

Q3/FY2019 FINANCIAL RESULTS

ENDED DECEMBER 31, 2019



Naoki Okamura

**Representative Director, Corporate Executive Vice President,
Chief Strategy Officer and Chief Financial Officer**

Astellas Pharma Inc.

January 31, 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.

AGENDA

I

Q3/FY2019 Consolidated Financial Results

II

Initiatives for Sustainable Growth

III

Capital Allocation

Q3/FY2019 FINANCIAL RESULTS: SUMMARY (YEAR ON YEAR)

- Revenue and Core OP decreased overall, while both increased when excluding FX impacts

Sales increased in XTANDI and mirabegron, as well as new products XOSPATA and EVENITY, offsetting most of the sales decreases in Vesicare, Tarceva, Symbicort and KM bio products

R&D expenses increased while amortisation of intangible assets decreased

- Full basis:
OP increased due to decrease in Other expense
Profit decreased slightly due to one-off preferential tax rate in previous fiscal year

Q3/FY2019 FINANCIAL RESULTS

(billion yen)	Q3/FY18	Q3/FY19	Change (amount)	Change (%)	CER growth
Revenue	1,005.0	988.5	-16.5	-1.6%	+1.4%
Cost of sales	227.7	221.6	-6.1	-2.7%	
% of revenue	22.7%	22.4%			
SG&A expenses	355.8	353.6	-2.2	-0.6%	
R&D expenses	150.0	159.8	+9.8	+6.5%	
Amortisation of intangible assets	26.5	15.4	-11.0	-41.7%	
Core operating profit	244.0	235.9	-8.0	-3.3%	+1.6%
<hr/>					
<Full basis>					
Other income	13.1	15.1	+1.9	+14.8%	
Other expense	47.8	13.4	-34.4	-72.0%	
Operating profit	209.4	237.7	+28.3	+13.5%	
Profit before tax	212.8	239.2	+26.4	+12.4%	
Profit	191.5	190.0	-1.5	-0.8%	



SALES OF MAIN PRODUCTS (YEAR ON YEAR)

Sales increases in XTANDI, XOSPATA, mirabegron and new products in Japan

(billion yen)	Q3/FY18	Q3/FY19	Change (amount)	Change (%)	
Revenue	1,005.0	988.5	-16.5	-1.6%	
XTANDI	253.4	297.9	+44.5	+17.6%	US+25.7, ex-US+18.8 M1 CSPC approved in US in Q3
XOSPATA	0.6	9.8	+9.1	-	US+7.0, Japan+2.0 Launched in Europe in Q3
mirabegron	109.9	121.0	+11.1	+10.1%	US+5.5, Japan+2.7
New products in Japan	18.6	45.3	+26.7	+143.3%	EVENITY+16.5
Other	622.5	514.5	-108.0	-17.3%	Vesicare-38.2, US Tarceva-6.4, Symbicort-17.9, KM bio products-17.3

COST ITEMS (YEAR ON YEAR)

		Change
Cost of sales % of revenue	Slight decrease due to FX impact on elimination of unrealized gain (-0.2ppt)	↓ (ratio)
SG&A expenses	<ul style="list-style-type: none"> Partially offsetting increases in XTANDI US co-promotion fee and launch costs for new products by efficiently managing expenses and optimizing resource allocation Decrease due to one-off reversal of loss allowance (booked in Q2/FY19: 8.2 billion yen) 	↓ (amount)
R&D expenses	Investment increased in key late-stage projects such as fezolinetant, gilteritinib and zolbetuximab, and Primary Focus	↑ (amount)
Amortisation of intangible assets	Completion of amortisation of US Tarceva intangible asset	↓ (amount)

PROGRESS AGAINST FY2019 FORECAST

- Business progresses favorably driven by XTANDI, XOSPATA, mirabegron and new products in Japan
- Although no changes have been made to FY2019 forecast revised in Oct 2019, one-off cost (Non-core cost: approximately \$100M) due to the acquisition of Audentes to be booked in Q4/FY19, will be a downside factor on full basis profit

(billion yen)	Q3/FY19 actual	FY19 forecast	Progress
Revenue	988.5	1,256.0	78.7%
R&D expenses	159.8	216.0	74.0%
Core operating profit	235.9	264.0	89.4%
Core profit	191.9	214.0	89.6%
<hr/>			
<Full basis>			
Operating profit	237.7	263.0	90.4%
Profit	190.0	210.0	90.5%

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EVRENZO: LAUNCHED IN JAPAN

Launched as a first-in-class orally administered HIF-PH inhibitor for renal anemia in patients on dialysis

- NDA approved based on the four Phase 3 studies in Japan including a ESA-controlled study that demonstrated non-inferiority to ESA
- Anemia is a frequent complication of chronic kidney disease, occurring in more than 90% of patients on dialysis. The number of patients on dialysis in Japan is increasing year-by-year and exceeded 330,000
- The number of adopted facilities has steadily increased, and the reaction from the prescribers regarding efficacy has been favorable

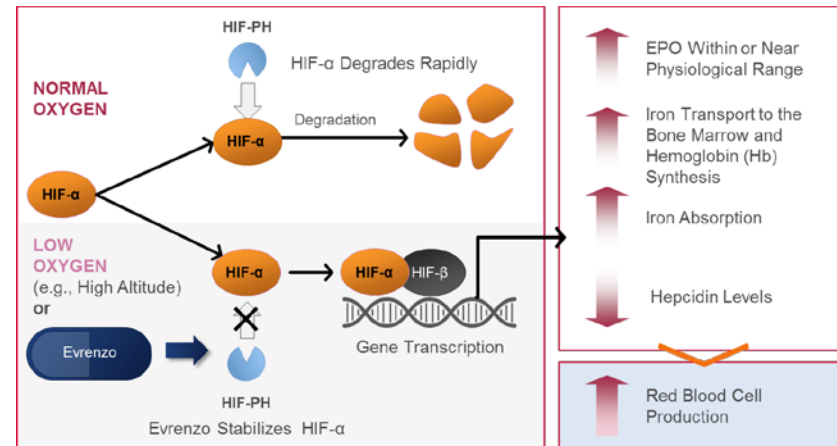
Patients who can benefit from Evrenzo

Renal anemia in patients on dialysis:

- ESA-naive patients
- Patients treating renal anemia by ESA therapy
 - ✓ with high ESA dose, or unstable/intolerant
 - ✓ with low response to ESA due to low efficiency in iron use and/or chronic inflammation



Mechanism of action

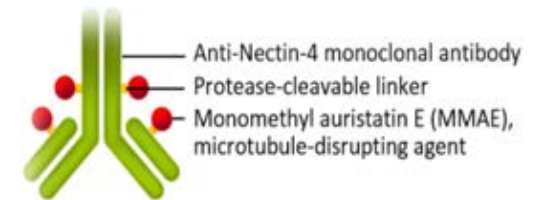


PADCEV: LAUNCHED IN US



The first treatment approved by FDA for locally advanced or mUC following treatment with platinum-based chemotherapy and a PD-1/L1 Inhibitor

- Breakthrough therapy designation for CPI-pretreated mUC patients was granted by FDA. Rapid development and approval were enabled by the strength of the pivotal Phase 2 clinical data
- Approx. 20,000 patients in US present each year with metastatic urothelial cancer¹. 5-year survival rate of 4%²
- We expect approx. 2,000 patients in US will be eligible for treatment with PADCEV in its labeled indication
- NCCN guidelines updated to add PADCEV as a preferred treatment option
- PADCEV is directed against Nectin-4, highly expressed in bladder cancer; no biomarker required for use
- Commercial teams were ready upon US approval; we have seen strong initial interest from oncologists
- PADCEV is jointly promoted by Astellas and Seattle Genetics in US



CONTINUED PROGRESS ON 6 POST-POC PROJECTS

Development advancing as intended in Strategic Plan 2018

■ Progress since Q2/FY2019 announcement in Oct 2019

	Indication	P1	P2	P3	Filed	Approved
enzalutamide	M1 castration-sensitive prostate cancer M0 castration-sensitive prostate cancer	■			EU, JP	US
gilteritinib	Relapsed or refractory AML	■				US, JP
	Newly diagnosed AML, intensive chemo eligible	■				EU
	Newly diagnosed AML, intensive chemo ineligible	■				
	AML, post-HSCT maintenance	■				
	AML, post-chemo maintenance	■				
enfortumab vedotin	mUC, platinum and PD-1/L1 inhibitor pretreated	■				US
	mUC, PD-1/L1 inhibitor pretreated	■				
	mUC, previously untreated (first line)	■				
	Other cancers	■				
zolbetuximab	Gastric and gastroesophageal junction adenocarcinoma	■				
	Pancreatic adenocarcinoma	■				
roxadustat	Japan, anemia associated with CKD, on dialysis	■				
	Japan, anemia associated with CKD, not on dialysis	■				
	EU, anemia associated with CKD	■				
	Chemotherapy-induced anemia	■				
fezolinetant	Menopause-related vasomotor symptoms	■				

M1: Metastatic, M0: Non-metastatic, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, mUC: Metastatic urothelial cancer, CKD: Chronic kidney disease

6 POST-POC PROJECTS: STATUS UPDATE

(Underlined: Updates since Q2/FY2019 announcement in Oct 2019)

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enzalutamide

M1 CSPC

- Approved in US in Dec 2019, filed in EU and JP (Jul 2019)

M0 CSPC

- **Phase 3 study:** Ongoing

China

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

gilteritinib

Earlier-stage acute myeloid leukemia

- **Phase 3 studies:** Ongoing

enfortumab vedotin

mUC, platinum and PD-1/L1 inhibitor pretreated

- Approved in US in Dec 2019 (under the Accelerated Approval Program)

mUC, previously untreated (first line)

- Phase 3 study combo with pembrolizumab to start in 1H 2020

Other cancers

- Phase 2 study to start in 1Q 2020

zolbetuximab

Gastric and gastroesophageal junction adenocarcinoma

- **Phase 3 studies:** Ongoing

Pancreatic adenocarcinoma

- **Phase 2 study:** Ongoing

roxadustat

Anemia associated with CKD

- **EU:** MAA targeting 2Q 2020
- **JP:** Positive data of the remaining Phase 3 study for non-dialysis obtained, and 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:** Phase 3 study in Asian countries including China to start in 1Q 2020

ENFORTUMAB VEDOTIN (EV): METASTATIC UROTHELIAL CANCER (mUC)

*Platinum and PD-1/L1 inhibitor pretreated: Approved in US in Dec 2019
(under the Accelerated Approval Program)*

First line: To start a Phase 3 study in combination with pembrolizumab

mUC patient treatment	Previously untreated (first line)	Platinum or PD-1/L1 inhibitor pretreated	Platinum and PD-1/L1 inhibitor pretreated
<p>Standard of care*</p>	<p>Cis-eligible:</p> <ul style="list-style-type: none"> Gem-Cis <p>Cis-ineligible:</p> <ul style="list-style-type: none"> Gem-Carbo PD-1/L1 inhibitor (for patients with high PD-L1 expression) 	<p>Platinum pretreated:</p> <ul style="list-style-type: none"> PD-1/L1 inhibitor <p>PD-1/L1-inhibitor pretreated:</p> <ul style="list-style-type: none"> Gem-Carbo 	<ul style="list-style-type: none"> Single agent chemo Clinical trial Palliative care <u>EV monotherapy (US only)</u>
<p>Clinical studies for EV</p> <ul style="list-style-type: none"> Phase 3 Phase 2 Phase 1 	<p>P3: EV-302 To be started soon</p> <p><u>Platinum eligible, EV + Pembro +/- Platinum (Carbo/Cis)</u></p> <p>P1b: EV-103 Results of combo with Pembro presented at ESMO2019</p> <p>Combo w/ Pembro & other chemotherapy</p>	<p>P2: EV-201 (Cohort 2)</p> <p>PD-1/L1 inhibitor pretreated, Platinum naïve and cis-ineligible</p>	<p>P2: EV-201 (Cohort 1) Approved in US</p> <p>Platinum and PD-1/L1 inhibitor pretreated</p> <p>P3: EV-301</p> <p>Platinum and PD-1/L1 inhibitor pretreated, vs. chemotherapy</p>

ENFORTUMAB VEDOTIN (EV): PHASE 3 STUDY FOR mUC FIRST LINE

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- Locally advanced or metastatic urothelial cancer
- Previously untreated
- Platinum eligible

1:1:1 Randomized, Open-label
n=1,095

Arm A

EV + Pembro

n=365

Arm B

Platinum
(Cis or Carbo)
+ Gem

n=365

Arm C

EV + Pembro
+ Platinum
(Cis or Carbo)

n=365

Phase 3 study (EV-302)

- Funded by 3 companies;
Seattle Genetics, Astellas, and Merck
- Efficacy endpoints:
 - ✓ Primary: PFS (BICR), OS
 - ✓ Secondary: PFS (INV), ORR, DOR, DCR
- Study initiation anticipated in 1H 2020

ENFORTUMAB VEDOTIN (EV): OTHER CANCERS

To start a Phase 2 study in other Nectin-4 expressing cancers

<i>Tumor types included in Phase 2 multi-cohort Trial</i>
HR+/HER2- breast cancer
Triple negative breast cancer
Squamous NSCLC
Non-squamous NSCLC
Head and neck cancer
Gastric, GEJ or esophageal cancer

Points for tumor selection

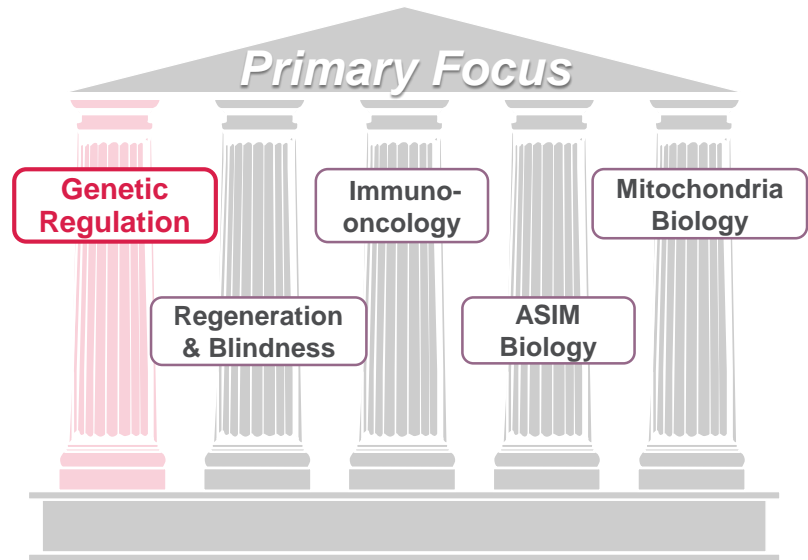
- ✓ Unmet medical needs
- ✓ Nectin-4 expression¹
- ✓ Sensitivity to microtubule inhibition

Phase 2 study (EV-202) outline:

- Open-label, Single-arm, Multi-cohort, EV monotherapy
 - Previously treated locally advanced or metastatic malignant solid tumors (6 tumor types above)
 - n=240 (n=40 per cohort / tumor type) at maximum
 - Primary efficacy endpoint: ORR
 - Study initiation anticipated in 1Q 2020
- => Any tumor type with a sufficient response rate may be selected for further development (Phase 3)*

PROGRESS IN FOCUS AREA APPROACH (1/2)

“Genetic regulation” added as our Primary Focus, with acquisition of Audentes



- Acquired in Jan 2020
- Audentes' capabilities for gene therapy:
 - ✓ Pipeline: PoC of the lead program AT132 clarified in XLMTM patients (Phase 1/2)
 - ✓ AAV-technology platform
 - ✓ Large-scale cGMP manufacturing capability

“Primary Focus” is selected from Focus Areas, based on:

- Scientific evidence
- Identified lead program
- Potential follow-on programs

=> *“Genetic Regulation” newly added as our 5th Primary Focus*

Further strengthen immuno-oncology area especially CAR-cell therapies, with acquisition of Xyphos Biosciences and collaboration with Adaptimmune

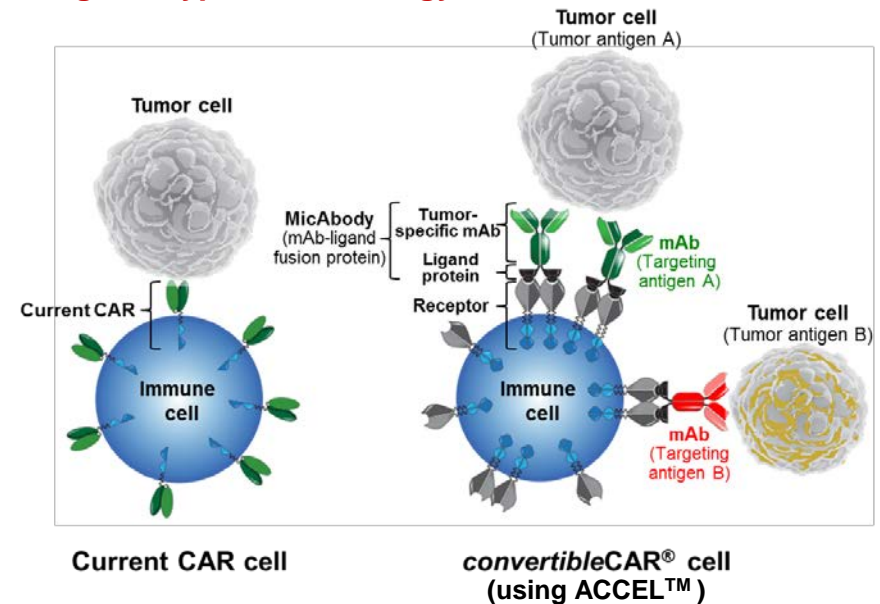
Xyphos' technology and pipeline

- CAR-cell therapy-related technology platform named ACCEL™ enables CAR-density and CAR-cell amount control, target switching, and multiplex targeting
 - Lead program, CAR-T therapy using autologous T-cells, expected to enter into clinical phase in 2021
- ⇒ *Their technology to be combined with Universal Donor Cells in near future to develop more promising CAR-cell therapies*

Adaptimmune's product and platform capabilities

- Identification and validation for generating target-specific TCRs and CARs
 - Stem-cell derived allogeneic T-cell platform
- ⇒ *Synergy with Universal Cells' technology such as Universal Donor Cells and gene editing platform expected*

Image of Xyphos technology



Rx+™ Program: Going to the next level to establish a solid foundation for business acceleration

- **Current Stage: Explore Rx+™ business feasibility**

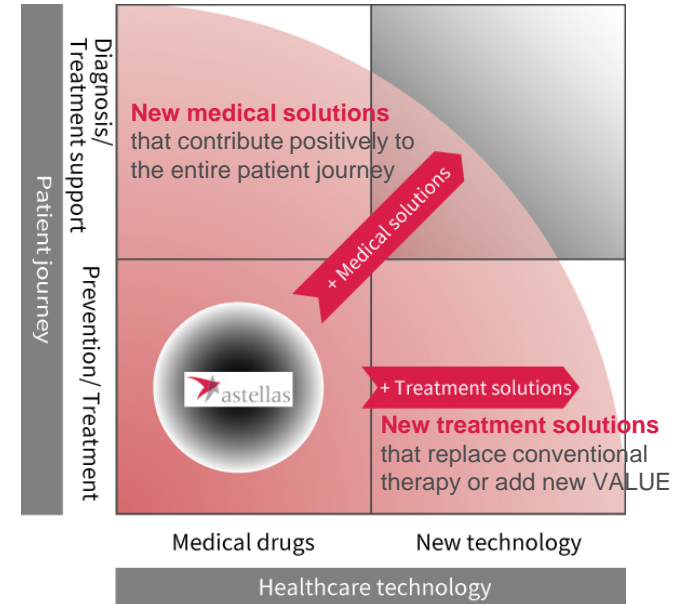
Sought the new business opportunities widely from the viewpoints of applying our pharmaceutical technologies to new treatment solutions and utilizing new technologies for medical solutions.

- **Identified Opportunities -**

- ✓ Drug-device combination
- ✓ Innovative medical devices
- ✓ Digital therapeutics

- **Challenges -**

- ✓ Broad business scope
- ✓ Keeping up with pace of technological advances and changes in the market



- **Next stage: Establish a solid foundation for business acceleration**

Strategic direction of Rx+™ with clarified focus and priority (Rx+ Story™)

- ✓ Enhance combination and synergy among business ideas
- ✓ Accelerate hypothesis testing
- ✓ Enable dynamic partnerships beyond program-based collaboration
- ✓ Build innovative business models

Rx+™ World

A world where people can live mentally and physically healthy lives and be true to themselves through healthcare solutions based on scientific evidence

Rx+™ Values

Prevent disease onset and slow progression by using personal data

Expand options for people with limited access to current therapeutics

Support active living by enhancing physical and sensory function

Spheres*

Chronic disease progression prevention



Motor function support/replacement



Digital x neuroscience



Patient w/o effective medicines



Patient outcome maximization



Sensory function support/replacement



Digital Therapeutics

- ◆ Strategic alliance with WellDoc

Digital healthcare solutions

- ◆ Co-development with BANDAI NAMCO Entertainment

Ultra-small implantable medical devices

- ◆ Co-research and development with Iota Biosciences

Image-guided precision surgery

- ◆ ASP5354

Theranostics using antibody with radioisotope label

* Sphere: Business area that embodies Rx+™ World/Rx+™ Values

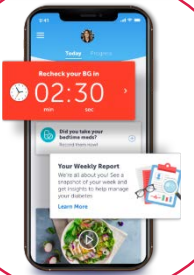
Progress in Rx+™ Program: Digital Therapeutics



Enter into Strategic Alliance with Welldoc for Digital Therapeutics - Development and commercialization of digital health solutions -

- **Co-development and co-commercialization of BlueStar®**
 - ✓ In Japan & other Asian market: Joint development and commercialization
 - ✓ In US market: Collaboration to broaden the adoption of this application
- **Joint development and commercialization of novel digital therapeutics**
 - ✓ Joint development and commercialization of digital therapeutics in other therapeutic areas globally

BlueStar®

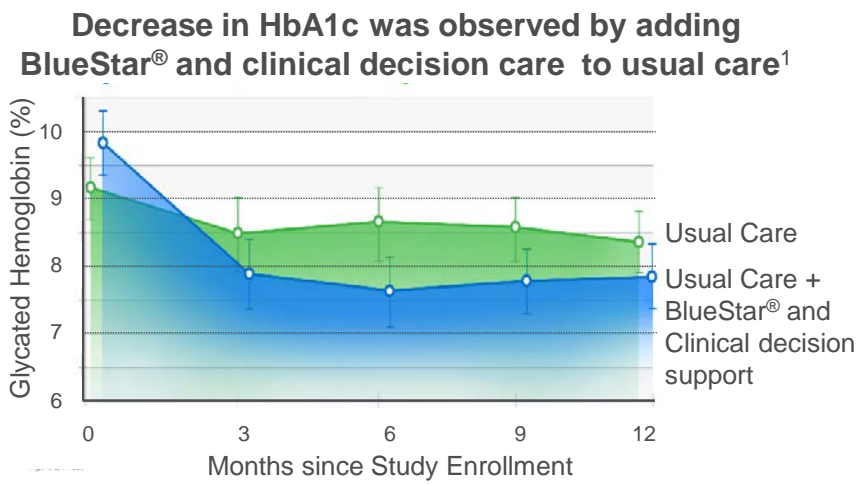


Aim

- Provide disease management support service for type 1 or 2 diabetes patient

Outline

- Encourage the changes of patients lifestyle by sending messages based on the data provided by there self and treatment algorithm
- Data are also shared with healthcare providers to provide effective and efficient medical intervention to patients
- A digital health solution that is cleared by FDA for use by adults with type 1 or 2 diabetes



1: Quinn CC, et al., Diabetes Care (2011), 34, 1934-1942.
FDA: Food and Drug Administration

AGENDA

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Initiatives for Sustainable Growth

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Capital Allocation

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

Acquisition of own shares announced in Oct 2019

- From Nov 1, 2019 to Jan 31, 2020
- Up to 32 million shares
- Up to 50 billion yen

APPENDIX

A water droplet is captured mid-fall, just above the surface of a pool of water. The droplet is clear and spherical, with a slight reflection on its top. 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.

Q3/FY2019: REVENUE BY REGION

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(billion yen)	Q3/FY18	Q3/FY19	Change
Japan	291.9	276.2	-5.4%
United States	321.2	331.9	+3.3%
Established Markets	228.9	218.0	-4.8%
Greater China	45.1	44.4	-1.5%
International	94.6	102.8	+8.7%

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.

Q3/FY2019: SALES OF MAIN PRODUCTS

26

(billion yen)	Q3/FY18	Q3/FY19	Change	CER growth	FY19 forecast	Progress
XTANDI	253.4	297.9	+17.6%	+21.9%	383.9	77.6%
XOSPATA	0.6	9.8	-	-	13.9	70.2%
OAB products	184.3	157.2	-14.7%	-12.3%	201.0	78.2%
mirabegron	109.9	121.0	+10.1%	+13.1%	158.8	76.2%
Vesicare	74.4	36.2	-51.4%	-49.9%	42.2	85.6%
Prograf	150.0	146.2	-2.5%	+1.7%	190.3	76.8%



OAB products: Vesicare + mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)

Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL

FX RATE (ACTUAL)

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Average rate for the period

Currency	Q3/FY18	Q3/FY19	change
USD	111 yen	109 yen	-2 yen
EUR	129 yen	121 yen	-8 yen

Change in closing rate from PY end

Currency	Q3/FY18	Q3/FY19
USD	+5 yen	-1 yen
EUR	-4 yen	-2 yen

<Impact of exchange rate on financial results>

30.6 billion yen decrease in revenue, 12.0 billion yen decrease in core OP

FX impact on elimination of unrealized gain: COGs ratio -0.2ppt

FY2019 FCST:FX SENSITIVITY

Forecast rates from Q3/FY2019 onwards: 108 USD/yen, 118 EUR/yen

Estimated FX sensitivity (Q3 and onward) of FY2019 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. -2.6 bil yen	Approx. -0.6 bil yen	Approx. +0.3 bil yen
EUR	Approx. -1.4 bil yen	Approx. -0.6 bil yen	Approx. +0.2 bil yen



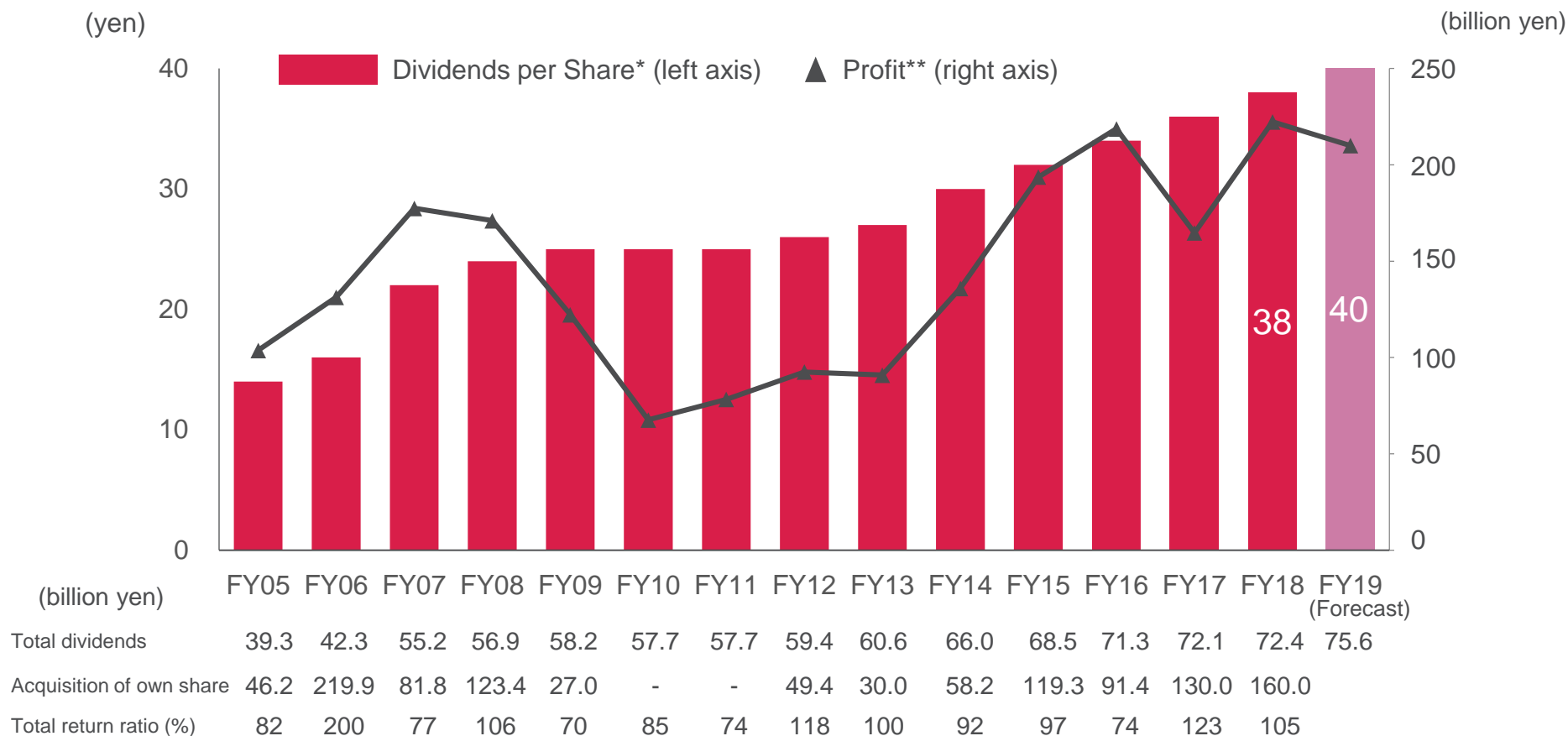
* Sensitivity to fluctuation of FX rates used for consolidation of overseas affiliates' results compared to forecasted rates from Q3/FY2019 and onwards

BALANCE SHEET/CASH FLOW HIGHLIGHTS

(billion yen)	FY18 end	Dec 2019
Total assets	1,897.6	1,989.8
Cash and cash equivalents	311.1	277.6
Total equity attributable to owners of the parent	1,258.4	1,317.4
Equity ratio (%)	66.3%	66.2%

(billion yen)	Q3/FY18	Q3/FY19	FY18
Cash flows from operating activities	203.7	170.3	258.6
Cash flows from investing activities	-28.5	-74.4	-41.8
Free cash flows	175.2	95.9	216.9
Cash flows from financing activities	-173.3	-125.2	-233.7
Acquisition of treasury shares	-100.4	-38.1	-160.4
Dividends paid	-72.1	-73.5	-72.1

DETAILS OF SHAREHOLDER RETURNS



* 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

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

FY2018	FY2019-2020	FY2021 or beyond
enzalutamide M0 CRPC (US,EU,JP) ✓ ✓ ✓	enzalutamide M1 CSPC (US) ✓ ✓ ✓ (EU,JP) ✓ ✓	enzalutamide M0 CSPC
gilteritinib R/R AML (US,EU,JP) ✓ ✓ ✓	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, CRPC: 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

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Phase 1

ASP1235/AGS62P1

ASP8374/PTZ-201

ASP1948/PTZ-329

ASP1951/PTZ-522

ASP9801

ASP7517

ASP0892

ASP0367/MA-0211

ASP2390

ASP0598

ASP8062

ASP1617

Phase 2

zolbetuximab
(Pancreatic adenocarcinoma)

ASP1650 (Testicular cancer)

enfortumab vedotin
(Other cancers)

reldesemtiv (SMA, ALS)

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)

ASP0819 (Fibromyalgia)

ASP4345 (CIAS)

isavuconazole (Pediatric: US)

Phase 3

enzalutamide
(M0 CSPC, M1 CSPC: China)

gilteritinib
(R/R AML: China, Other AML)

enfortumab vedotin
(Metastatic urothelial cancer)

zolbetuximab
(Gastric and GEJ adenocarcinoma)

peficitinib
(Rheumatoid arthritis: China)

mirabegron
(Pediatric OAB & NDO)

roxadustat
(Anemia associated with CKD: EU)

fezolinetant
(MR-VMS)

Filed

enzalutamide
(M1 CSPC: EU,JP)

enzalutamide
(M0 CRPC: China)

solifenacin*
(Pediatric NDO: US)

fidaxomicin
(*Clostridium difficile* infection in pediatric patients: EU)

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.



SMA: Spinal muscular atrophy, ALS: Amyotrophic lateral sclerosis, AMD: Age-related macular degeneration, AKI: Acute kidney injury, XLMTM: X-linked myotubular myopathy, rFSGS: Recurrence of focal segmental glomerulosclerosis, CIA: Chemotherapy-induced anemia, CIAS: Cognitive impairment associated with schizophrenia, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, GEJ: Gastroesophageal junction, OAB: Overactive bladder, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, MR-VMS: Menopause-related vasomotor symptoms, FDA: Food and Drug Administration

PROGRESS IN OVERALL PIPELINE

Phase 1 entry to approval, since Q2/2019 financial results announcement in Oct 2019

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Phase 1 Entry

ASP2390

House dust mite-induced allergic rhinitis

ASP0598

Chronic tympanic membrane perforation

Phase 2 Entry

enfortumab vedotin

Other cancers

Phase 3 Entry

enfortumab vedotin

Metastatic urothelial cancer, previously untreated (first line)

Filing

roxadustat

Renal anemia in patients not on dialysis: JP

Approval

enzalutamide

Metastatic castration-resistant prostate cancer: China

enzalutamide

Metastatic castration-sensitive prostate cancer: US

enfortumab vedotin

Locally advanced or metastatic urothelial cancer in patients who have received prior treatment with a PD-1/L1 inhibitor and platinum-containing chemotherapy: US

micafungin

Invasive candidiasis in neonates and young infants less than 120 days of life: US

Discontinuation

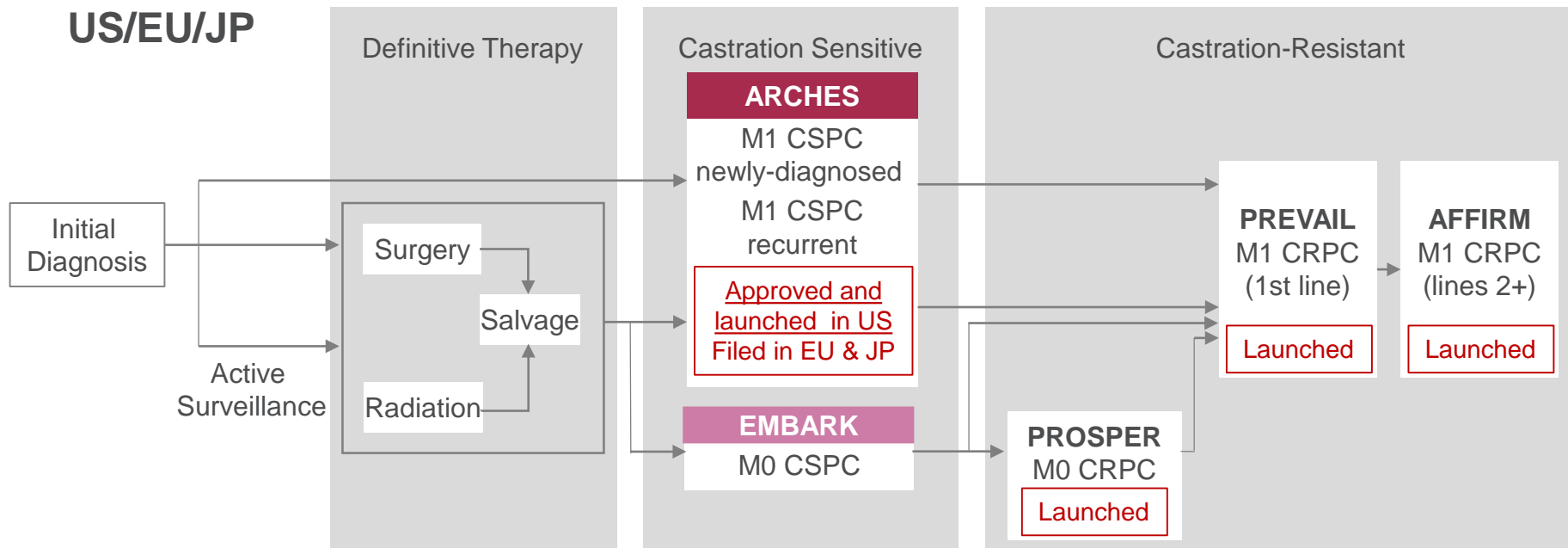
MucoRice-CTB: Prophylaxis of diarrhea caused by *Vibrio cholerae* (Phase 1)

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

IND: Investigational new drug



ENZALUTAMIDE: ANDROGEN RECEPTOR INHIBITOR



P3: ARCHES	M1 CSPC	Combo with ADT, vs. placebo	n=1,150	Filed in US in June 2019 (Priority Review) <u>and approved in Dec 2019</u> . Filed in EU and JP in July 2019
P3: EMBARK	M0 CSPC	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

China

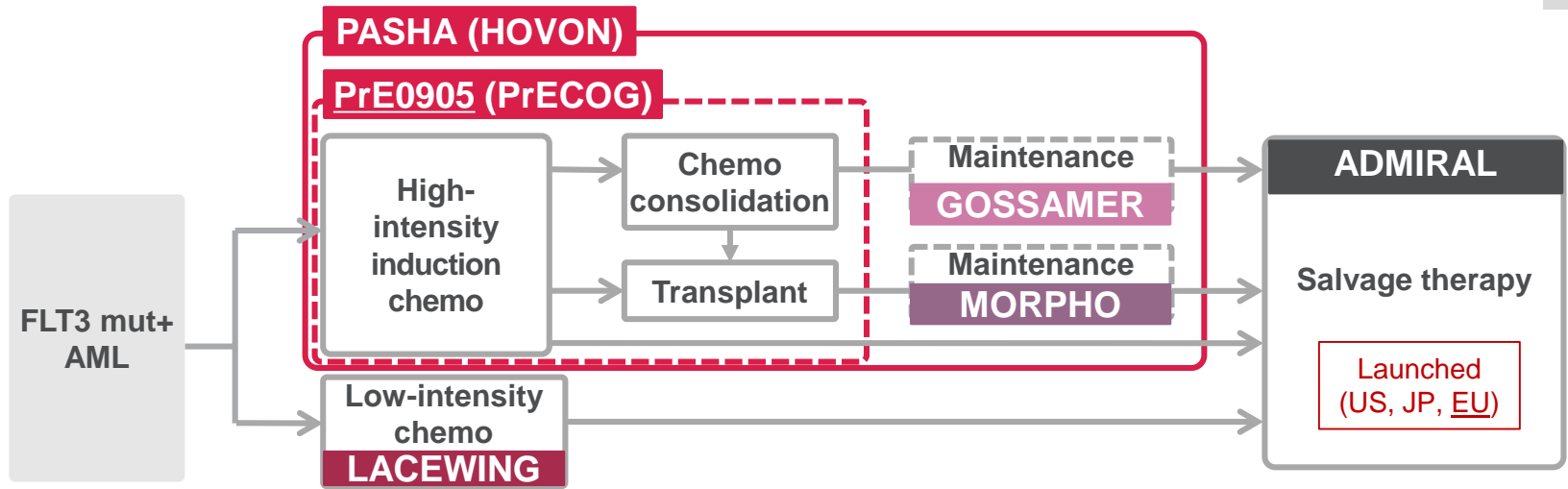
- **M1 CRPC**: Filed in Mar 2018 and approved in Nov 2019, based on Phase 3 Asian-PREVAIL study data
- **M0 CRPC**: Filed in Oct 2019, based on global Phase 3 PROSPER study data
- **M1 CSPC**: FSFT of Phase 3 China-ARCHES study in Sep 2019



Underlined: Updates since Q2/FY2019 announcement in Oct 2019

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 <u>EU</u>
Newly diagnosed (intensive chemo eligible)	P3: PASHA (HOVON)	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=768	<u>FSFT: Dec 2019</u> (Sponsor: HOVON)
	P2: PrE0905 (PrECOG)		n=179	<u>FSFT: Dec 2019</u> (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: July 2017 Collaborating with BMT-CTN
Post-chemo maintenance	P2: GOSSAMER	Monotherapy vs. placebo (2:1)	n=85	Enrollment completed: June 2019

ENFORTUMAB VEDOTIN (EV): NECTIN-4 TARGETED ADC

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Clinical studies in urothelial cancer

P3: EV-301	Metastatic UC, Platinum and PD-1/L1 inhibitor pretreated; vs. chemotherapy	<u>n=600</u>	FSFT: July 2018 Enrollment completed
P3: EV-302	<u>Locally advanced or metastatic UC, Previously untreated, Platinum-eligible; EV + Pembro +/- Platinum (Carbo/Cis)</u>	<u>n=1,095</u>	<u>Under preparation to start in 1H 2020</u>
P2: EV-201	Metastatic UC, PD-1/L1 inhibitor pretreated Cohort 1: Platinum pretreated Cohort 2: Platinum naïve/cisplatin ineligible	n=200	Cohort 1: Filed in US in July 2019 (Priority Review), <u>approved (under the Accelerated Approval Program) and launched in Dec 2019</u> Cohort 2: Recruiting
P1b: EV-103	Cohorts A - G (Locally advanced or metastatic UC): Combo with Pembro and other chemotherapy Cohorts H & J (Muscle invasive UC, Cisplatin-ineligible): EV monotherapy (H), Combo with Pembro (J)	<u>n=257</u>	FSFT: Nov 2017 Results from the cohorts in combination with Pembro presented at ESMO 2019
P1: EV-101	Part A: Metastatic UC pts Part B: Metastatic UC pts with renal insufficiency, Metastatic NSCLC, Metastatic ovarian cancer Part C: Metastatic UC pts (PD-1/L1 inhibitor pretreated)	n= 215	Enrollment completed

Clinical study in other cancers

P2: EV-202	<u>HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric, gastroesophageal junction or esophageal cancer</u>	<u>n=240</u>	<u>Under preparation to start in 1Q 2020</u>
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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

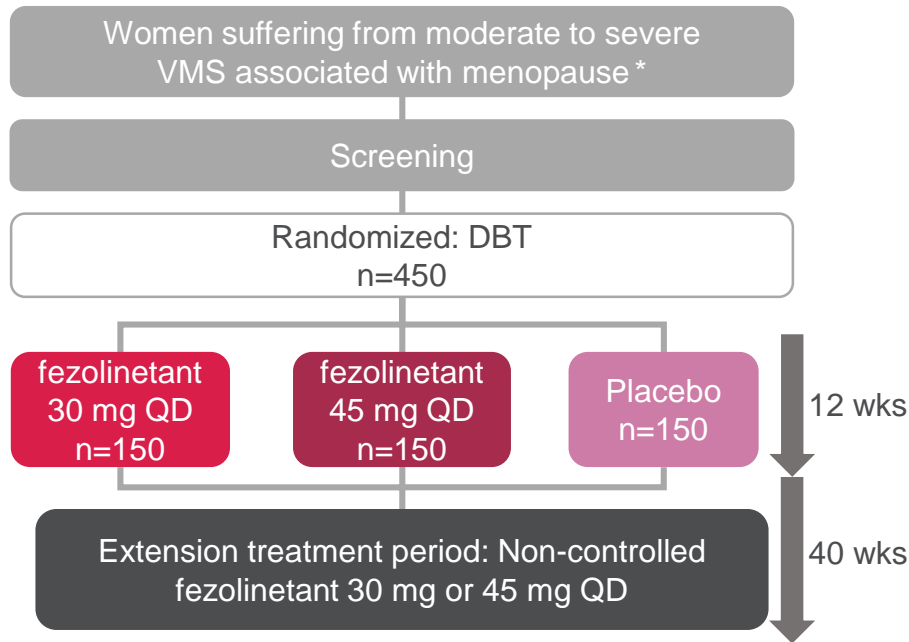
- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin 18.2 expression
- Gastric cancer is the third leading cause of cancer death worldwide ¹
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20% ^{2,3}
- Median overall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

Gastric and GEJ adenocarcinoma	P3: SPOTLIGHT	Combo with mFOLFOX6, vs. placebo	n=550	FSFT: Oct 2018
	P3: GLOW	Combo with CAPOX, vs. placebo	n=500	FSFT: Jan 2019
	P2: ILUSTRO	Monotherapy, Combo with mFOLFOX6	n=102	FSFT: Sep 2018
Pancreatic adenocarcinoma	P2	Combo with nab-paclitaxel and gemcitabine, vs. placebo	n=141	FSFT: May 2019

FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

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

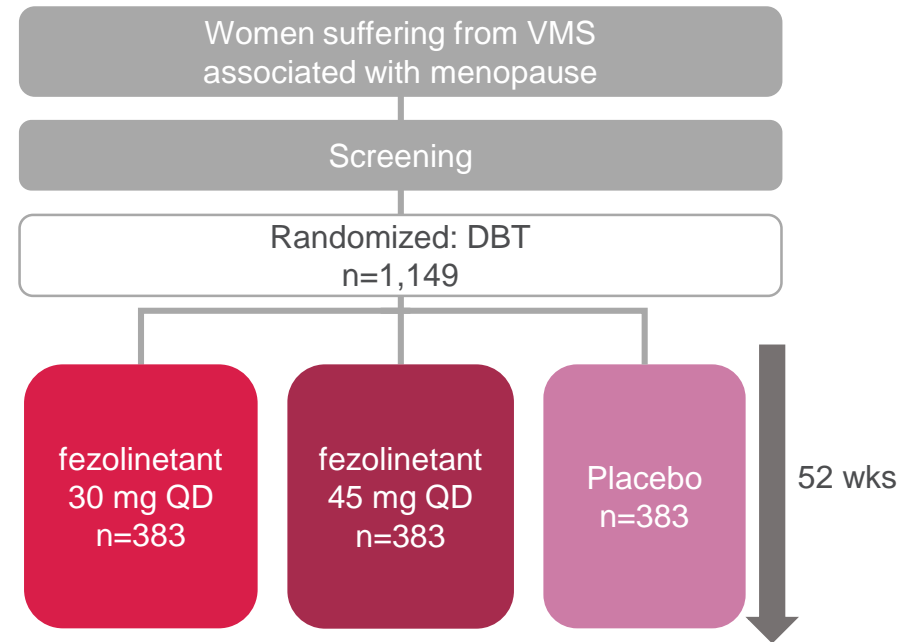
2 Pivotal studies (SKYLIGHT 1, SKYLIGHT 2)



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



ON THE FOREFRONT OF HEALTHCARE CHANGE

