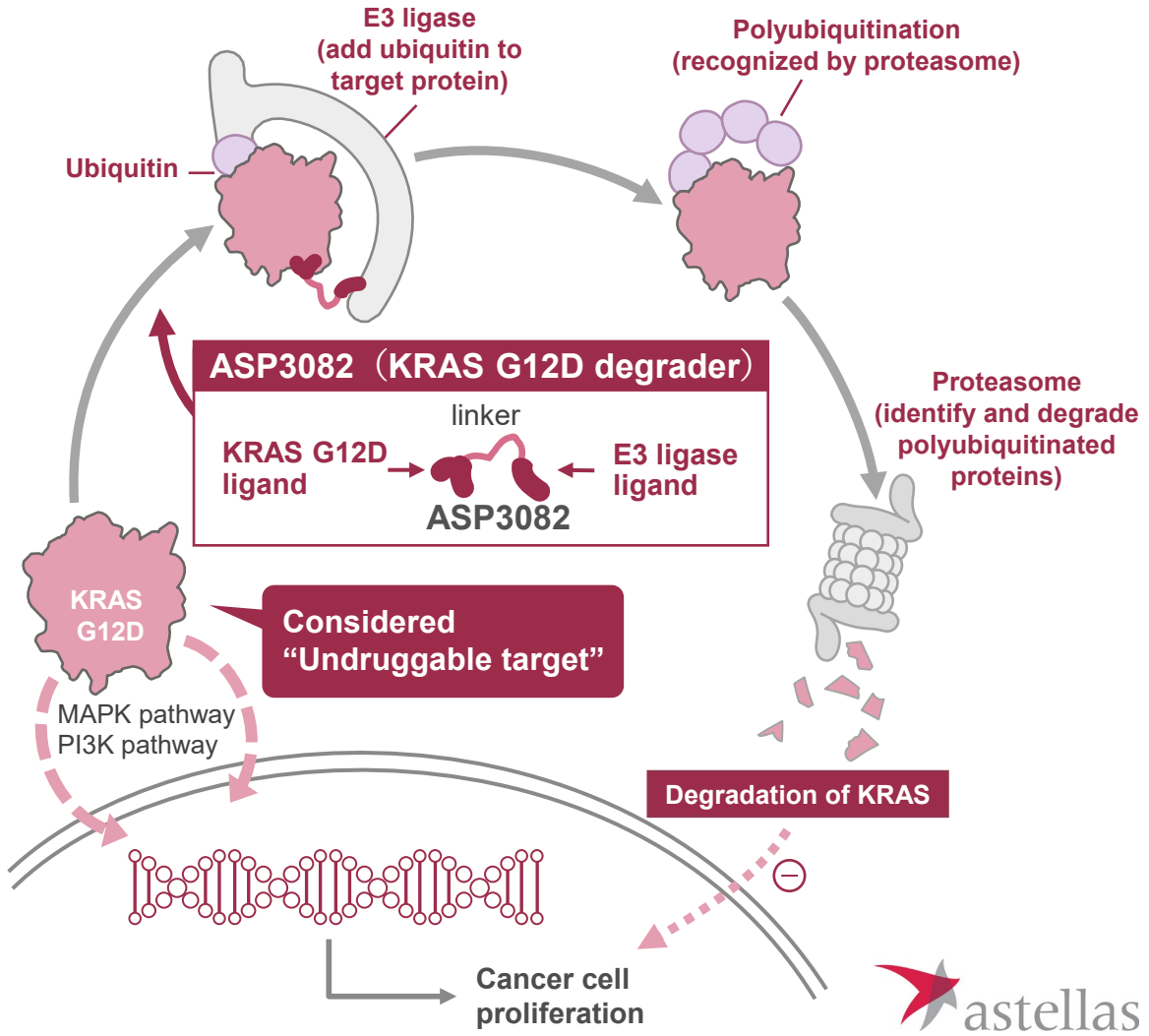
KRAS: Kirsten rat sarcoma viral oncogene homologue

PROGRESS IN FOCUS AREA APPROACH (3/4): NEW PRIMARY FOCUS “TARGETED PROTEIN DEGRADATION” (2)

Lead program ASP3082

- KRAS has been considered an undruggable target with less druggable pockets, making it difficult to develop inhibitors
- Multiple types of KRAS mutations are known
  - G12D mutation occurs most frequently:
    More than 51,000 new cancer cases annually in the US[1]
  - Inhibitors for G12C mutant have been developed which covalently bind to highly reactive cysteine residue
  - Difficult to create compounds that bind tightly to G12D mutant

- ASP3082 is a protein degrader targeting KRAS G12D mutant



1. Cancer Discov 12:924 (2022)
KRAS: Kirsten rat sarcoma viral oncogene homologue, MAPK: Mitogen-activated protein kinase, PI3K: Phosphatidylinositol-3 kinase

PROGRESS IN FOCUS AREA APPROACH (4/4): STRATEGIC INVESTMENT WITH TAYSHA GENE THERAPIES

Strategic investment with Taysha to expand gene therapy pipeline

Overview of agreement

- Investment of $50 million in total
  - 15% of the outstanding common stock of Taysha
  - One Board observer seat on Taysha's Board of Directors
  - Exclusive option to obtain exclusive license for two of Taysha's programs (TSHA-102 and TSHA-120)
  - Certain rights related to any potential change of control of Taysha

Strategic significance

- Taysha's strengths
  - Possesses multiple gene therapy programs in CNS
  - Employs AAV9, a clinically proven vector
  - Employs intrathecal dosing which avoids high systemic exposure
- Expand pipeline in CNS genetic diseases
- Possible to utilize the new manufacturing facility in Sanford, North Carolina

TAYSHA GENE THERAPIES

TSHA-102

- Target disease: Rett syndrome
  - Severe genetic neurodevelopmental disorder, mostly in females
  - Estimated incidence: 1 in 10,000 female births
- Mechanism of action: *MECP2* gene replacement
- Development phase: Phase 1/2
  - Preliminary clinical data from adult study expected in 1H 2023
- Timing of option exercise: After receipt of preliminary clinical data from pediatric study (to be initiated following the report of preliminary clinical data from adult study)

TSHA-120

- Target disease: Giant axonal neuropathy (GAN)
  - Progressive, ultra-rare neurodegenerative disease
- Mechanism of action: *gigaxonin* gene replacement
- Development phase: End-of-Phase 2
  - Positive motor function improvement and safety data obtained
- Timing of option exercise: After receipt of FDA Type B meeting minutes (Jan 2023)

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CNS: Central nervous system, AAV: Adeno-associated virus, MeCP2：methyl CpG binding protein 2, FDA: Food and Drug Administration

PROGRESS TOWARD ACHIEVING CSP2021

Revenue, Pipeline Value

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

- ✓ XTANDI: Sales in the US were below expectations, offset by strong performance in Europe and Japan
- ✓ PADCEV: Global sales growth exceeding expectations. sBLA submitted for 1L mUC in the US
- ✓ fezolinetant: Regulatory submission accepted in US and Europe

2 Post-PoC projects from Primary Focuses

3 Multiple technology platforms

4 Focus Area projects:
≥ ¥0.5T in FY2030

- ✓ ASP2074: Phase 1 entry
- ✓ ASP7317: Phase 1b study restart
- ✓ Launch Primary Focus "Targeted Protein Degradation"
- ✓ Gene Therapy: Strategic investment with Taysha

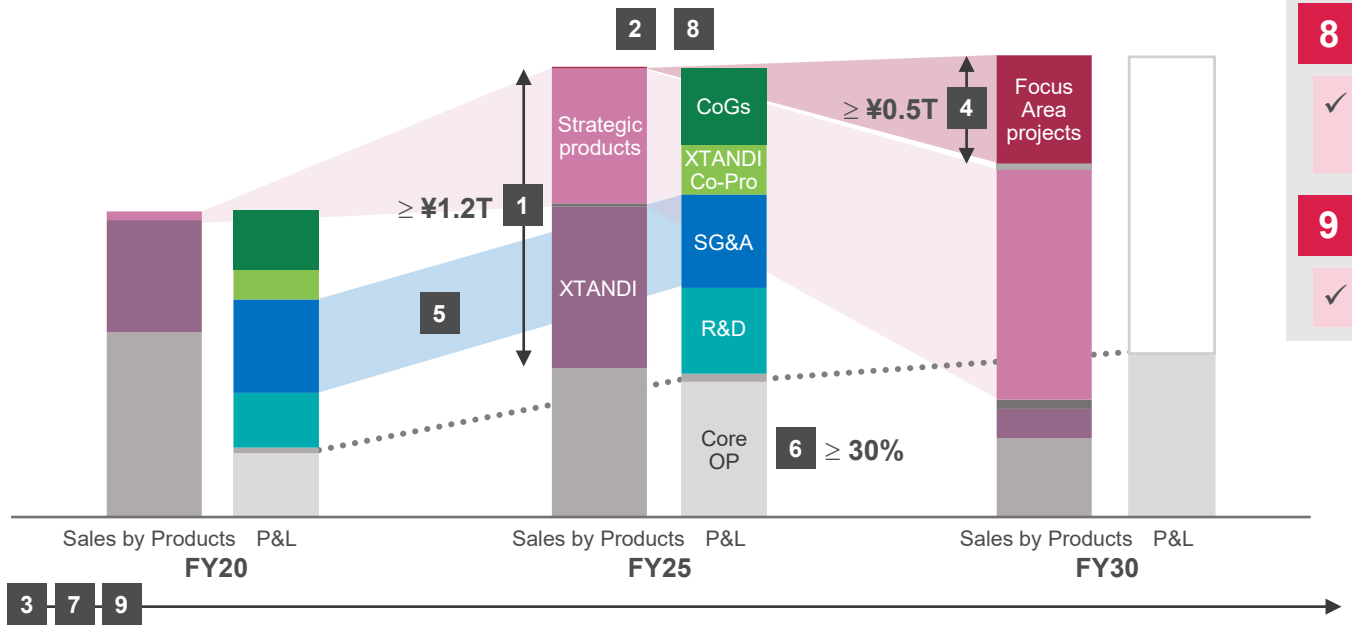
Core OP

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

- ✓ ASP5354: Initiation of Phase 2 study for additional indication

9 Sustainability

- ✓ Integrated Report 2022 released

Strategic products: PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132
CSP: Corporate Strategic Plan, sBLA: Supplemental Biologics License Application, 1L: First line, mUC: Metastatic urothelial cancer

R&D Meeting

- Dec 9th 2022, 10:00-11:30 (JST)

Sustainability Meeting

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

APPENDIX

CHANGE EXCHANGE RATES USED FOR ELIMINATION OF UNREALIZED PROFIT ON INVENTORIES

- In consideration of recent rapid exchange rate fluctuations, it was determined we changed our consolidation process taking into account its materiality as its financial impact is no longer negligible
- Changed the exchange rates used for eliminating unrealized profit on inventories held by foreign group affiliates
  （Change is underlined in the table below）
- This change does not represent a change in accounting policy, we will not restate our historical consolidated financial statements

	Until Q1/FY2022	From Q2/FY2022
Inventories (Statement of Financial Position Item)	Current rate	Current rate
Cost of sales (Statements of Income Item)	Current rate	Average rate
(Ref) Revenues and expenses of foreign group affiliates (Statements of Income Item)	Average rate	Average rate

- As a result, conversion differences between the current rate and the average rate for that period were previously recognized in cost of sales in the Consolidated Statement of Income, however, it will be recognized in equity through other comprehensive income going forward

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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	Q2/FY21	Q2/FY22	Change (%)
Revenue	**326.1**	**325.5**	**340.6**	**303.9**	**381.8**	**380.4**	**651.7**	**762.2**	**+17.0%**
Cost of sales	61.0	63.2	66.6	54.5	76.1	75.5	124.2	151.7	+22.1%
% of revenue	18.7%	19.4%	19.6%	17.9%	19.9%	19.9%	19.1%	19.9%	+0.8ppt
SG&A expenses	137.1	133.4	135.9	142.4	153.4	154.6	270.5	308.0	+13.8%
US XTANDI co-pro fee	34.5	36.6	37.6	30.6	43.1	46.5	71.1	89.7	+26.1%
SG&A excl. the above	102.6	96.8	98.3	111.8	110.3	108.0	199.4	218.3	+9.5%
R&D expenses	58.3	60.7	58.6	68.4	74.0	65.2	119.1	139.2	+16.9%
Amortisation of intangible assets	6.0	6.4	7.9	8.0	10.7	9.2	12.4	20.0	+61.3%
Gain on divestiture of intangible assets	-	-	24.1	0.1	0.2	0.0	-	0.2	-
Core operating profit	**64.1**	**61.8**	**97.5**	**29.2**	**68.1**	**77.3**	**125.8**	**145.4**	**+15.5%**
(Ref) Impact on Core OP*1	**+1.2**	**-0.7**	**+2.8**	**+4.5**	**+12.8*2**	**-12.8**	**+0.6**	**-**	**-**

*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

Q2/FY2022: REVENUE BY REGION

(billion yen)	Q2/FY21	Q2/FY22	Change (%)
Japan	130.5	133.3	+2.1%
United States	270.1	328.3	+21.5%
Established Markets	157.4	180.1	+14.5%
Greater China	33.1	45.0	+36.2%
International Markets	55.3	63.3	+14.5%

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

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Q2/FY2022: SALES OF MAIN PRODUCTS

(billion yen)	Q2/FY21	Q2/FY22	Change	CER growth	FY22 Initial FCST
XTANDI	267.6	332.0	+24.1%	+8.5%	642.5
PADCEV	9.1	20.8	+127.8%	+98.1%	36.5
XOSPATA	16.5	23.5	+42.5%	+23.6%	46.2
EVRENZO	1.4	1.5	+8.7%	+7.7%	9.9
mirabegron	84.4	93.4	+10.7%	-2.6%	178.7
Prograf	92.3	100.4	+8.7%	-0.9%	190.7

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

Q2/FY2022 ACTUAL: FX RATE

Average rate for the period

Currency	Q2/FY21	Q2/FY22	Change
USD	110 yen	134 yen	-24 yen
EUR	131 yen	139 yen	-8 yen

Change in current rate from previous fiscal year end

Currency	Q2/FY21	Q2/FY22
USD	-1 yen	-23 yen
EUR	+1 yen	-7 yen

<Impact of exchange rate on financial results>

- 84.3 billion yen increase in revenue, 16.0 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 Q2 end
Total assets	2,332.4	2,583.7
Cash and cash equivalents	316.0	361.1
Total equity attributable to owners of the parent	1,460.3	1,649.5
Equity ratio (%)	62.6%	63.8%

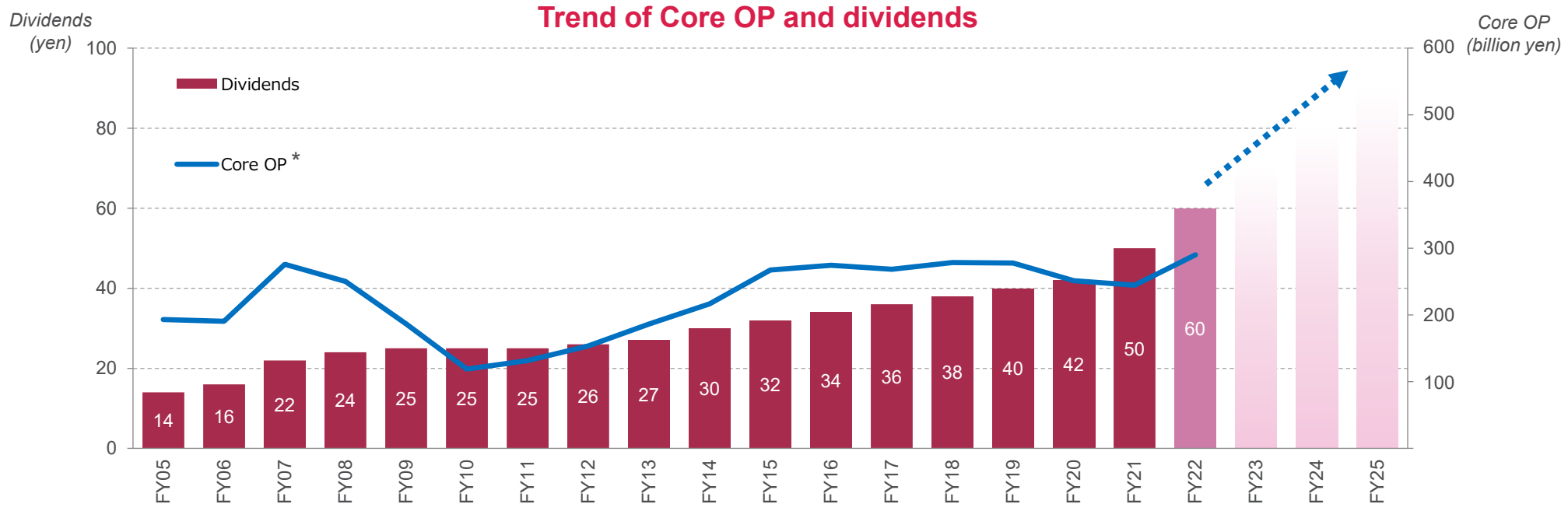
(billion yen)	Q2/FY21	Q2/FY22	FY21
Cash flows from operating activities	139.4	139.9	257.4
Cash flows from investing activities	-55.7	-34.7	-62.4
Free cash flows	83.6	105.2	195.0
Cash flows from financing activities	-89.9	-81.4	-216.3
Bonds and short-term borrowings	-40.0	-15.0	-30.0
Acquisition of treasury shares	-0.7	-10.6	-50.7
Dividends paid	-38.9	-45.7	-85.2

Balance of bonds and borrowings : 125.0 billion yen
(decreased 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
- ASP1570
- ASP2138
- ASP2074
- 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 associated with 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

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
ASP2074 Cancer			**enfortumab vedotin** Locally advanced or metastatic urothelial cancer who are ineligible to receive cisplatin-based chemotherapy in the first-line setting: US **fezolinetant** Vasomotor symptoms associated with menopause: Europe **peficitinib** Rheumatoid arthritis: China	

Discontinuation **roxadustat:** Chemotherapy-induced anemia (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: Approved label update to include the OS data in Sep 2022** • **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. **Results from Cohort K in EV-103 study presented at ESMO in Sep 2022. sBLA submitted in US in Oct 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
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	• **Discontinued development for Astellas-owned territories**
fezolinetant	VMS associated with menopause	• **US & Europe: NDA accepted in US in Aug 2022. MAA accepted in Europe in Sep 2022**. Phase 3b DAYLIGHT study ongoing **(enrollment completed). 52w data from Phase 3 SKYLIGHT 4 study at NAMS in Oct 2022** • **Asia:** LSLV in Phase 3 MOONLIGHT 1 study in Apr 2022. **Obtained topline results from Phase 3 MOONLIGHT 3 study in Sep 2022** • **Japan:** Phase 2b STARLIGHT study ongoing **(enrollment completed)**
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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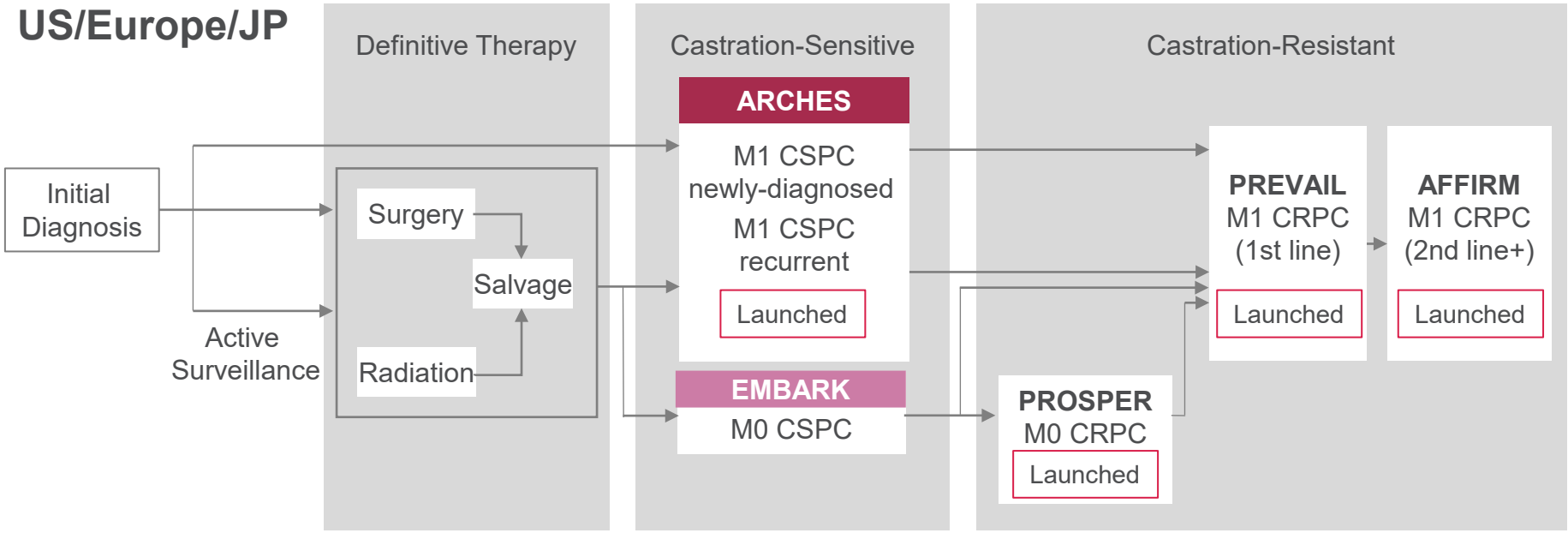
Strategic products: PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132. M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, OS: Overall survival, CHMP: Committee for Medicinal Products for Human Use, sBLA: Supplemental Biologics License Application, ESMO: European Society for Medical Oncology, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, GEJ: Gastroesophageal junction, Vasomotor symptoms, NDA: New Drug Application, MAA: Marketing Authorization Application, VMS: NAMS: North American Menopause Society, LSLV: Last subject last visit, FDA: Food and Drug Administration

ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

(Red: Updates since the last financial results announcement)



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

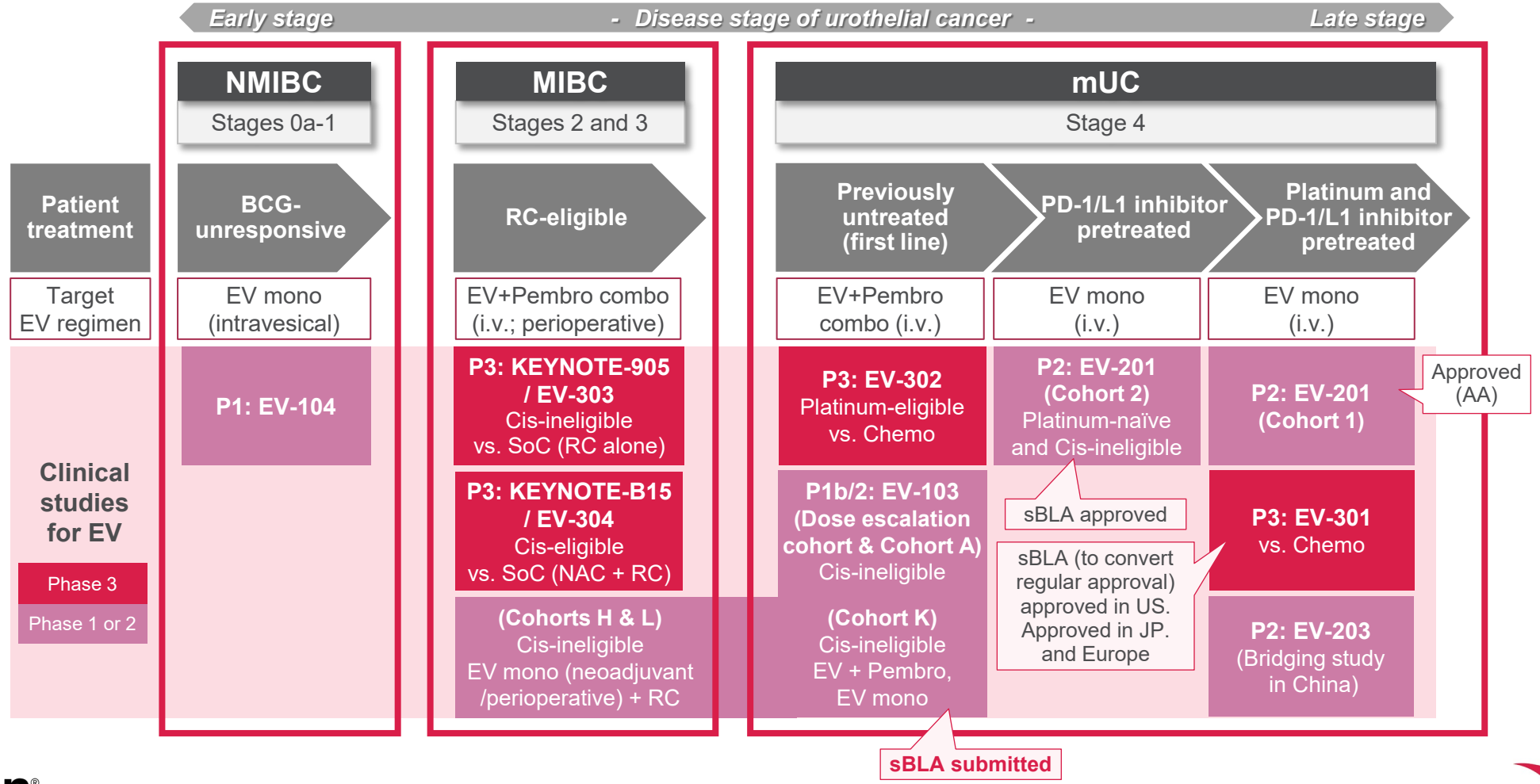
Disease stage	Early stage → Late stage					
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	**EMBARK**	**ARCHES**	**ENZAMET**	**PROSPER**	**PREVAIL**	**AFFIRM**
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary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



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

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

(Red: Updates since the last financial results announcement)

For urothelial cancer

	P3: EV-301	NCT03474107	mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono vs. Chemo	n=608	sBLA (to convert regular approval) approved in US in Jul 2021. Approved in JP in Sep 2021, in Europe in Apr 2022
	P3: EV-302	NCT04223856	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=990	FSFT: Apr 2020
	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 submitted in US in Oct 2022** Cohort L: Enrollment ongoing
	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	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) (3/4): STUDY DATA BY DISEASE STAGE OF UC

(Red: Updates since the last financial results announcement)

Disease stage	Early stage								Late stage
	MIBC		mUC						
	Surgery eligible		Previously untreated (first line)				PD-1/L1 inhibitor pretreated		
	Cis-eligible	Cis-ineligible	Platinum eligible	Cis-ineligible			Platinum naïve & Cis-ineligible	Platinum pretreated	
Study phase	Phase 3	Phase 3	Phase 3	Phase 1b/2		Phase 1b/2	Phase 2	Phase 2	Phase 3
Study No.	**KN-B15 / EV-304**	**KN-905 / EV-303**	**EV-302**	**EV-103 Cohort K**		**EV-103 Cohort A & Others**	**EV-201 Cohort 2**	**EV-201 Cohort 1**	**EV-301**
No. of subjects	784 (2 arms)	857 (3 arms)	990 (2 arms)	76	73	45	89	125	608 (2 arms)
EV regimen	Combo w/ Pembro (perioperative)	Combo w/ Pembro (perioperative)	Combo w/ Pembro	Combo w/ Pembro	Mono	Combo w/ Pembro	Mono	Mono	Mono
Control	Chemo (neoadjuvant)	SoC	Chemo	n/a	n/a	n/a	n/a	n/a	Chemo
Primary endpoint	pCR & EFS	pCR & EFS	PFS & OS	✔ ORR 64% **(CR 11%)**	**✔ ORR 45% (CR 4%)**	✔ ORR 73% ** (CR 16% **)	✔ ORR 51% ** (CR 22% **)	✔ ORR 44% (CR 12%)	✔ OS HR 0.70 *
OS	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	✔ (26.1 mos **)	✔ (14.7 mos)	✔ (12.4 mos **)	✔ HR 0.70 * (12.9 mos vs.9.0 mos)
PFS	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	✔ (12.3 mos **)	✔ (5.8 mos)	✔ (5.8 mos)	✔ HR 0.62 * (5.6 mos vs.3.7 mos)
ORR	(Ongoing)	(Ongoing)	(Ongoing)	✔ 64% **(CR 11%)**	**✔ 45% (CR 4%)**	✔ 73% ** (CR 16% **)	✔ 52% (CR 20%)	✔ 44% (CR 12%)	✔41% vs.18% * (CR 4.9% vs.2.7%)
DoR	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	**✔ 13.2 mos**	✔ 25.6 mos **	✔ 13.8 mos **	✔ 7.6 mos	✔ 7.4 mos vs. 8.1 mos *

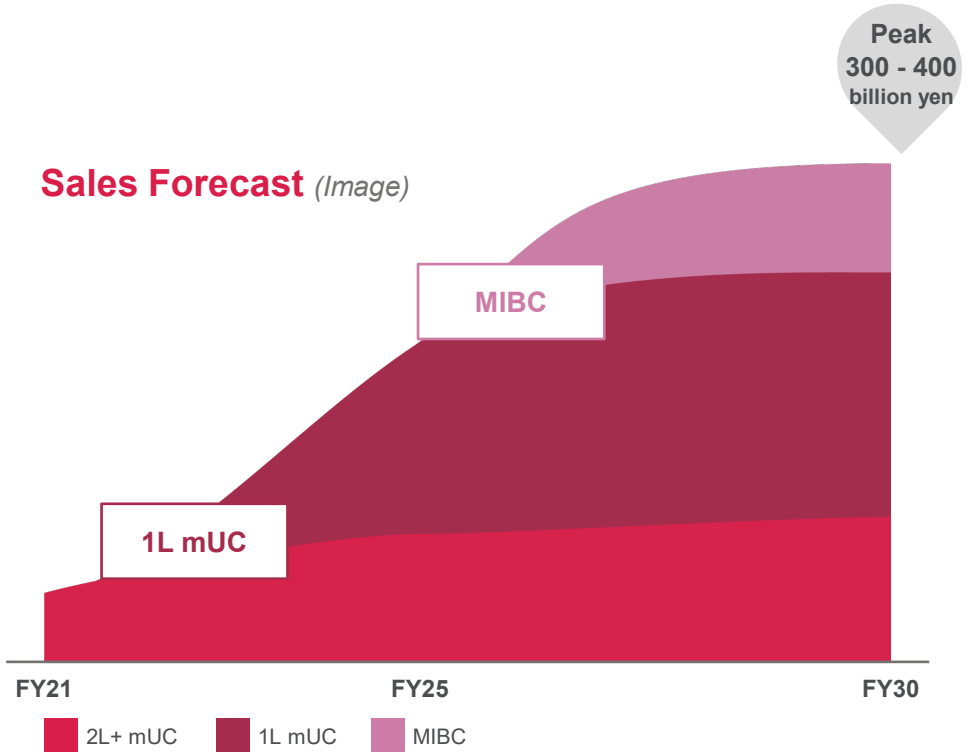
✔: Data obtained, *: Prespecified interim analysis, **: Updated data

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

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

- *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 *(Image)*



<Already approved / pivotal phase>

Patient segment		Pivotal study (PADCEV regimen)	Target filing timing	Number of eligible patients [1]
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** **FY2022** [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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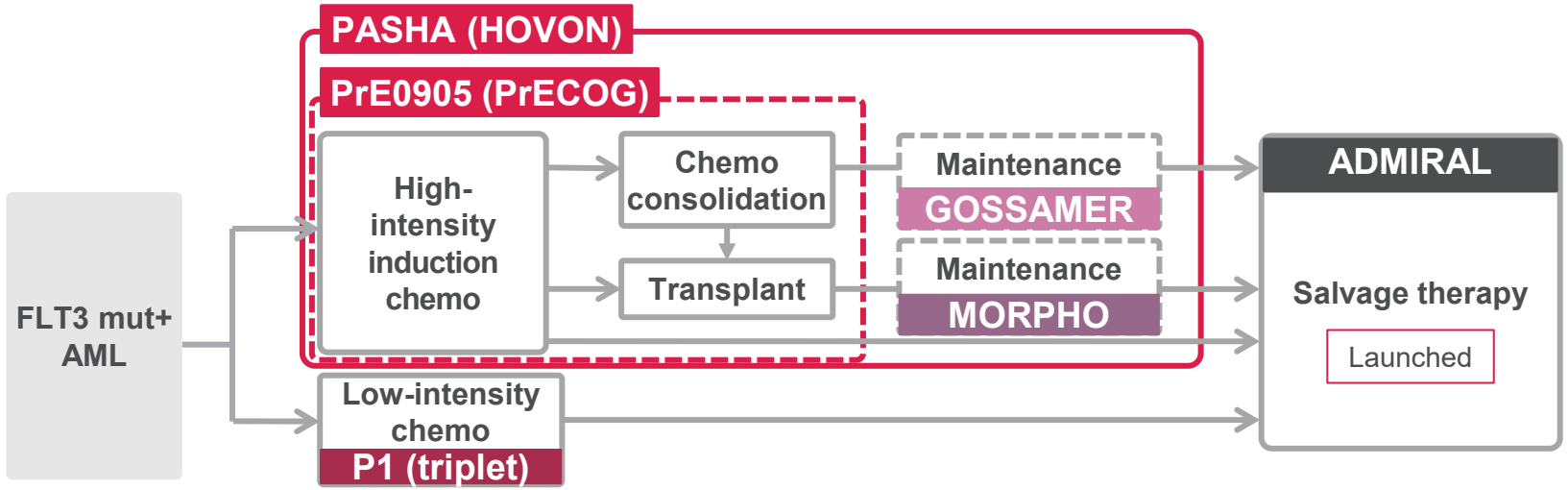
1. Based on internal estimates

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

GILTERITINIB: FLT3 INHIBITOR

(Red: Updates since the last financial results announcement)



	Relapsed or refractory	**P3: ADMIRAL**	NCT02421939	Monotherapy vs. salvage chemo (2:1)	n=371	Launched in US, JP, and Europe
	Newly diagnosed (HIC-eligible)	**P3: PASHA (HOVON)**	NCT04027309	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=768	FSFT: Dec 2019 (Sponsor: HOVON)
		P2: PrE0905 (PrECOG)	NCT03836209		n=179	FSFT: Dec 2019 (Sponsor: PrECOG, LLC.)
	Post-HSCT maintenance	**P3: MORPHO**	NCT02997202	Monotherapy vs. placebo (1:1)	n=356	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**	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

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**	NCT03504397	First line, Combo with mFOLFOX6, DB, vs. placebo	n=566	Enrollment completed
		P3: GLOW	NCT03653507	First line, Combo with CAPOX, DB, vs. placebo	n=507	Enrollment completed
		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

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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 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**	**Enrollment completed**

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

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)

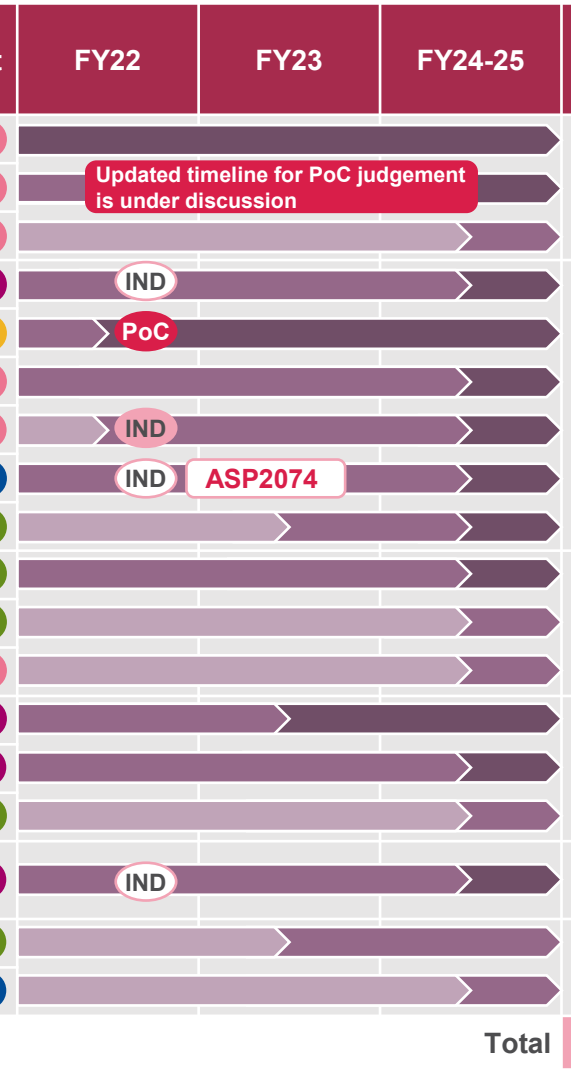
- Rare neuromuscular disease with X-linked, loss of function mutations in MTM1 gene
  - ✓ Approximately 1 in 40,000 to 50,000 newborn males
  - ✓ Estimated 50% mortality by 18 months
  - ✓ Up to 24 hours of invasive mechanical ventilation, 60% of patients require tracheostomy
  - ✓ > 80% require gastrostomy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

ASPIRO (clinical study for registration in XLMTM patients)	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

FOCUS AREA APPROACH: CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS

Primary Focus	Biology/Modality/Technology [1]	Lead project	No. of projects aiming 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



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

1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Oct 2022)
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

PROGRESS IN Rx+ PROGRAM

<Major updates>

- pudexacianinium chloride (ASP5354): Initiated Phase II study to expand indication to lymph nodes identification in lymphatic mapping performed prior to cancer resection surgery
- Smartphone game application “Moomin Move”: Partnership with Hokkaido and Aomori Prefectures to acquire and analyze data on walking habits and behavior
- Exercise support application (co-development with BANDAI NAMCO Entertainment): Discontinued

ON THE FOREFRONT OF HEALTHCARE CHANGE