

FY2019 FINANCIAL RESULTS ENDED MARCH 31, 2020

*- Presentation for FY2019 Financial Results
Scheduled on May 18, 2020 -*



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May 14, 2020

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.

Continuation of business and maintaining a stable supply of products

- In order to continue our social mission of ensuring a stable supply of drugs, quality control, managing safety, and providing information, our essential business continues to be carried out under the strict measures taken to prevent infections
- Except for some employees under specific instruction from the company, prohibiting employees to work in offices and instead work from home
- Basically refraining from sales activities, we continue to gather and provide necessary product information to medical institutions in accordance with the rules of each institution
- As for the supply of products, there are currently no problems as we manage risks by closely cooperating with outsourced manufacturers and suppliers of raw materials

For ensuring patient safety and alleviating strain on healthcare resources

- In countries and regions with continuing spread of COVID-19, we are suspending start-up activities at study sites for new interventional clinical studies. We are also suspending enrollment of new patients in ongoing studies
- We will frequently reassess this approach, which applies to all interventional clinical trials led by us

Contribution with in-line products and compounds in R&D stage

- Continue to take appropriate action in response to requests by the government such as providing drugs
- Provide compounds in response to a request from the Ministry of Health, Labour and Welfare and National Institute of Infectious Diseases to cooperate in the “Basic Screening Plan for Drugs for Coronavirus Disease”
- Respond to requests from the European Federation of Pharmaceutical Industries Associations (EFPIA) and the Innovative Medicines Initiative (IMI) to cooperate in “Activities Aimed at Developing Drugs for the Novel Virus”

Relief activities

- Donations in regions where infection is spreading such as China, the United States, Italy, and Spain
- Authorize paid leave for employees who are medically qualified and wish to contribute in volunteer activities

AGENDA

I

FY2019 Consolidated Financial Results
FY2020 Forecasts

II

Initiatives for Sustainable Growth

III

Capital Allocation

FY2019 FINANCIAL RESULTS

(billion yen)	FY18	FY19	Change (amount)	Change (%)	CER growth
Revenue	1,306.3	1,300.8	-5.5	-0.4%	+2.4%
Cost of sales	292.0	276.7	-15.3	-5.2%	
% of revenue	22.4%	21.3%			
SG&A expenses	490.3	499.3	+9.0	+1.8%	
R&D expenses	208.7	224.2	+15.5	+7.4%	
Amortisation of intangible assets	35.2	21.2	-14.0	-39.9%	
Core operating profit	278.5	277.8	-0.8	-0.3%	+4.3%
<Full basis>					
Other income	14.2	12.2	-2.0	-14.1%	
Other expense	48.8	45.9	-2.8	-5.8%	
Operating profit	243.9	244.0	+0.1	+0.0%	
Profit before tax	249.0	245.4	-3.6	-1.5%	
Profit	222.3	195.4	-26.9	-12.1%	

FY2019 FINANCIAL RESULTS: YEAR-ON-YEAR COMPARISON

- Revenue and Core OP were the same level as previous fiscal year, while both increased when excluding FX impacts
 - ✓ Sales increases for XTANDI and mirabegron, as well as new products XOSPATA and EVENITY, offset most of the sales decreases in Vesicare, Tarceva, Symbicort and KM bio products
 - ✓ SG&A and R&D expenses increased (Audentes' R&D expenses were one such increase factor), while amortisation of intangible assets decreased
- Full basis: OP was the same level as previous fiscal year and profit decreased
 - ✓ Booked Other expense in Q4:
liquidating unvested stock options, etc. of Audentes
Impairment losses of intangible asset due to renegotiation of contracts with Cytokinetics
 - ✓ Tax expense increased due to one-off lower tax rate in previous fiscal year

FY2019 FINANCIAL RESULTS: COMPARISON WITH FORECAST

(billion yen)	FY19 initial forecast*	FY19 revised forecast**	FY19 Actual
Revenue	1,224.0	1,256.0	1,300.8
Core operating profit	240.0	264.0	277.8
Core profit	194.0	214.0	223.2

<Full basis>

Operating profit	229.0	263.0	244.0
Profit	182.0	210.0	195.4

Main variance in revenue between actual and initial forecast

- Exceeded expectations due to focused resource allocation to growth drivers
- Earlier capture of growth planned for next fiscal year and beyond
 - ✓ XTANDI: Market penetration faster than expected in earlier stages of prostate cancer
 - ✓ EVENITY: Initial uptake following launch stronger than expected
- Unexpected one-off factors:
 - ✓ Transfer of products to Daiichi Sankyo
 - ✓ US Prograf: Increase in demand due to shortage of generic tacrolimus
 - ✓ Inventory build due to COVID-19
- Impact of generics lower than expected

FY2019 FINANCIAL RESULTS: SALES OF MAIN PRODUCTS

FY2019 sales

XTANDI

400.0 billion yen +66.9 (+20%)

XTANDI sales reached 400.0 billion yen
Significant growth higher than FY19 forecast

XOSPATA

14.3 billion yen +11.7 (+468%)

Contribute throughout the year
Launched in Europe in November following
Japan and US

PADCEV

1.8 billion yen +1.8

Launched in US in December
Positive initial uptake thus far

mirabegron

161.6 billion yen +14.4 (+10%)

Continued sales growth globally

New products in Japan

61.2 billion yen +35.0 (+134%)

Steady growth driven by
EVENTITY (+23.0) and Suglat-Family (+6.1)

ACCOUNTING TREATMENT OF BUSINESS COMBINATION WITH AUDENTES

Booked intangible assets of \$2,620 million and goodwill of \$391 million

<Balance sheet as of Jan 15, 2020* >

(\$ million)

<ul style="list-style-type: none"> • In-Process R&D: \$1,851M → To be amortised after launches • Patent and technology: \$769M → Amortisation started in FY2019 	Other assets 389	Other liabilities 116
	Intangible assets 2,620	Deferred tax liabilities 382
	Goodwill 391	Acquisition cost 2,902

Technology:
Platform and manufacturing technology

Amortisation of intangible assets for patent and technology:

FY19 ACT (Approx. 3 months) \$11M FY20 FCST (12 months) \$51M



* Subject to change due to the provisional accounting treatment at this moment

FY2020 FORECAST

(billion yen)	FY19 actual	FY20 forecast	Change (%)
Revenue	1,300.8	1,282.0	-1.4%
R&D expenses	224.2	239.0	+6.6%
Core operating profit	277.8	257.0	-7.5%
Core profit	223.2	206.0	-7.7%
<Full basis>			
Operating profit	244.0	252.0	+3.3%
Profit	195.4	202.0	+3.4%

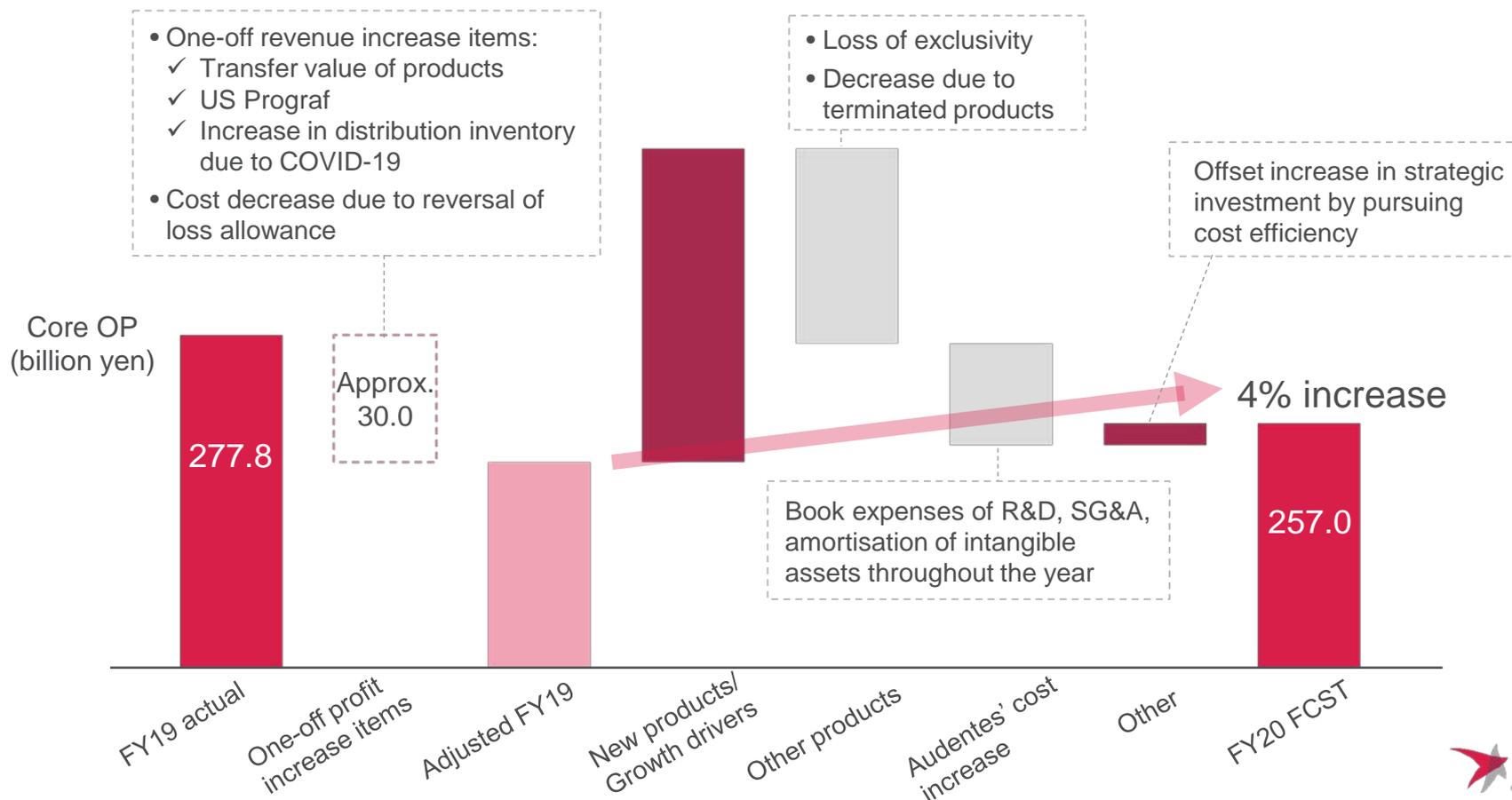
The impact of COVID-19 is not incorporated into FY2020 forecast

FY2020 FORECAST: OVERVIEW

- Expect to achieve target for final fiscal year of Strategic Plan 2018
- Main products continue to grow and new products will contribute throughout the year to secure revenues of the same level as FY2019, offsetting most of the impact of the LOE, termination of sales and distribution and NHI price revision in Japan
 - ✓ Increase factors: XTANDI, XOSPATA, PADCEV, mirabegron, Evrenzo, new products in Japan
 - ✓ Decrease factors: Vesicare EU, Celecox, MYCAMINE/Funguard, termination of sale and distribution (Symbicort, KM bio products, Micardis), NHI price revision in Japan*
- Resource allocation to key strategic areas such as R&D investment including Audentes and launch costs for new products, while reviewing costs not contributing to competitiveness. Aim to improve profit (over 30.0 billion yen) by promoting global procurement efficiencies and travel cost reduction, etc.
- As a result, Core OP margin for FY2020 to be 20%
Both revenue and OP expected to increase from FY2019 excluding one-off factors

FY2020 FORECAST: CORE OPERATING PROFIT

Core OP to grow excluding one-off items in FY2019 by growth of major products and pursuing cost efficiency to offset sales decrease in other products and increases in strategic investment



Impact in FY2019 financial results

- Impact of COVID-19 on FY2019 financial result was immaterial despite sales increase due to inventory build as well as cost decrease due to lower sales promotion activities, etc.

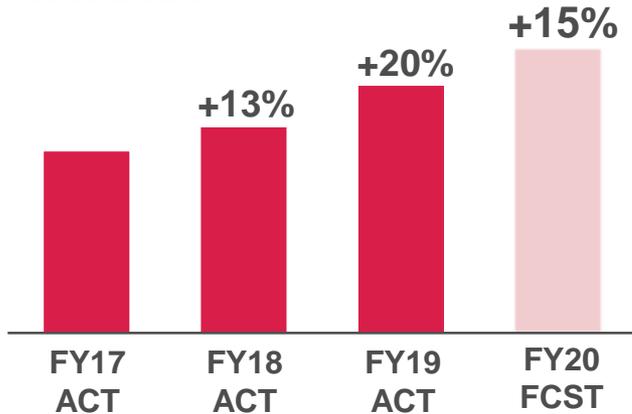
Assumption of FY2020 forecast

- The impact of COVID-19 is not incorporated into FY2020 forecast as it is difficult to assess properly at the moment
 - ✓ Market penetration of new products, regulatory timeline, R&D timeline and cost necessary for crisis management, etc.
- The FY2020 forecast will be reviewed at the time of Q1/FY2020 financial results announcement

MAIN GROWTH DRIVERS: XTANDI, MIRABEGRON

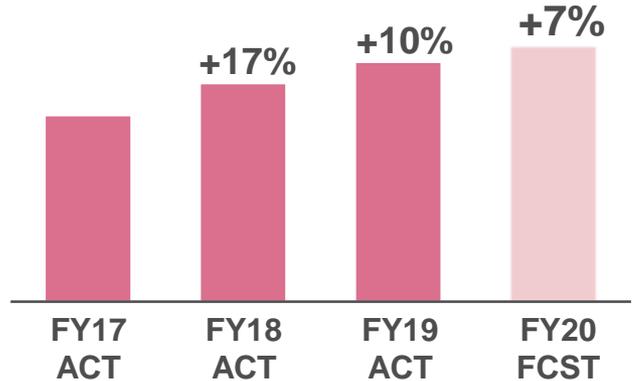
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XTANDI



- FY2017-FY2020 CAGR forecast: +16%
 - ✓ Sales growth exceeded expectations due to penetration in earlier stages of prostate cancer
- FY2020 initiatives
 - ✓ Enhance market access and conduct further engagement with urologists for M0 CRPC and M1 CSPC indications
 - ✓ Launched in Mar 2020 in China. Established the Oncology Business Unit to strengthen commercial functions
- FY2020 forecasts: 459.3 billion yen (YoY +59.3 bil. yen)

mirabegron



- FY2017-FY2020 CAGR forecast: +11%
 - ✓ Growth globally higher than expected through expansion of share in each market
- FY2020 initiatives
 - ✓ Continue to expand OAB market through ongoing disease awareness activities
 - ✓ Solidify the position of first therapy of choice through further penetration with mechanism of action and product features
- FY2020 forecasts: 172.5 billion yen (YoY +10.9 bil. yen)



mirabegron (Betanis/Myrbetriq/BETMIGA)

M1: Metastatic, M0: Non-metastatic, CRPC: Castration-resistant prostate cancer, CSPC: Castration-sensitive prostate cancer, OAB: Overactive bladder

LAUNCH OF 6 POST-POC PROJECTS

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XOSPATA

Available in Japan, US,
Established Markets



- In addition to Japan and US, expect sales contribution from Europe following launches
- Approved in South Korea and Australia. Filed in Mar 2020 in China
- Promote XOSPATA to hematologists/oncologists using Phase 3 ADMIRAL study results published in the New England Journal of Medicine and supported by NCCN guidelines Category 1 recommendation
- FY2020 forecasts: 23.2 billion yen (YoY +8.9 bil. yen)

PADCEV

Available in US



- Approved in US under the Accelerated Approval Program Launched in Dec 2019
- PADCEV is directed against Nectin-4, highly expressed in bladder cancer; no biomarker required for use
- NCCN guidelines updated to add PADCEV following FDA approval
- Ongoing efforts focused on solidifying PADCEV's position as the preferred post-platinum and post PD-1/L1 treatment option

Evrenzo

Available in Japan

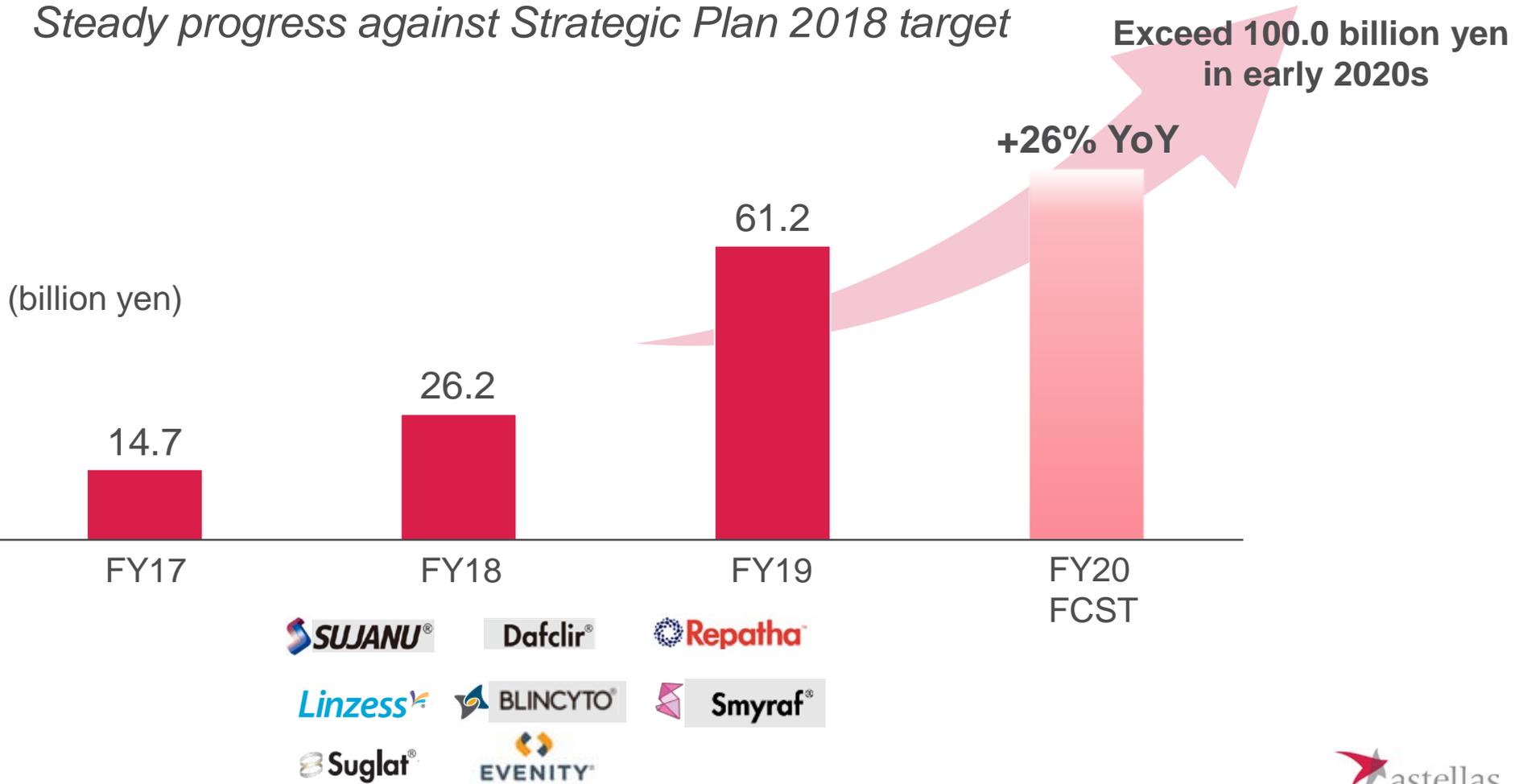


- First-in-class orally administered HIF-PH inhibitor for renal anemia in patients on dialysis. Launched in Nov 2019 in Japan
- Filed for non-dialysis in Jan 2020 in Japan
- Promote market penetration by differentiation through the dissemination of new mechanism of action



NEW LOCAL PRODUCTS IN JAPAN

Sales increased due to launch of new products and additional indications
Steady progress against Strategic Plan 2018 target



PROGRESS TOWARDS THE STRATEGIC PLAN 2018 GUIDANCE

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Achieve Strategic Plan 2018 target including strategic investments for sustainable growth

(billion yen)

Indicators	FY17 ACT	FY18 ACT	FY19 ACT	FY20 FCST	FY20 Guidance (Announced in May 2018)
Revenue	1,300.3	1,306.3	1,300.8	1,282.0	○ FY2017 level
R&D investment	220.8	208.7	224.2	239.0	○ More than 200.0 billion yen
Core OP	268.7 20.7%	278.5 21.3%	277.8 21.4%	257.0 20.0%	○ Core OP margin 20%
Core EPS	100.64 yen	129.07 yen	118.95 yen	110.90 yen	○ Exceed FY2017

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ENHANCEMENT OF INITIATIVES IN CHINA

*Enhancement of development and regulatory functions for late-stage projects
Accelerate development and launch of medicines in China as top-tier market*

Compound	Indication	Current Status
enzalutamide	M1 CRPC	Approved in Nov 2019 and launched in Mar 2020
	M0 CRPC	Filed in Oct 2019
	M1 CSPC	China Phase 3 study ongoing
gilteritinib	R/R AML	Filed in Mar 2020
enfortumab vedotin	mUC	Development plan in China under discussion
zolbetuximab	Gastric and GEJ adenocarcinoma	FSFT in China in Dec 2019 in global Phase 3 studies
fezolinetant	MR-VMS	IND active, to join Asian Phase 3 study
peficitinib	RA	Asian P3 study ongoing

6 POST-POC PROJECTS: PROGRESS IN FY2019

Achieved many important milestones

Project	Indication	Phase					* Milestone achieved in FY2019
		1	2	3	F	A	
enzalutamide	M1 castration-resistant prostate cancer				*	*	Approved in China
	M0 castration-resistant prostate cancer				*	*	Filed in China
	M1 castration-sensitive prostate cancer				*	*	Filed in US,EU,JP, and approved in US
	M0 castration-sensitive prostate cancer						
gilteritinib	Relapsed or refractory AML				*	*	Approved in EU and filed in China
	Newly diagnosed AML, intensive chemo eligible						
	Newly diagnosed AML, intensive chemo ineligible						
	AML, post-HSCT maintenance						
	AML, post-chemo maintenance						
enfortumab vedotin	mUC, platinum and PD-1/L1 inhibitor pretreated				*	*	Filed and approved in US (under AA)
	mUC, previously untreated (first line; combo w/ Pembro)				*		Entered into Phase 3
	mUC, PD-1/L1 inhibitor pretreated						
	Other solid tumors				*		Entered into Phase 2
zolbetuximab	Gastric and gastroesophageal junction adenocarcinoma						
	Pancreatic adenocarcinoma						
roxadustat	Japan, anemia associated with CKD, on dialysis				*	*	Approved
	Japan, anemia associated with CKD, not on dialysis				*		Filed
	EU, anemia associated with CKD						
	Chemotherapy-induced anemia				*		Entered into Phase 2
fezolinetant	Menopause-related vasomotor symptoms				*		Entered into Phase 3

PoC: Proof of concept; F: Filed; A: Approved; M1: Metastatic; M0: Non-metastatic; AML: Acute myeloid leukemia; HSCT: Hematopoietic stem cell transplant; mUC: Metastatic urothelial cancer; Pembro: pembrolizumab; AA: Accelerated Approval program; CKD: Chronic kidney disease

KEY POST-POC PROJECTS: STATUS UPDATE

(Underlined: Updates since Q3/FY2019 announcement in Jan 2020)

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enzalutamide

M0 CRPC

- Positive OS data of Phase 3 study obtained

M1 CSPC

- Filed in EU and JP in Jul 2019

M0 CSPC

- Phase 3 study ongoing

China

- **M0 CRPC**: Filed in Oct 2019
- **M1 CSPC**: Phase 3 study ongoing

zolbetuximab

Gastric and gastroesophageal junction adenocarcinoma

- Phase 3 studies ongoing

Pancreatic adenocarcinoma

- Phase 2 study ongoing

gilteritinib

Relapsed or refractory acute myeloid leukemia

- China: Filed in Mar 2020

Earlier-stage acute myeloid leukemia

- Phase 3 studies ongoing

enfortumab vedotin

Metastatic urothelial cancer

- Previously untreated (first line; combo with pembrolizumab): Breakthrough Therapy Designation granted by FDA in Feb 2020. FSFT in Phase 3 study achieved in Apr 2020
- **Second or later lines**: Phase 2 and Phase 3 studies ongoing

Other solid tumors

- FSFT in Phase 2 study achieved in Mar 2020

roxadustat

Anemia associated with CKD

- **EU**: MAA targeting 1Q FY2020
- **JP**: Filed for non-dialysis in Jan 2020

Chemotherapy-induced anemia

- Phase 2 study ongoing

fezolinetant

Menopause-related vasomotor symptoms

- **US & EU**: Phase 3 studies ongoing
- **JP**: Independent development plan under preparation
- **Asia**: FSFT in Asian Phase 3 study achieved in Apr 2020

AT132 (resamirigene bilparvovec) XLMTM Genetic Regulation

- Pivotal expansion cohort in the clinical registration study ongoing

PROGRESS IN FOCUS AREA APPROACH (1/3): MAJOR EVENTS IN FY2019



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Biology	Project-based	Business development-related
Immuno-oncology	<ul style="list-style-type: none"> Phase 1 entry: ASP9801 (oncolytic virus), ASP7517 (aAVC) 	<ul style="list-style-type: none"> License agreement with RIKEN for aAVC programs Acquisition of Xyphos Biosciences to add CAR-cell therapy-related capabilities Collaboration agreement with Adaptimmune Therapeutics for stem cell derived allogenic CAR-T and TCR T-cell therapies Collaboration agreement with CytomX Therapeutics for Probody[®] T-cell engaging bispecific therapies
Regeneration	<ul style="list-style-type: none"> Phase 1 entry: ASP0598 (rhHB-EGF for CTMP) 	<ul style="list-style-type: none"> License agreement with Frequency Therapeutics for FX-322 for sensorineural hearing loss
ASIM	<ul style="list-style-type: none"> Phase 1 entry: ASP2390 (LAMP-vax vaccine for HDM-induced allergic rhinitis) 	<ul style="list-style-type: none"> Collaboration agreement with Pandion Therapeutics for pancreas-targeted immunomodulators
Mitochondria	<ul style="list-style-type: none"> Fast Track designation: ASP1128 (PPARδ modulator for AKI) 	<ul style="list-style-type: none"> Acquisition of Nanna Therapeutics to add unique screening platform to strengthen mitochondria-related research *
Genetic Regulation	<ul style="list-style-type: none"> Phase 1 entry: AT845 (AAV8-GAA for Pompe disease) 	<ul style="list-style-type: none"> Acquisition of Audentes Therapeutics to add gene therapy-related capabilities

* Event in FY2020



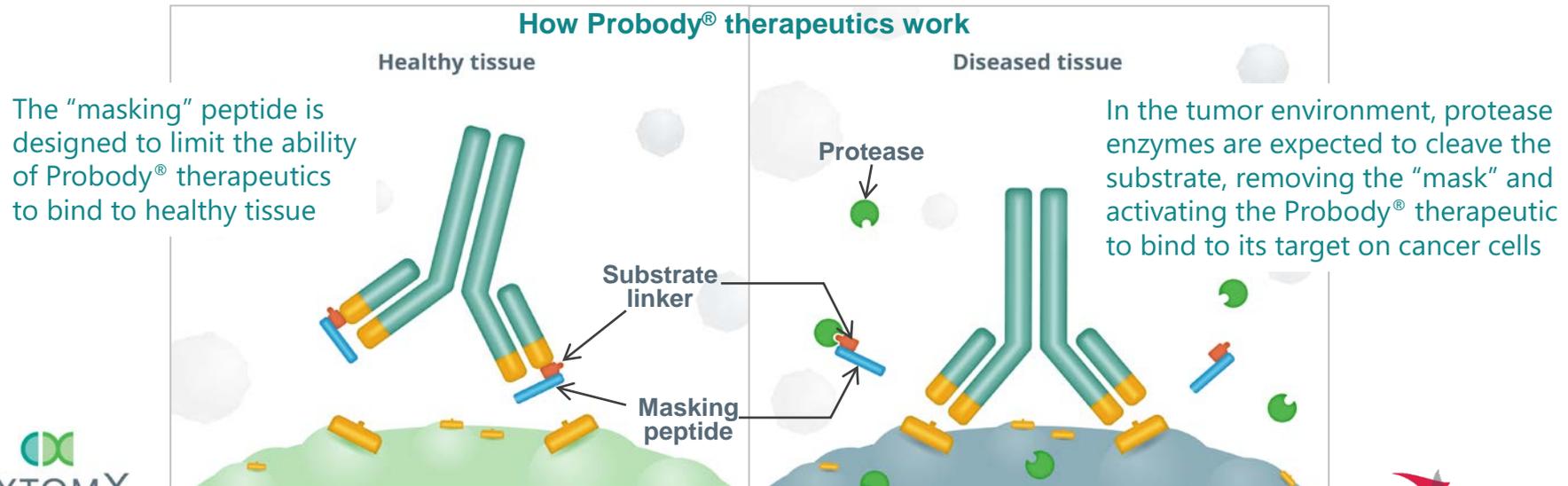
PROGRESS IN FOCUS AREA APPROACH (2/3): NEW MODALITY FOR IMMUNO-ONCOLOGY



Further strengthened immuno-oncology platform through collaboration with CytomX Therapeutics for Probody[®] T-cell engaging bispecific therapies

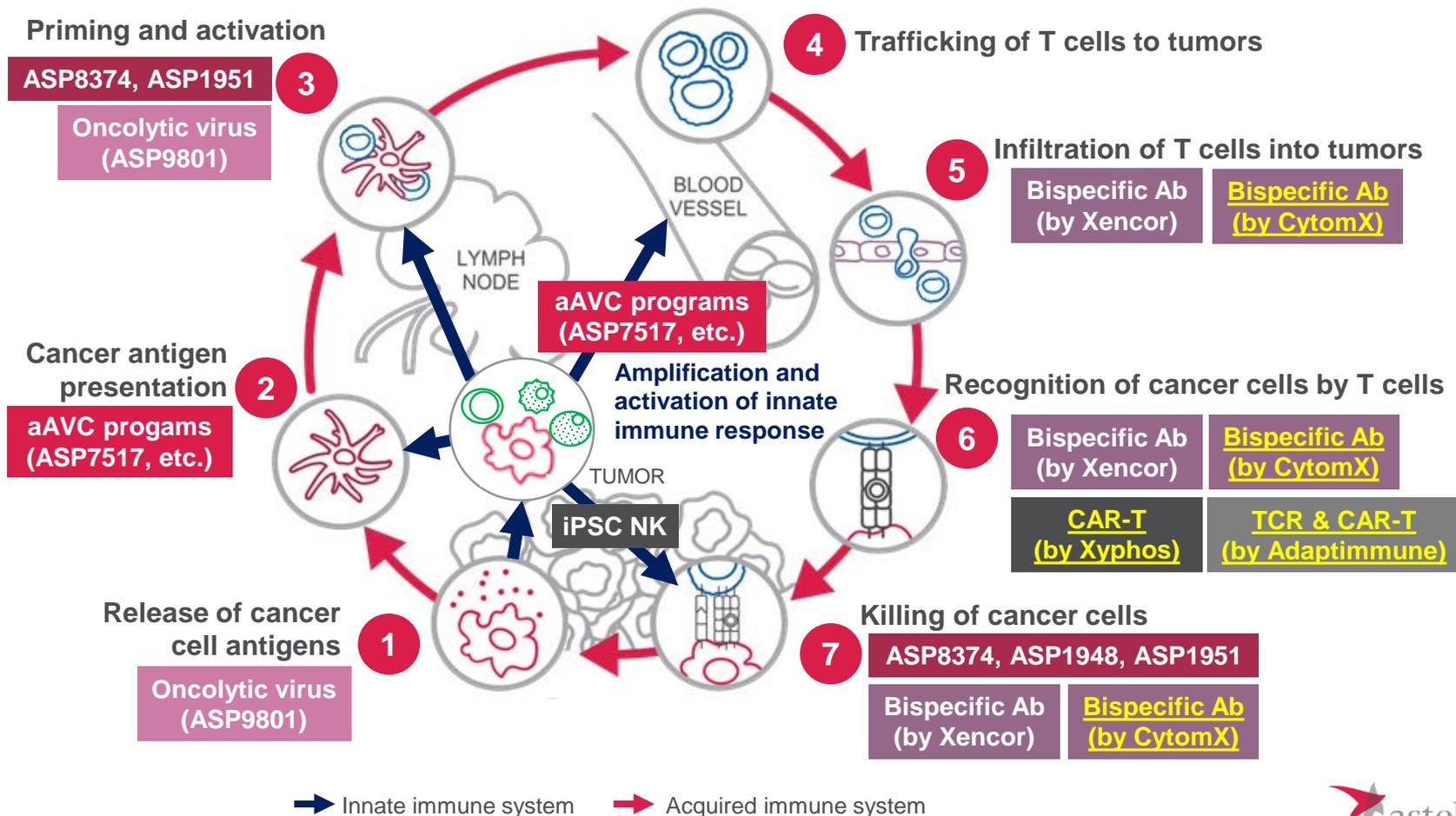
CytomX's Probody[®] platform

- Probody[®] masked antibodies remain inactive until they are activated by proteases in the tumor microenvironment
- Selectively binds to tumor cells and decreases binding to healthy tissue, potentially resulting in safer and more effective therapies



PROGRESS IN FOCUS AREA APPROACH (3/3): ASTELLAS ASSETS IN CANCER IMMUNITY CYCLE

Astellas' pre-clinical and clinical research spans full cancer immunity cycle



COVID-19 IMPACT ON CLINICAL DEVELOPMENT

- Changes implementing to our clinical trial operations, to ensure patient safety and alleviate strain on healthcare resources during the COVID-19 pandemic:
 - ✓ In countries and regions with continuing spread of COVID-19, we are suspending start-up activities involving study sites for new interventional clinical studies and enrollment of new patients in ongoing studies
 - ✓ In countries and regions no longer experiencing rapid COVID-19 case growth, we are resuming or continuing study activities
 - ✓ We are assessing protocols and implementing measures to reduce the burden to healthcare systems while ensuring that patient safety can be maintained
 - ✓ We will frequently reassess this approach, which applies to all interventional clinical trials led by Astellas, while monitoring the COVID-19 pandemic and its impact, locally, regionally and globally
- Impact on specific trials and major project milestones, including regulatory milestones and clinical study data readouts:
 - ✓ It is difficult to evaluate the impact for now, because the pandemic is still going on and evolving daily
 - ✓ We will provide updates at any other opportunities such as earnings and ClinicalTrials.gov as needed in a timely manner

PROGRESS IN Rx+™ PROGRAM (1/2): FY2019 PROGRESS

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Steadily progress to establish a solid ground for business acceleration

- Formulation of Rx+ Story™ (Strategic direction of Rx+™)
- Each program is steadily progressing toward commercialization



New digital healthcare solutions using gamification:

- Launched “Health Mock Lab.”, a virtual framework for industry-academia collaboration

Smartphone exercise support application:

- Entered into Agreement with BANDAI NAMCO Entertainment to Co-Develop and Co-Commercialize Smartphone Exercise Support Application

Digital therapeutics for mobile devices:

- Entered into a strategic alliance with Welldoc, Inc.



Image-guided precision surgery:

- End of Phase I study for ASP5354

Ultra-small implantable medical devices:

- Joint research and development agreement with Iota Biosciences Inc.



PROGRESS IN Rx+™ PROGRAM (2/2): SMARTPHONE EXERCISE SUPPORT APPLICATION

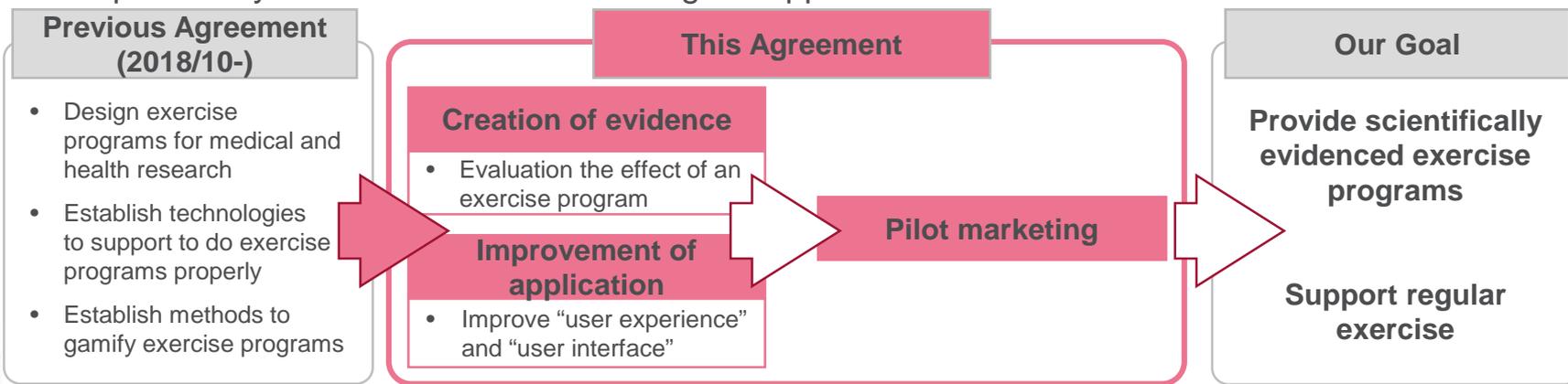


Moved to the next step toward commercialization

- Enter into Agreement with BANDAI NAMCO Entertainment to Co-Develop and Co-Commercialize Smartphone Exercise Support Application
 - ✓ Implementation of medical and health research
 - Conduct a medical and health research using the application

This medical and health research will evaluate the effect of an exercise program that combines aerobic and resistance exercises provided by the application on an individual's body by assessing indicators such as changes in visceral fat area
 - ✓ Co-development of application for pilot marketing
 - Improve “user experience” and “user interface”

The application used for the medical and health research is to be improved so that users will personally take interest and start using the application and continue the exercises



CLIMATE CHANGE MITIGATION MEASURES

Three Astellas' research and production facilities* in Japan started purchasing electricity generated by renewable energy sources, to reduce the volume of GHG emission



Our target

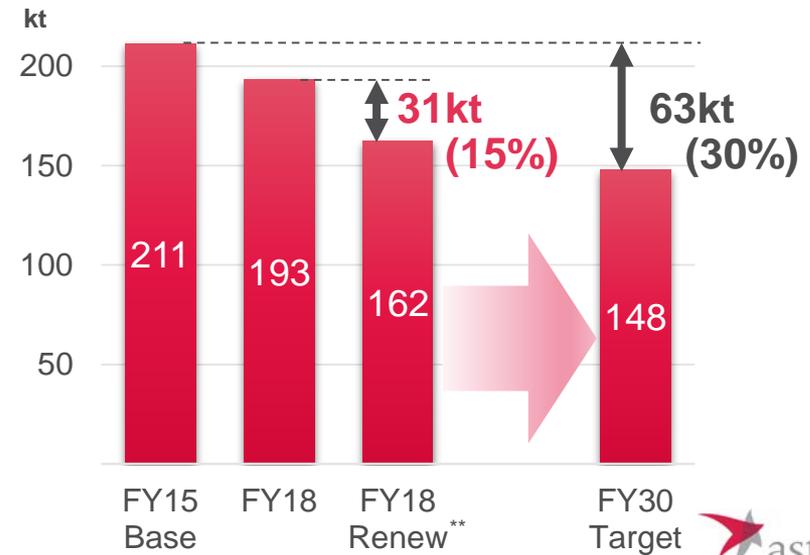
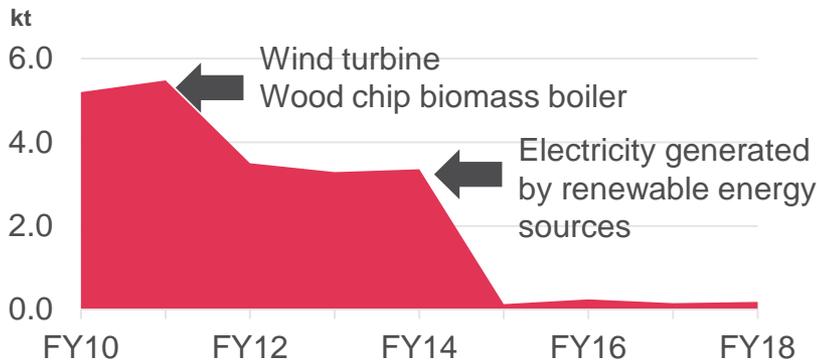
- **Astellas' Environmental Action Plan**
<Approved by SBTi in 2018>:
Reduce our total GHG emissions by 30% from the base year FY2015 levels by FY2030

Effects of this initiative on GHG emission

- Expect to reduce approx. 31 kt of GHG emission
- Greatly contribute to meeting the GHG emission reduction target for FY2030
✓ Reduce by approx. 15% from FY2015 base

Initiatives so far

- Kerry Plant (Ireland):
ZERO GHG emission is almost realized



* Astellas' Tsukuba Research Center, Tsukuba Biotechnology Research Center, and Takahagi Chemistry & Technology Development Center,
 ** Calculated by taking 31 kt of GHG emission, which was reduced by this initiative, from our GHG emission in FY2018
 GHG: Greenhouse gas, SBTi: Science Based Targets initiative



AGENDA

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CAPITAL ALLOCATION

Top priority is investment for strategic business growth

Dividends to be increased continuously based on mid-and long-term growth

Share buybacks to be implemented in a flexible manner



Business investment

Acquisition



Alliance



Shareholder return

Aiming for steady dividend increase during FY2018-FY2020

Flexible share buybacks

Dividends per share for FY2020: forecasted 2 yen increase to 42 yen

APPENDIX

The image features a central, high-speed photograph of a clear water droplet falling into a pool of water, creating concentric ripples. The background is a composition of geometric shapes: a white upper-left area, a grey lower-left area, and a large red area on the right side that tapers towards the top right corner.

FY2019 FINANCIAL RESULTS: COST ITEMS

Core basis: Year-on-Year comparison

Cost of sales % of revenue

1.1ppt decrease



- ✓ Decrease due to changes in product mix, etc. (-0.8ppt)
- ✓ FX impact on elimination of unrealized gain (-0.3ppt)

SG&A expenses

1.8% increase



- ✓ Pursue cost efficiency by resource allocation to investment in new products/growth drivers while reviewing other costs
- ✓ XTANDI US co-promotion fee increased significantly due to sales expansion
- ✓ Decrease due to one-off reversal of loss allowance (Q2: 8.2 bil. yen)

R&D expenses

7.4% increase



- ✓ Investment increased in key late-stage projects such as fezolinetant, gilteritinib and zolbetuximab, and Primary Focus including Audentes' R&D expenses

Amortisation of intangible assets

39.9% decrease



- ✓ Completion of amortisation of US Tarceva intangible asset

Direction of arrow: impact on profit

Full basis: main other expense

- ✓ liquidating unvested stock options, etc. of Audentes (Q4: 7.7 bil. yen)
- ✓ Impairment losses of intangible asset due to renegotiation of contracts with Cytokinetics (Q4: 10.9 bil. yen)

FY2019: REVENUE BY REGION

34

(billion yen)	FY18	FY19	Change
Japan	369.5	345.4	-6.5%
United States	421.6	443.5	+5.2%
Established Markets	300.0	296.1	-1.3%
Greater China	62.4	60.4	-3.3%
International	122.7	134.8	+9.9%

Established Markets: Europe, Canada, Australia

Greater China: China, Hong Kong, Taiwan

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

FY2019: SALES OF MAIN PRODUCTS

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(billion yen)	FY18	FY19	Change	CER growth	FY19 forecast	Achievement
XTANDI	333.1	400.0	+20.1%	+24.1%	383.9	104.2%
XOSPATA	2.5	14.3	+467.6%	+478.2%	13.9	102.7%
OAB products	242.2	206.3	-14.8%	-12.6%	201.0	102.6%
mirabegron	147.2	161.6	+9.8%	+12.5%	158.8	101.8%
Vesicare	95.0	44.7	-52.9%	-51.6%	42.2	105.9%
Prograf	195.7	192.9	-1.4%	+2.6%	190.3	101.4%



OAB products: Vesicare + mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
 Prograf: Incl. Advagraf/Gracaptor/ASTAGRAF XL

FY2019 ACTUAL: FX RATE

Average rate for the period

Currency	FY18	FY19	change
USD	111 yen	109 yen	-2 yen
EUR	128 yen	121 yen	-8 yen

Change in closing rate from PY end

Currency	FY18	FY19
USD	+5 yen	-2 yen
EUR	-6 yen	-5 yen

<Impact of exchange rate on financial results>

- 36.7 billion yen decrease in revenue, 12.6 billion yen decrease in core OP
- FX impact on elimination of unrealized gain: COGs ratio -0.3ppt

FY2020 FCST: FX RATE & FX SENSITIVITY

Average rate for the period

Currency	FY19	FY20 FCST	change
USD	109 yen	110 yen	+1 yen
EUR	121 yen	120 yen	-1 yen

Change in closing rate from PY end

Currency	FY19	FY20 FCST
USD	-2 yen	+1 yen
EUR	-5 yen	+0 yen

Estimated Fx sensitivity of FY2020 forecast by 1 yen appreciation

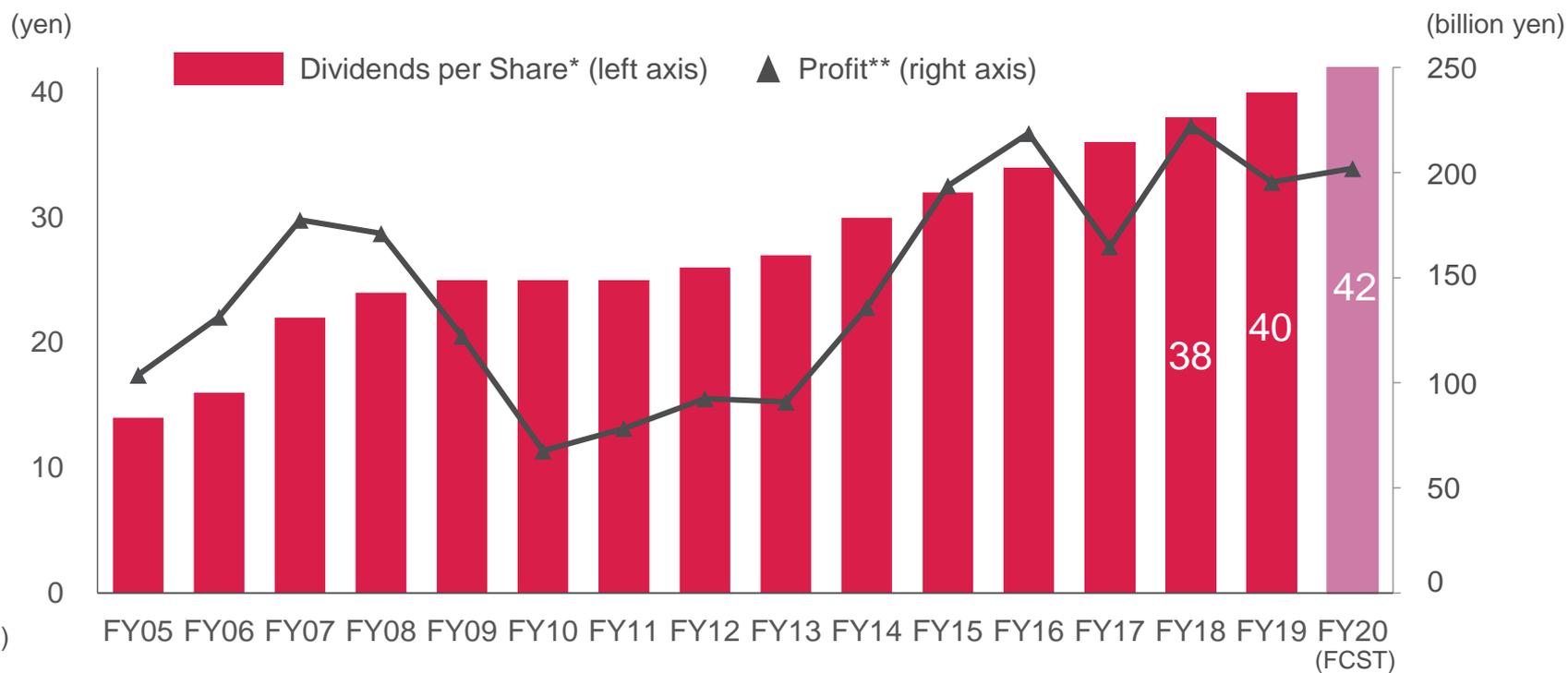
Currency	Average rate 1 yen higher than assumption		Year-end rate 1 yen higher than assumption
	Revenue	Core OP	Core OP
USD	Approx. -5.8 bil yen	Approx. -1.2 bil yen	Approx. +0.6 bil yen
EUR	Approx. -2.8 bil yen	Approx. -1.2 bil yen	Approx. +0.2 bil yen

BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY18 end	FY19 end
Total assets	1,897.6	2,318.2
Cash and cash equivalents	311.1	318.4
Total equity attributable to owners of the parent	1,258.4	1,289.2
Equity ratio (%)	66.3%	55.6%

(billion yen)	FY18	FY19
Cash flows from operating activities	258.6	222.0
Cash flows from investing activities	-41.8	-389.8
Free cash flows	216.9	-167.8
Cash flows from financing activities	-233.7	181.1
Bonds and loans	-	326.0
Acquisition of treasury shares	-160.4	-52.9
Dividends paid	-72.1	-73.5

DETAILS OF SHAREHOLDER RETURNS



	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20 (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	78.0
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	



* 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)

FILING OPPORTUNITIES ANNOUNCED IN STRATEGIC PLAN

As of May 2020

- ✓ ✓ ✓ : Approved
- ✓ ✓ : Filed
- ✓ : Data obtained,
filing under preparation

FY2018	FY2019-2020	FY2021 or beyond
enzalutamide M0 CRPC ✓ ✓ ✓	enzalutamide M1 CSPC (US) ✓ ✓ ✓ (EU,JP) ✓ ✓	enzalutamide M0 CSPC
gilteritinib R/R AML ✓ ✓ ✓	enfortumab vedotin Metastatic urothelial cancer, Platinum and PD-1/L1 inhibitor pretreated (US) ✓ ✓ ✓	zolbetuximab Gastric and gastroesophageal junction adenocarcinoma
roxadustat Anemia associated with CKD Dialysis (JP) ✓ ✓ ✓	roxadustat Anemia associated with CKD Non-dialysis (JP) ✓ ✓	gilteritinib AML (Post-HSCT maintenance)
	roxadustat Anemia associated with CKD Dialysis/Non-dialysis (EU) ✓	gilteritinib AML (Post-chemo maintenance)
		gilteritinib AML (1st line low intensity induction chemo)
		gilteritinib AML (1st line high intensity induction chemo)
		fezolinetant MR-VMS

Therapeutic area: ■ Oncology ■ Urology, Nephrology ■ Others

Note) Subject to internal assessment, decision and regulatory consultation, as appropriate. Filing (submission) timing in the first country/region within US/EU/JP



M0: Non-metastatic, M1: Metastatic, CPRC: Castration-resistant prostate cancer, CSPC: Castration-sensitive prostate cancer, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, CKD: Chronic kidney disease, HSCT: hematopoietic stem cell transplantation, MR-VMS: menopause related vasomotor symptoms

ROBUST PIPELINE OF ASTELLAS

Phase 1

ASP1235/AGS62P1

ASP8374/PTZ-201

ASP1948/PTZ-329

ASP1951/PTZ-522

ASP9801

ASP7517

gilteritinib (Pediatric use)

ASP0892

ASP0367/MA-0211

ASP2390

ASP0598

AT845

ASP8062

ASP1617

Phase 2

zolbetuximab
(Pancreatic adenocarcinoma)

ASP1650 (Testicular cancer)

enfortumab vedotin
(Other solid tumors)

ASP7317 (Dry AMD, etc.)

ASP1128/MA-0217 (AKI)

ASP3772 (Pneumococcal disease)

FX-322 (Sensorineural hearing loss)

resamirigene bilparvovec
/AT132 (XLMTM)

bleselumab (rFSGS)

ASP8302 (Underactive bladder)

roxadustat (CIA)

isavuconazole (Pediatric use: US)

Phase 3

enzalutamide
(M0 CSPC, M1 CSPC: China)

gilteritinib
(Earlier-stage AML)

enfortumab vedotin
(Metastatic urothelial cancer)

zolbetuximab
(Gastric and GEJ adenocarcinoma)

peficitinib
(Rheumatoid arthritis: China)

mirabegron
(Pediatric use)

roxadustat
(Anemia associated with CKD: EU)

fezolinetant
(MR-VMS)

Filed

enzalutamide
(M1 CSPC: EU,JP)

enzalutamide
(M0 CRPC: China)

gilteritinib
(R/R AML: China)

solifenacin*
(Pediatric NDO: US)

roxadustat
(Anemia associated with CKD,
non-dialysis: JP)

* Received Complete Response Letter from FDA in Aug 2017

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

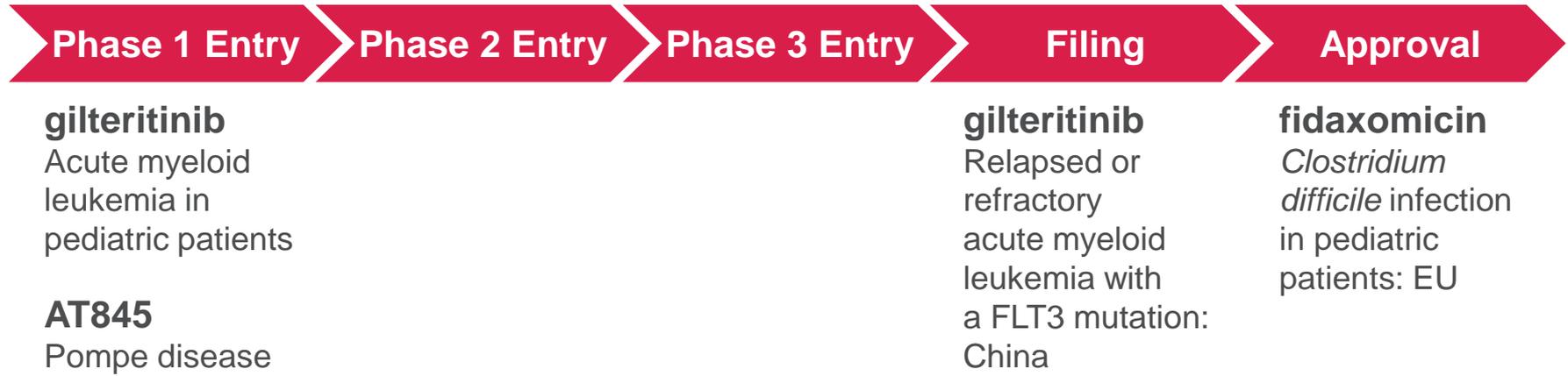
Please refer to R&D pipeline list for details including target disease.



PROGRESS IN OVERALL PIPELINE

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Phase 1 entry to approval since Q3/FY2019 financial results announcement in Jan 2020



Discontinuation

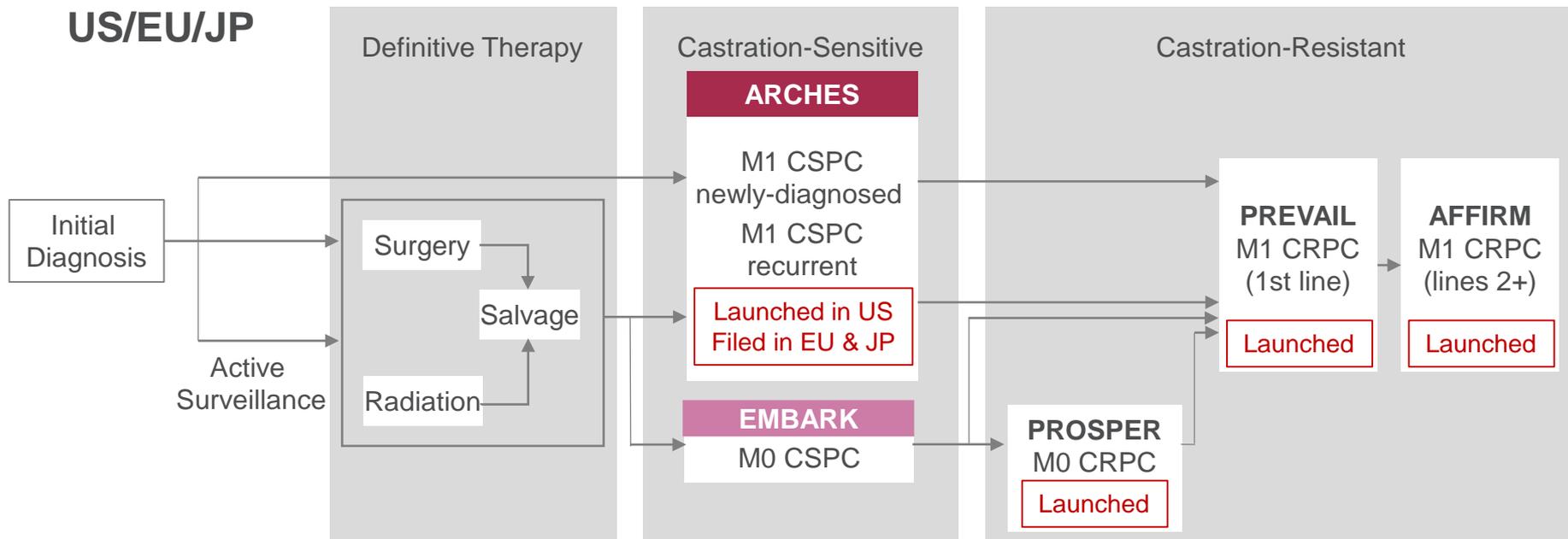
- reldesemtiv:** Spinal muscular atrophy (Phase 2), Amyotrophic lateral sclerosis (Phase 2)
- ASP4345:** Cognitive impairment associated with schizophrenia (Phase 2)
- ASP0819:** Fibromyalgia (Phase 2)

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



IND: Investigational new drug

ENZALUTAMIDE: ANDROGEN RECEPTOR INHIBITOR



P3: ARCHES	M1 CSPC	Combo with ADT, vs. placebo	n=1,150	Approved in US in Dec 2019, Filed in EU and JP in Jul 2019
P3: EMBARK	M0 CSPC	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

China

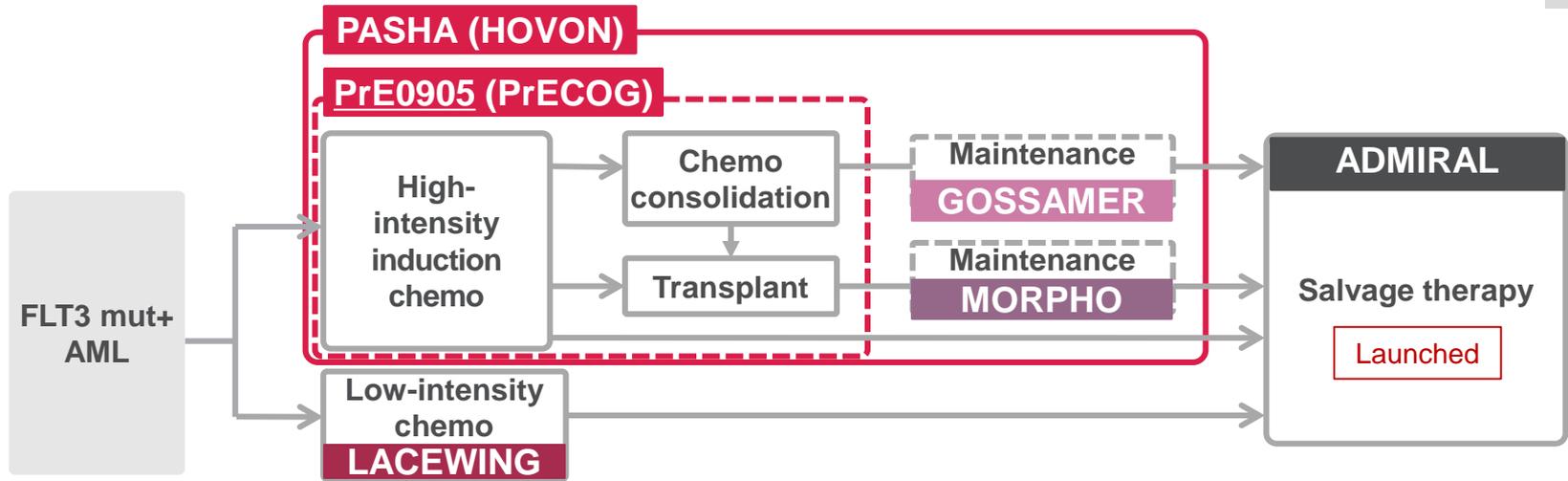
- **M1 CRPC:** Approved in Nov 2019 and launched in Mar 2020
- **M0 CRPC:** Filed in Oct 2019, based on global Phase 3 PROSPER study data
- **M1 CSPC:** FSFT of Phase 3 China-ARCHES study in Sep 2019



Underlined: Updates since Q3/FY2019 announcement in Jan 2020

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy, sNDA: Supplemental new drug application, FSFT: First subject first treatment

GILTERITINIB: FLT3 INHIBITOR



Relapsed or refractory	P3: ADMIRAL	Monotherapy vs salvage chemo (2:1)	n=371	Launched in US, JP, and EU Filed in China in Mar 2020
Newly diagnosed (intensive chemo 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 (intensive chemo ineligible)	P3: LACEWING	Combo with azacitidine vs. azacitidine alone (2:1)	n=323	FSFT: Nov 2016
Post-HSCT maintenance	P3: MORPHO	Monotherapy vs. placebo (1:1)	n=346	FSFT: Jul 2017 Collaborating with BMT-CTN
Post-chemo maintenance	P2: GOSSAMER	Monotherapy vs. placebo (2:1)	n=85	Enrollment completed

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

Treatment landscape for metastatic urothelial cancer and clinical studies for EV

mUC patient treatment	Previously untreated (first line)	Platinum or PD-1/L1 inhibitor pretreated	Platinum and PD-1/L1 inhibitor pretreated
Standard of care*	Cis-eligible: <ul style="list-style-type: none"> Gem-Cis Cis-ineligible: <ul style="list-style-type: none"> Gem-Carbo PD-1/L1 inhibitor (for patients with high PD-L1 expression) 	Platinum pretreated: <ul style="list-style-type: none"> PD-1/L1 inhibitor PD-1/L1-inhibitor pretreated: <ul style="list-style-type: none"> Gem-Carbo 	<ul style="list-style-type: none"> Single agent chemo Clinical trial Palliative care EV monotherapy (US only)
Clinical studies for EV Phase 3 Phase 2	P3: EV-302 Platinum eligible, EV + Pembro +/- Platinum (Carbo/Cis)	P2: EV-201 (Cohort 2) PD-1/L1 inhibitor pretreated, Platinum naïve and cis-ineligible	P2: EV-201 (Cohort 1) Approved in US Platinum and PD-1/L1 inhibitor pretreated
	P1b/2: EV-103 Combo w/ Pembro and other chemotherapy		P3: EV-301 Platinum and PD-1/L1 inhibitor pretreated, vs. chemotherapy

* Approved drugs and standard of care varies by region

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

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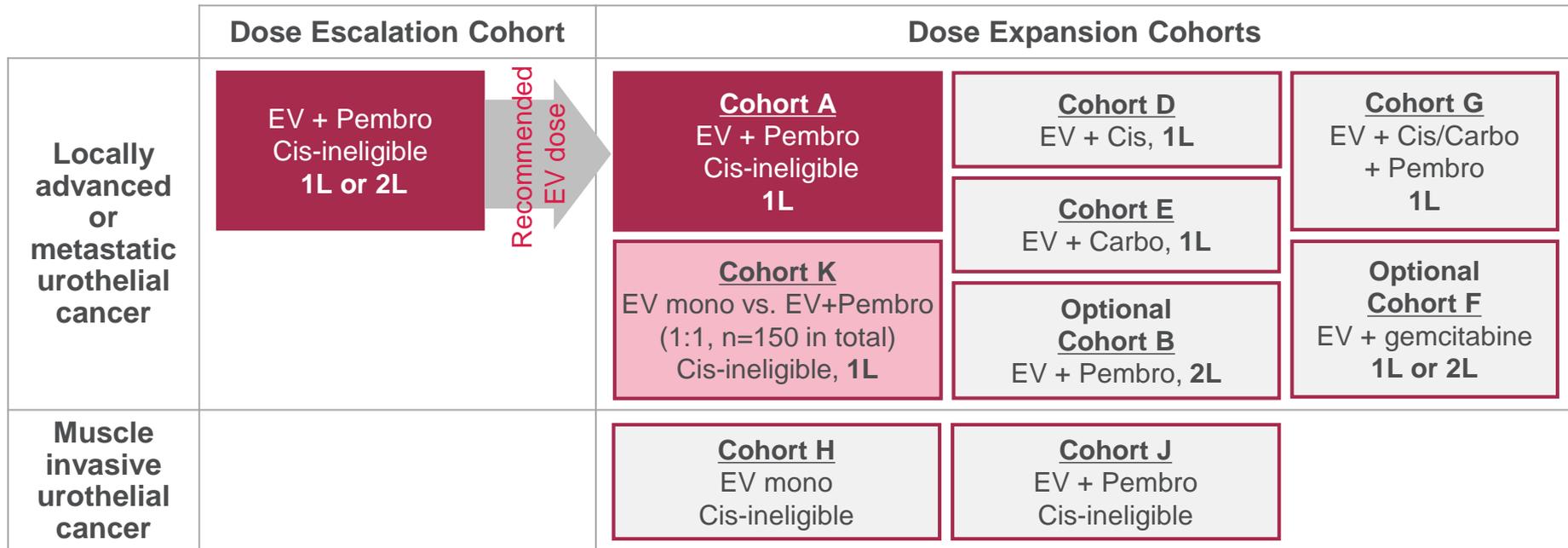
For urothelial cancer

P3: EV-301	mUC, Platinum and PD-1/L1 inhibitor pretreated; vs. chemotherapy	<u>n=608</u>	Enrollment completed
P3: EV-302	Locally advanced or mUC, Previously untreated, Platinum-eligible; EV + Pembro +/- Platinum (Carbo/Cis)	n=1,095	<u>FSFT: Apr 2020</u>
P2: EV-201	mUC, PD-1/L1 inhibitor pretreated Cohort 1: Platinum pretreated Cohort 2: Platinum naïve and cisplatin ineligible	n=200	Cohort 1: <u>Approved (under the Accelerated Approval program) in Dec 2019</u> Cohort 2: <u>Enrollment completed</u>
P1b/2: EV-103	Cohorts A - G <u>and K</u> (Locally advanced or mUC): A-G: Combo with Pembro and other chemotherapy K: <u>EV monotherapy vs. EV + Pembro</u> Cohorts H & J (Muscle invasive UC, Cisplatin-ineligible): H: EV monotherapy, J: EV + Pembro	<u>n=407</u>	<u>FSFT: Nov 2017</u> <ul style="list-style-type: none"> <u>Updated results from the cohorts in combo with Pembro presented at ASCO GU 2020.</u> <u>Breakthrough Therapy Designation granted by FDA for EV + Pembro combo in the first line for patients with mUC not eligible for cisplatin, based on the initial results from EV-103</u>
P1: EV-101	Part A: mUC Part B: mUC with renal insufficiency, Metastatic NSCLC, Metastatic ovarian cancer Part C: mUC (PD-1/L1 inhibitor pretreated)	n= 215	Enrollment completed

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	n=240	<u>FSFT: Mar 2020</u>
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ENFORTUMAB VEDOTIN (EV) (3/3): PHASE 1b/2 EV-103 STUDY DESIGN



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

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

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 ¹
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20% ^{2,3}
- Median overall survival for Stage IV gastric cancer is 10-15 months ^{4,5}

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	<u>n=112</u>	FSFT: Sep 2018
Pancreatic adenocarcinoma	P2	Combo with nab-paclitaxel and gemcitabine, vs. placebo	n=141	FSFT: May 2019



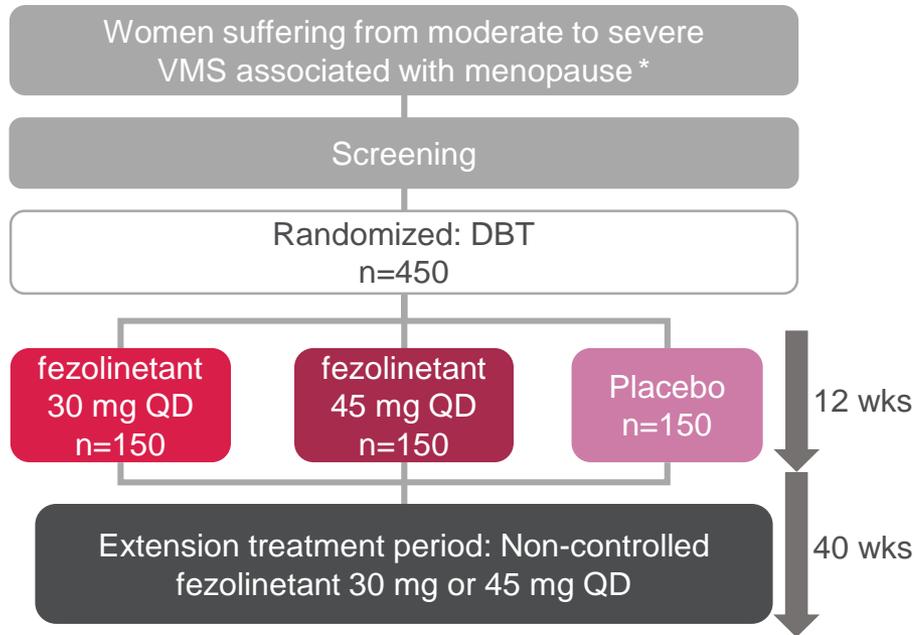
Underlined: Updates since Q3/FY2019 announcement in Jan 2020

1: WHO Cancer Fact Sheet - Globocan 2018, 2: Pennathur A, *et al.*, 2013, 3: Sahin U, *et al.*, 2008, 4: 2017 RDPAC survey, 5: Iizumi S, *et al.* 2018
mFOLFOX6: 5-FU, leucovorin and oxaliplatin, CAPOX: Capecitabine and oxaliplatin, FSFT: First subject first treatment

FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

US/EU Phase 3 studies: FSFT of all the 3 studies in Aug 2019

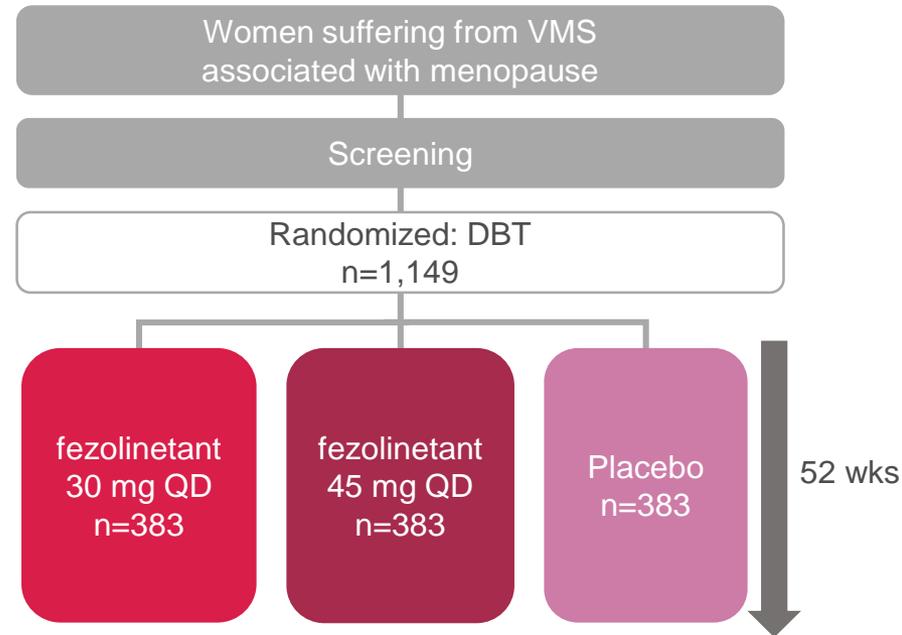
2 Pivotal studies (SKYLIGHT 1, SKYLIGHT 2)



Primary endpoint:

Mean change in the frequency and severity of moderate to severe VMS from baseline to week 4 and Week 12

Long-term safety study (SKYLIGHT 4)



Primary endpoint:

Frequency and severity of adverse events

* A minimum average of 7 to 8 moderate to severe VMS per day, or 50 to 60 per week

Moderate hot flush is associated with sensation of heat with sweating, and severe hot flush causes cessation of activity



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)	vs. Delayed-treatment control Part 1: Dose escalation Cohort 1: 1×10^{14} vg/kg Cohort 2: 3×10^{14} vg/kg Part 2: Pivotal expansion (3×10^{14} vg/kg)	n=24	Pivotal expansion cohort ongoing (Enrollment completed)
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ON THE FOREFRONT OF HEALTHCARE CHANGE

