

Q2/FY2021 FINANCIAL RESULTS

ENDED SEPTEMBER 30, 2021



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President and CEO
Astellas Pharma Inc.
October 29, 2021

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.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

AGENDA

I

Q2/FY2021 Consolidated Financial Results
FY2021 Revised Forecasts

II

Initiatives for Sustainable Growth

Q2/FY2021 FINANCIAL RESULTS AND FY2021 REVISED FORECAST: OVERVIEW

*Revenue increased by 6%, Core OP decreased
In line with assumptions of full-year forecast*

- Sales of XTANDI and Strategic products increased as expected, offsetting sales decrease due to termination of sales and distribution, transfer of products
- SG&A expenses are slightly above full-year forecast
R&D expenses are on track
- As a result, no changes have been made to Core basis FY2021 forecast

Downward revision of full basis profit FY2021 forecast

- Booked fair value remeasurement on contingent consideration for zolbetuximab as other expense, not included in full-year forecast (8.7 bil. yen)

Q2/FY2021 FINANCIAL RESULTS

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(billion yen)	Q2/FY20	Q2/FY21	Change	Change (%)	FY21 FCST*	Progress	FX impact
Revenue	615.5	651.7	+36.2	+5.9%	1,323.0	49.3%	+24.5 bil. yen
Cost of sales	119.5	124.7	+5.2	+4.3%			
% of revenue	19.4%	19.1%	-0.3 ppt				
SG&A expenses	242.1	270.5	+28.4	+11.7%	541.0	50.0%	
US XTANDI co-pro fee	60.9	71.1	+10.2	+16.8%			
SG&A excl. the above	181.3	199.4	+18.1	+10.0%			
R&D expenses	111.7	119.1	+7.4	+6.6%	242.0	49.2%	
Amortisation of intangible assets	11.5	12.4	+0.8	+7.2%			
Core operating profit	130.3	125.3	-5.0	-3.8%	270.0	46.4%	+11.5 bil. yen
<Full basis>							
Other income	4.3	2.8	-1.4	-			
Other expense	47.7	38.0	-9.7	-			
Operating profit	86.9	90.2	+3.3	+3.8%	227.0	39.7%	
Profit before tax	89.1	89.1	-0.0	-0.0%	225.0	39.6%	
Profit	72.8	71.6	-1.2	-1.7%	183.0	39.1%	

* Announced in July 2021

Q2/FY2021 FINANCIAL RESULTS: REVENUE

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

	Q2/FY20	Q2/FY21	Change	Change (%)
Revenue	615.5 bil. yen	651.7 bil. yen	+36.2 bil. yen	+5.9%

Increase in XTANDI and Strategic products

XTANDI, XOSPATA, PADCEV, EVRENZO

+51.8 bil. yen



➤ Returned sales of Lexiscan, negatively impacted by COVID-19 in Q1/FY20 **+10.8 bil. yen**

Termination of sales and distribution / transfer of products

Celecox, Lipitor, Eligard

-25.9 bil. yen



Q2/FY2021 FINANCIAL RESULTS: SALES OF MAIN PRODUCTS

Q2/FY2021 Act and FY2021 FCST (billion yen)

XTANDI	YoY: +42.1 (+19%)
267.6	Progress against FCST: 48%

FY2021 initial FCST: 557.2 → Revised FCST: 554.1

- ✓ Double-digit growth in global sales and in line with forecast
- ✓ In addition to US, sales expansion in EU following approval of M1 HSPC indication
- ✓ In China, demand grew higher than expected after reimbursement

XOSPATA	YoY: +5.5 (+50%)
16.5	Progress against FCST: 45%

FY2021 initial FCST: 36.7 → Revised FCST: 35.4

- ✓ Global sales increased and in line with forecast, driven by growth mainly in US and EU
- ✓ Sales contribution from China newly launched

PADCEV	YoY: +3.1 (+52%)
9.1	Progress against FCST: 45%

FY2021 initial FCST: 20.1 → Revised FCST: 20.7

- ✓ Revenue in US grew steadily and in line with forecast
- ✓ The NCCN updated its guidelines, adding PADCEV for cis-ineligible mUC 2L therapy as Category 2A

EVRENZO	YoY: +1.1 (+319%)
1.4	Progress against FCST: 16%

FY2021 initial FCST: 8.6 → Revised FCST: 7.2

- ✓ Sales have steadily increased as expected in Japan and continuous growth is expected
- ✓ Launched in EU in Sep 2021

mirabegron	YoY: +4.4 (+6%)
84.4	Progress against FCST: 48%

FY2021 initial FCST: 175.2 → Revised FCST: 176.3

- ✓ Global sales increased and in line with forecast, driven by growth mainly in Japan and Established Markets
- ✓ In US, Myrbetriq sales are behind forecast due to lower than expected OAB market growth



Q2/FY2021 FINANCIAL RESULTS: COST ITEMS

SG&A expenses increased YoY and slightly above full-year FCST
R&D expenses increased YoY, but in line with full-year FCST

Core basis: Main items for YoY and progress against FCST

Cost of sales % of revenue



YoY: -0.3ppt

- ✓ Decrease mainly due to changes in product mix

SG&A expenses

YoY: +11.7%

Progress

against FCST: 50.0%



- ✓ SG&A excl. XTANDI US co-pro fee: +18.1 bil. yen (YoY +10.0%)
- ✓ FX impact (+8.4 bil. yen)
- ✓ Investment in systems associated with globalization (Approx. +5.0 bil. yen)
- ✓ Increase in sales promotion expenses for new product launch readiness (Approx. +3.0 bil. yen)

R&D expenses

YoY: +6.6%

Progress

against FCST: 49.2%



- ✓ Increase in development cost of zolbetuximab and expanded investment in iota
- ✓ Decrease in development cost of fezolinetant
- ✓ On track with full-year forecast

FY2021 REVISED FORECAST: OVERVIEW

- No changes have been made to Revenue
 - Sales of XTANDI and Strategic products are on track
- Costs
 - SG&A expenses are slightly above full-year FCST but within controllable range for the full year
 - ✓ Thorough budget control on a quarter basis
 - ✓ Optimizing personnel globally aligned with transformation of product portfolio
 - R&D expenses are on track
- As a result, no changes have been made to Core OP
- Downward revision of Full basis profit announced in July 2021
 - Booked fair value remeasurement on contingent consideration as other expense (8.7 bil. yen) due to review of pancreatic adenocarcinoma development plan for zolbetuximab

FY2021 REVISED FORECAST

- No changes have been made to Core basis FY2021 forecast
- Downward revision of Full basis profit

(billion yen)	Previous FCST (Disclosed in July 2021)	Revised FCST	Change
Operating profit	227.0	218.0	-9.0
Profit	183.0	174.0	-9.0

AGENDA

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Initiatives for Sustainable Growth

XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT (1/2)

12

Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132

Key Events Expected in FY2021

Milestone	Project / Product	Indication / Clinical study	Achieved
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 ^c)	
		Radically unresectable UC that has progressed after anti-cancer chemotherapy (JP ^d)	Sep 2021
roxadustat / EVRENZO	Symptomatic anemia associated with CKD (EU)	Aug 2021	
Regulatory submission	gilteritinib / XOSPATA	R/R AML (China ^e)	
Data readout	fezolinetant	52-week safety results from Phase 3 SKYLIGHT 1, 2 & 4 studies	Jul 2021 (SKYLIGHT 2) Oct 2021 (SKYLIGHT 1)

Red: Updates since the last financial results announcement

a: Priority Review granted, Real-Time Oncology Review pilot program and Project Orbis applied

b: sBLA to convert Accelerated Approval to regular approval

c: Under review based on standard timeline instead of Accelerated Assessment

d: Priority Review granted

e: sNDA to convert conditional approval to full approval



XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT (2/2)

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Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132

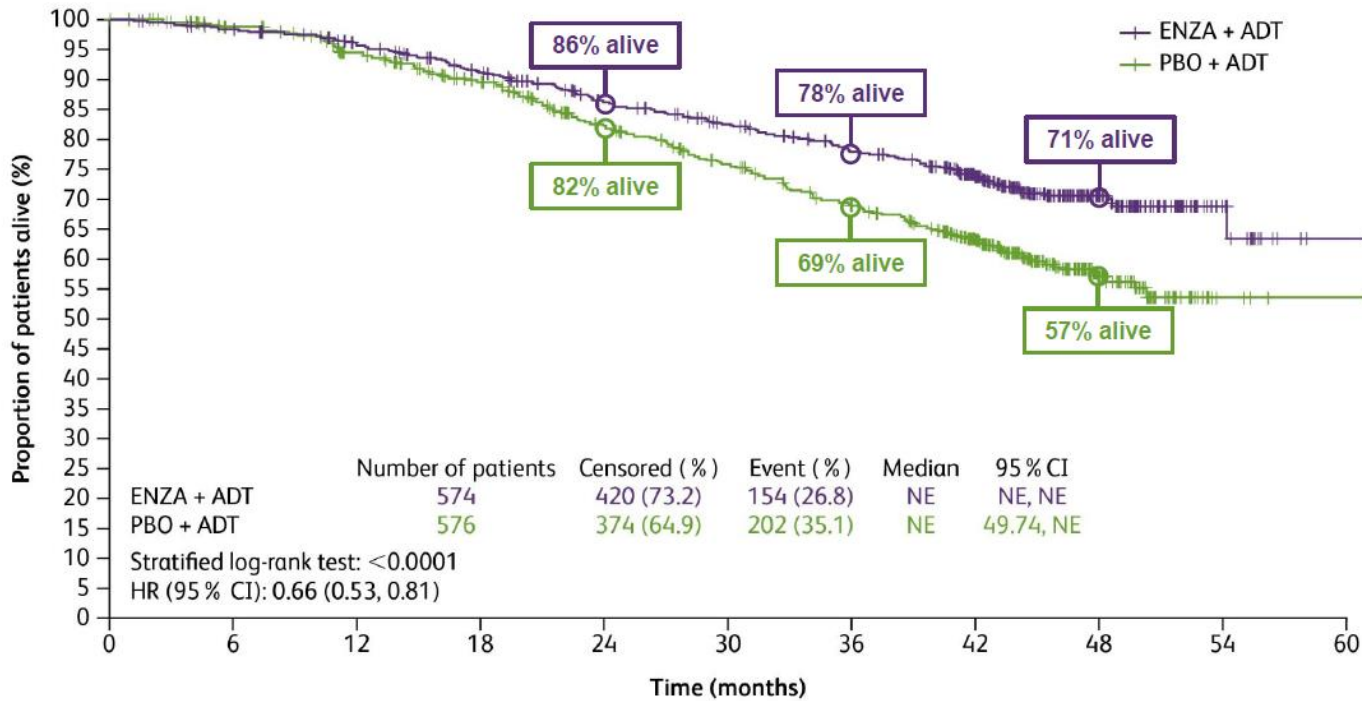
Other Updates since the last financial results announcement

Project / Product	Indication	Updated status
enzalutamide / XTANDI	M1 CSPC	OS data of Phase 3 ARCHES study presented at ESMO in Sep 2021
enfortumab vedotin / PADCEV	mUC, previously untreated	Enrollment of cohort K (combo with pembrolizumab) in EV-103 study completed in Oct 2021
zolbetuximab	Pancreatic adenocarcinoma	Phase 2 study protocol amended to expand the study
roxadustat / EVRENZO	Chemotherapy-induced anemia	Topline results of Phase 2 study obtained in Aug 2021
fezolinetant	VMS associated with menopause	12-week data of Phase 3 pivotal study (SKYLIGHT 2) presented at NAMS in Sep 2021 Phase 3b DAYLIGHT study in patients unsuitable for HRT under preparation to start in Q3 FY2021
AT132 (resamirigene bilparvovec)	XLMTM	ASPIRO study put on clinical hold by FDA in Sep 2021 due to a serious adverse event



ENZALUTAMIDE (XTANDI) (1/2): OS DATA IN PHASE 3 ARCHES STUDY IN M1 CSPC

OS data presented at ESMO 2021: reduced risk of death by 34%



	Number of patients	Censored (%)	Event (%)	Median	95% CI
ENZA + ADT	574	420 (73.2)	154 (26.8)	NE	NE, NE
PBO + ADT	576	374 (64.9)	202 (35.1)	NE	49.74, NE

Stratified log-rank test: <0.0001
HR (95% CI): 0.66 (0.53, 0.81)

Patients at risk

	0	6	12	18	24	30	36	42	48	54	60
ENZA + ADT	574	559	535	498	457	427	396	316	120	17	1
PBO + ADT	576	548	511	468	404	363	322	232	80	4	1



ENZALUTAMIDE (XTANDI) (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, **Yellow**: Data recently disclosed @ESMO 2021

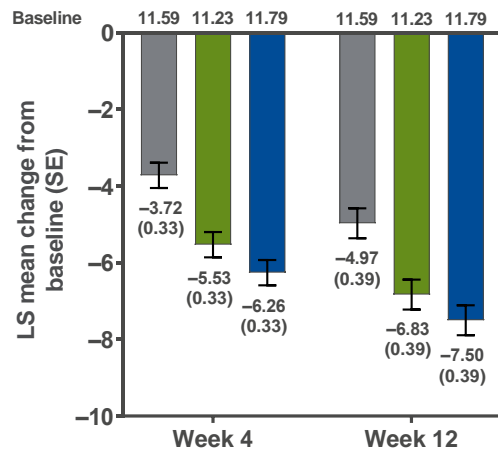


FEZOLINETANT: PHASE 3 STUDY DATA

12-week data of SKYLIGHT 2 study presented at NAMS 2021
52-week data of SKYLIGHT 1 study obtained

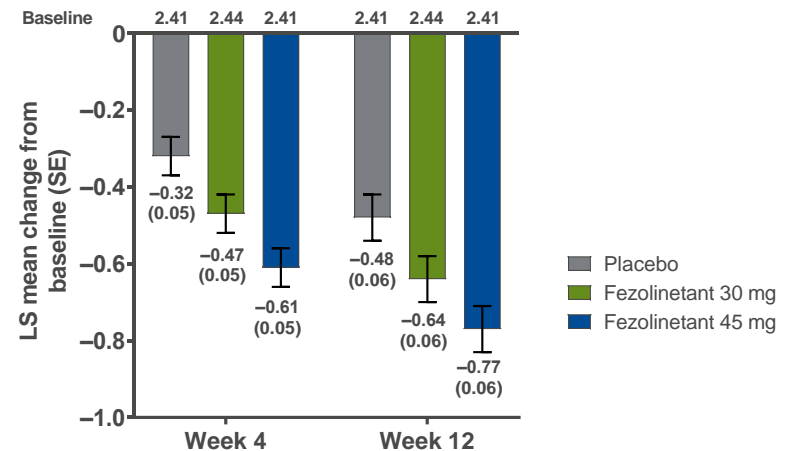
<SKYLIGHT 2: Co-primary efficacy endpoints> All four co-primary endpoints were met

Change from baseline in mean **frequency** of VMS



LS mean difference vs placebo (SE)	Fezolinetant 30 mg	Fezolinetant 45 mg
Week 4	-1.82 (0.46) P<0.001	-2.55 (0.46) P<0.001
Week 12	-1.86 (0.55) P<0.001	-2.53 (0.55) P<0.001

Change from baseline in mean **severity** of VMS



LS mean difference vs placebo (SE)	Fezolinetant 30 mg	Fezolinetant 45 mg
Week 4	-0.15 (0.06) P=0.021	-0.29 (0.06) P<0.001
Week 12	-0.16 (0.08) P=0.049	-0.29 (0.08) P<0.001

<SKYLIGHT 2: Safety>

No safety signals of concern were apparent for either fezolinetant dose

<SKYLIGHT 1: 52-w data>

Obtained in October 2021, which also support the long-term use of fezolinetant

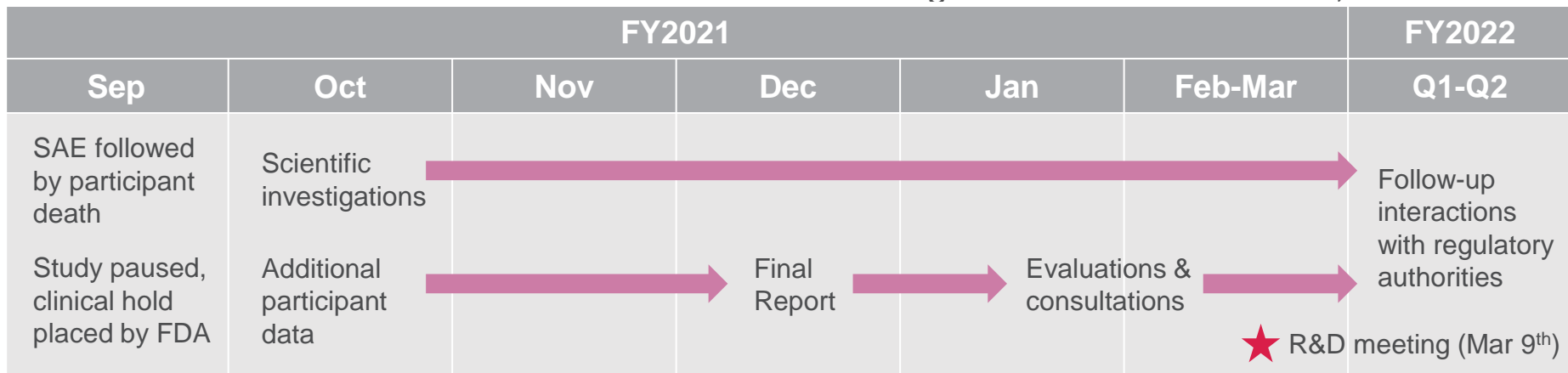
=> Full safety results will be obtained on completion of the Phase 3 program including SKYLIGHT 4 study



AT132 (RESAMIRIGENE BILPARVOVEC): UPDATED STATUS

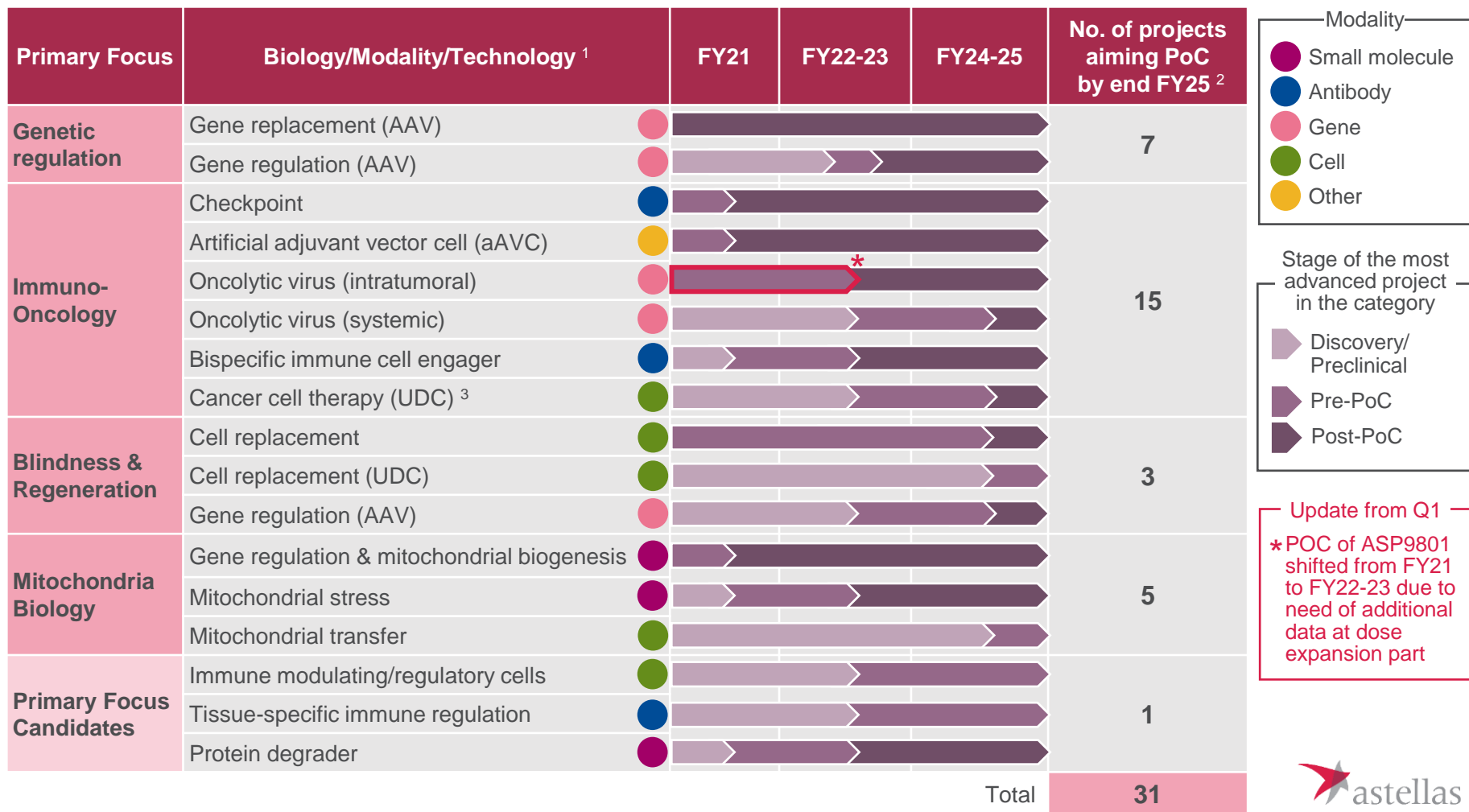
ASPIRO study in XLMTM put on clinical hold by FDA, due to the incidence of an SAE and subsequent participant death

- Received clinical hold letter from FDA in Sep 2021
- Additional participant data anticipated from the autopsy and follow-up analysis through Dec 2021
- Interactions with regulatory agencies to be initiated in early 2022 based on consultations with KOLs and results from scientific investigations as well as additional participant data
- Future directions to be confirmed after consultations with regulatory agencies on the path forward for AT132
- BLA to be delayed beyond FY2022
- The latest status to be communicated at R&D meeting scheduled on March 9th, 2022



PROGRESS IN FOCUS AREA APPROACH (1/2): CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS






Primary Focuses have robust pipeline to newly build Post-PoC portfolio by end FY2025



1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Oct 2021).
 3. The first convertibleCAR program (with autologous cells) IND is planned for late FY2021. 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 FOCUS AREA APPROACH (2/2): CURRENT STATUS IN PRIMARY FOCUS

Primary Focus	Biology/Modality/Technology ¹	Project	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	(See the slides for “XTANDI and Strategic products”)
		AT845	Phase 1 study ongoing
	Gene regulation (AAV)		
Immuno-Oncology	Checkpoint	ASP1948	Phase 1 study ongoing
		ASP1951	Phase 1 study ongoing
	Artificial adjuvant vector cell (aAVC)	ASP7517	<u>FSFT in Phase 2 study in R/R AML and MDS in Oct 2021</u> Phase 1 study in advanced solid tumors to start in Q3 FY2021
		ASP0739	Phase 1 study to start in Q3 FY2021
	Oncolytic virus (intratumoral)	ASP9801	Phase 1 study ongoing (<u>progress to dose expansion part</u>)
	Oncolytic virus (systemic)		
	Bispecific immune cell engager		
	Cancer cell therapy (UDC)		
(other)	ASP1570	Phase 1 study to start in Q3 FY2021	
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	<u>Enrollment discontinued in Phase 2a study, based on the interim analysis for futility</u>
		ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD ongoing
	Mitochondrial stress		
	Mitochondrial transfer		
Primary Focus Candidates	Immune modulating/regulatory cells		
	Tissue-specific immune regulation		
	Protein degrader		

Modality	
	Small molecule
	Antibody
	Gene
	Cell
	Other

Underlined: Updates since the last financial results announcement. 1. Not exhaustively listed.

AAV: Adeno-associated virus, UDC: Universal donor cell, 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 Rx+ PROGRAM (1/2)



Key events expected in FY2021 (announced in Apr 2021)

Sphere *	Program	Event	Achieved
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	
	BlueStar	Initiation of clinical study (Japan)	
	My Holter II	Commercialization of service	Jul 2021
Patient outcome maximization	ASP5354	Topline results for Phase 2 study	

Further updates

Sphere *	Program	Event	Achieved
Chronic disease progression prevention	ECG testing service	Partnering with Nitto and M. Heart	Sep 2021



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

PROGRESS IN Rx+ PROGRAM (2/2): PARTNERING FOR ECG TESTING SERVICE



Total solution for early detection of atrial fibrillation using disposable Holter ECG device and AI-Based Analysis Service

Disposable ECG device “EG Holter”

- Disposable and hygienic; 6 mm thick, 11 g weight, with no cords, waterproof (IPX4)
- M. Heart obtained certification as a medical device (Class II) in Aug 2021
- Nitto will develop and manufacture, and Astellas will aim to sell in Japan after pilot sales



Disposable Holter ECG device “EG Holter”

Combination with ECG Analysis Service

- Promote early detection and appropriate treatment of atrial fibrillation, etc. by providing a total solution combining EG Holter and MYHOLTER II developed by Astellas and M. Heart



Process for analysis using EG Holter

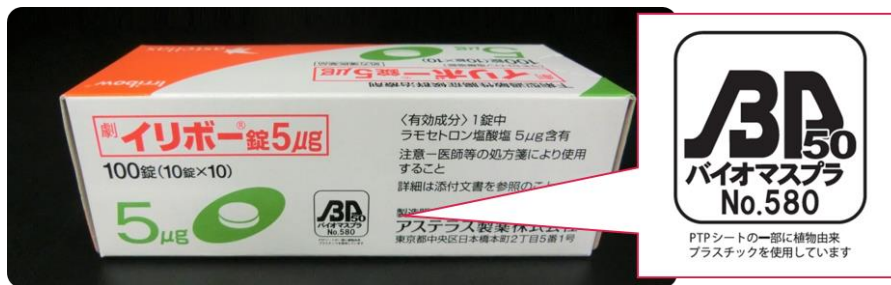


SUSTAINABILITY: ENVIRONMENT INITIATIVES



World's first use of environmentally friendly biomass-based plastic for blister packages of drugs

- The blister package is made of biomass-based plastic, polyethylene derived from sugarcane, as 50% of its raw material. It is an environmentally friendly packaging that match with the concept of "carbon neutrality," which is the idea of balancing greenhouse gas emissions and absorption
- Started commercial production for Iribow Tablet 5 μ g (indication: diarrhea-predominant irritable bowel syndrome) in Japan
- Considering to switch from the conventional petroleum-derived plastic blister package to the biomass-based plastic blister package for other products as well



Sustainability meeting scheduled on February 28th, 2022

PROGRESS TOWARD ACHIEVING CSP2021

Revenue, Pipeline Value

- 1** XTANDI and Strategic products:
≥ ¥1.2T in FY2025
- ✓ Sales growth in line with ambitious forecast
 - ✓ XTANDI: OS data in ARCHES study obtained
 - ✓ PADCEV: Approval in JP, enrollment completion in clinical study for 1L mUC (Cohort K in EV-103)
 - ✓ EVRENZO: Approval in EU
 - ✓ fezolinetant: Presentation of efficacy data of SKYLIGHT 2 study

- 2** Post-PoC projects from Primary Focuses

- 3** Multiple technology platforms

- 4** Focus Area projects:
≥ ¥0.5T in FY2030

- ✓ AT132: Several scenarios under consideration toward restart of clinical study
- ✓ ASP7517 (AML and MDS): FSFT in Phase 2 study:
- ✓ Shift to new research organization

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

- ✓ Investment for new product launch
- ✓ Thorough budget control on a quarter basis

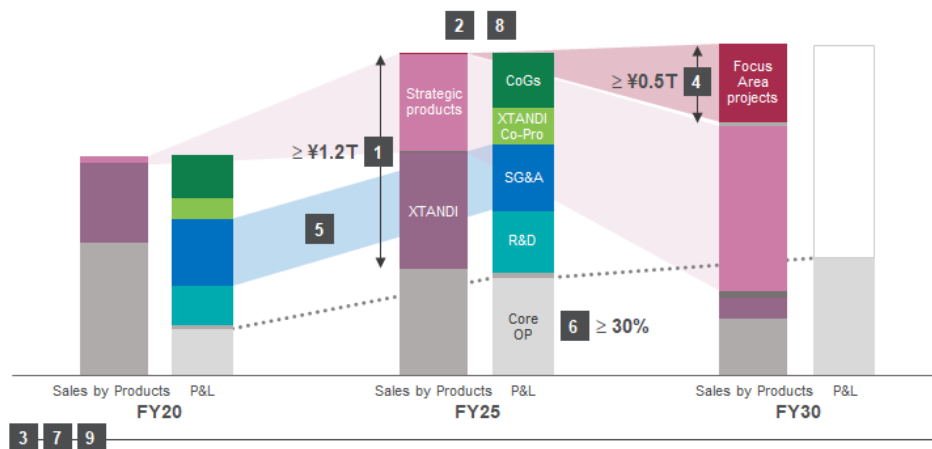
Future Growth

- 8** Rx+:
Breakeven by FY2025

- ✓ Pilot marketing of Fit-eNce Home
- ✓ Partnering for ECG testing service

- 9** Sustainability

- ✓ Use of biomass-based plastic for blister package



R&D meeting

- Dec 7th 2021, 15:30-16:45 (JST)
- New research organization structure -
- Mar 9th 2022, 9:30-11:00 (JST)
- Initiatives for gene therapy -

Sustainability meeting

- Feb 28th 2022, 15:00-16:30 (JST)

APPENDIX



Q2/FY2021: REVENUE BY REGION

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(billion yen)	Q2/FY20	Q2/FY21	Change (%)
Japan	144.2	130.5	-9.5%
United States	236.7	270.1	+14.1%
Established Markets	138.9	157.4	+13.3%
Greater China	29.6	33.1	+11.8%
International Markets	56.7	55.3	-2.5%

Established Markets: Europe, Canada, Australia

Greater China: China, Hong Kong, Taiwan

International Markets: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

Q2/FY2021: SALES OF MAIN PRODUCTS

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(billion yen)	Q2/FY20	Q2/FY21	Change	CER growth	FY21 FCST*
XTANDI	225.5	267.6	+18.7%	+13.9%	554.1
XOSPATA	11.0	16.5	+50.3%	+44.4%	35.4
PADCEV	6.0	9.1	+51.5%	+47.6%	20.7
EVRENZO	0.3	1.4	+319.1%	+316.7%	7.2
mirabegron	80.0	84.4	+5.5%	+2.2%	176.3
Prograf	89.6	92.3	+3.0%	-2.7%	185.7

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



*Announced revised forecast
 in October 2021

Q2/FY2021 FINANCIAL RESULTS: BUSINESS UPDATE FOR MAIN PRODUCTS

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XTANDI

Global sales increased steadily as expected and continuous strong growth is expected. In US, demand grew 15% YoY. In EU, reimbursement for M1 HSPC continues to expand (Germany, UK, Spain Switzerland, Netherlands) supporting the recent uptake. In China, demand grew higher than expected after reimbursement in March 2021

XOSPATA

Sales across regions steadily expanded and global sales are in line with forecast. Initial sales trend is positive thus far in China launched in April 2021 (Q2/FY21 sales: 1.0 billion yen)

PADCEV

Revenue in US grew steadily as expected following approval of additional indication in Jul 2021. The NCCN updated its guidelines, adding PADCEV for cis-ineligible mUC 2L therapy as Category 2A recommendation. In Japan, PADCEV was approved in September 2021 for radically unresectable urothelial carcinoma that has progressed after anti-cancer chemotherapy

EVRENZO

Sales in Japan increased aligned with the expansion of the HIF-PHI class. In EU, EVRENZO was approved in August 2021 and subsequently launched in Germany and UK in September 2021. Reimbursement has started in Netherlands from October 2021

mirabegron

Global sales increased as expected, driven by growth mainly in Japan and Established Markets. In US, Myrbetriq demand growth against forecast are slightly behind due to lower than expected US OAB market growth



Q2/FY2021 ACTUAL: FX RATE

Average rate for the period

Currency	Q2/FY20	Q2/FY21	Change
USD	107 yen	110 yen	+3 yen
EUR	121 yen	131 yen	+10 yen

Change in closing rate from previous fiscal year end

Currency	Q2/FY20	Q2/FY21
USD	-3 yen	+1 yen
EUR	+5 yen	-1 yen

<Impact of exchange rate on financial results>

- 24.5 billion yen increase in revenue, 11.5 billion yen increase in core OP
- FX impact on elimination of unrealized gain: COGs ratio -0.1 ppt

FY2021 REVISED FCST: FX RATE & FX SENSITIVITY

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Exchange rate Average for the period	FY2021 Initial FCST	FY2021 Revised FCST
USD	110 yen	110 yen
EUR	130 yen	130 yen

Forecast rates from Q3/FY2021 onwards: 110 USD/yen, 130 EUR/yen

Estimated FX sensitivity (Q3 and onward) of FY2021 revised forecasts 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. -6.4 bil. yen	Approx. -0.8 bil. yen	Approx. +0.6 bil. yen
EUR	Approx. -2.8 bil. yen	Approx. -1.0 bil. yen	Approx. +0.3 bil. yen



* Sensitivity to fluctuation of FX rates used for consolidation of overseas affiliates' results compared to forecasted rates from Q3/FY2021 and onwards

BALANCE SHEET & CASH FLOW HIGHLIGHTS

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(billion yen)	FY20 end	Sep. 30, 2021
Total assets	2,273.6	2,261.5
Cash and cash equivalents	326.1	318.3
Total equity attributable to owners of the parent	1,386.1	1,417.6
Equity ratio (%)	61.0%	62.7%

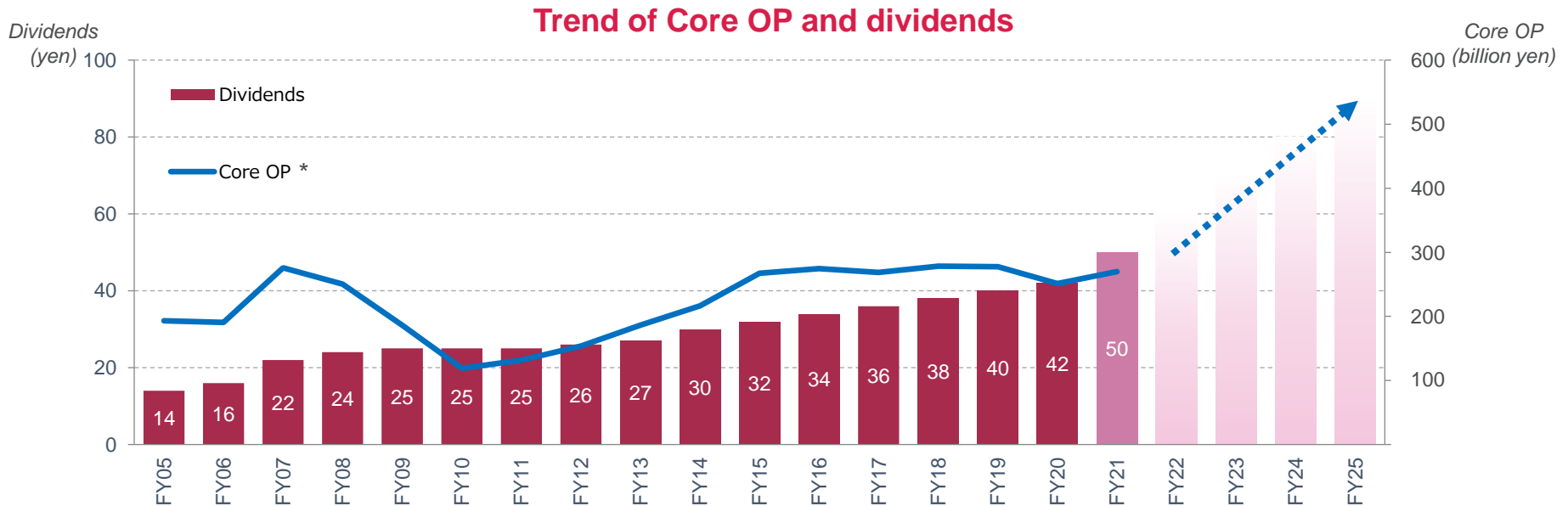
(billion yen)	Q2/FY20	Q2/FY21	FY20
Cash flows from operating activities	115.0	139.4	306.8
Cash flows from investing activities	-38.3	-55.7	-81.9
Free cash flows	76.7	83.6	224.9
Cash flows from financing activities	-109.7	-89.9	-229.5
Bonds and short-term borrowings	-142.0	-40.0	-206.0
Proceeds from long-term borrowings	80.0	-	80.0
Dividends paid	-37.2	-38.9	-76.2

Balance of bonds and borrowings : 160.0 billion yen
(Decreased by 40.0 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

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

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Phase 1

enfortumab vedotin
(NMIBC)

ASP1948

ASP1951

ASP9801

ASP7517
(Solid tumors)

ASP0739

ASP7317

bocidelpar/ASP0367
(Duchenne muscular dystrophy)

AT845

ASP0598

ASP2390

ASP1570

ASP8062
(Alcohol use disorder)

Phase 2

enfortumab vedotin
(Other solid tumors)

zolbetuximab
(Pancreatic adenocarcinoma)

roxadustat
(Chemotherapy-induced anemia)

resamirigene bilparovect
/AT132 (XLMTM)

ASP7517
(AML and MDS)

ASP1128
(Acute kidney injury)

bocidelpar/ASP0367
(Primary mitochondrial myopathies)

ASP3772
(Pneumococcal disease)

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

Filed

enfortumab vedotin
(mUC, pretreated: EU)

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

The listed compounds are investigational agents the safety and efficacy of which has not yet been established.

There is no guarantee that the agents will receive regulatory approval or become commercially available for uses being investigated

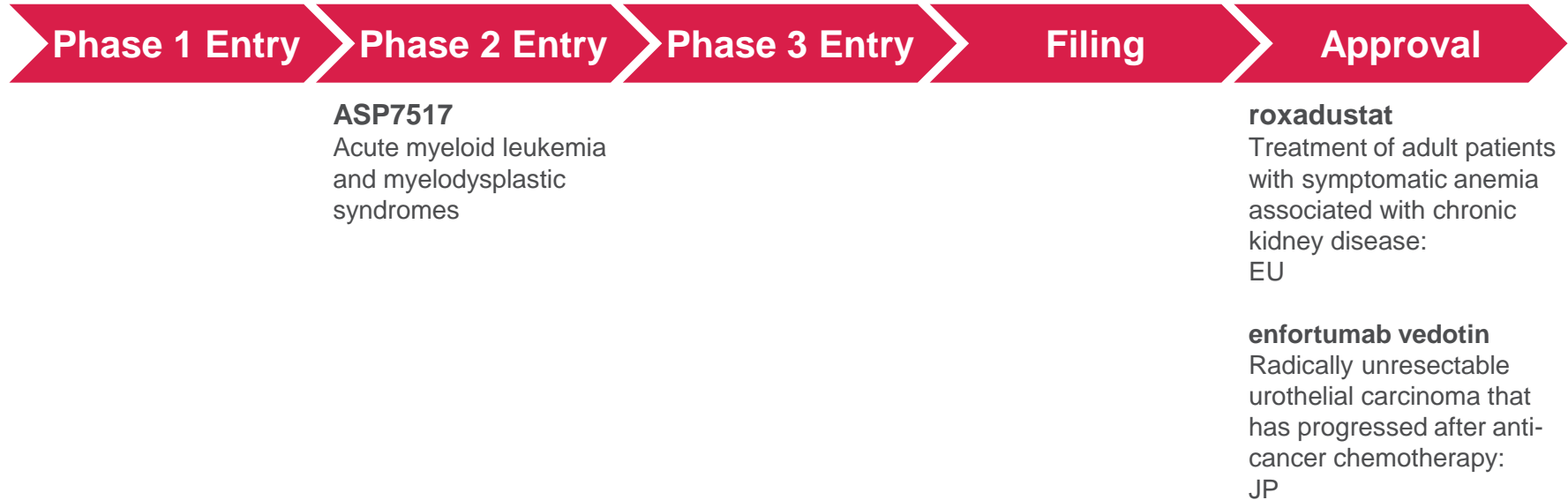


NMIBC: Non-muscle-invasive bladder cancer, XLMTM: X-linked myotubular myopathy, AML: Acute myeloid leukemia, MDS: Myelodysplastic syndrome, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms

PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since the Last Financial Results Announcement

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Discontinuation

ASP1617: Systemic lupus erythematosus (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



IND: Investigational new drug

XTANDI & STRATEGIC PRODUCTS: STATUS UPDATE

(Underlined: Updates since the last financial results announcement)

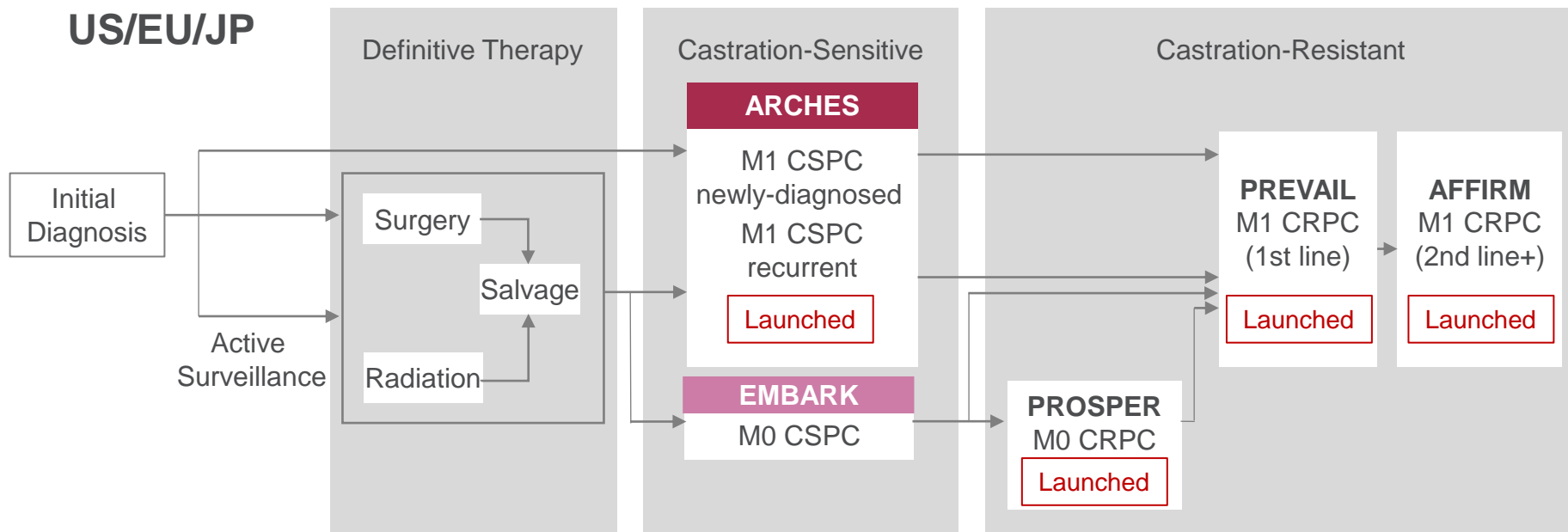
35

	Indication	Current status
enzalutamide / XTANDI	M1 CSPC	<ul style="list-style-type: none"> Global: <u>Positive OS data in Phase 3 ARCHES study presented at ESMO in Sep 2021</u> China: Phase 3 study ongoing (enrollment completed)
	M0 CSPC	<ul style="list-style-type: none"> Phase 3 study ongoing (enrollment completed)
gilteritinib / XOSPATA	Relapsed and refractory AML	<ul style="list-style-type: none"> China: Phase 3 study stopped due to efficacy
	AML, post-HSCT maintenance	<ul style="list-style-type: none"> Phase 3 study ongoing (enrollment completed)
	AML, newly diagnosed (HIC-eligible)	<ul style="list-style-type: none"> Phase 3 study ongoing
	AML, post-chemotherapy	<ul style="list-style-type: none"> <u>Obtained topline results of Phase 2 GOSSAMER study in Aug 2021</u>
enfortumab vedotin / PADCEV	Metastatic urothelial cancer	<ul style="list-style-type: none"> Pretreated: <u>Approved in JP in Sep 2021</u>. Filed in EU in Mar 2021 Previously untreated (first line): Phase 3 study ongoing China: <u>FSFT in Phase 2 bridging study in Aug 2021</u>
	Muscle-invasive bladder cancer	<ul style="list-style-type: none"> Phase 3 studies ongoing
	Non-muscle-invasive bladder cancer	<ul style="list-style-type: none"> <u>Phase 1 study under preparation to start in Q3 FY2021</u>
	Other solid tumors	<ul style="list-style-type: none"> Phase 2 study ongoing
zolbetuximab	Gastric & GEJ adenocarcinoma	<ul style="list-style-type: none"> Phase 3 studies ongoing
	Pancreatic adenocarcinoma	<ul style="list-style-type: none"> Phase 2 study ongoing (<u>protocol amended to expand the study</u>)
roxadustat / EVRENZO	Anemia associated with CKD	<ul style="list-style-type: none"> EU: <u>Approved in Aug 2021</u>
	Chemotherapy-induced anemia	<ul style="list-style-type: none"> <u>Obtained topline results of Phase 2 study in Aug 2021</u>
fezolinetant	VMS associated with menopause	<ul style="list-style-type: none"> US & EU: <u>Obtained 52w data of Phase 3 pivotal studies, SKYLIGHT 2 (Jul 2021) and SKYLIGHT 1 (Oct 2021). 12w data of SKYLIGHT 2 presented at NAMS in Sep 2021. Phase 3 long-term study (SKYLIGHT 4) ongoing (enrollment completed). Phase 3b DAYLIGHT study in patients unsuitable for HRT to start in Q3 FY2021</u> Asia: Phase 3 studies ongoing (enrollment completed in both <u>pivotal</u> and long-term study: MOONLIGHT 1 and 3) Japan: Phase 2b study to start in Q3 FY2021
AT132 (resamirigene bilparvovec)	X-linked myotubular myopathy	<ul style="list-style-type: none"> <u>ASPIRO study put on clinical hold by FDA in Sep 2021 due to a serious adverse event</u>

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, OS: Overall survival, ESMO: European Society Medical Oncology, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, FSFT: First subject first treatment, GEJ: Gastroesophageal junction, CKD: Chronic kidney disease, VMS: Vasomotor symptoms, NAMS: North American Menopause Society, HRT: Hormone replacement therapy FDA: Food and Drug Administration

ENZALUTAMIDE: ANDROGEN RECEPTOR INHIBITOR

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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. <u>Positive OS data presented at ESMO in Sep 2021</u>
P3: EMBARK	M0 CSPC	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

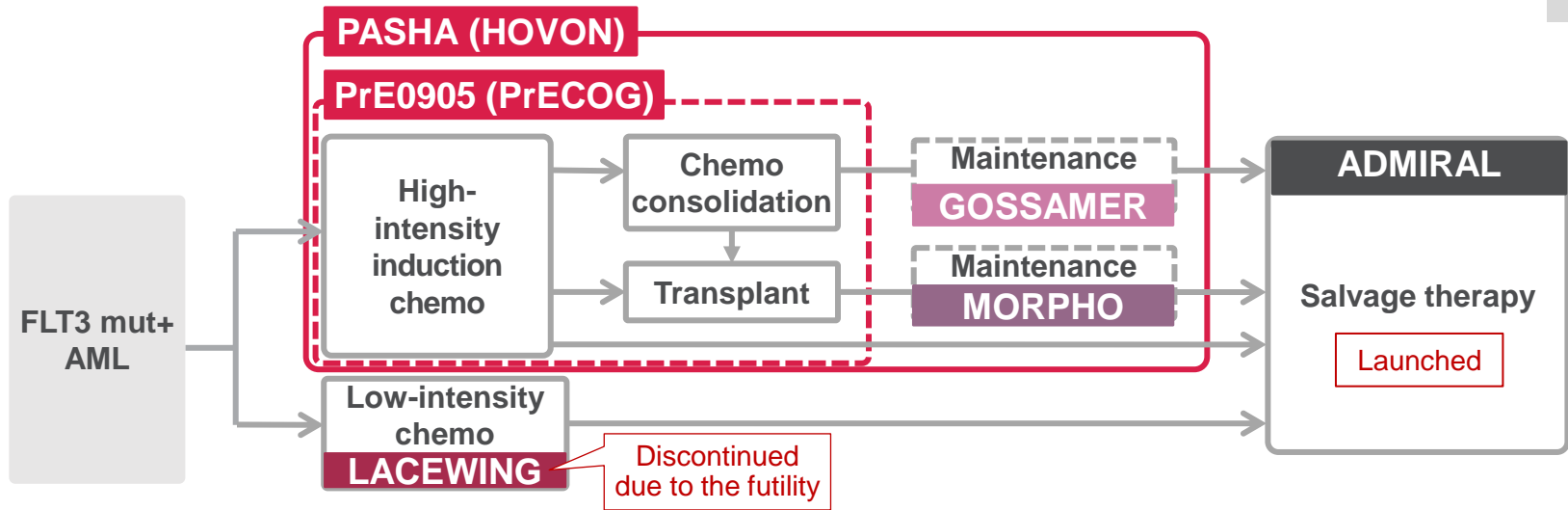
China • **M1 CSPC**: Enrollment completed in Phase 3 China-ARCHES study



Underlined: Updates since the last financial results announcement

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy, OS: Overall survival, ESMO: European Society for Medical Oncology

GILTERITINIB: FLT3 INHIBITOR



Relapsed or refractory (R/R)	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.)
Newly diagnosed (HIC-ineligible)	P3: LACEWING	Combo with azacitidine vs. azacitidine alone (2:1)	n=146	Discontinued due to the futility based on the planned interim analysis
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	Obtained topline results in Aug 2021

- 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



Underlined: Updates since the last financial results announcement

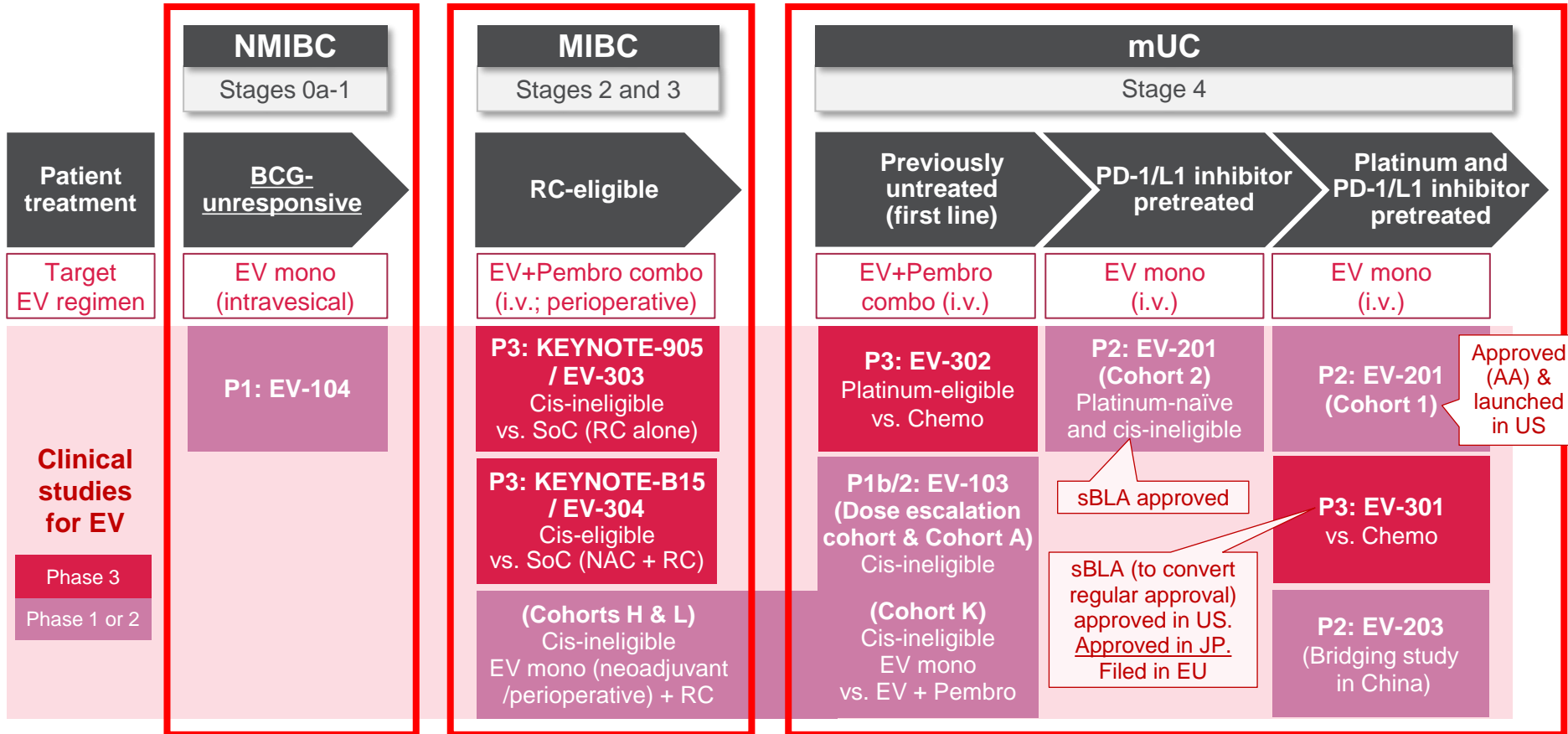
FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, FSFT: First subject first treatment, HIC: High-intensity chemotherapy, HSCT: Hematopoietic stem cell transplant, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands, BMT-CTN: Blood and Marrow Transplant - Clinical Trial Network, R/R: Relapsed or refractory

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

Early stage

- Disease stage of urothelial cancer -

Late stage



Underlined: 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) (2/3): CLINICAL STUDIES

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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. Filed in EU in Mar 2021
P3: EV-302	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=760	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	<u>Cohort K: Enrollment completed in Oct 2021</u> 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	<u>FSFT: Aug 2021</u>
P1: EV-104	NMIBC, High-risk BCG-unresponsive; Intravesical EV mono	<u>n=58</u>	<u>To start in Q3 FY2021</u>

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, gastroesophageal junction or esophageal cancer; EV mono	n=240	FSFT: Mar 2020
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Underlined: Updates since the last financial results announcement

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, IND: Investigational New Drug application, NMIBC: Non-muscle-invasive bladder cancer, BCG: Bacillus Calmette-Guerin, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer

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

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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)	760 (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 *



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



(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

ZOLBETUXIMAB: ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

Target: Claudin 18.2

- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- Broadly expressed in various cancer types
 - ✓ Prevalence of patients with high expression of Claudin 18.2 is substantial: 33% - 37%
 - ✓ ~60% of primary pancreatic adenocarcinomas; approx. 20% of these meet the eligibility criteria for the ongoing Phase 2 study

Gastric and (GEJ) adenocarcinoma

- Target patient population: HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma
- Metastatic gastric cancer is an area of significant unmet need, especially in advanced stages with ~4% five-year survival rate at Stage IV and limited treatment options have been limited

Gastric and GEJ adenocarcinoma	P3: SPOTLIGHT	First line, Combo with mFOLFOX6, DB, vs. placebo	n=550	FSFT: Oct 2018
	P3: GLOW	First line, Combo with CAPOX, DB, vs. placebo	n=500	FSFT: Jan 2019
	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	<u>n=369</u>	FSFT: May 2019

FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

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 life¹

Women's Health Initiative (WHI) Study²

- Initial data analyses showed an association between chronic HRT use and increased risk of cardiovascular disease and cancer
- Since WHI's findings, use of HRT has dropped precipitously, leaving an unmet need for a product that is effective for VMS without significant safety concerns.

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). <u>Obtained 52w data in Oct 2021</u>
P3: SKYLIGHT 2		n=501	Primary endpoints met (12w DB period topline results => <u>Presented at NAMS in Sep 2021</u>). Obtained 52w data in Jul 2021
P3: SKYLIGHT 4	VMS associated with menopause; 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)	n=1,833	Enrollment completed
P3b: DAYLIGHT	<u>Moderate to severe VMS associated with menopause, unsuitable for HRT;</u> 24 weeks, DB, 45 mg vs. placebo (1:1)	n=440	<u>To start in Q3 FY2021</u>

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	<u>Enrollment completed</u>
P3: MOONLIGHT 3	VMS associated with menopause; open label, 30 mg for 52 weeks	n=150	Enrollment completed

Japan

P2b (dose finding)	<u>Peri- and post-menopausal patients with mild to severe VMS;</u> 12 weeks: DB, 2 doses vs. placebo (1:1:1)	n=135	To start in Q3 FY2021
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Underlined: Updates since the last financial results announcement

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, NAMS: North American Menopause Society, FSFT: First subject first treatment

AT132 (RESAMIRIGENE BILPARVOVEC): rAAV8-Des-hMTM1

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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



Underlined: Updates since the last financial results announcement

(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

