FY2021 FINANCIAL RESULTS
ENDED MARCH 31, 2022

Kenji Yasukawa, Ph.D.
President and CEO
Astellas Pharma Inc.
April 27, 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 FY2021 Consolidated Financial Results

II Initiatives for Sustainable Growth

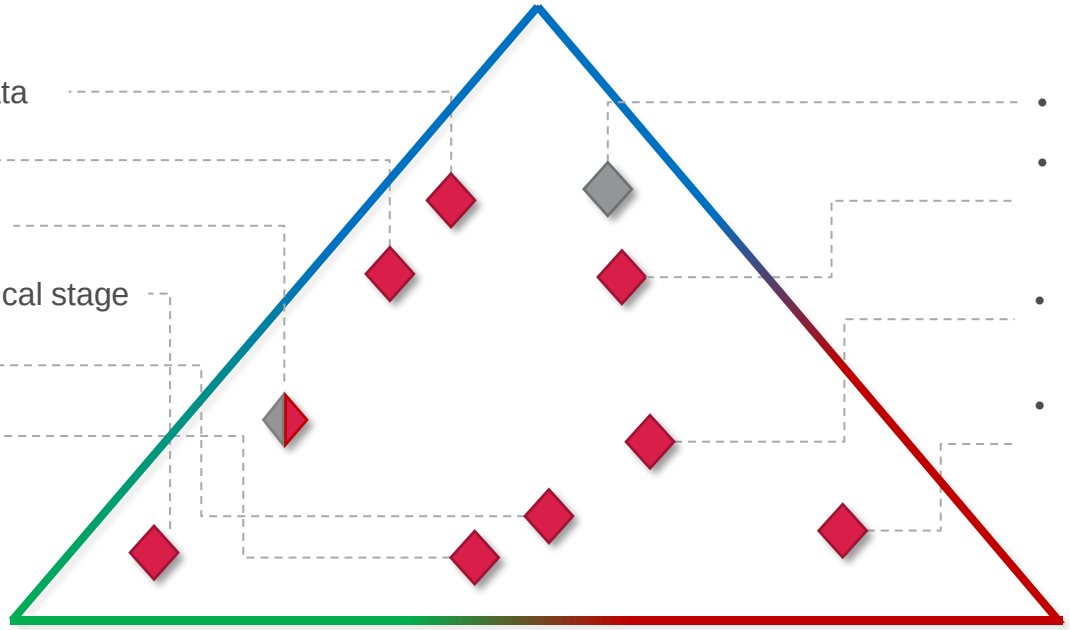
III FY2022 Forecasts and Key Expected Events

CSP2021 MAJOR PROGRESS IN Q4FY2021

Performance Goals

1. ***Revenue: XTANDI and Strategic products sales ≥¥1.2T in FY2025***
2. ***Pipeline value: Focus Area projects expected sales ≥¥0.5T in FY2030***
3. ***Core operating profit margin: ≥30% in FY2025***

- Obtained fezolinetant long-term safety data
- PADCEV approval in EU
- AT132 revision of the development plan
- ASP8731 and ASP3082 advanced to clinical stage
- Updated Materiality Matrix
- Conducted 1st Sustainability Meeting



- SG&A control
- Reorganization of commercial functions in order to centralize and standardize functions globally and build stronger capabilities
- Introduction of shared objectives and ambitious objectives to divisional objective setting
- Established “Astellas Leadership Expectations” and training commenced for all leaders (~3,000)

Strategic Goals

1. ***Enable patients to achieve better outcomes***
2. ***Translate innovative science into proven VALUE***
3. ***Advance the Rx+ Business***
4. ***Deepen engagement in sustainability***

Progress *Challenges*

Organizational Health Goals

1. ***Brave ideas pursue ambitious outcomes***
2. ***Talent and leadership thrives***
3. ***Excel as one Astellas***

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FY2021 FINANCIAL RESULTS: OVERVIEW

Record revenue increase for the first time since FY2018
Revenue increased 4% YoY and was slightly behind full-year forecast

- Sales of XTANDI and Strategic products increased 19% YoY, offsetting sales decrease due to termination of sales and distribution / transfer of product, but were behind ambitious full-year forecast aligned to CSP2021
- SG&A expenses were above full-year forecast
  R&D expenses were on track, but below full-year forecast when excluding one-off factors

Operating profit

- Core OP was behind full-year forecast due to promotion of standardization / rationalization investment for the future, temporary slowdown of XTANDI sales in Q4, and cost of sales increase due to rapid yen depreciation at end of FY2021
- Full basis was also behind full-year forecast
  - Booked impairment losses on intangible assets and goodwill in Q4/FY2021 not included in full-year forecast :
    Review of AT132 development plan (31.2 billion yen), termination of development for ASP2390 (11.3 billion yen), and termination of development for ASP1951 (5.2 billion yen)

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Strategic products: XOSPATA, PADCEV, EVRENZO
CSP2021: Corporate Strategic Plan 2021

FY2021 FINANCIAL RESULTS

(billion yen)	FY2020	FY2021	Change	Change (%)	FY2021 FCST*	Achievement	FX impact
Revenue	**1,249.5**	**1,296.2**	**+46.6**	**+3.7%**	**1,323.0**	**98.0%**	+59.6 bil. yen
Cost of sales	246.1	253.0	+6.9	+2.8%			
% of revenue	19.7%	19.5%	-0.2 ppt				
SG&A expenses	504.3	548.8	+44.5	+8.8%	541.0	101.4%	+25.0 bil. yen
US XTANDI co-pro fee	120.2	139.3	+19.1	+15.9%			
SG&A excl. the above	384.2	409.5	+25.4	+6.6%			+17.2 bil. yen
R&D expenses	224.5	246.0	+21.5	+9.6%	242.0	101.7%	+8.0 bil. yen
Amortisation of intangible assets	23.8	28.3	+4.5	+19.0%			
Gain on divestiture of intangible assets	-	24.2	+24.2	-			
Core operating profit	**251.4**	**244.7**	**-6.6**	**-2.6%**	**270.0**	**90.6%**	+18.5 bil. yen
<Full basis>							
Other income	7.6	15.3	+7.6	-			
Other expense	123.0	104.3	-18.6	-			
Operating profit	**136.1**	**155.7**	**+19.6**	**+14.4%**	**218.0**	**71.4%**	
Profit before tax	145.3	156.9	+11.6	+8.0%	216.0	72.6%	
Profit	**120.6**	**124.1**	**+3.5**	**+2.9%**	**174.0**	**71.3%**	

* Announced in Oct 2021

FY2021 FINANCIAL RESULTS: SALES OF MAIN PRODUCTS

FY2021 Actual (billion yen)

XTANDI

534.3

YoY: +75.9 (+17%)

Achievement against FCST: 96%

FY2021 FCST: 554.1

- ✓ Double-digit growth continues globally
- ✓ Sales against ambitious forecast were behind due to the following factors;
  US: Impact of COVID-19 (less sales promotion activities/ slowdown of new patient starts) and increased impact from competition
  EU: Reimbursement delay, increased pricing pressure and competition

XOSPATA

34.1

YoY: +10.2 (+43%)

Achievement against FCST: 96%

FY2021 FCST: 35.4

- ✓ Global sales increased driven by growth mainly in US, EU and China
- ✓ Captured high market share in US and Japan within the current indication
- ✓ Sales against full-year forecast were behind

PADCEV

21.7

YoY: +8.9 (+70%)

Achievement against FCST: 105%

FY2021 FCST: 20.7

- ✓ Global sales exceeded full-year forecast
- ✓ Revenue in US grew steadily and in line with forecast
- ✓ Launched in Japan in Nov. 2021 and initial uptake has been very strong and exceeded expected market penetration

EVRENZO

2.6

YoY: +1.5 (+132%)

Achievement against FCST: 36%

FY2021 FCST: 7.2

- ✓ Sales in Japan were behind forecast due to increased competitive pressure
- ✓ Launched in EU from Sep. 2021 and sales were behind forecast due to the impact of COVID-19 (restriction of sales promotion activities) and the low penetration of differentiation from standard of care

mirabegron

172.3

YoY: +8.7 (+5%)

Achievement against FCST: 98%

FY2021 FCST: 176.3

- ✓ Global sales increased, but were behind full-year forecast
- ✓ In the US, sales were behind forecast due to lower than expected US OAB market growth and increased pricing pressure

PADCEV (US): Co-promotion revenue from Seagen,
mirabegron (Product name: Betanis/Myrbetriq/BETMIGA), OAB: Overactive bladder

FY2021 FINANCIAL RESULTS: COST ITEMS

SG&A expenses increased YoY and were above full-year FCST
R&D expenses increased YoY and were below full-year FCST when excluding one-off factors

Core basis: Main items for YoY and achievement against FCST

Cost of sales
% of revenue

YoY: -0.2ppt

- ✓ Decrease mainly due to changes in product mix
- ✓ FX impact on elimination of unrealized gain: +0.2 ppt

SG&A expenses

YoY: +8.8%
Achievement against FCST: 101%

- ✓ SG&A excl. XTANDI US co-pro fee: +8.2 bil. yen (YoY +2.1%) (excl. FX impact)
- ✓ Investment in Digital Transformation (Approx. +8.0 bil. yen)
- ✓ Increase in sales promotion expenses for new product launch readiness (Approx. +5.0 bil. yen)
- ✓ Global optimization of personnel aligned with transformation of product portfolio (Approx. -9.0 bil. yen)

R&D expenses

YoY: +9.6%
Achievement against FCST: 102%

- ✓ FX impact (+8.0 bil. Yen)
- ✓ Increase in development cost of zolbetuximab and expanded investment in iota
- ✓ Inventories related to commercial production of development projects booked as R&D expenses (Approx.+8.0 bil. yen)
- ✓ Underspend against full-year forecast when excluding one-off factors

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CSP: Corporate Strategic Plan

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Key Expected Events

XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT

(Red: Updates since the last financial results announcement)

Key Events Expected in FY2021 (announced in Apr 2021)

Milestone	Project / Product	Indication / Clinical study	Result	Timing
Regulatory decision	enzalutamide / XTANDI	M1 hormone-sensitive prostate cancer (EU)	✓	Apr 2021
	enfortumab vedotin / PADCEV	mUC, platinum and PD-1/L1 inhibitor pretreated (US [a,b])	✓	Jul 2021
		mUC, cis-ineligible and who have previously received one or more therapy (US [a])	✓	Jul 2021
		mUC, platinum and PD-1/L1 inhibitor pretreated (EU)	✓	**Apr 2022**
		Radically unresectable UC that has progressed after anti-cancer chemotherapy (JP [c])	✓	Sep 2021
	roxadustat / EVRENZO	Symptomatic anemia associated with CKD (EU)	✓	Aug 2021
Regulatory submission	gilteritinib / XOSPATA	R/R AML (China [d])	**Not achieved**	
Data readout	fezolinetant	52-week safety results from Phase 3 SKYLIGHT 1, 2 & 4 studies	✓	Jul 2021 (SKYLIGHT 2) Oct 2021 (SKYLIGHT 1) **Mar 2022 (SKYLIGHT 4)**

(✓: Achieved)

a: Priority Review granted, Real-Time Oncology Review pilot program and Project Orbis applied
b: sBLA to convert Accelerated Approval to regular approval
c: Priority Review granted
d: sNDA to convert conditional approval to full approval

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Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132
M1: Metastatic, (m)UC: (metastatic) Urothelial cancer, CKD: Chronic kidney disease, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, sBLA: Supplemental Biologics License Application, sNDA: Supplemental New Drug Application

ENFORTUMAB VEDOTIN (EV): FIRST RESULTS IN MIBC

Obtained encouraging data supporting the ongoing Phase 3 studies in MIBC

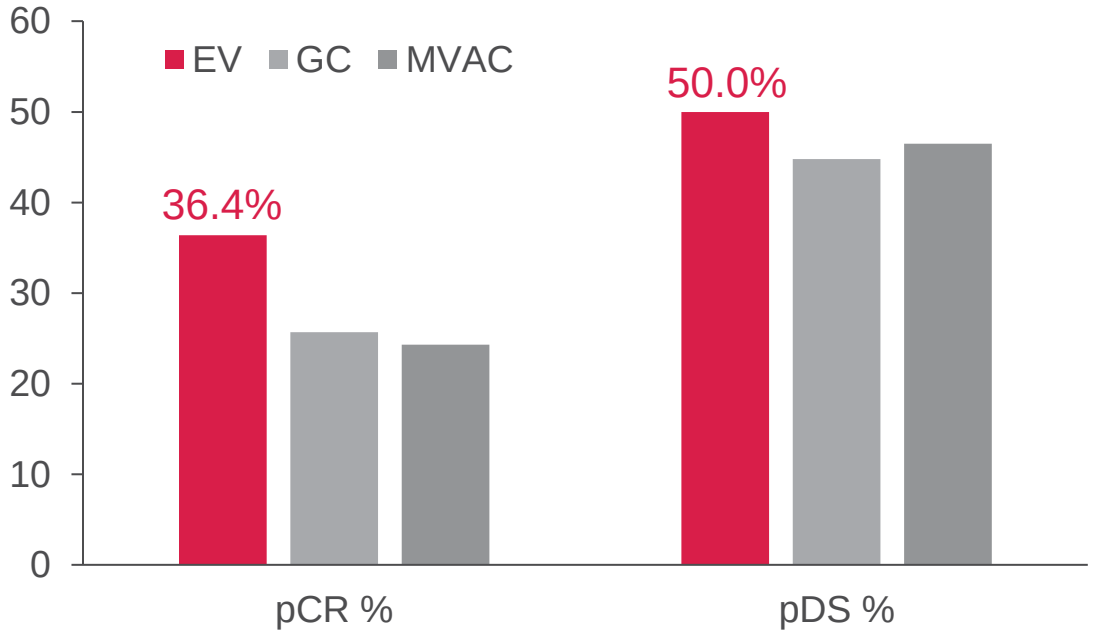
<Cohort H in EV-103 study>

Patient segment	Patients with MIBC who are ineligible for cisplatin-based chemotherapy
Study design	Neoadjuvant monotherapy 3 cycles, on days 1 & 8 of 21-day cycle
Enrolled participants	22
Primary endpoint	pCR rate by central pathology review
Secondary endpoint	pDS rate by central pathology review, safety, etc.

Neoadjuvant EV monotherapy → **Radical cystectomy & pelvic lymph node dissection** → microscopic examination

4 to 12 weeks after last dose of neoadjuvant EV

<Antitumor activity: comparison with cisplatin-based chemotherapy data*>



EV: EV-103 Cohort H, cisplatin-ineligible MIBC patients
GC, MVAC: cisplatin-eligible MIBC patients

MIBC: Muscle-invasive bladder cancer, pCR: Pathological complete response, pDS: Pathologic downstaging, GC: Gemcitabine and cisplatin/carboplatin, MVAC: Methotrexate, vinblastine, doxorubicin, and cisplatin
* Oncologist 21:708 (2016)

FEZOLINETANT: TOPLINE RESULTS OF MOONLIGHT 1 AND SKYLIGHT 4 STUDIES

- Minimal impact of MOONLIGHT 1 study results on CSP2021 sales forecast is anticipated
- SKYLIGHT 4 study results further support proceeding with regulatory filings in US & EU

	MOONLIGHT 1	(ref.) SKYLIGHT 1/2	SKYLIGHT 4
Study type	**Non-IND study**	**IND study**	IND study
Patient segment	Women with moderate to severe VMS associated with menopause	Women with moderate to severe VMS associated with menopause	Women with VMS associated with menopause
Study design	• First 12 weeks: DB, **30 mg** vs. placebo (1:1) • Last 12 weeks: active extension treatment, 30 mg	• First 12 weeks: DB, **30 mg and 45 mg** vs. placebo (1:1:1) • Last 40 weeks: active extension treatment, 30 mg or 45 mg	• 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)
Study region	**China, Korea and Taiwan**	**US, Canada and Europe**	US, Canada and Europe
Enrolled participants	**302**	**527 / 501**	1,831
Primary endpoint	• Mean change in the frequency and severity of moderate to severe VMS from baseline to week 4 & 12	• Mean change in the frequency and severity of moderate to severe VMS from baseline to week 4 &12	• Frequency and severity of adverse events • Percentage of participants with endometrial hyperplasia and/or endometrial cancer
Topline result	• Primary endpoints: **Not met** ✓ Numerical improvements from baseline observed but statistical significance not met • 12-week safety data: aligned with what was previously observed	• Primary endpoints: **Met** • 12-week safety data: No new safety signal of concern	• Primary endpoint (endometrial health): Met • The most common TEAE: consistent with placebo

Red: difference between MOONLIGHT 1 and SKYLIGHT 1/2 studies (up to 12 weeks)

<Upcoming conference presentation> May 2022: 12-week data of SKYLIGHT 1 study at ACOG
Jun 2022: 52-week data of SKYLIGHT 2 study at ENDO

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IND: Investigational New Drug, VMS: Vasomotor symptoms, DB: Double-blind, TEAE: treatment-emergent adverse events, ACOG: American College of Obstetricians and Gynecologists, ENDO: Endocrine Society

PROGRESS IN FOCUS AREA APPROACH (1/2): CURRENT STATUS OF CLINICAL PROGRAMS

(Red: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology [1]	Project	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	Phase 1 study ongoing **Interim data presented at WORLD*Symposium* in Feb 2022**
	Gene regulation (AAV)		
Immuno-Oncology	Checkpoint	ASP1951	**Terminated**
		ASP1570	Phase 1 study ongoing
	Artificial adjuvant vector cell (aAVC)	ASP7517	Phase 2 study in R/R AML and MDS ongoing Phase 1 study in advanced solid tumors ongoing
		ASP0739	Phase 1 study ongoing
	Oncolytic virus (intratumoral)	ASP9801	Phase 1 study ongoing
	Oncolytic virus (systemic)		
	Bispecific immune cell engager	ASP2138	Phase 1 study to start in Q1 FY2022
	Cancer cell therapy (UDC)		
Blindness & Regeneration	Cell replacement	ASP7317	Screening and enrollment in Phase 1b study put on hold, due to a manufacturing delay
	Cell replacement (UDC)		
	Gene regulation (AAV)		
Mitochondria Biology	Gene regulation & mitochondrial biogenesis	ASP1128	**Terminated**
		ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD ongoing
	Mitochondrial stress	**ASP8731**	**FSFT in Phase 1 study in Mar 2022**
	Mitochondrial transfer		
Primary Focus Candidates	Immune modulating/regulatory cells		
	Tissue-specific immune regulation		
	Targeted protein degradation	**ASP3082**	**Phase 1 study to start in Q1 FY2022**

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

1. Not exhaustively listed.

AAV: Adeno-associated virus, UDC: Universal donor cell, FDA: Food and Drug Administration, R/R: Relapsed and refractory, AML: Acute myeloid leukemia, MDS: Myelodysplastic syndrome, FSFT: First subject first treatment, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

PROGRESS IN FOCUS AREA APPROACH (2/2): SUMMARY OF FY2021

Primary Focus	Biology/Modality/Technology [1]	Achievement in FY2021: Number of new drug candidates [2]	Achievement in FY2021: Phase 1 entry	Achievement in FY2021: PoC achieved	No. of projects aiming PoC by end FY25: CSP2021 [3]	No. of projects aiming PoC by end FY25: Terminated before PoC judgement	No. of projects aiming PoC by end FY25: PoC not achieved	No. of projects aiming PoC by end FY25: As of Apr 2022
Genetic regulation	Gene replacement (AAV)	**1**			**7**	**3** (AT702, AT751, AT753)		**4**
	Gene regulation (AAV)							
Immuno-Oncology	Checkpoint	**1**	**2** (ASP1570, ASP2138)		**15**	**1** (preclinical project)	**2** (ASP1948, ASP1951)	**12**
	Artificial adjuvant vector cell (aAVC)							
	Oncolytic virus (intratumoral)							
	Oncolytic virus (systemic)							
	Bispecific immune cell engager							
	Cancer cell therapy (UDC)							
Blindness & Regeneration	Cell replacement	**1**			**3**			**3**
	Cell replacement (UDC)							
	Gene regulation (AAV)							
Mitochondria Biology	Gene regulation & mitochondrial biogenesis	**1**	**1** (ASP8731)		**5**		**1** (ASP1128)	**4**
	Mitochondrial stress							
	Mitochondrial transfer							
Primary Focus Candidates	Immune modulating/regulatory cells	**5**	**1** (ASP3082)		**1**			**1**
	Tissue-specific immune regulation							
	Targeted protein degradation							
Others								
	Total	**9**	**4**	**0**	**31**	**4**	**3**	**24**

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

1. Not exhaustively listed. 2. Number of therapeutic entities that entered the preparation phase toward IND (Investigational New Drug)/clinical development.
3. Estimated based on standard development timelines, assuming 100% probability of success (at CSP2021 announcement).
CSP: Corporate Strategic Plan, PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

PROGRESS IN Rx+ PROGRAM (1/2): SUMMARY OF FY2021

Key events expected in FY2021 (announced in Apr 2021)

Sphere *	Program	Event	Result	Timing
Chronic disease progression prevention	Fit-eNce	Initiation of pilot marketing for at-home service (Fit-eNce Home)	✓	Sep 2021
	Game application for exercise support	Initiation of pilot marketing	**Not achieved** (Product specifications under investigation)	
	BlueStar	Initiation of clinical study (Japan)	**Not achieved** (Clinical strategy under investigation)	
	My Holter II	Commercialization of service	✓	Jul 2021
Patient outcome maximization	pudexacianinium chloride (ASP5354)	Topline results for Phase 2 study	✓	Nov 2021

(✓: Achieved)

Other updates

- **Partnering with Nitto and M. Heart for ECG testing service (Sep 2021)**

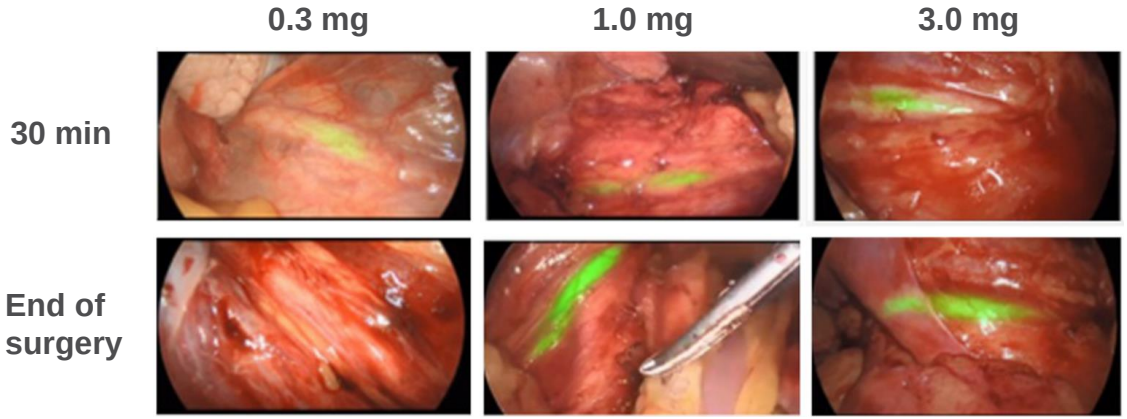
* Business areas to focus on for realization of Rx+ Story
ECG: Electrocardiography

PROGRESS IN Rx+ PROGRAM (2/2): PUDEXACIANINIUM CHLORIDE (ASP5354)

Pudexacianinium showed favorable efficacy and safety in Phase 2 study, which support further development

Results of Phase 2 study

- Pudexacianinium enhanced intraoperative ureter visualization under near-infrared fluorescence conditions
- Pudexacianinium appeared safe and well-tolerated;
  To date, no safety issues have been reported, no clinically relevant changes in vital signs, ECG or hematology, biochemistry or urine analysis. No related SAE and only 1 TEAE assessed as related by the investigator (grade 1 = mild proteinuria).
- 1.0 mg/patient pudexacianinium is the effective dose for intraoperative ureter visualization



Ureter Visualization at 30 Minutes Post Pudexacianinium Administration and at End of Surgery

Participants undergoing laparoscopic, minimally invasive colorectal surgery
single intraoperative IV dose of 0.3 mg, 1.0 mg, or 3.0 mg
The green signal indicates the fluorescence from pudexacianinium, which is the location of the ureter (SAGES conference in March 2022)

Next steps

- Phase 3 study is planned to start in FY2022
- Regulatory submission for the U.S. is planned in FY2023
- Business partnership with a device manufacturer is under consideration for commercialization

ECG: Electrocardiography, SAE: serious adverse event, TEAE: treatment-emergent adverse events, IV: intravenous, SAGES: Society of American Gastrointestinal and Endoscopic Surgeons

REVIEW OF THE FIRST YEAR OF CSP2021

Performance Goals are achievable despite some challenges

Progress in CSP2021
- As expected
- Recognized as challenge

Revenue, Pipeline Value

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

- Sales growth by 19% YoY, on track toward the target
- Achieved most of the expected key development milestones

2 Post-PoC projects from Primary Focuses

3 Multiple technology platforms

4 Focus Area projects:
≥ ¥0.5T in FY2030

- New drug candidates in 9 projects, Phase 1 entry in 4 projects
- Judgement in 7 projects
- No progress to Post-PoC stage from Primary Focus
- Clinical hold of AT132

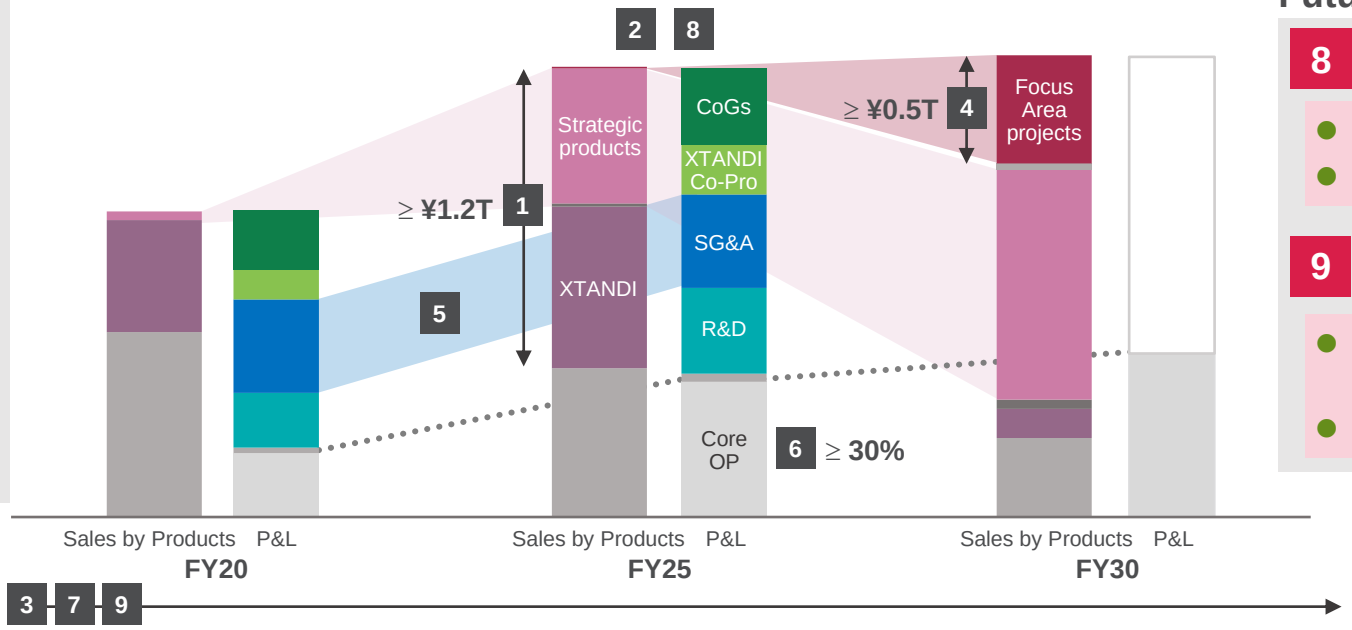
Core OP

5 Flat SG&A in absolute terms

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

7 Steady increase in dividends

- Strategic upfront investment for future growth
- Increase of SG&A more than expected (increased investment for future growth such as OHG activities, DX and new products could not be covered by reduction of traditional cost spending)



Future growth

8 Rx+: Breakeven by FY2025

- First commercialization of service
- ASP5354: progress to Phase 3

9 Sustainability

- Disclosure aligning with TCFD recommendations
- Update of materiality matrix

Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132
CSP: Corporate Strategic Plan, PoC: Proof of concept, OHG: Organizational Health Goals, DX: Digital transformation, TCFD：Task Force on Climate-related Financial Disclosures

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FY2022 FORECAST: OVERVIEW

- *Revenue and Profit to increase in FY2022*
  Core OP margin for FY2022 to be 20.1%
- *XTANDI and Strategic products continue to grow (+24%, YoY)*
  Growth to more than offset the decrease of mature products
- *Resource allocation to key strategic areas such as R&D investment for Primary Focus and investment for new product launch readiness (mainly for fezolinetant and zolbetuximab); reviewing costs not contributing to competitiveness and increase of value.*

  Control SG&A strictly by cost reduction from global optimization of personnel, thorough reduction of mature products-related costs and optimization of procurement costs.

  Aiming to improve the labor productivity of Astellas by "Dansharism" movement*
- *Dividend per share: Forecasted 10 yen increase to 60 yen*

Strategic products: XOSPATA, PADCEV, EVRENZO
*Dansharism: Please refer to slide 28 in appendix

FY2022 FORECAST

(billion yen)	FY2021 actual	FY2022 forecast	Change (%)
Revenue	**1,296.2**	**1,443.0**	**+11.3%**
SG&A expenses	548.8	598.0	+9.0%
US XTANDI co-pro fee	139.3	182.0	+30.6%
SG&A excl. the above	409.5	416.0	+1.6%
R&D expenses	246.0	254.0	+3.2%
Core operating profit	**244.7**	**290.0**	**+18.5%**
<Full basis>			
Operating profit	**155.7**	**269.0**	**+72.8%**
Profit	**124.1**	**208.0**	**+67.6%**

FY2022 FCST (FX rate)
USD: 120 yen
EUR: 135 yen

Impairment losses on intangible assets due to termination of development for AT702, AT751, AT753 to be booked in Q1/FY2022 ($170M)
*Already included this impact into full-year forecast (full basis)

FY2022 FORECAST: XTANDI AND STRATEGIC PRODUCTS

	FY2022 Forecast	FY2022 initiatives and growth factors
XTANDI	**642.5 billion yen** **+108.2, YoY (+20%)**	• Expand sales in M1 CSPC in US, Japan and International Markets • Continue strong growth in M1 CRPC in China
XOSPATA	**46.2 billion yen** **+12.1 (+36%)**	• Expect continued growth in US, Established Markets and sales contribution from International Markets due to the increase of launched countries
PADCEV	**36.5 billion yen** **+14.8 (+68%)**	• Expect continued growth in US within the current US indication • Continued market share gain in Japan, launched in Dec 2021 • Launch in priority EU countries and the preparation for reimbursement
EVRENZO	**9.9 billion yen** **+7.3 (+281%)**	• Expect growth in Japan whilst reinforcing market position in the HIF-PHI class • Secure reimbursement in European countries and drive market share growth • Expect sales contribution from International Markets

Strategic products: XOSPATA, PADCEV, EVRENZO
M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, HIF-PHI: Hypoxia-inducible factor prolyl hydroxylase inhibitor

XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2022

	Q1	Q2	Q3	Q4
enzalutamide / XTANDI		EMBARK TLR [1]	Filing (M0 CSPC; US)	China ARCHES TLR [1]
enfortumab vedotin / PADCEV		EV-103 Cohort K TLR [1]	Filing (1L mUC; US)	EV-203 TLR (pre-treated mUC; China) [1]
		EV-202 TLR (other solid tumors; initial results) [1]		
zolbetuximab*			SPOTLIGHT TLR [1]	GLOW TLR [1]
fezolinetant		Filing (US)	Filing (EU)	
AT132			Response to FDA clinical hold	

Regulatory submission

Data readout

Others

* Target filing timeline shifted to FY2023

Education and awareness activities for Claudin 18.2

- Disease state and biomarker education for HCPs managing gastric cancer and for pathologists
- Multiple initiatives to help ensure Claudin 18.2 test availability at launch, including publications on exploratory biomarkers and clinical trial data
- Initiatives to support payers understanding and awareness of Claudin 18.2 biomarker and its relevance as an important target in metastatic gastric cancer

Education and awareness activities for VMS

- Disease state education and awareness intended to reach over 100K HCPs and over 10M women
- VMS educational discussions with payers to highlight the impact on their customers lives and the clinical and economic burden
- Data driven omnichannel communications designed to optimize reach and engagement through non-personal (including digital) and personal activities

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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, VMS: Vasomotor symptoms, HCP: Healthcare Professionals, FDA: Food and Drug Administration

POTENTIAL PEAK SALES: XTANDI AND STRATEGIC PRODUCTS (UPDATE)

Assumptions reviewed for each product, expect continued strong growth
Downward revision of potential peak sales for AT132, reflecting the latest situation

Product	Potential Peak Sales *(Global, billions of yen)*	Assumptions Update
XTANDI (enzalutamide)	**600 - 700**	✓ Reviewed assumptions for XTANDI, PADCEV and XOSPATA, taking into account the global competitive environment, recent sales and prescription trends (duration and treatment rate), and ongoing clinical studies ✓ Reviewed assumptions for fezolinetant, taking into account the latest market research, number of patients, and the results of Phase 3 studies obtained in FY2021 ✓ As a result of the review, potential peak sales remains unchanged
fezolinetant	**300 - 500**	
PADCEV (enfortumab vedotin) [1]	**300 - 400**	
XOSPATA (gilteritinib)	**100 - 200**	
zolbetuximab	**100 - 200**	✓ Reviewed assumptions taking into account the competitive environment for zolbetuximab, and recent sales trend and market environment for EVRENZO. Potential peak sales revised downward within range
EVRENZO (roxadustat) [2]	**50 - 100**	
AT132 (resamirigene bilparvovec)	**under 50** [3]	✓ Potential peak sales revised downward based on the assumptions of the delay of approval timing and change in target patient population

Note) Only indications undergoing pivotal studies are included for projection (as of April 2022)

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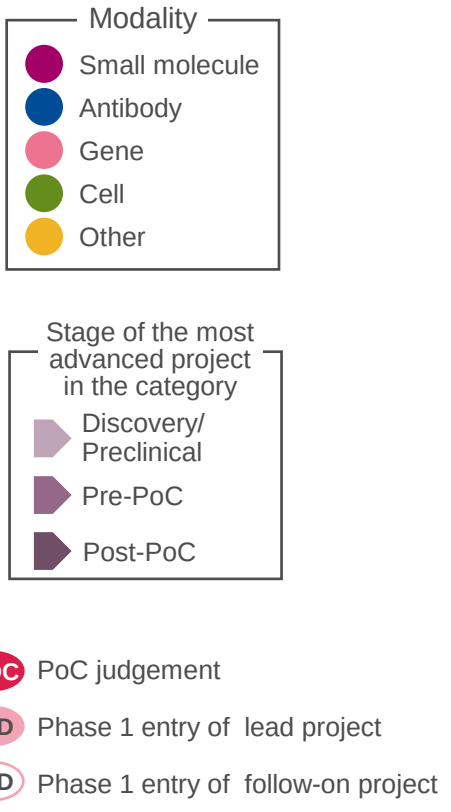
1. Sales for Americas are calculated based on the sales booked by Seagen, 2. Astellas territories only; Japan, Europe, the Commonwealth of Independent States, the Middle East, South Africa, etc.
3. Previous potential peak sales: 50 - 100 billion yen (announced in May 2021)

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	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 Biology	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	
		Total	24



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

Rx+ PROGRAM: KEY EVENTS EXPECTED IN FY2022

Category	Program	Event
Digital health Other services	EG Holter	Initiation of pilot marketing
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

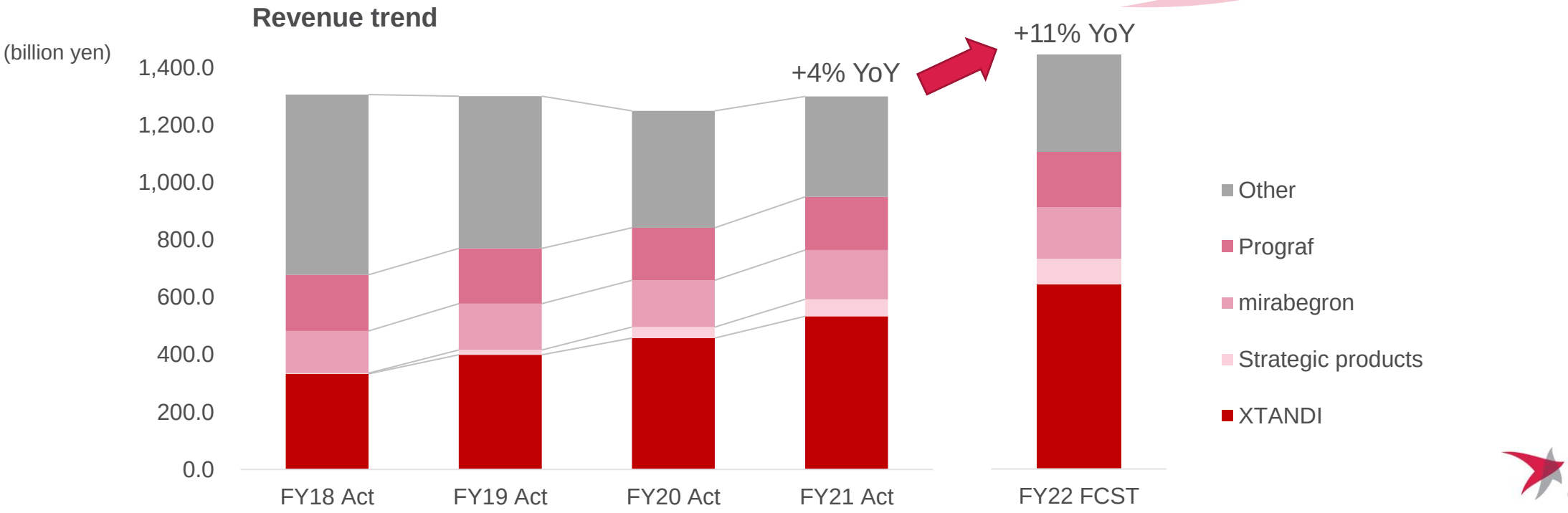
IDE: Investigational Device Exemption, FSFT: First subject first treatment

CONCLUSION: TOWARD MID- TO LONG-TERM GROWTH TREND

Product portfolio has changed and sales of XTANDI and Strategic products growing significantly
Record revenue increase in FY2021 for the first time since FY2018
Continued growth in FY2022 and aiming to achieve rich development milestones

Key development milestones in FY2022

- XTANDI: Filing M0 CSPC in US
- fezolinetant: Filing in US and EU
- PADCEV: Filing mUC 1st line in US
- zolbetuximab: Topline results for Phase 3 studies



Strategic products: XOSPATA, PADCEV, EVRENZO
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, mUC: Metastatic urothelial cancer

APPENDIX

“*DANSHARISM*” MOVEMENT

- Perfectly fitting for a Japanese company, expanding the concept of “Danshari,” which is the thoroughly elimination of waste, globally and into daily operations
- At the same time, ensuring that managers have financial discipline and cost ownership, and transforming into an organization that creates innovation by improving our labor productivity
- Having a mindset that enables us to invest resources into new initiatives while maintaining the absolute amount of SG&A expenses

<Step of “Dansharism” >

1. Thoroughly reevaluate our work and activities without exception	2. Define what work to halt or terminate	3. Actually halting or terminating that work
Target : All work, including accepted practices continuing on from the past, old work processes, and routine work	**Specification:** Specify work that bring “less” ROI or are “less” priority	**Execution :** Be "courageous" and halt work that was specified in order of less importance and eventually secure a white space for employees
Classification : Categorize each work with a “Must have” or “Nice to have” perspective	(Example) Existing old processes, reports of similar content, reports of excessive quality, review of meeting attendees, etc.	Consequently, invest resources in new things while reducing costs

Building an environment that enables the creation of innovation in a sustainable manner through thorough efficiency improvements

What is “Danshari”? -Japanese minimalism-
It is the Japanese concept of "decluttering" and is the process of cutting out what is unnecessary, detaching from things, and readjusting one's life accordingly.

ROI: Return On Investment, White space: Resources needed to explore new ideas

FY2021 FINANCIAL RESULTS: REVENUE

Revenue increase driven by growth of XTANDI and Strategic products, which offset sales decrease due to termination of sales and distribution / transfer of products

	FY2020	FY2021	Change	Change (%)
Revenue	**1,249.5 bil. yen**	**1,296.2 bil. yen**	**+46.6 bil. yen**	**+3.7%**

Increase in XTANDI and Strategic products

XTANDI, XOSPATA, PADCEV, EVRENZO **+96.5 bil. yen**

- Recovered sales level of Lexiscan, negatively impacted by COVID-19 in Q1/FY20 **+15.5 bil. yen**

Termination of sales and distribution / transfer of products

Celecox, Lipitor, Eligard **-39.0 bil. yen**

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Strategic products: XOSPATA, PADCEV, EVRENZO

FY2021: REVENUE BY REGION

(billion yen)	FY2020	FY2021	Change (%)
Japan	279.1	258.8	-7.3%
United States	473.2	537.5	+13.6%
Established Markets	293.2	315.2	+7.5%
Greater China	59.3	66.3	+11.8%
International Markets	111.1	110.1	-0.9%

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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FY2021: SALES OF MAIN PRODUCTS

(billion yen)	FY2020	FY2021	Change	CER growth	FY21 FCST*
XTANDI	458.4	534.3	+16.6%	+10.6%	554.1
XOSPATA	23.8	34.1	+42.9%	+35.6%	35.4
PADCEV	12.8	21.7	+69.5%	+60.8%	20.7
EVRENZO	1.1	2.6	+131.5%	+131.0%	7.2
mirabegron	163.6	172.3	+5.3%	+0.7%	176.3
Prograf	182.7	185.4	+1.5%	-3.8%	185.7

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

*Announced in Oct 2021

FY2021 FINANCIAL RESULTS: BUSINESS UPDATE FOR MAIN PRODUCTS

XTANDI	Global sales increased +17% given the ongoing focus on recent M1 HSPC launches, but did not achieve the ambitious forecast. In the US, demand grew in excess of 10% YoY, but sales growth has been below expectations due to the impact of COVID-19 (less sales promotion activities/ fewer patients entering the market) and increased impact from competition. In the EU, delay of reimbursement approvals (M1 HSPC), increased pricing pressure and competition impacted net sales
XOSPATA	Sales across regions steadily expanded and global sales were slightly behind forecast. Initial sales trend is positive thus far in China - launched in Apr 2021 (FY21 sales: 1.5 billion yen). Recent approvals in International Markets will contribute to the future growth of XOSPATA
PADCEV	Global sales exceeded full year forecast. Revenue in the US grew steadily as expected following approval of additional indication in Jul 2021. Further global launches occurred in FY2021: Japan (Nov 2021), Switzerland (Dec 2021) Initial PADCEV uptake has been very strong thus far in Japan and exceeded expectations (FY21 sales: 1.8 billion yen)
EVRENZO	Overall sales performance was behind full-year forecast. While sales grew YoY, performance was behind expectations due to intense competition from other HIF-PHIs in Japan and a slightly later and slower launch in Germany, Netherlands and UK
mirabegron	Global sales increased, driven by growth mainly in Japan and Established Markets, but did not achieve full-year forecast. In the US, Myrbetriq sales were behind full-year forecast due to lower than expected US OAB market growth and increased pricing pressure

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M1 HSPC: Metastatic Hormone-sensitive prostate cancer, HIF-PHI: Hypoxia-inducible factor prolyl hydroxylase inhibitor, OAB: Overactive bladder

FY2021 ACTUAL: FX RATE

Average rate for the period

Currency	FY2020	FY2021	Change
USD	106 yen	112 yen	+6 yen
EUR	124 yen	131 yen	+7 yen

Change in closing rate from previous fiscal year end

Currency	FY2020	FY2021
USD	+2 yen	+11 yen
EUR	+10 yen	+5 yen

<Impact of exchange rate on financial results>

- 59.6 billion yen increase in revenue, 18.5 billion yen increase in core OP
- FX impact on elimination of unrealized gain: COGs ratio +0.2 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 FY2021 forecast by 1 yen appreciation

Currency	Average rate 1 yen higher than assumption		Year-end rate 1 yen higher 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)	FY2020 end	FY2021 end
Total assets	2,273.6	2,332.4
Cash and cash equivalents	326.1	316.0
Total equity attributable to owners of the parent	1,386.1	1,460.3
Equity ratio (%)	61.0%	62.6%

(billion yen)	FY2020	FY2021
Cash flows from operating activities	306.8	257.4
Cash flows from investing activities	-81.9	-62.4
Free cash flows	224.9	195.0
Cash flows from financing activities	-229.5	-216.3
Bonds and short-term borrowings	-206.0	-30.0
Proceeds from long-term borrowings	80.0	-
Repayments of long-term borrowings	-	-30.0
Acquisition of treasury shares	-9.2	-50.7
Dividends paid	-76.2	-85.2

Balance of bonds and borrowings：140.0 billion yen
(Decreased by 60.0 billion yen from FY2020 end)

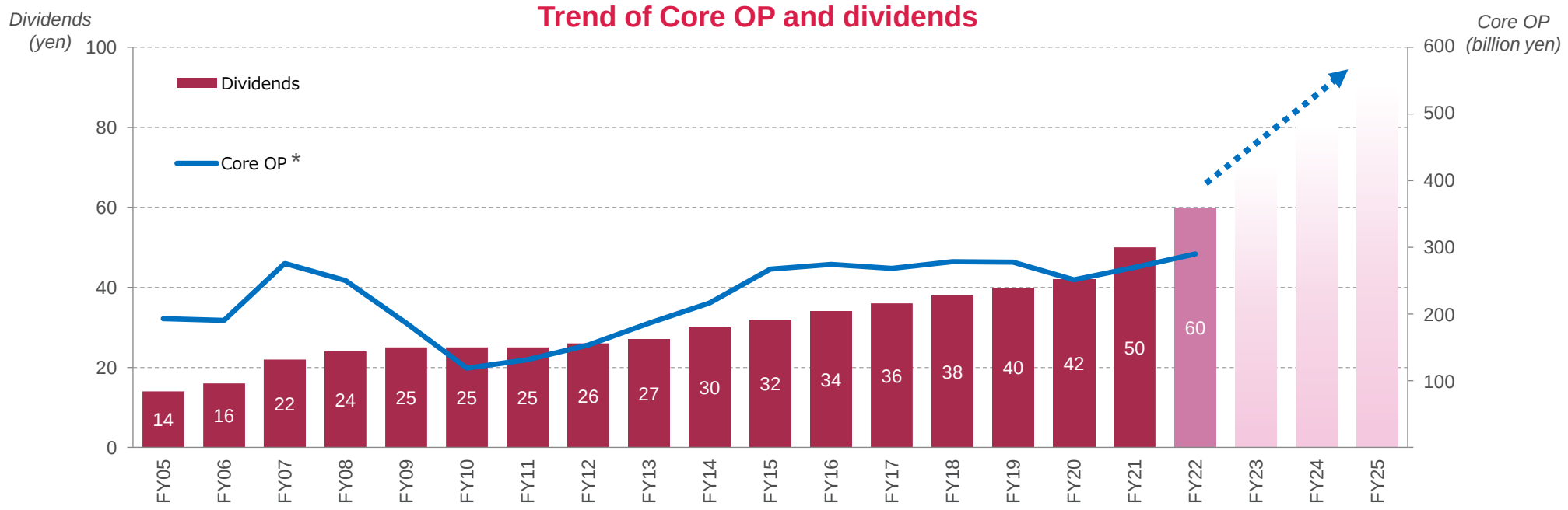
CAPITAL ALLOCATION

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

Acquisition of own shares announced in Feb. 2022

- From Feb. 3 to Mar. 9, 2022
- 26 million shares
- 50.0 billion yen

Aiming for higher level of dividends increase during CSP2021 aligned with the robust profit growth forecast



For illustrative purposes only

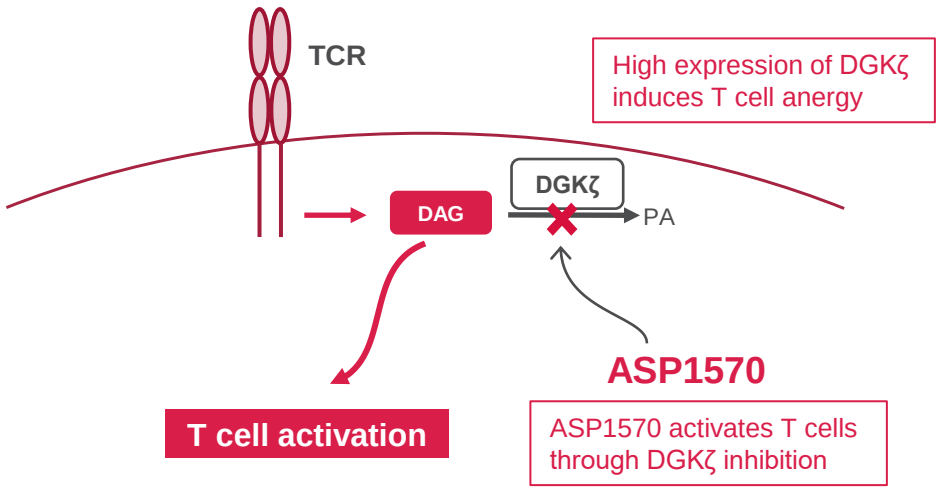
* Prior to FY2012, operating profit is in accordance with J-GAAP
CSP: Corporate Strategic Plan

PROGRESS IN FOCUS AREA APPROACH: NEW CLINICAL PROGRAMS

First-in-class programs from Focus Area approach entered clinical phase

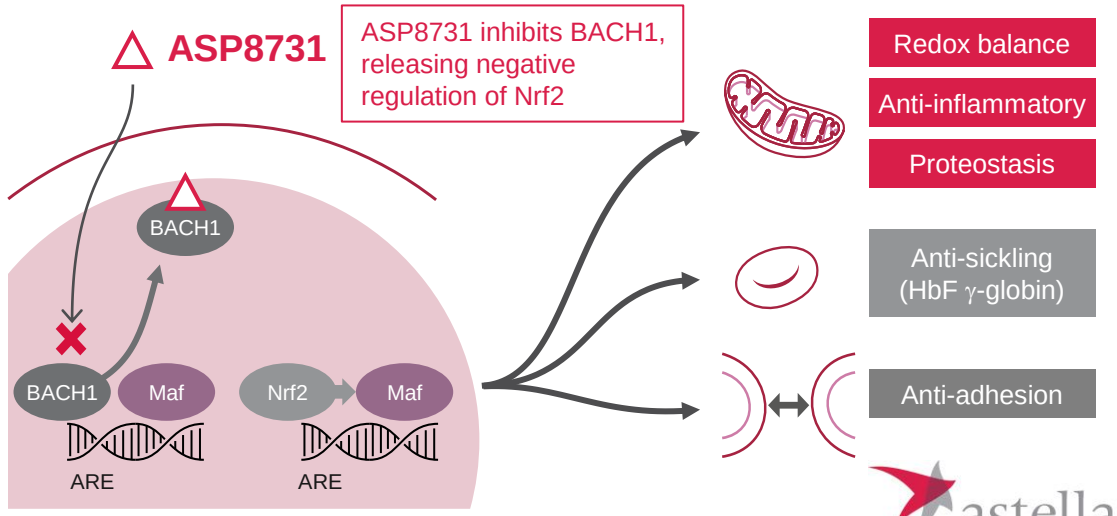
ASP1570 (PF Immuno-Oncology)

- Small molecule DGKζ inhibitor
- Target disease: Cancer
- DGKζ expressed in T cells down regulates adoptive immune responses against tumor cell growth
- DGKζ inhibition potentiates T cell activation and promotes immune-mediated tumor killing. The mechanism is separate from, and downstream to, current checkpoint inhibitors



ASP8731 (PF Mitochondria Biology)

- Small molecule BACH1 inhibitor
- Target disease: Sickle Cell Disease
  - ✓ Serious and lifelong health condition
  - ✓ Cause major organ damage, impacting quality of life and reducing life expectancy
- ASP8731 upregulates cytoprotective transcription and addresses the root cause of sickle cell disease



PF: Primary Focus, DAG: Diacylglycerol, DGK: Diacylglycerol kinase, PA: Phosphatidic acid, BACH1: BTB and CNC homology 1, ARE: Anti-oxidant response element, HbF: Fetal hemoglobin

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 (Alcohol use disorder)

Phase 2

- enfortumab vedotin (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- roxadustat (Chemotherapy-induced anemia)
- resamirigene bilparvovec /AT132 (XLMTM)
- ASP7517 (AML and MDS)
- bocidelpar/ASP0367 (Primary mitochondrial myopathies)
- FX-322 (Sensorineural hearing loss)
- isavuconazole (Pediatric use: US)
- ASP8062 (Opioid use disorder)

Phase 3

- enzalutamide (M0 CSPC, M1 CSPC: China)
- gilteritinib (Earlier-stage AML, pediatric use)
- enfortumab vedotin (mUC previously untreated, MIBC)
- zolbetuximab (Gastric and GEJ adenocarcinoma)
- fezolinetant (VMS associated with menopause)
- peficitinib (Rheumatoid arthritis: China)
- mirabegron (Pediatric use: EU)

- XTANDI and Strategic products (XOSPATA, PADCEV, 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
ASP8731 Sickle cell disease **ASP3082** Cancer				**enfortumab vedotin** Locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a PD-1/L1 inhibitor: EU

Discontinuation

ASP1951: Cancer (Phase 1)
ASP1128: Acute kidney injury (Phase 2)
ASP3772: Prevention of pneumococcal disease (Phase 2)
ASP2390: House dust mite-induced allergic rhinitis (Phase 1)

Note: Phase 1 entry is defined as confirmation of IND open.
Phase transition is defined by approval of company decision body for entering to next clinical phase.
Filing is defined as submission of application to health authorities.
Discontinuation is defined by the decision of company decision body.

AML: Acute myeloid leukemia, 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)
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 **Q3 FY2022**
	AML, post-chemotherapy	• **Data of Phase 2 GOSSAMER study presented at AACR in Apr 2022**
enfortumab vedotin / PADCEV	Metastatic urothelial cancer	• **Pretreated: Approved in EU in Apr 2022** • **Previously untreated (first line):** Phase 3 study ongoing • **China:** Phase 2 bridging study ongoing (enrollment completed)
	Muscle-invasive bladder cancer	• Phase 3 studies ongoing. **Cohort H data in EV-103 study presented at ASCO GU in Feb 2022**
	Non-muscle-invasive bladder cancer	• Phase 1 study ongoing
	Other solid tumors	• Phase 2 study ongoing
zolbetuximab	Gastric & GEJ adenocarcinoma	• Phase 3 studies ongoing (**enrollment completed**)
	Pancreatic adenocarcinoma	• Phase 2 study ongoing
roxadustat / EVRENZO	Chemotherapy-induced anemia	• Obtained topline results of Phase 2 study
fezolinetant	VMS associated with menopause	• **US & EU:** Obtained 52w data of Phase 3 pivotal studies (SKYLIGHT 1 and SKYLIGHT 2) **and long-term study (SKYLIGHT 4)**. Phase 3b DAYLIGHT study ongoing. **12w data from Phase 3 SKYLIGHT 1 study to be presented at ACOG in May 2022. 52w data from Phase 3 SKYLIGHT 2 study to be presented at ENDO in Jun 2022** • **Asia: Obtained 12w data** of Phase 3 pivotal study (MOONLIGHT 1) **in Mar 2022, LSLV in Apr 2022**. Phase 3 long-term study (MOONLIGHT 3) ongoing (enrollment completed) • **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: XOSPATA, PADCEV, 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, ASCO GU: American Society of Clinical Oncology Genitourinary Cancers Symposium, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms, ACOG: American College of Obstetricians and Gynecologists, ENDO: Endocrine Society, LSLV: Last subject last visit, FDA: Food and Drug Administration

XTANDI & STRATEGIC PRODUCTS: REGULATORY TIMELINE (UPDATE)

Expand additional indications for XTANDI, XOSPATA and PADCEV
Expect new launch for zolbetuximab, fezolinetant

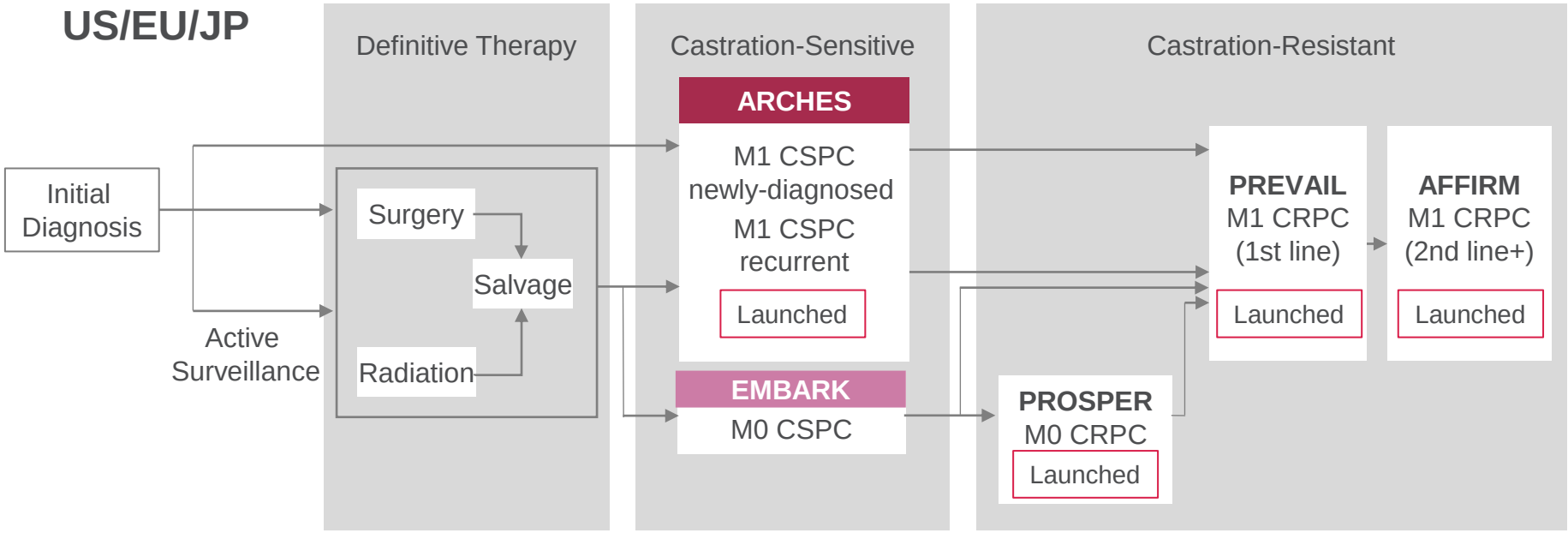
Product	Target Filing Timing				
	FY2021	FY2022	FY2023	FY2024	FY2025 or later
XTANDI (enzalutamide)		M0 CSPC			
XOSPATA (gilteritinib)			AML, post-HSCT maintenance		AML, newly diagnosed and HIC-eligible
PADCEV (enfortumab vedotin)		mUC, previously untreated (AA in US)	*based on EV-103 study cohort data*	mUC, previously untreated (1L)	MIBC
zolbetuximab			Gastric and GEJ adenocarcinoma		
fezolinetant		Moderate to severe VMS associated w/ menopause			
AT132 (resamirigene bilparvovec)					XLMTM

Note) Only indications undergoing pivotal studies are included (as of Apr 2022).
Subject to internal assessment, decision and regulatory consultation, as appropriate.
Filing (submission) timing in the first country/region within US, EU, JP

M0 CSPC: Non-metastatic castration-sensitive prostate cancer, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplantation, HIC: High-intensity chemotherapy, mUC: Metastatic urothelial cancer, AA: Accelerated Approval, 1L: First line, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms, XLMTM: X-linked myotubular myopathy

ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

(Red: Updates since the last financial results announcement)



	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 EU in Apr 2021 **Filed label update to include the OS data in US and EU 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

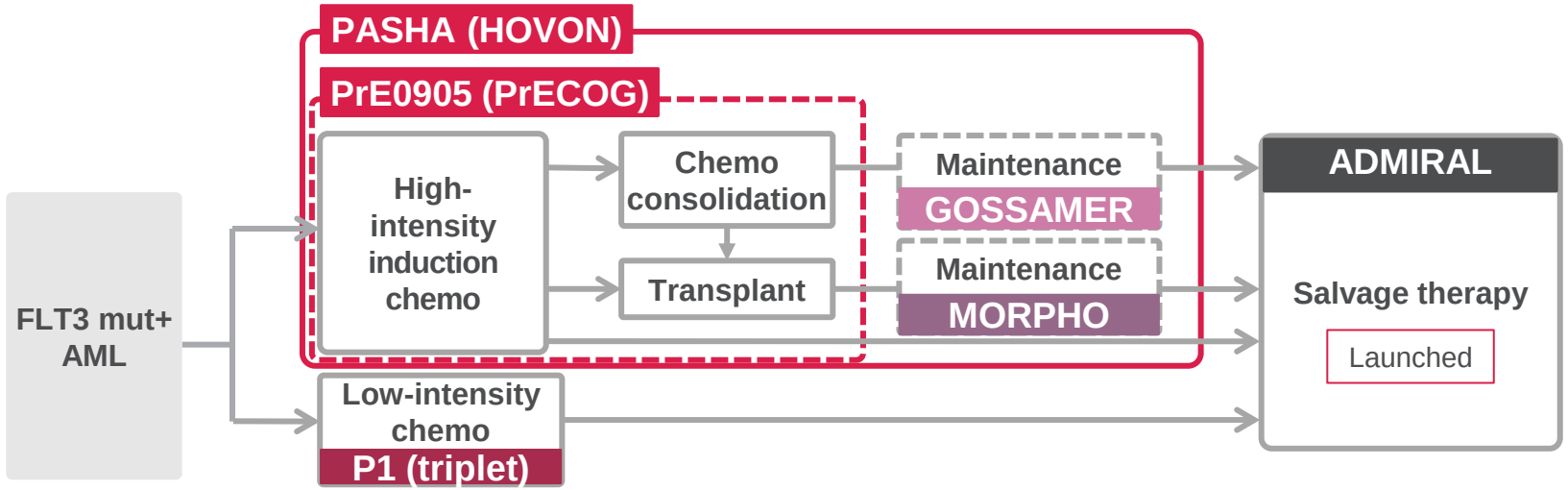
Disease stage	Early stage → Late stage					
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	**EMBARK**	**ARCHES**	**ENZAMET**	**PROSPER**	**PREVAIL**	**AFFIRM**
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary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

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 EU
	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	**Data presented at AACR in Apr 2022**
	Newly diagnosed (HIC-ineligible)	**P1**	Combo with venetoclax and azacitidine	TBD	To start in **Q3 FY2022**

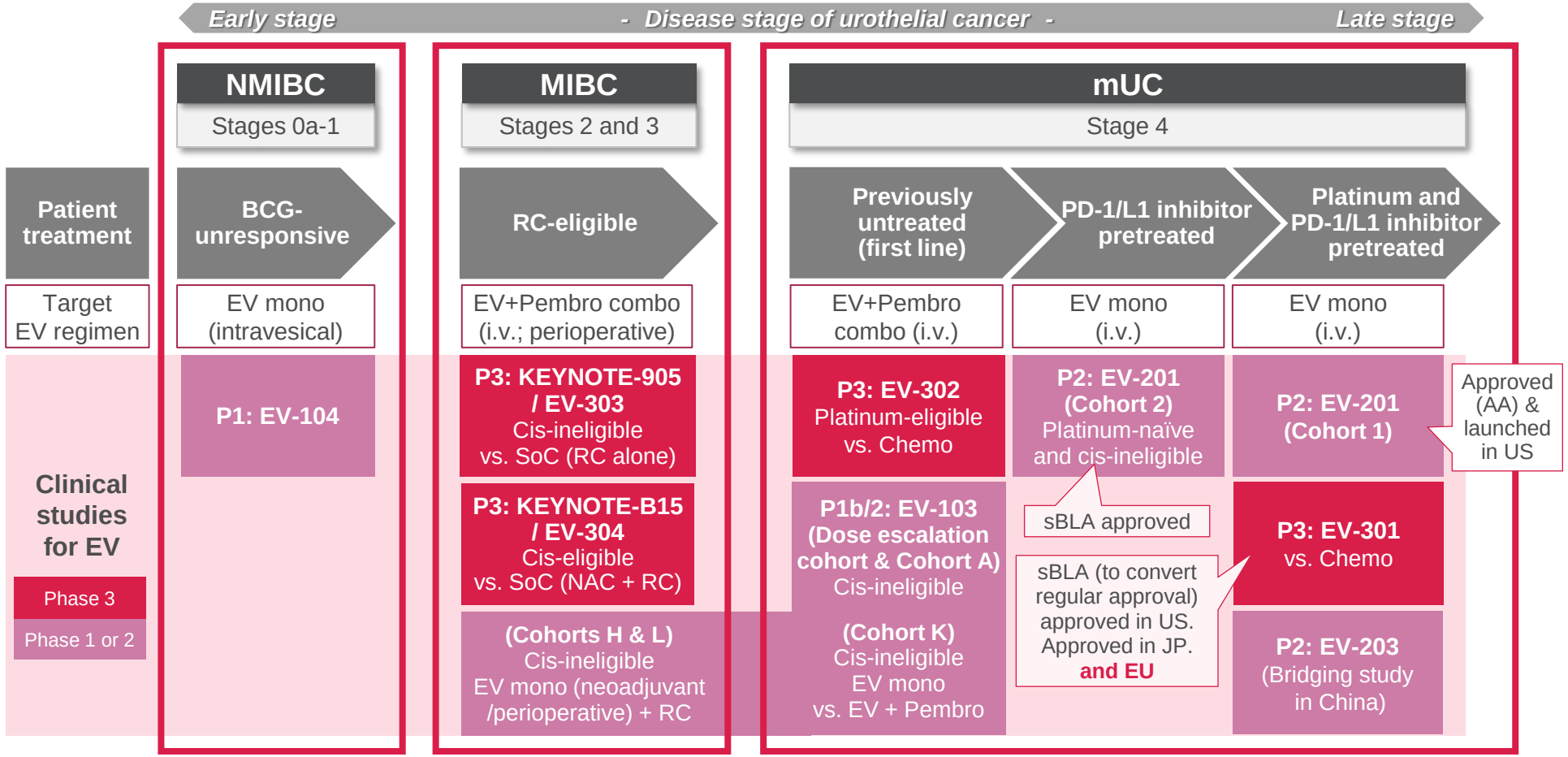
China

- **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

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	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 EU 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) and launched in US in Dec 2019 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: Enrollment completed in Oct 2021 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 carcinoma or GEJ adenocarcinoma, Esophageal squamous cell carcinoma; EV mono	n=280	FSFT: Mar 2020

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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

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 and 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)	150 (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	✔ 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 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)	(Ongoing)	✔ 73% ** (CR 16% **)	✔ 52% (CR 20%)	✔ 44% (CR 12%)	✔41% vs.18% * (CR 4.9% vs.2.7%)
DoR	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	✔ 25.6 mos **	✔ 13.8 mos **	✔ 7.6 mos	✔ 7.39 mos vs. 8.11 mos *

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

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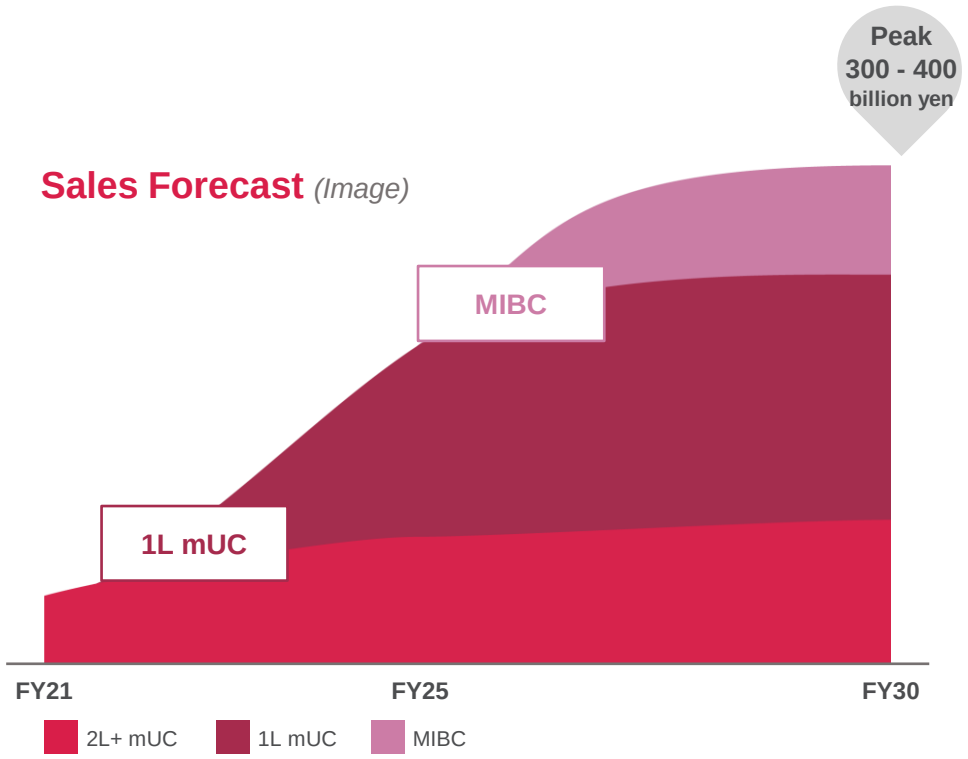
(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer, Pembro: Pembrolizumab, mono: Monotherapy, Chemo: Chemotherapy, pCR: Pathologic complete response, EFS: Event-free survival, ORR: Objective response rate, CR: Complete response, OS: Overall survival, HR: Hazard ratio, PFS: Progression-free 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
MIBC, cis-ineligible	EV-303 / KEYNOTE-905 (combo w/ pembrolizumab)	FY2025 or later
MIBC, cis-eligible	EV-304 / KEYNOTE-B15 (combo w/ pembrolizumab)	FY2025 or later
mUC, previously untreated (1L)	EV-302 EV-103 Cohorts [Phase 1b/2 for AA in US] (combo w/ pembrolizumab)	FY2024 FY2022 [AA in US]
mUC, PD-1/L1 inhibitor treated and cis-ineligible	EV-201 Cohort 2 [Phase 2] (monotherapy)	Approved
mUC, platinum and PD-1/L1 inhibitor treated	EV-301 EV-201 Cohort 1 [Phase 2 for AA in US] (monotherapy)	Approved

<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 carcinoma or GEJ adenocarcinoma, Esophageal squamous cell carcinoma;

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

ZOLBETUXIMAB: ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

(Red: Updates since the last financial results announcement)

Target: Claudin 18.2

- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- Broadly expressed in various cancer types
  - ✓ Prevalence of patients with high expression of Claudin 18.2 is substantial: 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 in Feb 2022**
		P3: GLOW	First line, Combo with CAPOX, DB, vs. placebo	n=500	**Enrollment completed in Feb 2022**
		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	Primary endpoints met (12w DB period topline results). Obtained 52w data
P3: SKYLIGHT 2		n=501	Primary endpoints met (12w DB period topline results). Obtained 52w data
P3: SKYLIGHT 4	VMS associated with menopause; 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)	n=1,831	**Obtained 52w data in Mar 2022**
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	Enrollment completed

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
  - ✓ <EU> 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

ON THE FOREFRONT OF HEALTHCARE CHANGE