

# **FY2020 FINANCIAL RESULTS**

## **ENDED MARCH 31, 2021**



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**April 27, 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

FY2020 Consolidated Financial Results  
FY2021 Forecasts

II

Initiatives for Sustainable Growth

III

Review of Corporate Strategic Plan 2018

# FY2020 FINANCIAL RESULTS

(billion yen)	FY2019	FY2020	Change	Change (%)	FY2020 FCST	Achievement
<b>Revenue</b>	<b>1,300.8</b>	<b>1,249.5</b>	<b>-51.3</b>	<b>-3.9%</b>	<b>1,256.5</b>	<b>99.4%</b>
Cost of sales	276.7	246.1	-30.7	-11.1%		
% of revenue	21.3%	19.7%	-1.6 ppt			
SG&A expenses	499.3	504.3	+5.0	+1.0%		
R&D expenses	224.2	224.5	+0.3	+0.1%	233.5	96.1%
Amortisation of intangible assets	21.2	23.8	+2.6	+12.3%		
<b>Core operating profit</b>	<b>277.8</b>	<b>251.4</b>	<b>-26.4</b>	<b>-9.5%</b>	<b>251.0</b>	<b>100.1%</b>
<b>&lt;Full basis&gt;</b>						
Other income	12.2	7.6	-4.5	-		
Other expense	45.9	123.0	+77.0	-		
<b>Operating profit</b>	<b>244.0</b>	<b>136.1</b>	<b>-107.9</b>	<b>-44.2%</b>	<b>210.5</b>	<b>64.6%</b>
Profit before tax	245.4	145.3	-100.0	-40.8%	209.5	69.4%
<b>Profit</b>	<b>195.4</b>	<b>120.6</b>	<b>-74.8</b>	<b>-38.3%</b>	<b>169.5</b>	<b>71.1%</b>

# FY2020 FINANCIAL RESULTS: YEAR-ON-YEAR COMPARISON

- *Revenue and Core operating profit decreased, YoY*
  - ✓ Sales of growth drivers steadily increased
  - ✓ Sales decreased due to termination of sales and distribution in Japan and loss of exclusivity
  - ✓ Negatively impacted by COVID-19 mainly during Q1/FY2020
  - ✓ SG&A expenses slightly increased, and R&D expenses were almost flat
  
- *Full basis: Operating profit and Profit decreased, YoY*
  - ✓ Booked impairment losses on intangible asset as other expense:
    - Termination of development for ASP8374 (Q2/FY2020: 30.2 billion yen)
    - Decrease in asset value due to review of AT132 development plan (Q4/FY2020: 58.8 billion yen)

# FY2020 FINANCIAL RESULTS: COMPARISON WITH FORECAST

- *Revenue was slightly behind forecast, but achieved when adjusted to exclude FX impact.*  
*Core operating profit achieved*
  - ✓ FX impact (Revenue: -11.8 billion yen, Core OP: -6.5 billion yen)
  - ✓ Steady performance for main oncology products
  - ✓ In China, revenue was behind forecast due to delayed reimbursement start and the impact of Volume Based Procurement
  - ✓ R&D expenses were slightly behind forecast
- *Full basis: Operating profit and Profit were behind forecast*
  - ✓ Booked impairment losses on intangible asset, not included into full-year forecast
    - Decrease in asset value due to review of AT132 development plan (Q4/FY2020: 58.8 billion yen)

# FY2020 FINANCIAL RESULTS: REVENUE

*Main oncology products continue to grow strongly*

**FY2020 actual** (billion yen)

YoY

<b>XTANDI</b>	<b>458.4</b>	<b>+58.4</b>
<b>XOSPATA</b>	<b>23.8</b>	<b>+9.6</b>
<b>PADCEV</b>	<b>12.8</b>	<b>+11.0</b>
<b>Evrenzo</b>	<b>1.1</b>	<b>+0.9</b>
<b>mirabegron</b>	<b>163.6</b>	<b>+2.0</b>
<b>New products in Japan</b>	<b>70.5</b>	<b>+9.3</b>



Total sales of  
3 oncology products, YoY

**+79.0** billion yen

Consolidated revenue for FY2020: -51.3 billion yen, YoY

Main decrease items:

- ✓ Sales decreases due to termination of sales and distribution in Japan (-36.3 billion yen) and loss of exclusivity (-55.7 billion yen)
- ✓ Negatively impacted by COVID-19 mainly during Q1/FY2020



Loss of exclusivity (LOE) products: Products with LOE in FY2019 or FY2020 (Vesicare, Tarceva, Celecox, MYCAMINE/Funguard)

Terminated products in Japan: Micardis-family, Symbicort, KM Bio products

New products in Japan: Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf

# FY2020 FINANCIAL RESULTS: BUSINESS UPDATE FOR MAIN PRODUCTS

## **XTANDI**

Global sales excl. FX impact achieved full-year forecast. US sales were slightly behind forecast due to COVID-19 (slowdown of new patients' diagnosis and treatment initiation), but demand grew approx. 20% YoY and continued growth is expected. In China, reimbursement for M1 CRPC indication has started from Mar 2021

## **XOSPATA**

Sales in US and EU steadily expanded and global sales exceeded full-year forecast. Launched in Singapore (Feb 2021) and China (Apr 2021). Reimbursement has started in Italy from Mar 2021 in addition to UK and Germany

## **PADCEV**

Revenue grew steadily through rapid market penetration and achieved full-year forecast on a local currency basis. EV-301 study results published in New England Journal of Medicine. The NCCN updated its guidelines, changing PADCEV's listing from a Category 2A to a Category 1 recommendation. This category is for treatment with the highest level of evidence

## **Evrenzo**

Following expansion of the indication in Japan to include patients who are not dialysis dependent in Nov 2020 and the subsequent lifting of the 2-week prescribing restriction in Dec 2020, sales have steadily increased, driven by large scale adoption in new institutions. Evrenzo is now the market leading HIF-PHI in Japan

## **mirabegron**

Global sales increased slightly behind full-year forecast due to demand impact of COVID-19. In China, NRDL reimbursement started from Mar 2021. The FDA granted pediatric exclusivity for Myrbetriq, resulting in an additional 6-month period of market exclusivity in US

## **New products in Japan**

Sales of EVENITY and Suglat-Family increased, but progress against forecast was behind due to the impact of COVID-19 such as restrictions on promotion activities, reduction of hospital/clinic visits by patients, etc.



# FY2021 FORECAST

(billion yen)	FY2020 actual	FY2021 forecast	Change (%)
<b>Revenue</b>	<b>1,249.5</b>	<b>1,323.0</b>	<b>+5.9%</b>
SG&A expenses	504.3	541.0	+7.3%
R&D expenses	224.5	242.0	+7.8%
<b>Core operating profit</b>	<b>251.4</b>	<b>270.0</b>	<b>+7.4%</b>
<b>Core profit</b>	<b>209.9</b>	<b>213.0</b>	<b>+1.5%</b>
<b>&lt;Full basis&gt;</b>			
<b>Operating profit</b>	<b>136.1</b>	<b>265.0</b>	<b>+94.8%</b>
<b>Profit</b>	<b>120.6</b>	<b>209.0</b>	<b>+73.3%</b>

# FY2021 FORECAST: OVERVIEW

- *Revenue and Profit to increase in FY2021  
Core OP margin for FY2021 to be 20%*
- *Main products and new products continue to grow.  
Growth to more than offset the impact of the LOE, termination of sales and distribution, transfer of products and NHI price revision*
  - ✓ Increase factors: XTANDI, XOSPATA, PADCEV, Evrenzo, mirabegron
  - ✓ Decrease factors: Vesicare Japan, MYCAMINE/Funguard, termination of sale and distribution, transfer of products (Celecox, Lipitor, Eligard, legacy products in EU, etc.), reversal of product transfer value (Difclir, Protopic), NHI price revision in Japan
- *Resource allocation to key strategic areas such as R&D investment for Primary Focus and launch costs for new products, while reviewing costs not contributing to competitiveness and increase of value*
- *Dividends per share: Forecasted 8 yen increase to 50 yen*

# FY2021 FORECAST: MAIN GROWTH DRIVERS

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## FY2021 Forecast

## FY2021 initiatives and growth factors

### XTANDI

**557.2** billion yen  
+98.8, YoY (+21.5%)

- Drive market share in earlier stages of prostate cancer
- Expand sales in the additional indication (M1 CSPC) in Established markets and International markets
- Continued growth in China with M1 CRPC reimbursed launch

### XOSPATA

**36.7** billion yen  
+12.8 (+53.8%)

- Maintain market leadership US/Japan and drive market share growth in other markets
- Expect sales contribution from China launched in Apr 2021
- Increase product awareness and FLT3 testing rates

### PADCEV

**20.1** billion yen  
+7.3 (+57.1%)

- Solidify the position as the preferred treatment option in the current indication in US. Expect to penetrate new patient segment with additional indication
- Successfully launch in Japan and Established markets

### Evrenzo

**8.6** billion yen  
+7.4 (+661.0%)

- Drive class growth in Japan whilst maintaining leadership within the HIF-PHI class
- Successfully launch in Established markets and International markets



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# KEY POST-POC PROJECTS: STATUS UPDATE

(Underlined: Updates since Q3/FY2020 Financial Results Announcement in Jan 2021)

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## enzalutamide

### M0 CRPC

- **EU:** CHMP positive opinion received in Jan 2021 for label update to include the OS data

### M1 CSPC

- **EU:** CHMP positive opinion received in Mar 2021
- **China:** Phase 3 study ongoing

### M0 CSPC

- Phase 3 study ongoing

## gilteritinib

### R/R AML

- **China:** Conditional approval obtained in Jan 2021 (full approval contingent on COMMODORE study data). Phase 3 COMMODORE study stopped due to efficacy based on the planned interim analysis

### Earlier-stage AML

- Phase 3 studies ongoing

## enfortumab vedotin

### mUC

- **Pretreated:** Filed in US (2 sBLAs) in Feb 2021, and in EU and JP in Mar 2021. Data of EV-301 study data presented at ASCO GU 2021 and published in NEJM. EV-201 study Cohort 2 data presented at ASCO GU 2021
- **Previously untreated (first line; combo with pembrolizumab):** Phase 3 study ongoing
- **China:** Currently under preparation to start clinical studies

### MIBC (combo with pembrolizumab)

- Phase 3 studies ongoing

### Other solid tumors

- Phase 2 study ongoing

## AT132 (resamirigene bilparvovec) XLMTM

- Clinical trial re-start activities underway. Discussions planned on the path forward toward global registration filings

## zolbetuximab

### Gastric & GEJ adenocarcinoma

- Phase 3 studies ongoing

### Pancreatic adenocarcinoma

- Phase 2 study ongoing

## roxadustat

### Anemia associated with CKD

- **EU:** Filed in Apr 2020

### Chemotherapy-induced anemia

- Phase 2 study ongoing

## fezolinetant

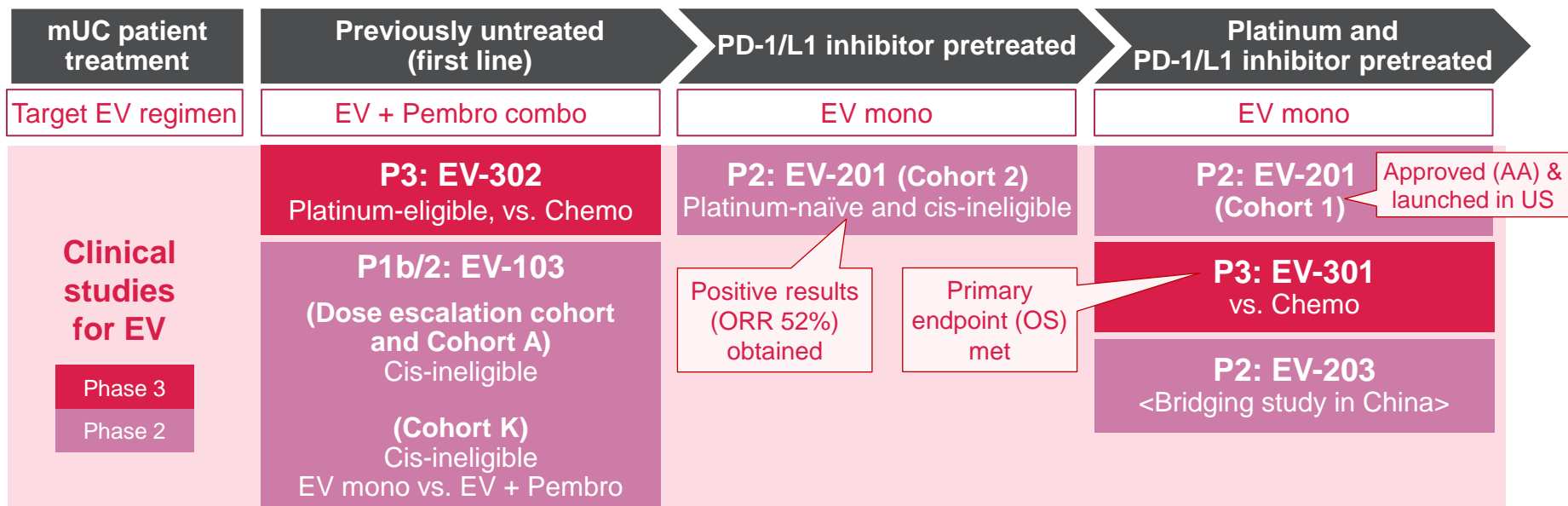
### VMS associated w/ menopause

- **US & EU:** Phase 3 studies ongoing. Primary endpoints (12w DB period topline results) met in both Phase 3 pivotal studies, SKYLIGHT 1 and 2
- **Asia:** Phase 3 studies ongoing

# ENFORTUMAB VEDOTIN (EV) (1/2): mUC PROGRAM REGULATORY STATUS

*Filed in US, EU and Japan*

- US: Filed (2 sBLAs) in Feb 2021 and PDUFA set on Aug 17, 2021 <sup>a</sup>
  1. To convert “Accelerated Approval” to “Regular Approval”, based on EV-301 study results
  2. To expand the indication to include mUC, PD-1/L1 inhibitor pretreated and cis-ineligible, based on EV-201 study Cohort 2 results
- EU: Filed in Mar 2021, based on EV-301 study results <sup>b</sup>
- JP: Filed in Mar 2021, based on EV-301 study and EV-201 study results



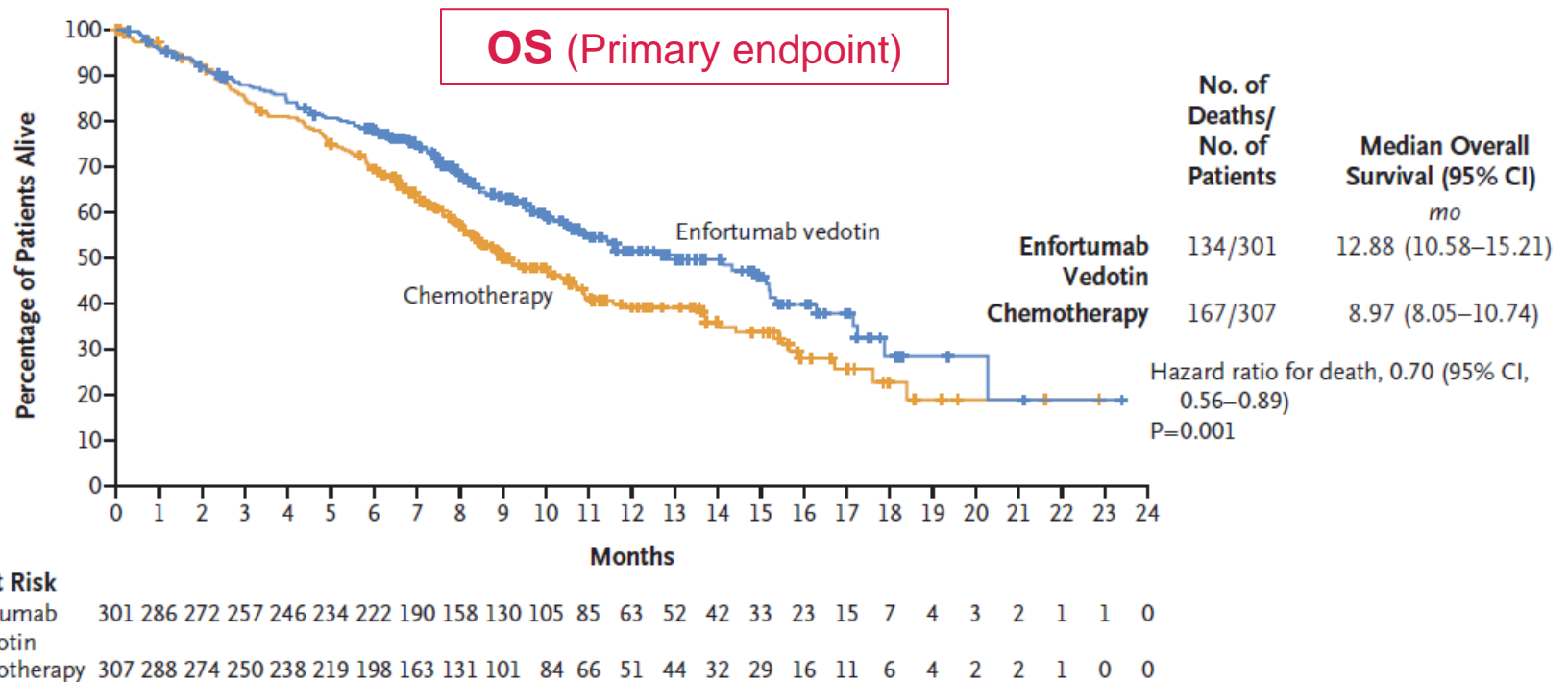
a: Priority Review granted, Real-Time Oncology Review pilot program and Project Orbis applied  
 b: Accelerated Assessment granted



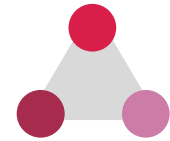
# ENFORTUMAB VEDOTIN (EV) (2/2): mUC PROGRAM PHASE 3 EV-301 STUDY RESULTS

*In patients with advanced UC who had previously received platinum-based chemotherapy and a PD-1/L1 inhibitor,*

- ✓ *EV monotherapy showed superior OS, compared with chemotherapy*
- ✓ *Safety profile was consistent with prior EV studies*



# PROGRESS IN FOCUS AREA APPROACH: GENETIC REGULATION



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*To build our position as a global leader in the field of genetic regulation*

## “Astellas Gene Therapies” as Gene Therapy Center of Excellence of Astellas

- Established (effective Apr 1, 2021), integrating our wholly owned subsidiary, Audentes Therapeutics, to achieve more effective and efficient operations for gene therapy programs
- Consists of three divisions specializing in gene therapies including research and technical operations, medical and development, and commercial

### Status of AT132 for XLMTM

- ASPIRO study re-start activities underway
  - ✓ To resume dosing at the lower dose of AT132 in Q1/FY2021
- Discussions planned on the path forward toward global registration filings
  - ✓ Next meeting with FDA planned in Q1/FY2021
  - ✓ Meeting with EMA planned in Q2/FY2021

### Status of AT845 for Pompe disease

- First-in-human Phase 1/2 FORTIS study in adult patients with late onset Pompe disease started
  - ✓ First subject dosed in Mar 2021





# KEY EVENTS EXPECTED IN FY2021

<b>Regulatory decision</b>	enzalutamide	M1 CSPC (EU)
	enfortumab vedotin	mUC, PD-1/L1 inhibitor pretreated and cisplatin ineligible (US <sup>a</sup> ) mUC, platinum and PD-1/L1 inhibitor pretreated (US <sup>a,b</sup> , EU <sup>c</sup> ) mUC, progressed after anti-cancer medication (JP)
	roxadustat	Anemia associated with CKD (EU)
<b>Regulatory submission</b>	gilteritinib	R/R AML (China <sup>d</sup> )
<b>Data readout</b>	fezolinetant	52-week safety results from Phase 3 SKYLIGHT 1, 2 and 4 studies

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

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

b: sBLA to convert Accelerated Approval to regular approval

c: Accelerated Assessment granted

d: sNDA to convert conditional approval to full approval

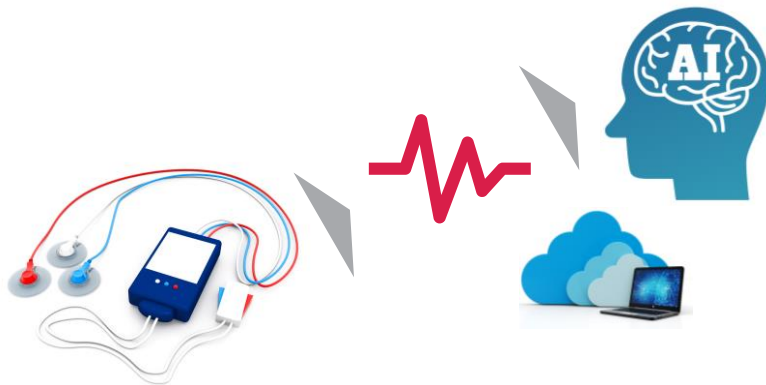


# PROGRESS IN Rx+ PROGRAM (1/2): DEVELOPMENT OF AI-BASED PROGRAM FOR HOLTER ANALYSIS DEVICES



*Developed an AI-based data analysis algorithm for Holter ECG test through research collaboration with M. Heart*

- Developed an efficient analytical algorithm with low computer load (patent pending)
- Data described in accordance with MFER, an international standard, can be analyzed in the cloud regardless of type of Holter monitor
- Received certification as a medical device program in Mar 2021 and scheduled to be commercialized (implemented into ECG analysis service of M. Heart) in FY2021
- The next version with improved accuracy and efficiency will be developed through deep learning utilizing ECG data obtained clinically



Brand name	My Holter II
Classification	Class II (Controlled medical devices)
Certification No.	303AGBZX00015000



# PROGRESS IN Rx+ PROGRAM (2/2): KEY EVENTS EXPECTED IN FY2021



Sphere *	Program	Expected key event
Chronic disease progression prevention	Fitness service for exercise support (Fit-eNce)	Initiation of pilot marketing for at-home service
	Smartphone game application for exercise support	Initiation of pilot marketing
	BlueStar	Initiation of clinical study (Japan)
	Program for Holter analysis devices (My Holter II)	Commercialization of service
Patient outcome maximization	ASP5354	Topline results for Phase 2 study

# SUSTAINABILITY: ACCESS TO HEALTH



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## *A new collaborative research agreement with TB Alliance to identify lead compounds for the treatment of tuberculosis*



- Astellas and TB Alliance have conducted joint research for exploration of new compounds for *Mycobacterium tuberculosis* since Oct 2017
- This new joint research aims to identify lead compounds with improved pharmacological activity, pharmacokinetics, and safety by utilizing multiple hit compounds obtained from the exploration research
- Funded by the Global Health Innovative Technology Fund

### Position on Access to Health

- Efforts to create innovative medicines and medical solution, and deliver them to patients
- Identified four areas, “creating innovation”, “enhancing availability”, “strengthening healthcare system” and “improving health literacy”

### Other initiatives for “creating innovation”

- Participated in a project regarding the development of pediatric formulation for schistosomiasis as a research and development project pursuing social benefits
- Working on various initiatives to improve Access to Health through collaboration with external partners

### Acceleration to drive Access to Health activities

- “Sustainability” will form one of the strategic goals in the new Corporate Strategic Plan, and Access to Health will be the core piece



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# REVIEW OF CORPORATE STRATEGIC PLAN 2018 (STRATEGIC PART)

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*Initiatives aiming at 3 Strategic Goals advancing as planned.  
Building a foundation to create innovative treatments*

## Strategic Goal 1

### Maximizing Product VALUE and Operational Excellence

#### Maximizing Product VALUE

- ✓ Sales of XTANDI and mirabegron steadily increased. XTANDI's growth exceeded original expectations
- ✓ Continued launches of new products in Japan
- ✓ 6 post-PoC projects: Achieved important milestones as planned. Successful launches of XOSPATA, PADCEV, Evrenzo and positive initial uptake

#### Operational Excellence

- ✓ Prioritize sales promotion expenses and promote global procurement efficiencies and travel cost reduction (Approx. 50.0 bil. yen\* profit improvement)

\* Cumulative total of FY2018-FY2020

## Strategic Goal 2

### Evolving How We Create VALUE - With Focus Area Approach -

- ✓ Progressed clinical programs in the designated Primary Focus
- ✓ Strengthened capabilities by collaborations and acquisitions to continuously produce innovative projects
- ✓ Enhanced utilization of innovative platforms among multiple Primary Focus and produced multiple promising projects

## Strategic Goal 3

### Developing Rx+ Programs

- ✓ Progressed toward establishment of a foundation for Rx+ business
- ✓ Achieved partnerships with various technologies from different fields
- ✓ Successfully advanced multiple programs toward commercialization

# PROGRESS IN 6 POST-POC PROJECTS

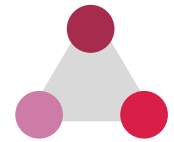
*Achieved all the targeted submission goals in Strategic Plan 2018 and obtained the global approvals*

● As of Apr 2021 (Progress since May 2018 ○)  
 ● As of Apr 2021 (No update in phase since May 2018)

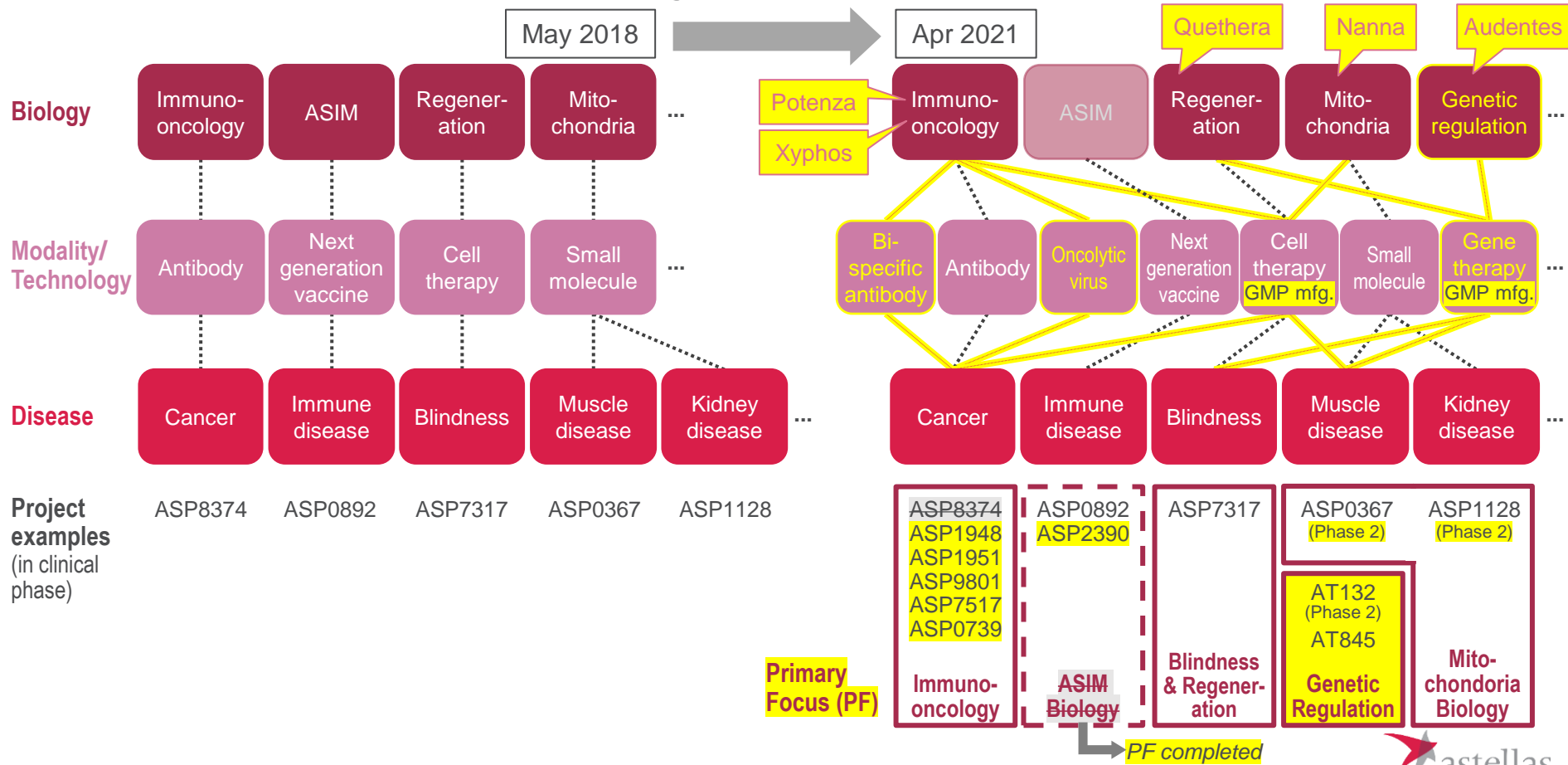
Project	Indication	Phase			
		Phase 2	Phase 3	Filed	Approved
<b>enzalutamide</b>	M1 CRPC			○	● CN
	M0 CRPC			○	● US, EU, CN
	M1 CSPC		○	● EU	● US, JP
	M0 CSPC		●		
<b>gilteritinib</b>	Refractory and relapsed AML		○		● JP, US, EU, CN
	AML, 1st line, intensive chemo eligible	○	●		
	AML, 1st line, intensive chemo ineligible		●		Phase 3 study stopped due to futility
	AML, post-HSCT maintenance		●		
	AML, post-chemo maintenance		●		
<b>enfortumab vedotin</b>	mUC, pretreated	○		● EU, JP	● US
	mUC, previously untreated (1st line)	○	●		
	Muscle-invasive bladder cancer		●		
	Other solid tumors	●			
<b>zolbetuximab</b>	Gastric and GEJ adenocarcinoma		●		
	Pancreatic adenocarcinoma	●			
<b>roxadustat</b>	Anemia associated with CKD		○		● JP
	Chemotherapy-induced anemia	●	○	● EU	
<b>fezolinetant</b>	VMS associated with menopause	○	●		Primary endpoints met in US & EU pivotal studies

PoC: Proof of concept, M1: Metastatic, M0: Nonmetastatic, CRPC: Castration-resistant prostate cancer, CSPC: Castration-sensitive prostate cancer, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplantation, mUC: Metastatic urothelial cancer, GEJ: Gastroesophageal junction, CKD: Chronic kidney disease, VMS: Vasomotor symptoms

# PROGRESS IN FOCUS AREA APPROACH (1/2): ORGANIC APPLICATION AMONG MULTIPLE PRIMARY FOCUS



*Enhanced utilization of innovative platforms among multiple Primary Focus and produced multiple promising projects*

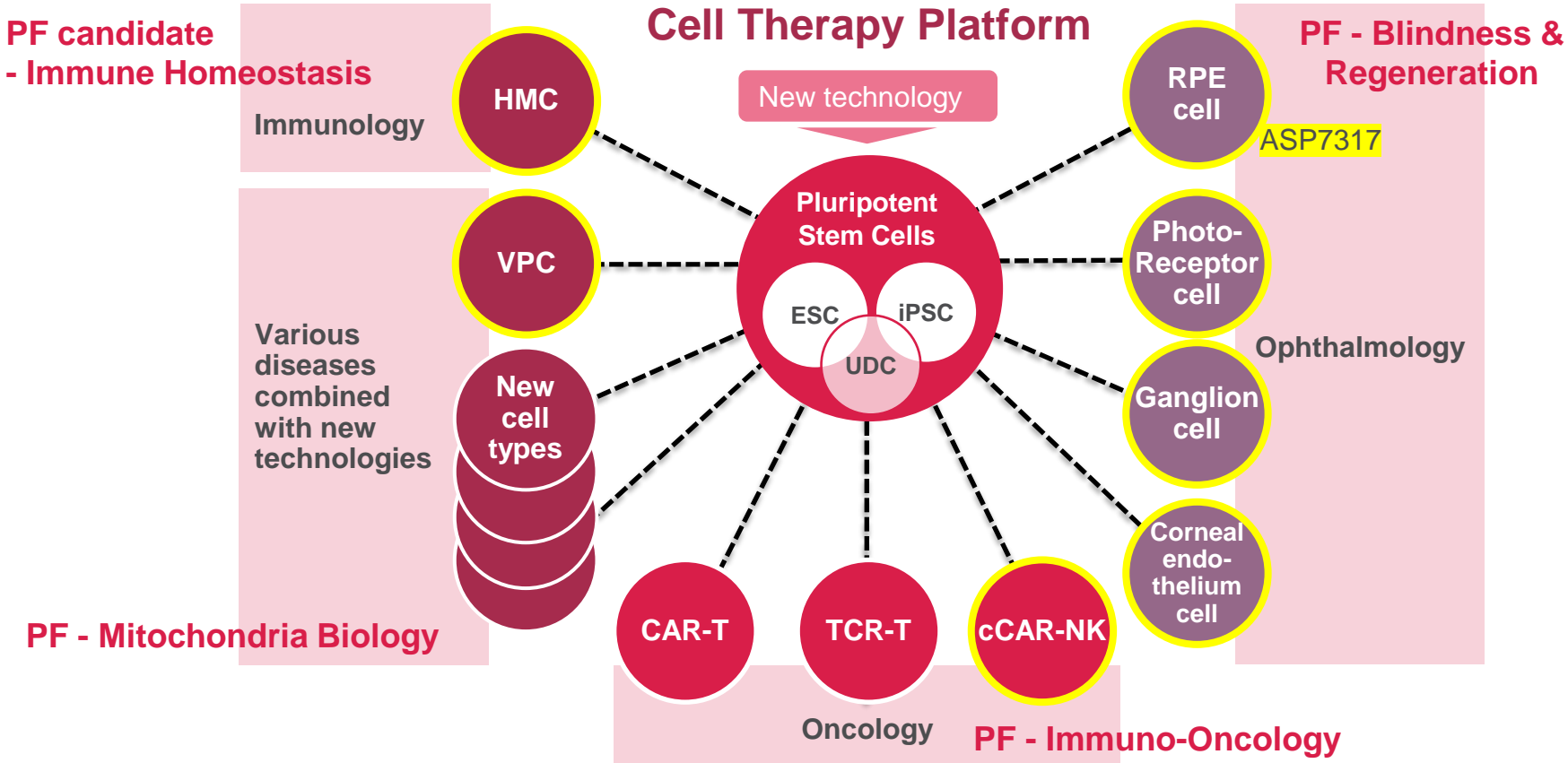




# PROGRESS IN FOCUS AREA APPROACH (2/2): ORGANIC APPLICATION OF CELL THERAPY PLATFORM TO REALIZE MULTIPLE PF STRATEGY



*Established cell differentiation protocols in multiple projects*



**Yellow:** Cell differentiation protocols established

PF: Primary Focus, ESC: Embryonic stem cell, iPSC: Induced pluripotent stem cell, UDC: Universal donor cell, RPE: Retinal pigment epithelium, HMC: Hemangioblast-derived mesenchymal stem cell, VPC: Vascular progenitor cell, CAR: Chimeric antigen receptor, TCR: T-cell receptor, cCAR: convertibleCAR, NK: Natural killer

# PROGRESS IN Rx+ PROGRAM

*Steadily progressed to establish a solid foundation*

- ✓ Formulated Rx+ Story (strategic direction of Rx+ business creation)
- ✓ Established a US base for Rx+ business

*Successfully advanced multiple programs toward commercialization*



## Service and smartphone application for exercise support

- Initiated pilot marketing of a science-based exercise support service “Fit-eNce”
- Entered into agreement with BANDAI NAMCO Entertainment to co-develop and co-commercialize smartphone exercise support application
- Launched “Health Mock Lab.”, a virtual framework for industry-academia collaboration

## Digital therapeutics

- Entered into a strategic alliance with Welldoc to develop and commercialize digital therapeutics

## Support ecosystem for patients with heart disease

- Developed a program for Holter analysis devices “My Holter II” through research collaboration with M. Heart and received certification as a class II medical device program



## Image-guided precision surgery

- ASP5354: FSFT in Phase 2 study (US)
- ASP5354: Received FDA Fast Track Designation

## Theranostics\* utilizing radioisotope-labeled antibodies

- Entered into a research collaboration for molecular targeted radiotherapies with Actinium Pharmaceuticals



## Ultra-small implantable medical devices

- Completed acquisition of Iota Biosciences

\* The term that combines “Therapeutics” and “Diagnostics”. Treatment protocol or concept in which healthcare professionals assess lesion sites and simultaneously determine the appropriate treatment for each patient

FSFT: First subject first treatment, FDA: Food and Drug Administration

# REVIEW OF CORPORATE STRATEGIC PLAN 2018 (FINANCIAL PART) (1/2)

*Revenue was behind original forecast, but achieved Core OP margin including investment for sustainable growth*

(billion yen)

Indicators	FY2017 ACT	FY2020 ACT	FY2020 Guidance (Announced in May 2018)
Revenue	1,300.3	1,249.5	✗ FY2017 level
R&D investment	220.8	224.5	○ More than 200.0 billion yen
Core OP	268.7 20.7%	251.4 20.1%	○ Core OP margin 20%
Core EPS	100.64 yen	113.03 yen	○ Exceed FY2017

# REVIEW OF CORPORATE STRATEGIC PLAN 2018 (FINANCIAL PART) (2/2)

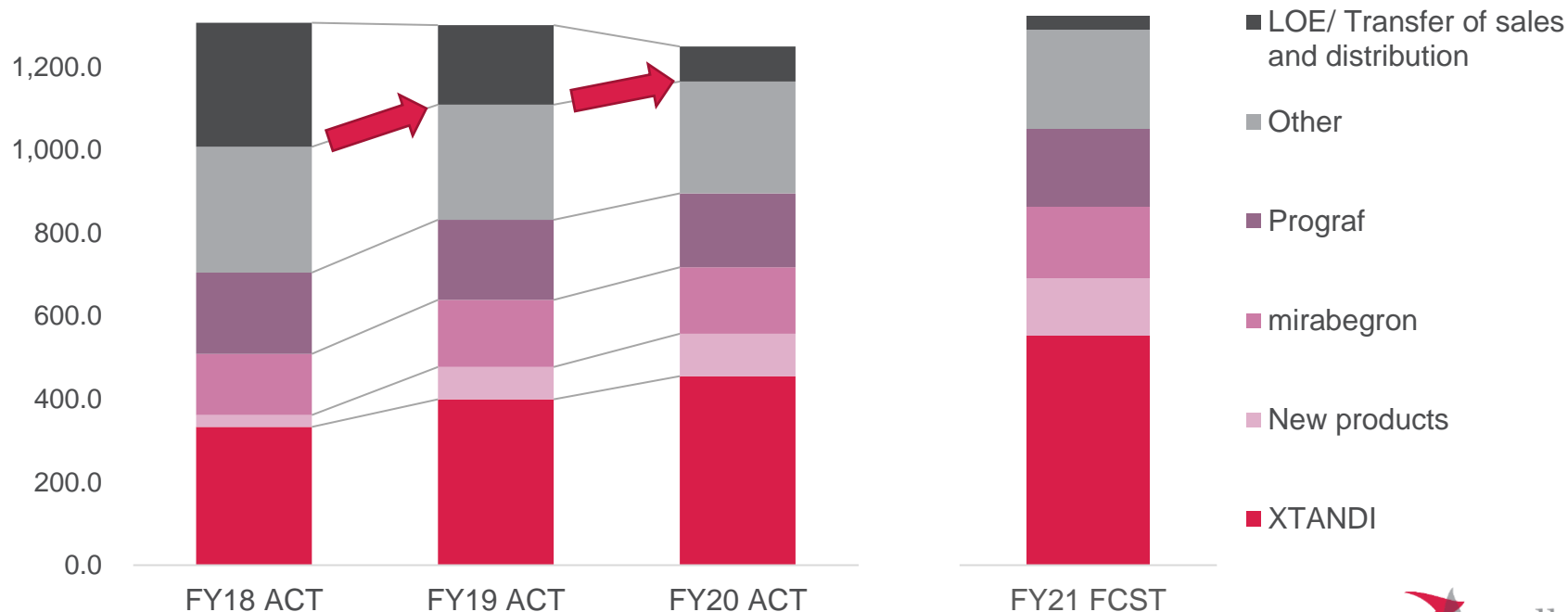
*Product portfolio has changed in 3 years and sales of main products and new products grew significantly.*

*Negative impact from LOE/ transfer of sales and distribution has almost ended.*

*Aiming for mid- to long-term growth trend during the next corporate strategic plan*

**Revenue trend**

(billion yen) 1,400.0



LOE: Loss of exclusivity

LOE products/ Transfer of sales and distribution: Vesicare, Tarceva, MYCAMINE/ Funguard, Celecox, Symbicort, KM bio products, Micardis, etc.

New products: XOSPATA, PADCEV, Evrenzo, New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

# APPENDIX

A water droplet is captured in mid-fall, just above a pool of water. The droplet is clear and spherical, with a slight reflection on its surface. Below it, the water surface is disturbed, creating concentric ripples that spread outwards. The background is a composition of geometric shapes: a large white area at the top, a grey area on the right, and a red area at the bottom right. The overall aesthetic is clean and modern.

# FY2020: REVENUE BY REGION

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(billion yen)	FY2019	FY2020	Change (%)
<b>Japan</b>	345.4	279.1	-19.2%
<b>United States</b>	443.5	473.2	+6.7%
<b>Established Markets</b>	296.1	293.2	-1.0%
<b>Greater China</b>	60.4	59.3	-1.8%
<b>International Markets</b>	134.8	111.1	-17.6%

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.



# FY2020: SALES OF MAIN PRODUCTS

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(billion yen)	FY2019	FY2020	Change	CER growth	FY2020 FCST *
<b>XTANDI</b>	400.0	458.4	+14.6%	+15.3%	464.6
<b>XOSPATA</b>	14.3	23.8	+67.2%	+68.3%	23.1
<b>PADCEV</b>	1.8	12.8	+607.3%	-	13.0
<b>Evrenzo</b>	0.2	1.1	-	-	
<b>mirabegron</b>	161.6	163.6	+1.2%	+2.3%	167.9
<b>New products in Japan</b>	61.2	70.5	+15.3%	-	
<b>Prograf</b>	192.9	182.7	-5.3%	-5.9%	182.0



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

\*Announced in Aug 2020

# FY2020 ACTUAL: FX RATE

## Average rate for the period

Currency	FY2019	FY2020	Change
USD	109 yen	106 yen	-3 yen
EUR	121 yen	124 yen	+3 yen

## Change in closing rate from previous fiscal year end

Currency	FY2019	FY2020
USD	-2 yen	+2 yen
EUR	-5 yen	+10 yen

### <Impact of exchange rate on financial results>

- 4.6 billion yen decrease in revenue, 7.3 billion yen decrease in core OP
- FX impact on elimination of unrealized gain: COGs ratio +0.8 ppt



# FY2021 FCST: FX RATE & FX SENSITIVITY

## Average rate for the period

Currency	FY2020	FY2021 FCST	change
USD	106 yen	110 yen	+4 yen
EUR	124 yen	130 yen	+6 yen

## Change in closing rate from the previous FY end

Currency	FY2020	FY2021 FCST
USD	+2 yen	-1 yen
EUR	+10 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. -6.3 bil. yen	Approx. -1.3 bil. yen	Approx. +0.6 bil. yen
EUR	Approx. -2.9 bil. yen	Approx. -1.4 bil. yen	Approx. +0.3 bil. yen

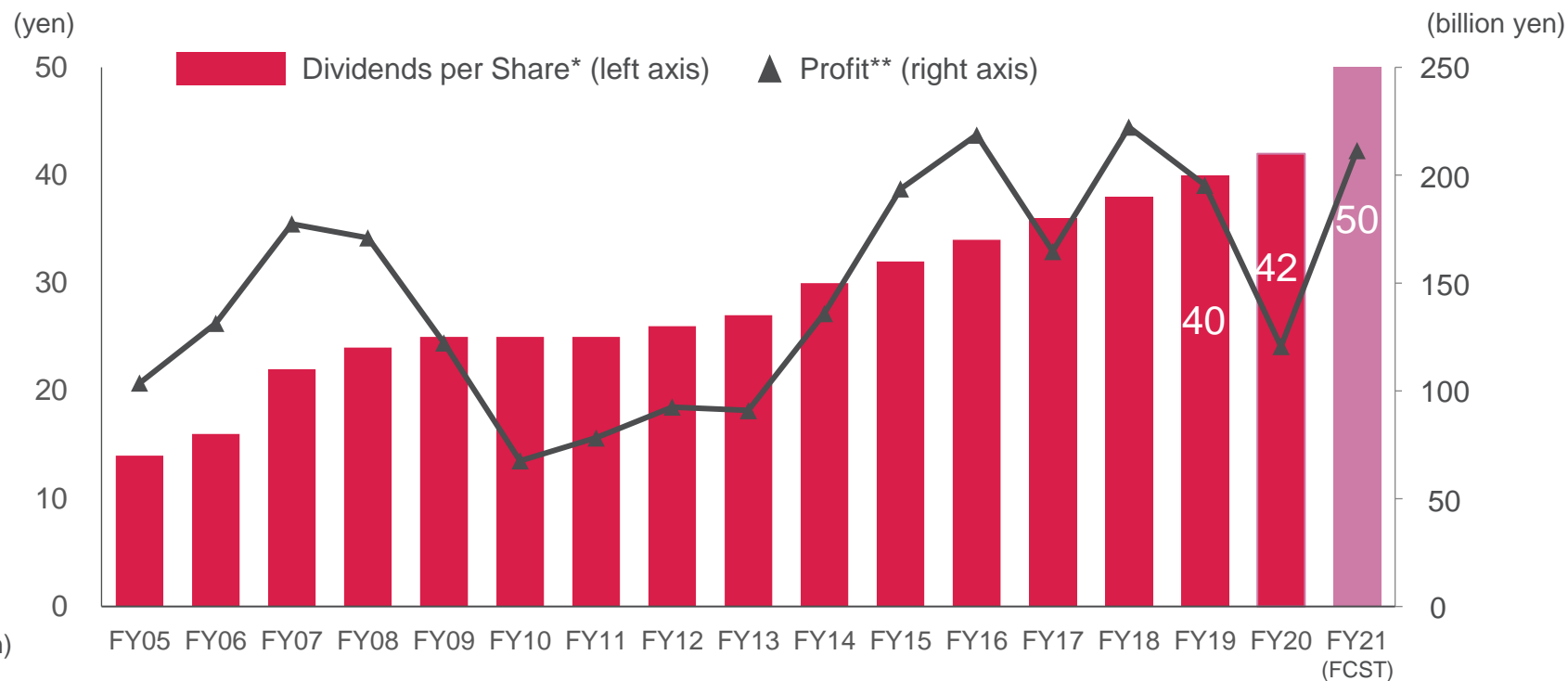
# BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY2019 end	FY2020 end
Total assets	2,315.2	2,273.6
Cash and cash equivalents	318.4	326.1
Total equity attributable to owners of the parent	1,289.2	1,386.1
Equity ratio (%)	55.7%	61.0%

(billion yen)	FY2019	FY2020
Cash flows from operating activities	222.0	306.8
Cash flows from investing activities	-389.8	-81.9
Free cash flows	-167.8	224.9
Cash flows from financing activities	181.1	-229.5
Bonds and short-term borrowings	326.0	-206.0
Proceeds from long-term borrowings	-	80.0
Dividends paid	-73.5	-76.2

Balance of bonds and borrowings : 200.0 billion yen  
(Decreased by 126.0 billion yen from FY2019 end)

# DETAILS OF SHAREHOLDER RETURNS



	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21 (FCST)
Total dividends (billion yen)	39.3	42.3	55.2	56.9	58.2	57.7	57.7	59.4	60.6	66.0	68.5	71.3	72.1	72.4	75.0	78.1	93.0
Acquisition of own share (billion yen)	46.2	219.9	81.8	123.4	27.0	-	-	49.4	30.0	58.2	119.3	91.4	130.0	160.0	50.0	-	-
Total return ratio (%)	82	200	77	106	70	85	74	118	100	92	97	74	123	105	64	65	-



\* The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014, Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal year 2005.

\*\* From fiscal year 2013, figures are in accordance with International Financial Reporting Standards (IFRS)

# ROBUST PIPELINE OF ASTELLAS

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## Phase 1

ASP1948/PTZ-329

ASP1951/PTZ-522

ASP9801

ASP7517

ASP0739

ASP7317

ASP0892

ASP0367/MA-0211  
(Duchenne muscular dystrophy)

ASP2390

ASP0598

AT845

ASP8062  
(Alcohol use disorder)

ASP1617

## Phase 2

zolbetuximab  
(Pancreatic adenocarcinoma)

enfortumab vedotin  
(Other solid tumors)

ASP1128/MA-0217  
(Acute kidney injury)

ASP3772  
(Pneumococcal disease)

FX-322  
(Sensorineural hearing loss)

resamirigene bilparvovec  
/AT132 (XLMTM)

ASP0367/MA-0211  
(Primary mitochondrial myopathies)

bleselumab  
(rFSGS)

roxadustat  
(Chemotherapy-induced anemia)

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)

peficitinib  
(Rheumatoid arthritis: China)

mirabegron  
(Pediatric use: EU)

fezolinetant  
(VMS associated with menopause)

## Filed

enzalutamide  
(M1 CSPC: EU)

enfortumab vedotin  
(mUC, pretreated: US [sBLA], EU, JP)

roxadustat  
(Anemia associated with CKD: EU)

tacrolimus  
(Lung transplantation: US)

■ Oncology ■ Projects with Focus Area approach (excluding Immuno-oncology projects) ■ Others

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

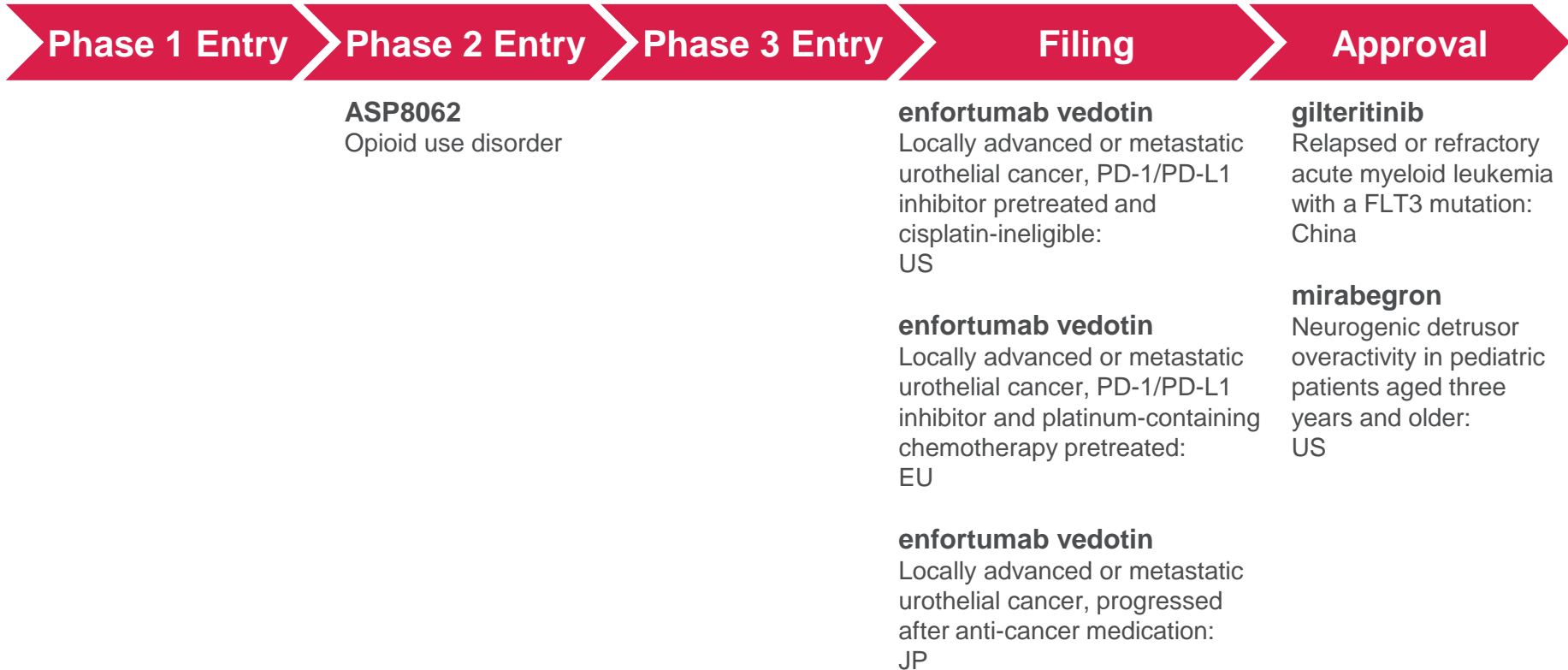


XLMTM: X-linked myotubular myopathy, rFSGS: Recurrence of focal segmental glomerulosclerosis, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, AML: Acute myeloid leukemia, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms, sBLA: Supplemental Biologics License Application, CKD: Chronic kidney disease

# PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since Q3/FY2020 Financial Results Announcement in Jan 2021

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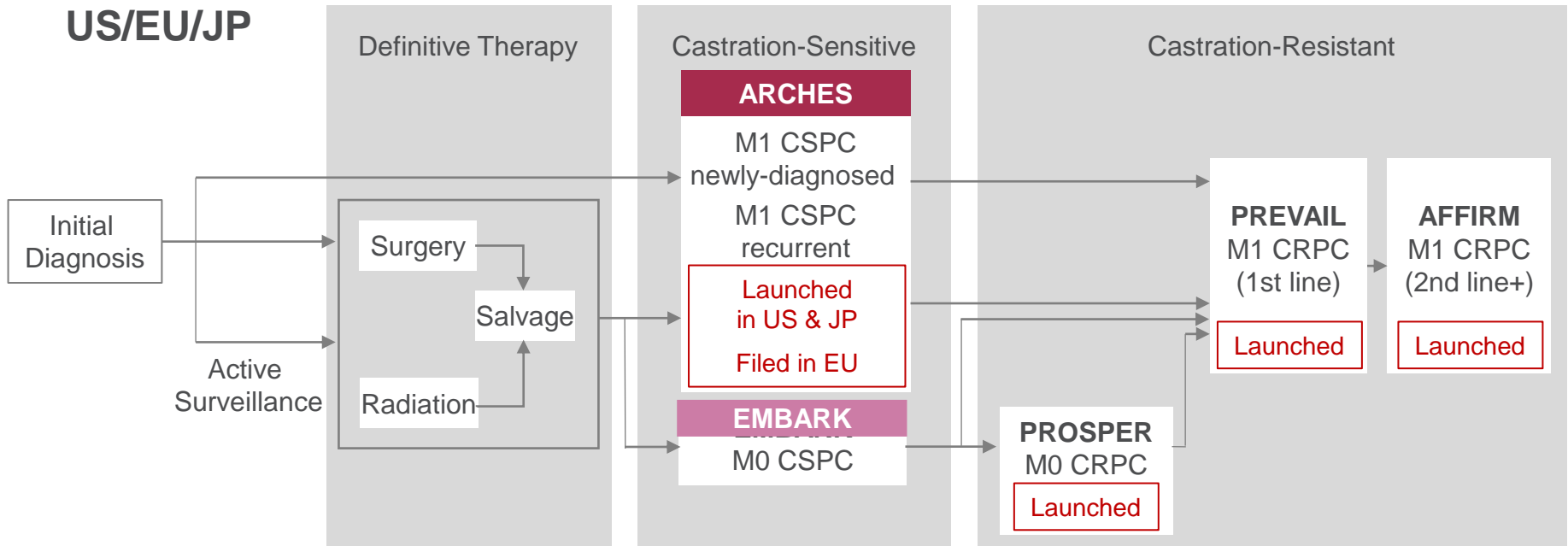


Note: Phase 1 entry is defined as confirmation of IND open. Phase transition is defined by approval of company decision body for entering to next clinical phase. Filing is defined as submission of application to health authorities. Discontinuation is defined by the decision of company decision body



IND: Investigational new drug

# ENZALUTAMIDE: ANDROGEN RECEPTOR INHIBITOR (1/2)



<b>P3: ARCHES</b>	<b>M1 CSPC</b>	Combo with ADT, vs. placebo	n=1,150	Approved in US in Dec 2019 and in JP in May 2020 Filed in EU in Jul 2019 and CHMP positive opinion received in Mar 2021
<b>P3: EMBARK</b>	<b>M0 CSPC</b>	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

- China**
- **M1 CRPC:** Approved in Nov 2019 and launched in Mar 2020
  - **M0 CRPC:** Approved in Nov 2020
  - **M1 CSPC:** Enrollment completed in Phase 3 China-ARCHES study



Underlined: Updates since Q3/FY2020 financial results announcement in Jan 2021  
M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy

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

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

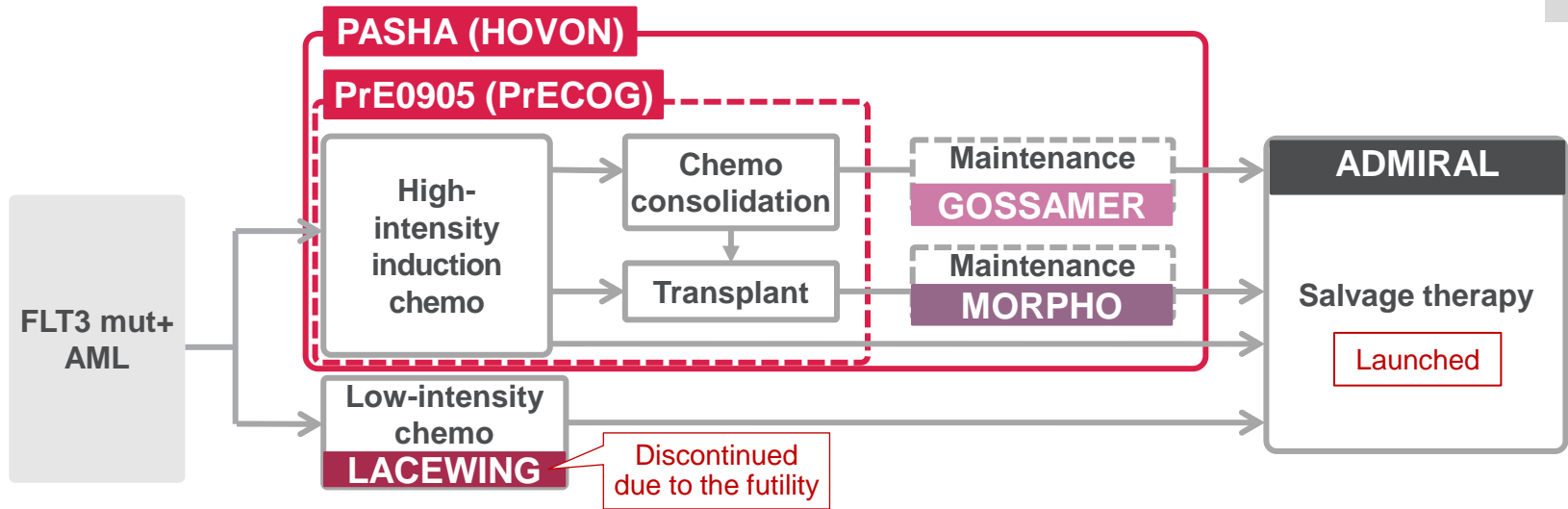
Disease stage	Early stage			Late stage		
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	<b>EMBARK</b>	<b>ARCHES</b>	<b>ENZAMET</b>	<b>PROSPER</b>	<b>PREVAIL</b>	<b>AFFIRM</b>
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	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)	(Not reached)	✓ HR 0.67	✓ HR 0.73	✓ HR 0.77	✓ HR 0.63
DoT	(Ongoing)	(Not reached)	✓ 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



Relapsed or refractory (R/R)	<b>P3: ADMIRAL</b>	Monotherapy vs salvage chemo (2:1)	n=371	Launched in US, JP, and EU
Newly diagnosed (intensive chemo eligible)	<b>P3: PASHA (HOVON)</b>	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=768	FSFT: Dec 2019 (Sponsor: HOVON)
	<b>P2: PrE0905 (PrECOG)</b>		n=179	FSFT: Dec 2019 (Sponsor: PrECOG, LLC.)
Newly diagnosed (intensive chemo ineligible)	<b>P3: LACEWING</b>	Combo with azacitidine vs. azacitidine alone (2:1)	n=146	Discontinued due to the futility based on the planned interim analysis
Post-HSCT maintenance	<b>P3: MORPHO</b>	Monotherapy vs. placebo (1:1)	n=346	Enrollment completed Collaborating with BMT-CTN
Post-chemo maintenance	<b>P2: GOSSAMER</b>	Monotherapy vs. placebo (2:1)	n=98	Enrollment completed

- 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 Q3/FY2020 financial results announcement in Jan 2021

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



# ENFORTUMAB VEDOTIN (EV) : NECTIN-4 TARGETED ADC (1/9)

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## For urothelial cancer

<b>P3: EV-301</b>	mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono vs. Chemo	n=608	Primary endpoint (OS) met (data presented at ASCO GU 2021 and published in NEJM). Filed in US (sBLA) in Feb 2021, in EU and JP in Mar 2021
<b>P3: EV-302</b>	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=760	FSFT: Apr 2020
<b>P3: EV-303 /KEYNOTE-905</b>	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=836	FSFT in Pembro + EV arm: Dec 2020
<b>P3: EV-304 /KEYNOTE-B15</b>	MIBC, Cis-eligible; EV+Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=784	To start in <u>Q1 FY2021</u>
<b>P2: EV-201</b>	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: Obtained positive ORR (data presented at ASCO GU 2021). Filed in US (sBLA) in Feb 2021
<b>P1b/2: EV-103</b>	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	Enrollment ongoing in Cohort K <u>and L</u>
<b>P2: EV-203</b>	<Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono	n≈40	Currently under preparation (IND approved)

## For other solid tumors


<b>P2: EV-202</b>	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 Q3/FY2020 financial results announcement in Jan 2021

ADC: Antibody-drug conjugate, mUC: Metastatic urothelial cancer, mono: Monotherapy, Chemo: Chemotherapy, OS: Overall survival, ASCO GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium, NEJM: New England Journal of Medicine, sBLA: Supplemental Biologics License Application, Pembro: Pembrolizumab, FSFT: First subject first treatment, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, RC: Radical cystectomy, ORR: Objective response rate, IND: Investigational New Drug application, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer

# ENFORTUMAB VEDOTIN (EV) (2/9): PHASE 1b/2 EV-103 STUDY DESIGN

	Dose Escalation Cohort	Dose Expansion Cohorts		
Locally advanced or metastatic urothelial cancer	<div style="background-color: #800000; color: white; padding: 10px; text-align: center;">                     EV + Pembro Cis-ineligible 1L or 2L                 </div> <div style="text-align: center; margin-top: 10px;">  </div>	<div style="background-color: #800000; color: white; padding: 10px; text-align: center;"> <b>Cohort A</b> EV + Pembro Cis-ineligible 1L                 </div>	<div style="border: 1px solid #800000; padding: 10px; text-align: center;"> <b>Cohort D</b> EV + Cis, 1L                 </div>	<div style="border: 1px solid #800000; padding: 10px; text-align: center;"> <b>Cohort G</b> EV + Cis/Carbo + Pembro 1L                 </div>
		<div style="border: 1px solid #800000; padding: 10px; text-align: center;"> <b>Cohort K</b> EV mono vs. EV+Pembro (1:1, n=150 in total) Cis-ineligible, 1L                 </div>	<div style="border: 1px solid #800000; padding: 10px; text-align: center;"> <b>Cohort E</b> EV + Carbo, 1L                 </div>	<div style="border: 1px solid #800000; padding: 10px; text-align: center;"> <b>Optional Cohort B</b> EV + Pembro, 2L                 </div>
Muscle-invasive bladder cancer		<div style="border: 1px solid #800000; padding: 10px; text-align: center;"> <b>Cohort H</b> EV mono (neoadjuvant) + RC Cis-ineligible                 </div>	<div style="border: 1px solid #800000; padding: 10px; text-align: center;"> <b>Optional Cohort J</b> EV+Pembro (neoadjuvant) + RC Cis-ineligible                 </div>	<div style="border: 1px solid #800000; padding: 10px; text-align: center;"> <b>Cohort L</b> EV mono (perioperative) + RC Cis-ineligible                 </div>

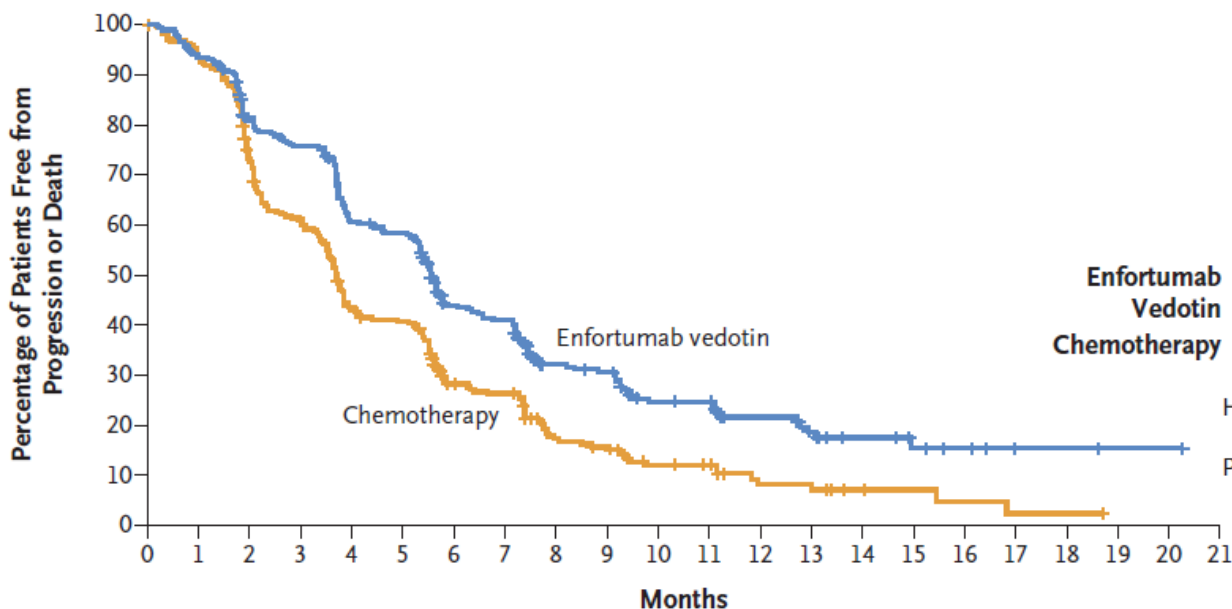
■ Results from cis-ineligible and 1L in these cohorts presented at ESMO 2019 and ASCO GU 2020

*Data from Cohort K, along with other data from the EV-103 study evaluating EV combined with pembrolizumab as first-line therapy for cisplatin-ineligible patients, could potentially support registration under Accelerated Approval regulations in US*



# ENFORTUMAB VEDOTIN (3/9): PHASE 3 EV-301 STUDY RESULTS - EFFICACY

## PFS (Secondary endpoint)



	No. of Events/ No. of Patients	Median Progression-free Survival (95% CI) mo
<b>Enfortumab Vedotin</b>	201/301	5.55 (5.32–5.82)
<b>Chemotherapy</b>	231/307	3.71 (3.52–3.94)

Hazard ratio for disease progression or death, 0.62 (95% CI, 0.51–0.75)  
P < 0.001

No. at Risk	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Enfortumab vedotin	301	269	224	208	165	158	102	95	60	56	38	36	23	17	11	7	5	2	2	1	1	0
Chemotherapy	307	259	200	166	116	107	62	57	33	29	18	16	8	8	4	3	2	1	1	0	0	0

# ENFORTUMAB VEDOTIN (EV) (4/9): PHASE 3 EV-301 STUDY RESULTS - SAFETY

*Safety profile was consistent with prior EV studies*

TRAЕ	No. of patients (%)			
	EV (n=296)		Chemo (n=291)	
	Any grade	≥ Grade 3	Any grade	≥ Grade 3
Any grade in ≥ 20% of patients and ≥ Grade 3 in ≥ 5% of patients				
<b>Any adverse event</b>	<b>278 (93.9)</b>	<b>152 (51.4)</b>	<b>267 (91.8)</b>	<b>145 (49.8)</b>
Alopecia	134 (45.3)	0	106 (36.4)	0
Peripheral sensory neuropathy	100 (33.8)	9 (3.0)	62 (21.3)	6 (2.1)
Pruritus	95 (32.1)	4 (1.4)	13 (4.5)	0
Fatigue	92 (31.1)	19 (6.4)	66 (22.7)	13 (4.5)
Decreased appetite	91 (30.7)	9 (3.0)	68 (23.4)	5 (1.7)
Diarrhea	72 (24.3)	10 (3.4)	48 (16.5)	5 (1.7)
Dysgeusia	72 (24.3)	0	21 (7.2)	0
Nausea	67 (22.6)	3 (1.0)	63 (21.6)	4 (1.4)
Maculopapular rash	48 (16.2)	22 (7.4)	5 (1.7)	0
Anemia	34 (11.5)	8 (2.7)	59 (20.3)	22 (7.6)
Decreased neutrophil count	30 (10.1)	18 (6.1)	49 (16.8)	39 (13.4)
Neutropenia	20 (6.8)	14 (4.7)	24 (8.2)	18 (6.2)
Decrease white-cell count	16 (5.4)	4 (1.4)	31 (10.7)	20 (6.9)
Febrile neutropenia	2 (0.7)	2 (0.7)	16 (5.5)	16 (5.5)

- ≥ Grade 3 TRAEs were experienced by approx. 50% of patients in both arms
- Adverse events of special interest (e.g., skin reactions, peripheral neuropathy, and hyperglycemia) were generally mild/moderate in severity and consistent with those reported in prior studies

# ENFORTUMAB VEDOTIN (5/9): PHASE 2 EV-201 STUDY COHORT 2 RESULTS - EFFICACY (1)

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## ORR (Primary endpoint)

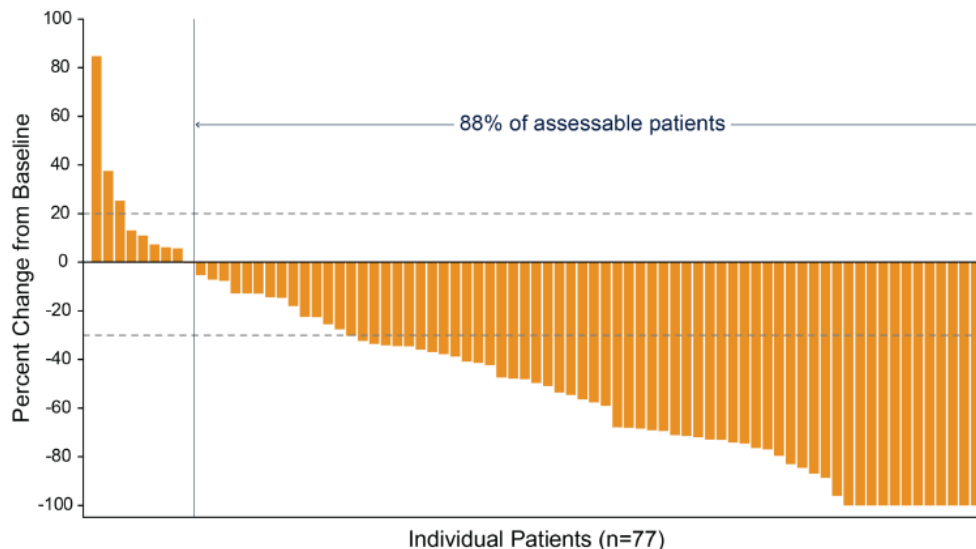
<b>ORR per RECIST v1.1 assessed by BICR</b>	<b>Patients (%) (n=89)</b>
<b>Confirmed ORR</b> 95% CI	<b>52</b> (40.8, 62.4)
<b>Best Overall Response per RECIST v1.1</b>	
Complete response	20
Partial response	31
Stable disease	30
Progressive disease	9
Not evaluable *	9

\* Includes five subjects who did not have response assessment post-baseline, two subjects whose post-baseline assessment did not meet the minimum interval requirement for stable disease, and one subject whose response cannot be assessed due to incomplete anatomy.

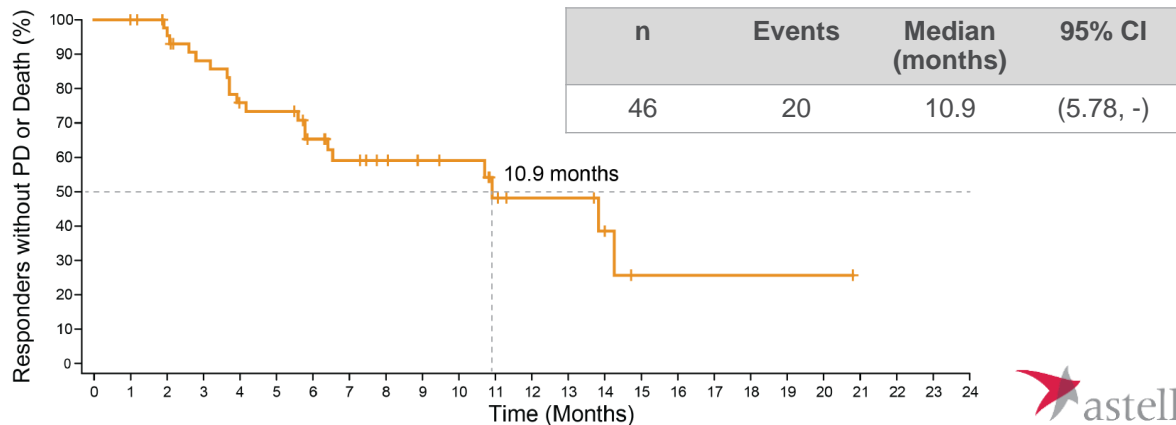
# ENFORTUMAB VEDOTIN (6/9): PHASE 2 EV-201 STUDY COHORT 2 RESULTS - EFFICACY (2)

## Change in tumor measurements per BICR

Data are not available for 12 subjects due to no response assessment post-baseline (n=5), incomplete assessment of target lesions post-baseline (n=1), or no measurable disease at baseline per BICR (n=6)



## DoR per BICR



# ENFORTUMAB VEDOTIN (EV) (7/9): PHASE 2 EV-201 STUDY COHORT 2 RESULTS - SAFETY

*Safety profile was consistent with prior EV studies*

TRAE Any grade in ≥ 20% of patients and ≥ Grade 3 in ≥ 5% of patients	No. of patients (%) (n=89)	
	Any grade	≥ Grade 3
<b>Overall TRAEs</b>	<b>86 (97)</b>	<b>49 (55)</b>
Alopecia	45 (51)	-
Peripheral sensory neuropathy	42 (47)	3 (3)
Fatigue	30 (34)	6 (7)
Decreased appetite	29 (33)	5 (6)
Pruritus	27 (30)	3 (3)
Rash maculo-papular	27 (30)	7 (8)
Dysgeusia	24 (27)	-
Weight decreased	23 (26)	1 (1)
Anemia	22 (25)	5 (6)
Diarrhea	20 (22)	5 (6)
Nausea	20 (22)	1 (1)
Neutropenia	11 (12)	8 (9)
Hyperglycemia	8 (9)	5 (6)
Lipase increased	7 (8)	5 (6)

- ≥ Grade 3 TRAEs of interest included skin reactions (17%), peripheral neuropathy (8%) and hyperglycemia (6%)
- Four deaths were reported as treatment-related by investigators in patients aged 75 years and older with multiple comorbidities

# ENFORTUMAB VEDOTIN (EV) (8/9): STUDY DATA BY DISEASE STAGE

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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.	<b>KN-B15 / EV-304</b>	<b>KN-905 / EV-303</b>	<b>EV-302</b>	<b>EV-103 Cohort K</b>	<b>EV-103 Cohort A &amp; Others</b>	<b>EV-201 Cohort 2</b>	<b>EV-201 Cohort 1</b>	<b>EV-301</b>
No. of subjects	734 (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 52% <b>(CR 20%)</b>	✓ ORR 44% (CR 12%)	✓ OS * HR 0.70
OS	(To be started soon)	(Ongoing)	(Ongoing)	(Ongoing)	(Not reached)	✓ <b>(14.7 mos)</b>	✓ (12.4 mos) **	✓ HR 0.70 * <b>(12.9 mos vs. 9 mos)</b>
PFS	(To be started soon)	(Ongoing)	(Ongoing)	(Ongoing)	(Not reached)	✓ <b>(5.8 mos)</b>	✓ (5.8 mos)	✓ HR 0.62 * <b>(5.6 mos vs. 3.7 mos)</b>
ORR	(To be started soon)	(Ongoing)	(Ongoing)	(Ongoing)	✓ 73% ** (CR 16%)	✓ 52% <b>(CR 20%)</b>	✓ 44% (CR 12%)	✓ 41% vs. 18% * <b>(CR 4.9% vs. 2.7%)</b>
DoR	(To be started soon)	(Ongoing)	(Ongoing)	(Ongoing)	(Not reached)	✓ 10.9 mos	✓ 7.6 mos	✓ <b>7.39 mos vs. 8.11 mos *</b>



✓: Data obtained, \*: Prespecified interim analysis, \*\*: Updated data, **Yellow**: Data recently disclosed



MIBC: Muscle-invasive bladder cancer, mUC: Metastatic urothelial 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 (9/9): NUMBER OF UC PATIENTS

Urothelial cancer (Annual)	All stages (Incidence)	MIBC	mUC		
		Post-cystectomy	Total (Incident + Newly recurrent)	Drug treated (1L)	Drug treated (2L+*)
US	<u>83,000</u>	20,000	<u>20,700</u>	<u>15,600</u>	<u>8,500</u>
EU5	<u>120,000</u>	32,000	<u>29,600</u>	<u>28,000</u>	<u>13,600</u>
JP	<u>46,000</u>	<u>11,500</u>	<u>10,500</u>	<u>7,500</u>	<u>3,800</u>
China ( <u>urban</u> )	<u>54,000</u>	<u>14,000</u>	<u>30,000</u>	<u>25,000</u>	<u>12,300</u>

*Number of drug-treated patients expected to rise after new drug launch*

# 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
  - ✓ ~70% of gastric tumors; ~30% of these meet the eligibility criteria for the ongoing Phase 3 studies
  - ✓ ~60% of primary pancreatic adenocarcinomas; approx. 20% of these meet the eligibility criteria for the ongoing Phase 2 study

## Gastric and gastroesophageal junction (GEJ) adenocarcinoma

- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin 18.2 expression
- Gastric cancer is the third leading cause of cancer death worldwide <sup>1</sup>
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20% <sup>2,3</sup>
- Median overall survival for Stage IV gastric cancer is 10-15 months <sup>4,5</sup>

Gastric and GEJ adenocarcinoma	P3: SPOTLIGHT	First line, combo with mFOLFOX6, vs. placebo	n=550	FSFT: Oct 2018
	P3: GLOW	First line, combo with CAPOX, 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	n=112	FSFT: Sep 2018
Pancreatic adenocarcinoma	P2	Combo with nab-paclitaxel and gemcitabine, vs. placebo	n=141	FSFT: May 2019



# FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

## VMS has a significant negative impact on quality of life

- Physical symptoms include hot flashes and sweating/night sweats, which can impact sleep.
- Physical symptoms lead to emotional impact including embarrassment, irritability, anxiety, and sadness
- Symptoms have a negative impact on multiple aspects of everyday life <sup>1</sup>

## Women’s Health Initiative (WHI) Study <sup>2</sup>

- Initial data analyses showed an association between chronic HRT use and increased risk of cardiovascular disease and cancer
- Since WHI’s findings, no replacement for HRT with similar efficacy and no significant safety concern, resulting in significant unmet medical needs

## US and EU

<b>P3: SKYLIGHT 1</b>	Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg vs. 45 mg vs. placebo (1:1:1)	n=527	<u>Primary endpoints met (12w DB period topline results)</u>
<b>P3: SKYLIGHT 2</b>	The last 40 weeks: Active extension treatment period, 30 mg or 45 mg	n=501	Primary endpoints met (12w DB period topline results)
<b>P3: SKYLIGHT 4</b>	VMS associated with menopause; 52 weeks: DB, 30 mg vs. 45 mg vs. placebo (1:1:1)	n=1,833	Enrollment completed

## Asia (except for Japan)

<b>P3: MOONLIGHT 1</b>	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=300	FSFT: Apr 2020
<b>P3: MOONLIGHT 3</b>	VMS associated with menopause; open label, 30 mg for 52 weeks	n=150	FSFT: Aug 2020

## JP: Independent development plan under preparation

Underlined: Updates since Q3/FY2020 financial results announcement in Jan 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, HRT: Hormone replacement therapy, DB: Double-blind, LSLV: Last subject last visit, FSFT: First subject first treatment

# 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
- > 80% require ventilator support
- Motor milestones substantially delayed
- No treatment available; supportive care only

**ASPIRO**  
**(clinical study for registration**  
**in XLMTM patients)**

n=26

Clinical hold lifted by FDA in Dec 2020.  
Clinical trial re-start activities underway  
Discussions planned on the path forward  
toward global registration filings

# PROGRESS IN FOCUS AREA APPROACH: MANUFACTURING CAPABILITY - CELL THERAPY & GENE THERAPY



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## Cell Therapy: Astellas Institute for Regenerative Medicine (AIMR)



April 2020 in operation

Westborough,  
Massachusetts, US

- A complex of research, CMC/manufacturing, and clinical development, optimized for the promotion of cell therapy
- CMC/GMP manufacturing occupy half of 24,000 m<sup>2</sup>
- 7 GMP clean rooms complied with US/EU/JP regulations. Expandable for future demands
- Independent air controlling system for clean rooms, enabling production of different cell types in parallel

### Cell Drug Substance Manufacturing

- 10 years' experiences of PSC-derived cell therapy and GMP manufacturing cultivated as a pioneer
- Accumulated regulatory know-how accumulated through interactions with regulatory authorities
- Now promoting GMP manufacturing with protocols optimized for each cell type

### Cell Drug Product Manufacturing

- Experience in supplying CTM to US and UK
- Plans to expand our capabilities as a center of future supply chain (DP shipping)

## Gene Therapy: Astellas Gene Therapies (Audentes Therapeutics)



South San Francisco,  
California, US

- Internal AAV manufacturing capability provides self sufficiency from research to commercial
- Capabilities to expand to support future AAV manufacturing and supply chain needs

### AAV Drug Substance Manufacturing

- Suspension bioreactor systems at 1,000L (2x500L) scale
- AAV production supports clinical-stage GMP material with preparations in place for AT132 commercial launch

### AAV Drug Product (DP) Manufacturing

- All AAV DP batches filled in-house (no CMO reliance)
- Capacity to support all CoE programs in the future

This fully approved capital project is currently under construction in Sanford, North Carolina.

Scheduled to be operational and GMP ready by mid 2022. First phase provides 4,000L of bioreactor capacity

# ON THE FOREFRONT OF HEALTHCARE CHANGE

