



Q2/FY2019 FINANCIAL RESULTS

ENDED SEPTEMBER 30, 2019



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October 31, 2019

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.

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Q2/FY2019 Consolidated Financial Results
and FY2019 Revised Forecasts

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Capital Allocation

Q2/FY2019 FINANCIAL RESULTS (CORE BASIS)

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(billion yen)	Q2/FY18	Q2/FY19	Change	FY19 FCST *	Progress	CER growth
Revenue	647.1	650.5	+0.5%	1,224.0	53.1%	+3.4%
Cost of sales	143.5	138.9	-3.3%			
% of revenue	22.2%	21.3%				
SG&A expenses	231.5	226.1	-2.4%			
% of revenue	35.8%	34.8%				
R&D expenses	99.6	105.0	+5.4%	211.0	49.8%	
% of revenue	15.4%	16.1%		17.2%		
Amortisation of intangible assets	17.7	11.2	-36.6%			
Share of profit (loss) of investments accounted for using equity method	- 0.6	- 1.4	-			
Core operating profit	154.2	168.0	+8.9%	240.0	70.0%	+9.4%
Core profit	124.8	135.9	+8.9%	194.0	70.1%	
Core EPS (yen)	63.92	72.07	+12.8%	102.87	70.1%	

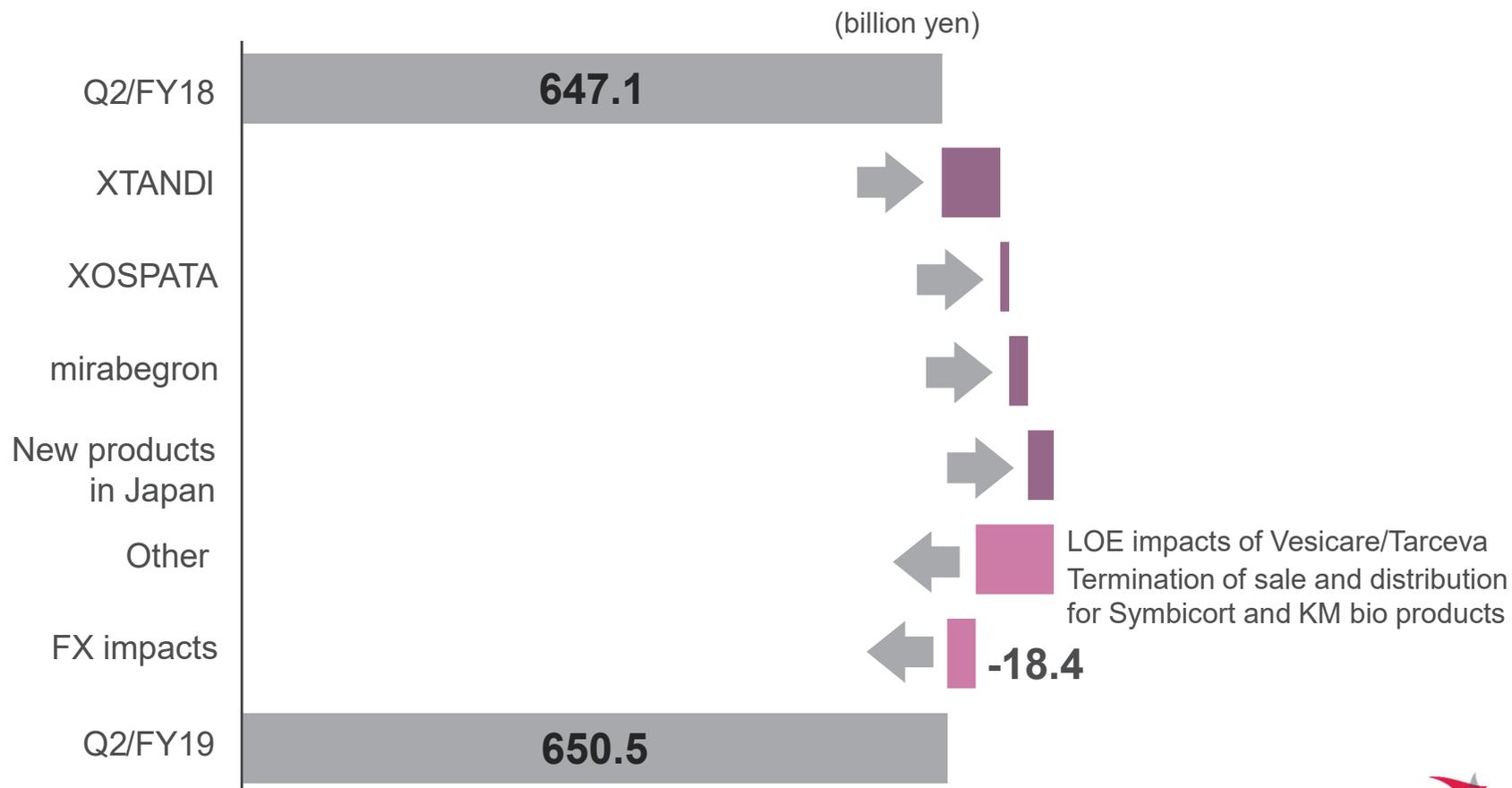


CER: Constant exchange rate

* Announced in Apr 2019

REVENUE ANALYSIS (YEAR ON YEAR)

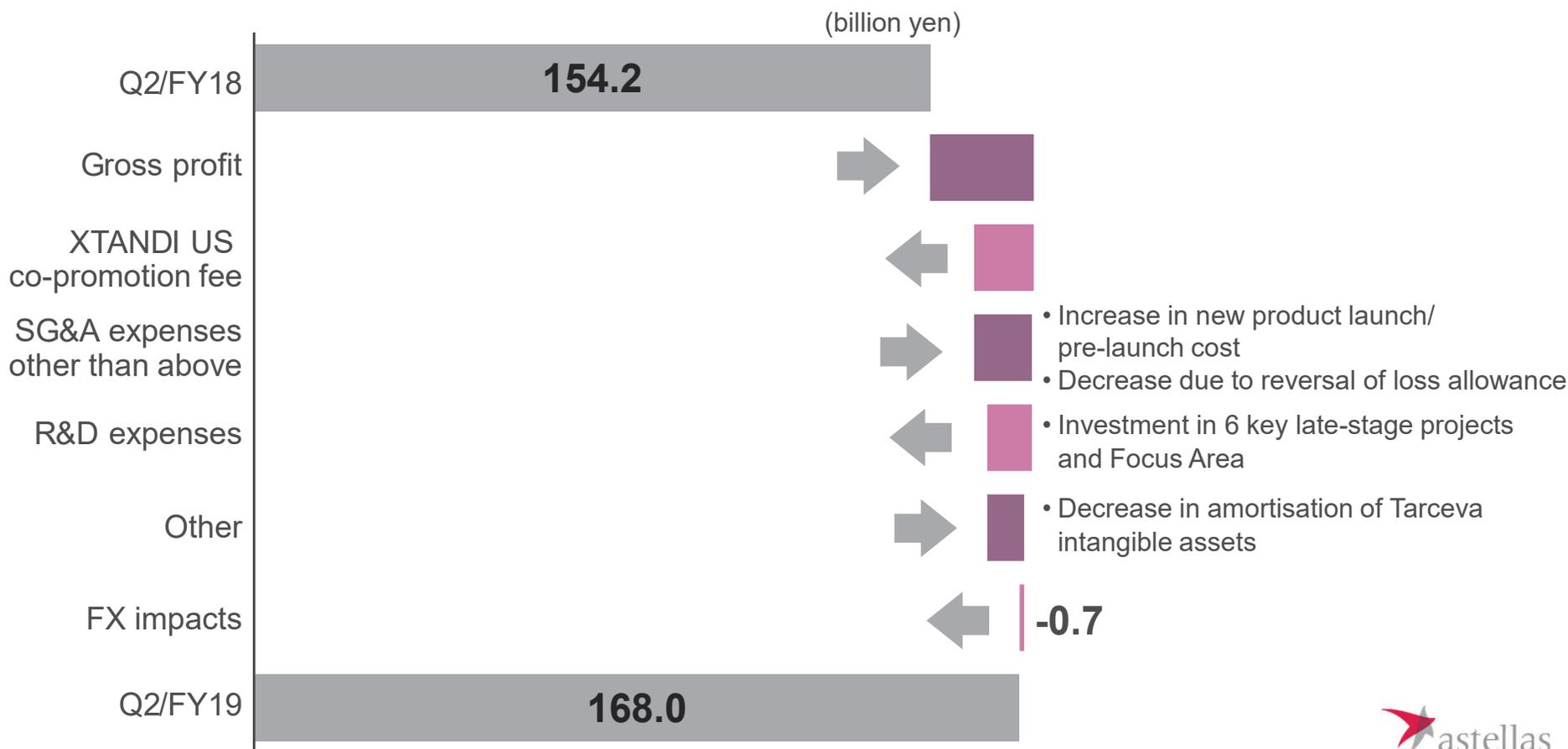
Sales increase in XTANDI, XOSPATA, mirabegron and new products in Japan offset the LOE impacts of Vesicare and Tarceva, etc.



mirabegron (Betanis/Myrbetriq/BETMIGA)
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

CORE OP ANALYSIS (YEAR ON YEAR)

In addition to major products/new products contributing to an increase in gross profit, SG&A expenses decreased due to one-off factor resulting in 9% core OP increase



Q2/FY2019 FINANCIAL RESULTS (FULL BASIS)

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(billion yen)	Q2/FY18	Q2/FY19	Change	FY19 FCST *	Progress
Core operating profit	154.2	168.0	+8.9%	240.0	70.0%
Other income	4.7	7.2	+54.3%		
Other expense	32.0	13.0	-59.4%		
Operating profit	126.8	162.2	+27.9%	229.0	70.8%
Profit before tax	128.3	161.6	+25.9%	230.0	70.3%
Profit	103.9	128.5	+23.7%	182.0	70.6%
EPS (yen)	53.20	68.16	+28.1%	96.51	70.6%



* Announced in Apr 2019

SALES OF MAIN PRODUCTS: XTANDI, XOSPATA, MIRABEGRON

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	Q2/FY18	Q2/FY19	(billion yen)
XTANDI	164.0	195.0 (+19%)	<ul style="list-style-type: none"> Steady growth in all regions due to penetration in earlier stage of prostate cancer Increase of US M0 CRPC prescriptions
XOSPATA* (Launched in Dec. 2018) <small>* Total of JP, US</small>	—	5.7	<ul style="list-style-type: none"> In 2019 NCCN guideline, XOSPATA has been added as Category 1 for the treatment of FLT3 mut+ R/R AML patients. This category is for treatment with the highest level of evidence ADMIRAL study results published in New England Journal of Medicine
mirabegron	68.6	78.8 (+15%)	<ul style="list-style-type: none"> Double-digit growth in all regions Conducting disease awareness activities Increasing prescriptions as first choice therapy based on mechanism of action and product features

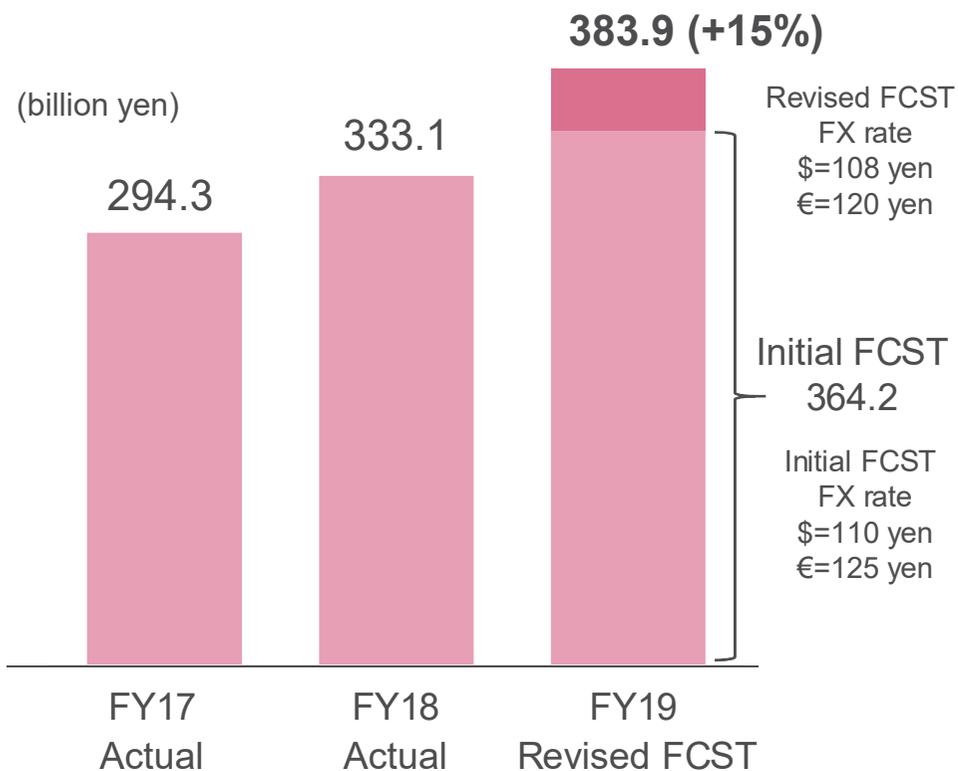


mirabegron (Betanis/Myrbetriq/BETMIGA)

M0: Non-metastatic, CRPC: Castration-resistant prostate cancer, NCCN: National Comprehensive Cancer Network, FLT3 mut+ : FLT3 mutation positive, R/R: Relapsed or refractory, AML: Acute myeloid leukemia

Upward revision of initial forecasts (Global sales: 364.2 → 383.9 billion yen)

Global sales trend



FY19 forecasts: Adjustment amount

US	+\$174M
Established Markets	€ 68M
International	+1.4 bil. yen
Japan	No change
Greater China	-0.5 bil. yen



Established Markets: Europe, Canada, Australia

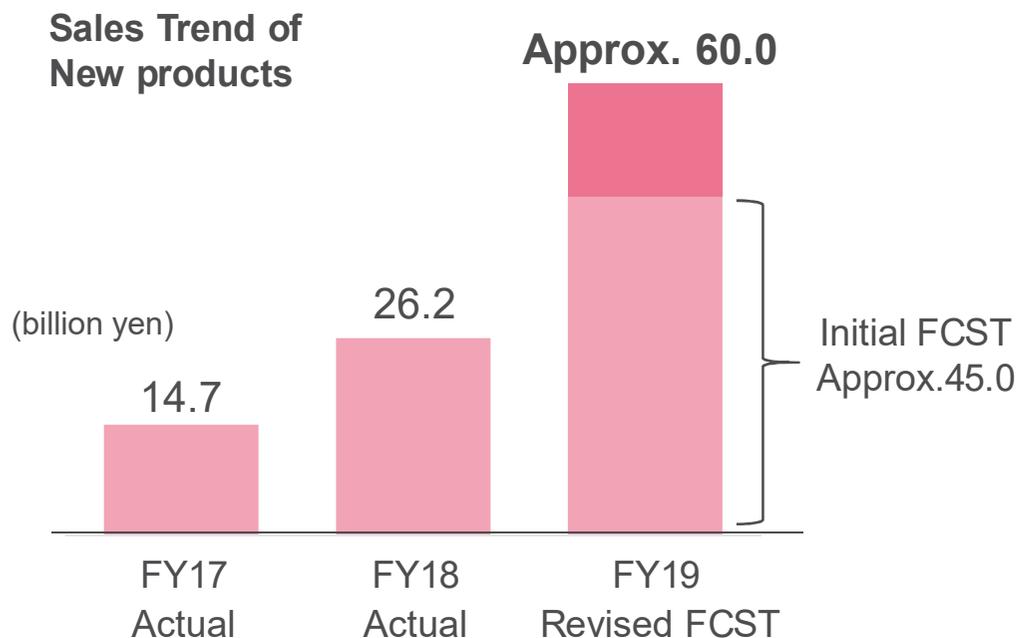
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

Greater China: China, Hong Kong, Taiwan

NEW PRODUCTS IN JAPAN*

Q2 sales increased significantly with continued launches/additional indications
 Upward revision of initial forecasts for new products (Approx.45.0 → 60.0 billion yen)

(billion yen)	Q2/FY18	Q2/FY19	YoY
Total Sales of New products	11.2	27.8	+147%



Exceed 100.0 billion yen in early 2020s



Additional indication
June 2019



Additional indication
Aug 2018



Launched in
Sep 2018



Launched in
Mar 2019



Additional indication
Dec 2018



Launched in
May 2018



Launched in
Nov 2018



Launched in
July 2019



* New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

- **Steady performance of XTANDI and new products in Japan such as EVENITY**
- **One-off factors that were not included into initial forecasts**
 - ✓ Revenue
 - Transfer of three products in Asia region to Daiichi Sankyo
 - Upward revision of US Prograf (Increase in demand due to shortage of generic tacrolimus in the market)
 - ✓ Expenses
 - Reversal of loss allowance related to a domestic partner
- **Factors affecting lower revenue in the second half that have been included into initial forecasts**
 - LOE impact of Vesicare and Tarceva
 - Termination of sale and distribution for Symbicort and KM bio products
 - NHI price revision in Oct. 2019 and lower sales prior to NHI price revision in Apr. 2020

REVISED FORECASTS FOR FY2019

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(billion yen)	FY19 Initial FCST	FY19 Revised FCST	Change
Revenue	1,224.0	1,256.0	+32.0
R&D expenses	211.0	216.0	+5.0
% of revenue			
Core operating profit	240.0	264.0	+24.0
Core profit	194.0	214.0	+20.0
Core EPS (yen)	102.87	113.49	+10.62
Operating profit	229.0	263.0	+34.0
Profit	182.0	210.0	+28.0
EPS (yen)	96.51	111.37	+14.86



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ENHANCEMENT OF INITIATIVES IN CHINA

Enhancement of development and regulatory functions for the development of late-stage projects

Aiming for 200.0 billion yen sales in the overall Chinese business in late 2020s

Progress of clinical development in China

Projects	indication	Current Status
enzalutamide (XTANDI)	M1 CRPC	Regulatory decision expected in FY19
	M0 CRPC	sNDA submitted in Oct 2019 based on global P3 study data
	M1 HSPC	FSFT of China P3 study in Sep 2019
gilteritinib (XOSPATA)	R/R AML	P3 study ongoing including China
enfortumab vedotin	mUC	Development plan under discussion
zolbetuximab	Gastric and GEJ adenocarcinoma	Will begin enrollment in China in global P3 studies in FY19
fezolinetant	MR-VMS	IND for P3 studies submitted
peficitinib	RA	Asian P3 study ongoing



M1: Metastatic, M0: Non-metastatic, CRPC: Castration-resistant prostate cancer, HSPC: Hormone-sensitive prostate cancer, sNDA: Supplemental new drug application, FSFT: First subject first treatment, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, mUC: Metastatic urothelial cancer, GEJ: Gastroesophageal junction, MR-VMS: Menopause-related vasomotor symptoms, IND: Investigational new drug, RA: Rheumatoid arthritis

CONTINUED PROGRESS ON 6 POST-POC PROJECTS

Development advancing as planned in Strategic Plan 2018

Progress since Q1/FY2019 announcement in July 2019

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

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 Q1/FY2019 announcement in July 2019)

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enzalutamide

M1 HSPC

- Filed in US (June 2019; PDUFA Date set in Dec 2019 under Priority Review), EU (July 2019) and JP (July 2019)

M0 HSPC

- **Phase 3 study:** Ongoing

China

- **M1 CRPC:** Regulatory decision expected in FY2019
- **M0 CRPC:** sNDA submitted in Oct 2019
- **M1 HSPC:** Phase 3 study FSFT achieved in Sep 2019

gilteritinib

R/R FLT3 mut+ AML

- **JP:** Label updated in Aug 2019 to include OS data
- **EU:** Approved in Oct 2019

Other AMLs

- **Phase 3 studies:** Ongoing

enfortumab vedotin

mUC (platinum and PD-1/L1 inhibitor pretreated)

- Filed in US in July 2019 (PDUFA Date set in Mar 2020 under Priority Review)

mUC (1st line)

- Results from Phase 1 study in combination with pembrolizumab presented at ESMO 2019

zolbetuximab

Gastric and gastroesophageal junction adenocarcinoma

- **Phase 3 studies:** Ongoing

Pancreatic adenocarcinoma

- **Phase 2 study:** Ongoing

roxadustat

Anemia associated with CKD

- **EU:** MAA targeting FY2019
- **JP:** Approved for patients on dialysis in Sep 2019. For non-dialysis, TLR of the remaining study expected in 2019

Chemotherapy-induced anemia

- **Phase 2 study:** FSFT achieved in Aug 2019

fezolinetant

Menopause-related vasomotor symptoms

- **US/EU:** Phase 3 studies FSFT achieved in Aug 2019
- **JP:** Development plan under preparation
- **China:** IND for Phase 3 studies submitted

ENFORTUMAB VEDOTIN: mUC

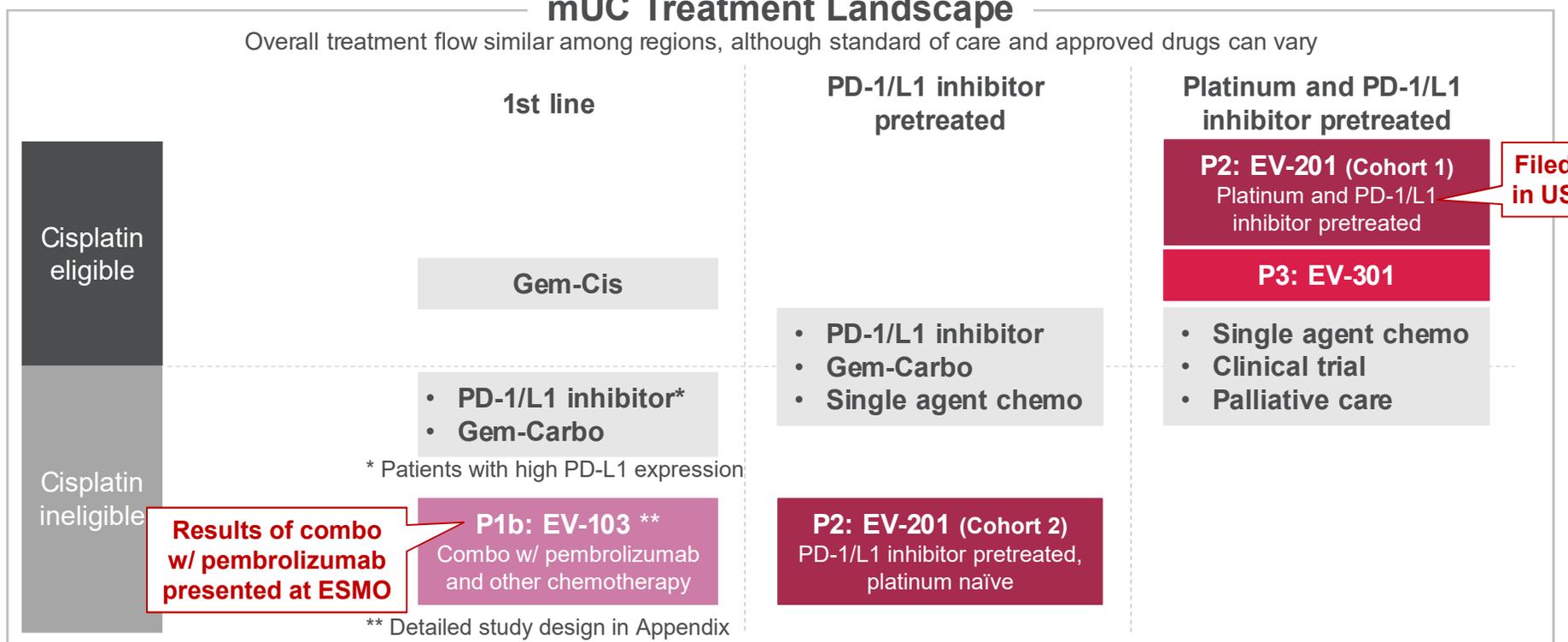
Platinum and PD-1/L1 inhibitor pretreated:

Filed in US in July 2019, PDUFA Date set in March 2020 under Priority Review

1st line: Results from Phase 1 EV-103 study in combination with pembrolizumab presented at ESMO 2019, Phase 3 program currently under preparation

mUC Treatment Landscape

Overall treatment flow similar among regions, although standard of care and approved drugs can vary



ENFORTUMAB VEDOTIN: EV-103 RESULTS (1/3)

Objective Response Rate (ORR)

18

High ORR (71%) in enfortumab vedotin + pembrolizumab cohorts in cisplatin-ineligible patients with locally advanced or metastatic UC

ORR per RECIST v1.1 by investigator

18 Jun 2019 data cut-off

Patients (N=45)

n (%)

Confirmed ORR

95% confidence interval

32 (71)

(55.7, 83.6)

Best Overall Response per RECIST v1.1

Complete response

6 (13)

Partial response

26 (58)

Stable disease

10 (22)

Progressive disease

1 (2)

Not evaluable¹

2 (4)

1: Two patients did not have post-baseline response assessments before end-of-treatment; 1 withdrew consent and 1 died before any post-baseline response assessment

ENFORTUMAB VEDOTIN: EV-103 RESULTS (3/3)

Treatment-Related Adverse Events (TRAE)

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TRAEs by preferred term Any grade in ≥ 20% of patients and ≥ Grade 3 in ≥ 10% of patients	Patients (N=45) n (%)	
	Any Grade	≥ Grade 3
Overall	43 (96)	23 (51)
Fatigue	22 (49)	4 (9)
Alopecia	21 (47)	N/A
Peripheral sensory neuropathy	21 (47)	2 (4)
Diarrhea	18 (40)	2 (4)
Decreased appetite	15 (33)	0
Dysgeusia	14 (31)	N/A
Nausea	13 (29)	0
Pruritus	12 (27)	1 (2)
Rash maculo-papular	12 (27)	3 (7)
Weight decreased	10 (22)	0
Anemia	9 (20)	2 (4)
Lipase increased	7 (16)	6 (13)

- 7 patients had treatment-related serious adverse events (16%)
- 4 treatment-related discontinuations of enfortumab vedotin + pembrolizumab due to adverse events (9%)
 - Peripheral sensory neuropathy most common: 2 patients
- 1 treatment-related death as reported by investigator (2%)
 - Multiple organ dysfunction syndrome
 - Confounded by concomitant acute onset of atrial fibrillation, corticosteroids, and amiodarone

N/A: Not applicable

ENFORTUMAB VEDOTIN:

Number of 1st Line Drug Treated Patients with Metastatic UC

In addition to expanding the target patient number, expected to have longer duration of therapy in 1st line

Potential sales size at peak including 1st line to be 100.0 - 200.0 billion yen

Urothelial Cancer (Annual)	All Stages (Incidence)	Metastatic (Incident + Newly Recurrent)	Drug Treated mUC (1L)	Drug Treated mUC (2L+*)
Total G7 (US/EU5/JP)	236,000	56,000	49,000	23,000
US	79,000	19,000	15,000	8,000
EU5	118,000	29,000	27,000	12,000
JP	39,000	8,000	7,000	3,000

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



Kantar Health incident and newly recurrent patients
mUC: Metastatic urothelial cancer

*2L+: Platinum and/or PD-1/L1 inhibitor pretreated

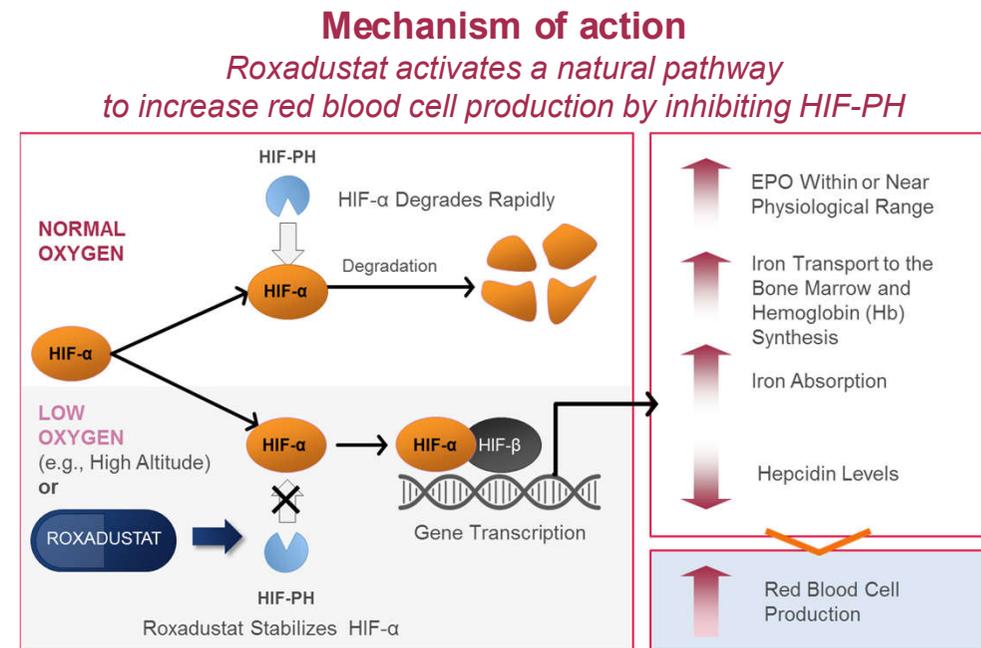
ROXADUSTAT: DEVELOPMENT IN JAPAN



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Approved in Japan in Sep 2019 for renal anemia in patients on dialysis as a first-in-class orally administered HIF-PH inhibitor

- Discovered by FibroGen and being developed by Astellas in Japan
- Novel mechanism of action, which is different from that of the current standard of care such as erythropoiesis-stimulating agents (ESAs)
- Orally administered, three times per week
- NDA approved for dialysis patients, based on the four Phase 3 studies in Japan, where roxadustat showed comparable efficacy (raising hemoglobin) to ESA and was well-tolerated
- For non-dialysis, one Phase 3 study completed and another study TLR expected in 2019, followed by supplemental NDA submission



FOCUS AREA APPROACH: IMMUNO-ONCOLOGY ASSETS

Details of the immuno-oncology assets to be introduced at Astellas R&D Meeting on Dec 10, 2019



Compound	Modality/Mechanism	Origin/Partner	Target Tumor	Current Stage	
				Preclinical /Research	Clinical Phase 1
ASP8374	Anti-TIGIT antibody	 POTENZA [*] therapeutics	(To be determined)		
ASP1948	Anti-NRP1 antibody	 POTENZA [*] therapeutics	(To be determined)		
ASP1951	GITR agonistic antibody	 POTENZA [*] therapeutics	(To be determined)		
ASP9801	Oncolytic virus	 Tottori University ^{**}	(To be determined)		
ASP7517	WT1 loaded artificial adjuvant vector cell (aAVC)	 RIKEN ^{**}	Acute myeloid leukemia, Myelodysplastic syndrome (as the first targets)		
(Not disclosed)	Other tumor antigens loaded aAVC	 RIKEN ^{**}	(Not disclosed yet)		

* Acquired in 2018 (currently their programs classified into in-house ones), ** Programs developed under joint research

PROGRESS IN FOCUS AREA APPROACH (1/2)

Licensing agreement with RIKEN for artificial adjuvant vector cell (aAVC) technology as a novel and promising immuno-oncology platform

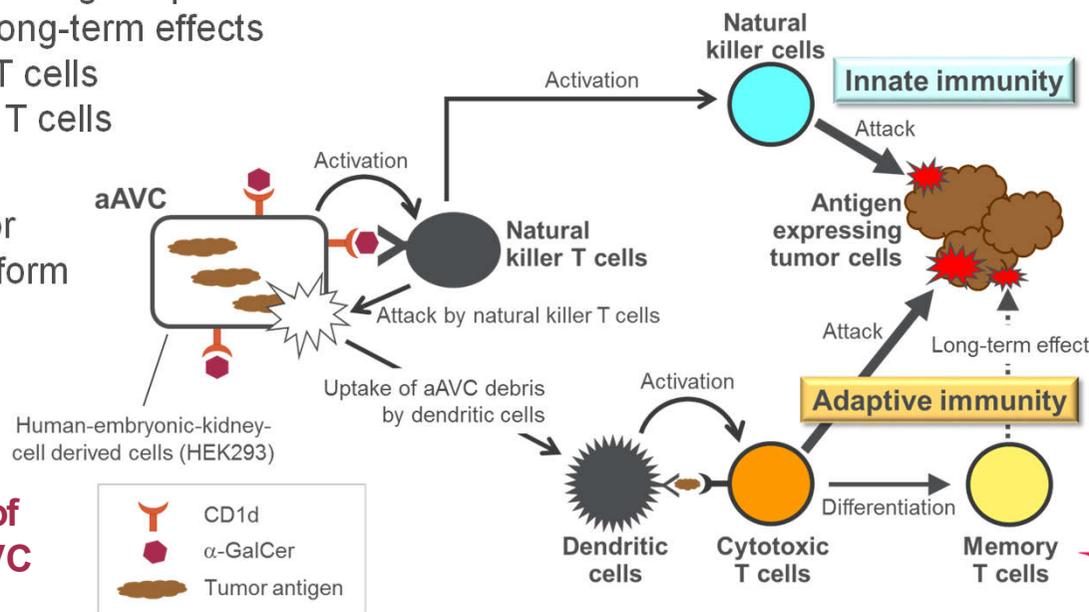


aAVC characteristics

- Expects to show anti-tumor effects by activating both
 - ✓ “Innate immunity” through natural killer cells and
 - ✓ “Adaptive immunity” through antigen-specific cytotoxic T cells as well as long-term effects through long-lived memory T cells differentiated from cytotoxic T cells
- Has potential to target many tumor types by changing tumor antigen loaded into aAVC platform

Lead aAVC program - ASP7517

- aAVC loading WT1, a tumor antigen highly expressed in AML
- FSFT of Phase 1 part in Phase 1/2 study in AML and MDS achieved in Oct 2019



PROGRESS IN FOCUS AREA APPROACH (2/2)

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Fast Track designated by FDA for ASP1128/MA-0217 program for patients at risk of acute kidney injury (AKI) after cardiac surgery



Mitochondria biology

- Mitochondrial dysfunction contributes to various disease pathogenesis
- Acquired Mitobridge that has expertise in mitochondrial biology-based R&D in 2018 and obtained their clinical and preclinical programs targeting mitochondrial functions for kidney, muscle and other kind of diseases
- “Mitochondria biology” is one of our four “Primary Focus”

Unmet medical needs of AKI

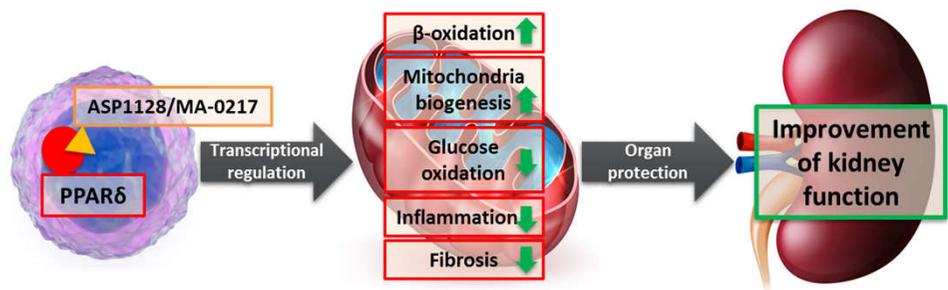
- AKI is rapid loss of renal function and associated with progression to chronic kidney disease and end-stage renal disease¹ and increased morbidity/mortality^{2,3}
- AKI occurs in up to 30% of cardiac surgery patients⁴, and 2% to 6% of these cases require dialysis^{2,5,6}
- No approved therapies available for either preventing or treating AKI

ASP1128/MA-0217 characteristics

- Selective PPAR δ modulator, discovered by Mitobridge
- Designated by FDA as a Fast Track development program for patients who are at increased risk of developing moderate to severe AKI after coronary artery bypass graft and/or valve surgery
- Phase 2a study ongoing



Mechanism of action of ASP1128/MA-0217



1: Molitoris BA, 2014, 2: Hu J, *et al.*, 2016, 3: Bellomo R, *et al.*, 2012, 4 : Rosner MH & Okusa MD, 2006, 5: Thiele RH, *et al.*, 2015, 6: Bastin AJ, *et al.*, 2013
FDA: Food and Drug Administration, PPAR δ : peroxisome proliferator-activated receptor delta

KEY EVENTS EXPECTED IN FY2019

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Regulatory decisions	enzalutamide	M1 castration-resistant prostate cancer (China) M1 hormone-sensitive prostate cancer (US ^a)
	enfortumab vedotin	Metastatic urothelial cancer, platinum and PD-1/L1 inhibitor pretreated (US ^{a,b})
Regulatory submissions *	roxadustat	Anemia associated with chronic kidney disease, dialysis/non-dialysis (EU)
Data readouts	roxadustat	P3 study in Japanese patients (anemia associated with chronic kidney disease, non-dialysis: 1517-CL-0310)

* Subject to study outcome, internal assessment, decision and regulatory consultation, as appropriate

a: Priority Review granted, b: Breakthrough Therapy designated

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



UPDATES IN Rx+™ PROGRAM

- New digital healthcare solutions using gamification-

- “Health Mock Lab.”, a virtual framework for industry-academia collaboration with Yokohama City University and Tokyo University of the Arts, has launched.
- Aiming to create and commercialize new digital healthcare solutions using gamification.

Yokohama City University

- Screen and refine ideas from medical perspectives
- Plan and conduct clinical studies.



Tokyo University of the Arts

- Screen and refine ideas from gamification perspectives
- The production of prototypes



Health Mock Lab.

- ✓ Creation of new healthcare solutions
- ✓ Creation of interdisciplinary studies

- Screen and refine ideas from business perspectives
- Support to plan and conduct clinical studies.

Astellas

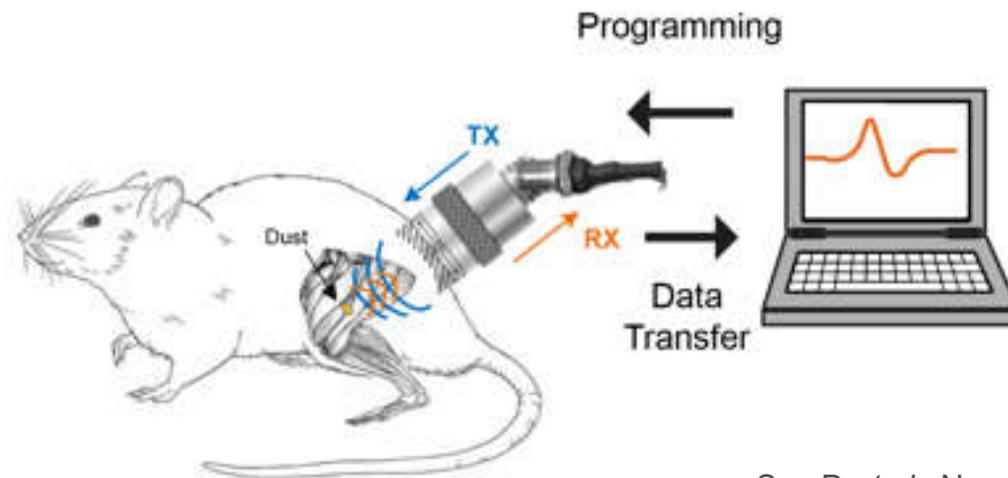
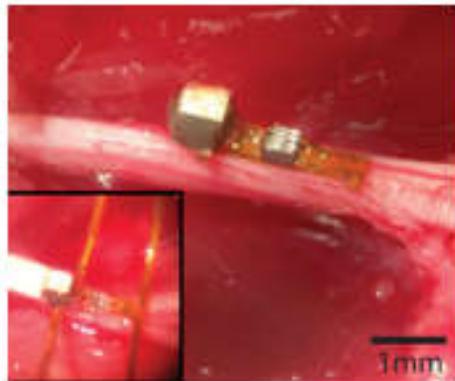


UPDATES IN Rx+™ PROGRAM

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- Novel ultra-small implantable medical devices-

- *Joint research and development agreement with Iota Biosciences, Inc.*
- *Expecting to develop new bio sensing and treatment measures using ultra-small implantable medical devices.*
- *Iota and Astellas will jointly design detailed specifications of implantable medical devices and conduct preclinical studies for several diseases with high unmet medical needs.*



Seo D *et al.*, Neuron, 2016

iota's proprietary technology-

- ✓ Uses ultrasound as a tool for power supply and wireless communication
- ✓ Ability to develop battery-free and wireless ultra-small implantable medical devices.
- ✓ This platform enables monitor and stimulate organs directly.



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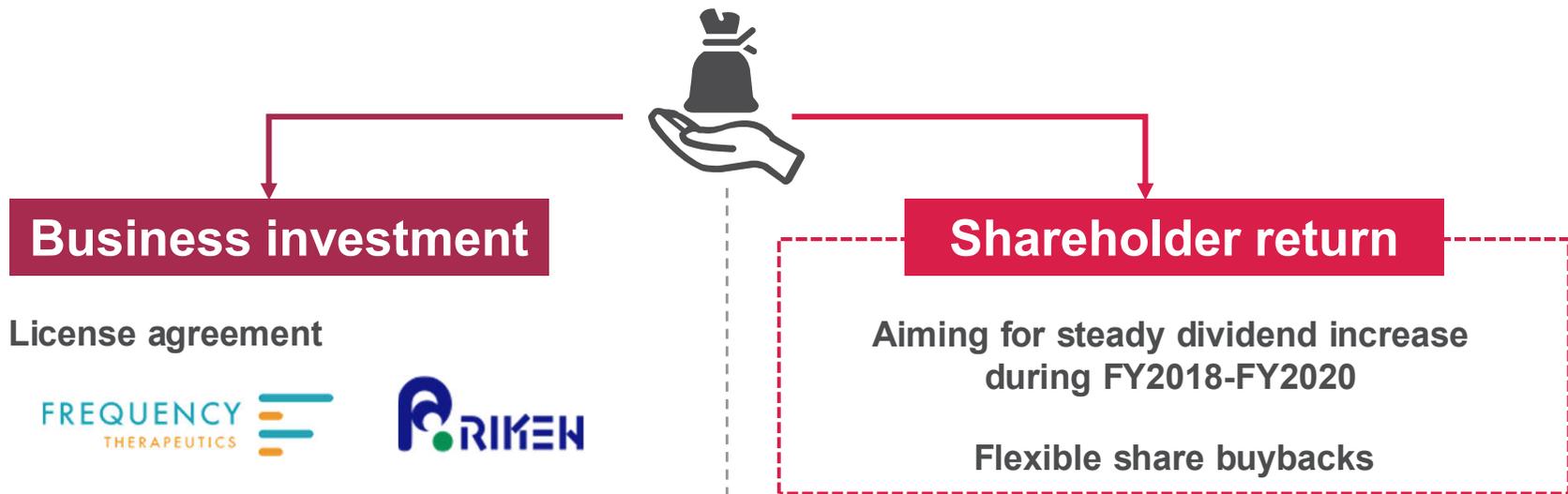
Capital Allocation

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



	FY2017 ACT	FY2018 ACT	FY2019 FCST
Dividend	36 yen	38 yen	40 yen (forecast)
Share buybacks	130.0 billion yen	160.0 billion yen	Flexible share buybacks
Total return ratio	123%	105%	-

R&D meeting
- Approaches to immuno-oncology -

Date: December 10, 2019



APPENDIX

Q2/FY2019: REVENUE BY REGION

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(billion yen)	Q2/FY18	Q2/FY19	Change
Japan	180.7	183.3	+1.5%
United States	207.9	216.7	+4.2%
Established Markets	149.6	146.7	-1.9%
Greater China	29.3	29.4	+0.4%
International	63.2	63.4	+0.3%

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.



Q2/FY2019: SALES OF MAIN PRODUCTS

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(billion yen)	Q2/FY18	Q2/FY19	Change	CER growth	FY19 FCST*	Progress
XTANDI	164.0	195.0	+18.9%	+22.8%	364.2	53.5%
XOSPATA	-	5.7	-	-	15.1	37.7%
OAB products	116.7	103.8	-11.0%	-8.8%	202.4	51.3%
mirabegron	68.6	78.8	+14.9%	+17.5%	160.6	49.1%
Vesicare	48.1	25.1	-47.9%	-46.2%	41.8	60.0%
Prograf	100.4	96.2	-4.2%	-0.0%	187.7	51.2%



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

*Announced in Apr. 2019

FX RATE (ACTUAL)

35

Average rate for the period

Currency	Q2/FY18	Q2/FY19	change
USD	110 yen	109 yen	-2 yen
EUR	130 yen	121 yen	-8 yen

Change in closing rate from PY end

Currency	Q2/FY18	Q2/FY19
USD	+7 yen	-3 yen
EUR	+2 yen	-7 yen

Fx impact on elimination of unrealized gain: COGs ratio -1.4ppt

FY2019 REVISED FCST: FX RATE & FX SENSITIVITY

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Exchange rate (yen) Average for the period	FY19 Initial FCST	FY19 Revised FCST
USD	110 yen	108 yen
EUR	125 yen	120 yen

FX impacts vs. initial forecasts
(billion yen)

- Revenue : -27.9
- Core operating profit: -7.0

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

Estimated Fx sensitivity (Q3 and onward) of FY2019 revised forecasts by 1 yen appreciation*

Currency	Average rate 1 yen higher than assumption		Year-end rate 1 yen higher than assumption
	Revenue	Core OP	Core OP
USD	Approx. -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

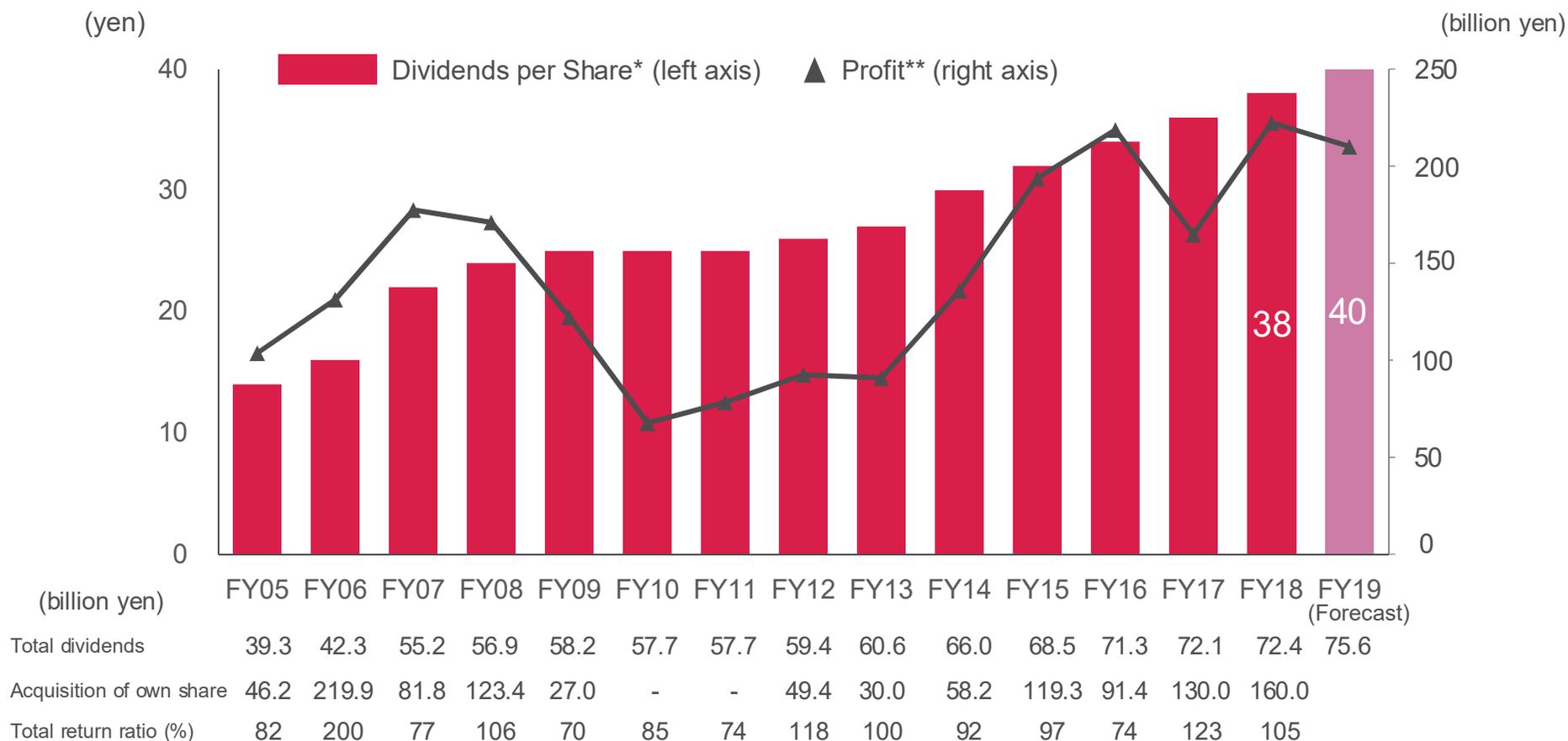
37

(billion yen)	FY18 end	Sep. 2019
Total assets	1,897.6	1,979.8
Cash and cash equivalents	311.1	311.4
Total equity attributable to owners of the parent	1,258.4	1,296.1
Equity ratio (%)	66.3%	65.5%

(billion yen)	Q2/FY18	Q2/FY19	FY18
Cash flows from operating activities	112.1	101.7	258.6
Cash flows from investing activities	-7.8	-46.6	-41.8
Free cash flows	104.3	55.1	216.9
Cash flows from financing activities	-136.5	-46.0	-233.7
Acquisition of treasury shares	-100.4	-1.2	-160.4
Dividends paid	-35.6	-35.8	-72.1

DETAILS OF SHAREHOLDER RETURNS

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* 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 HSPC (US,EU,JP) ✓ ✓	enzalutamide M0 HSPC
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 (1 st line low intensity induction chemo)
		gilteritinib AML (1 st 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, HSPC: Hormone-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	Phase 2	Phase 3	Filed
ASP1235/AGS62P1	zolbetuximab (Pancreatic adenocarcinoma)	enzalutamide (M0 HSPC, M1 HSPC: China)	enzalutamide (M1 CRPC: China)
ASP8374/PTZ-201	ASP1650 (Testicular cancer)	gilteritinib (R/R AML: China, Other AML)	enzalutamide (M1 HSPC: US,EU,JP)
ASP1948/PTZ-329	reldesemtiv (SMA, ALS)	enfortumab vedotin (Urothelial cancer)	enzalutamide (M0 CRPC: China)
ASP1951/PTZ-522	ASP7317 (Dry AMD, etc.)	zolbetuximab (Gastric and GEJ adenocarcinoma)	enfortumab vedotin (Metastatic urothelial cancer, platinum and PD-1/L1 pretreated: US)
ASP9801	ASP1128/MA-0217 (AKI)	peficitinib (Rheumatoid arthritis: China)	solifenadin* (Pediatric NDO: US)
ASP7517	ASP3772 (Pneumococcal disease)	mirabegron (Pediatric OAB & NDO)	fidaxomicin (<i>Clostridium difficile</i> infection in pediatric patients: EU)
ASP0892	FX-322 (Sensorineural hearing loss)	roxadustat (Anemia associated with CKD, EU: Non-dialysis/dialysis, JP: Non-dialysis)	micafungin (Invasive candidiasis in neonates and young infants: US)
ASP0367/MA-0211	bleselumab (rFSGS)	fezolinetant (MR-VMS)	
MucoRice-CTB	ASP8302 (Underactive bladder)		
ASP8062	roxadustat (CIA)		
ASP1617	ASP0819 (Fibromyalgia)		
	ASP4345 (CIAS)		
	isavuconazole (Pediatric, US)		

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

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



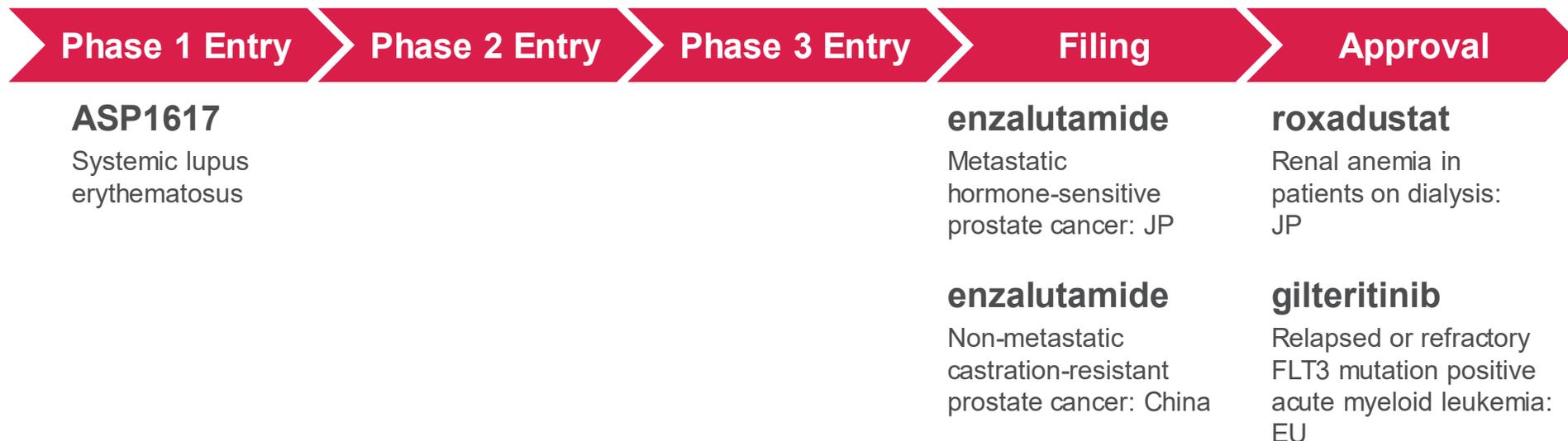
SMA: Spinal muscular atrophy, ALS: Amyotrophic lateral sclerosis, AMD: Age-related macular degeneration, AKI: Acute kidney injury, rFSGS: Recurrence of focal segmental glomerulosclerosis, CIA: Chemotherapy-induced anemia, CIAS: Cognitive impairment associated with schizophrenia, M0: Non-metastatic, M1: Metastatic, HSPC: Hormone-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

* Received Complete Response Letter from FDA in Aug 2017

PROGRESS IN OVERALL PIPELINE

Phase 1 entry to approval, since 1Q/2019 financial results announcement in July 2019

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Discontinuation

AGS-16C3F: Renal cell carcinoma (Phase 2)

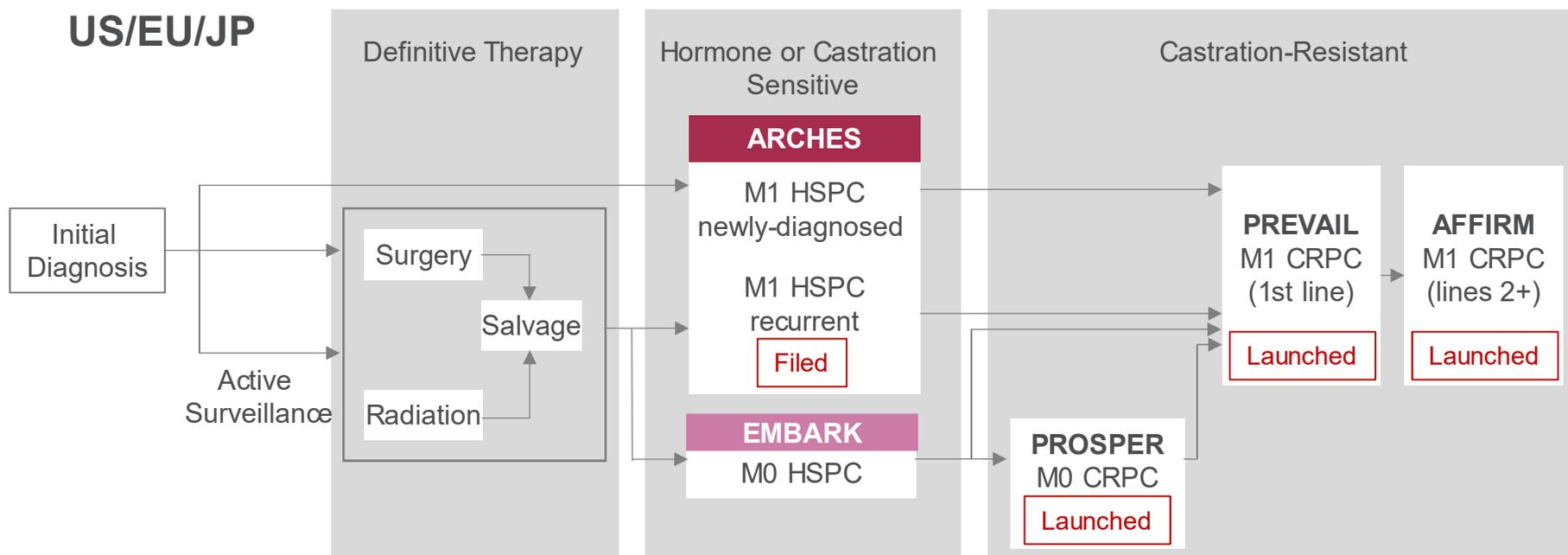
ASP6294: Bladder pain syndrome / interstitial cystitis (Phase 2)

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 HSPC	Combo with ADT, vs. placebo	n=1,150	Filed in US in June 2019 (PDUFA Date set in Dec 2019 under Priority Review), in EU and JP in July 2019 with ARCHES data supported by ENZAMET data
P3: EMBARK	M0 HSPC	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

China

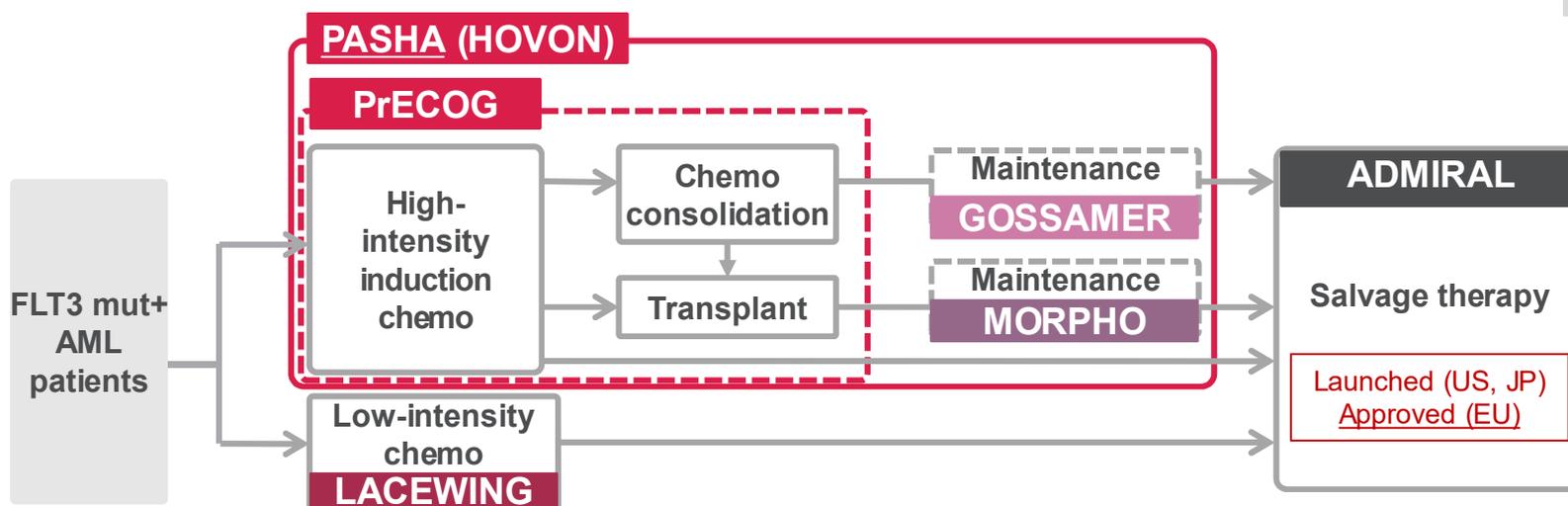
- **M1 CRPC:** Filed in Mar 2018, based on Phase 3 Asian-PREVAIL study data
- **M0 CRPC:** sNDA submitted in Oct 2019, based on global Phase 3 PROSPER study data
- **M1 HSPC:** FSFT of Phase 3 China-ARCHES study in Sep 2019



Underlined: Updates since Q1/FY2019 announcement in July 2019

M1: Metastatic, M0: Non-metastatic, HSPC: Hormone-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy, PDUFA: Prescription Drug User Fee Act, 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	JP: <u>Label updated in Aug 2019 to include OS data</u> EU: <u>Approved in Oct 2019</u>
Newly diagnosed (intensive chemo eligible)	P3: PASHA (HOVON)	Combo with high intensity chemo gilteritinib vs midostaurin (1:1)	n=768	FSFT planned in <u>4Q</u> 2019 (Sponsor: HOVON)
	P2: PrECOG		n=179	FSFT planned in <u>4Q</u> 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: July 2017 Collaborating with BMT-CTN
Post-chemo maintenance	P2: GOSSAMER	Monotherapy vs placebo (2:1)	n=85	Enrollment completed: June 2019

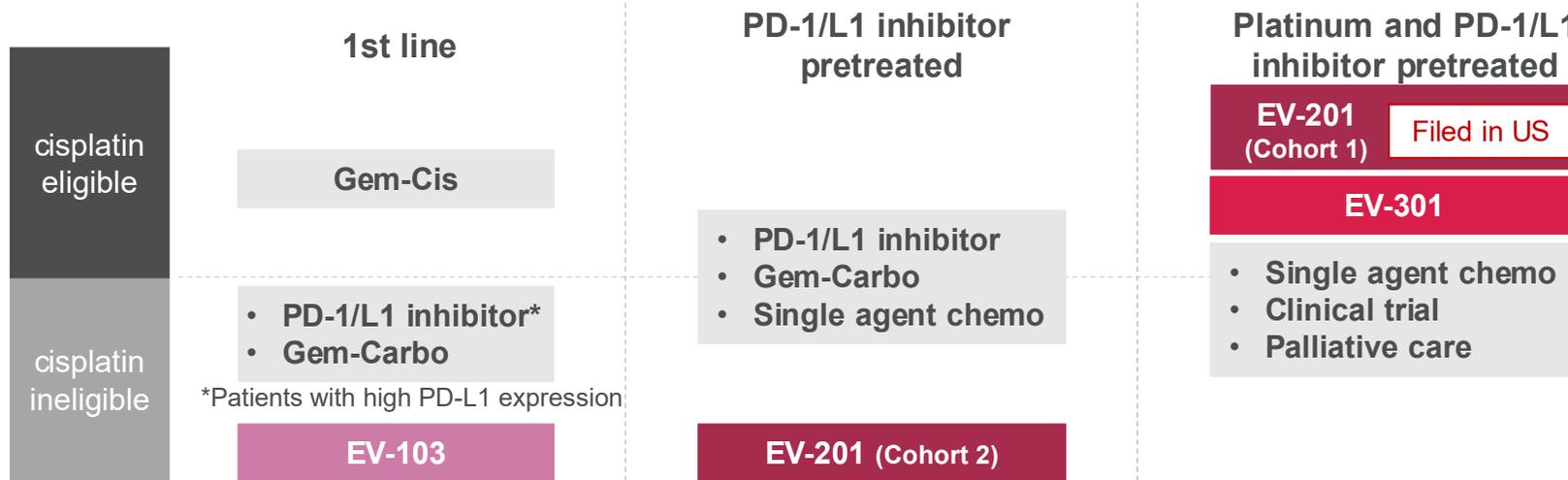


Underlined: Updates since Q1/FY2019 announcement in July 2019

FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, OS: Overall survival, FSFT: First subject first treatment, HSCT: Hematopoietic stem cell transplant, BMT-CTN: Blood and Marrow Transplant - Clinical Trial Network

ENFORTUMAB VEDOTIN: NECTION-4 TARGETED ADC

mUC Treatment Landscape Overall treatment flow similar among regions, although standard of care and approved drugs can vary

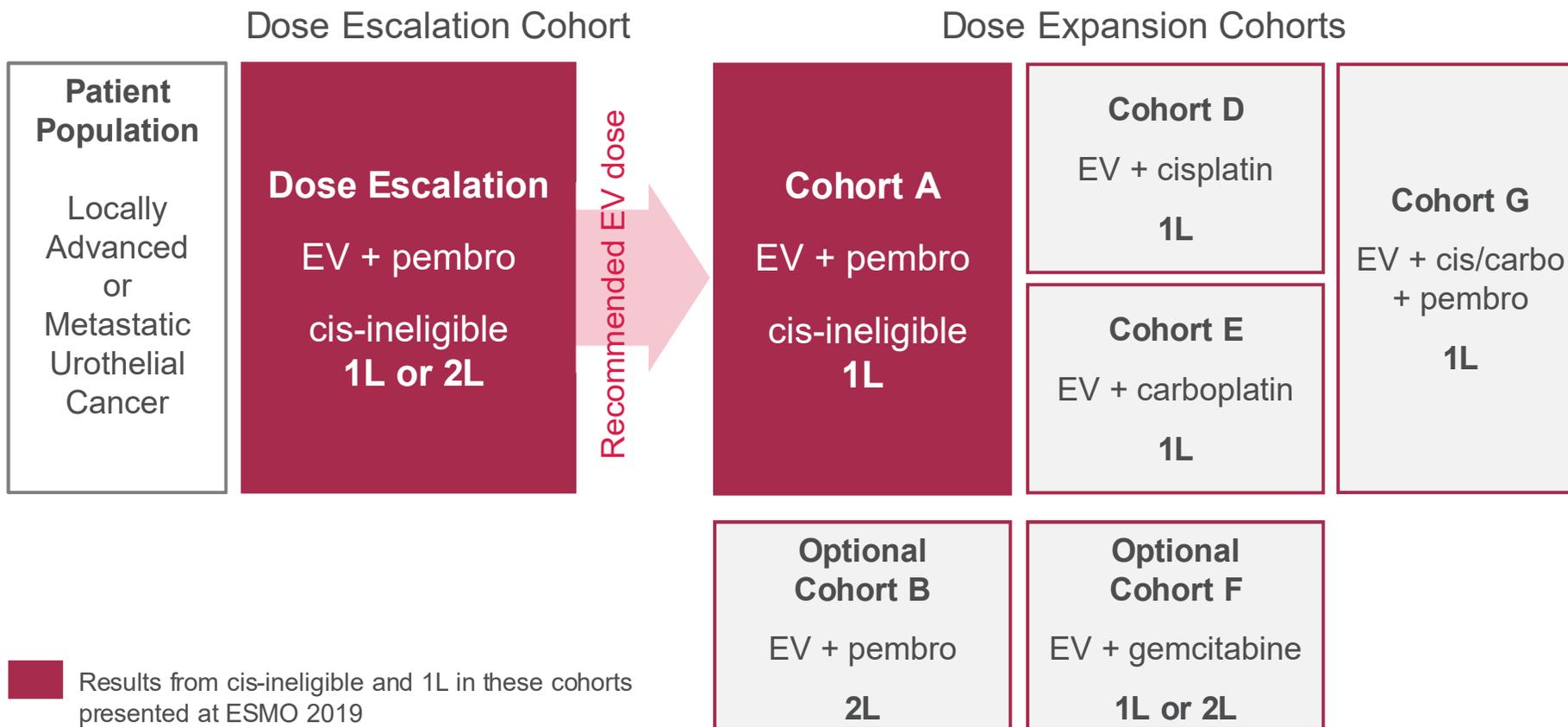


P3: EV-301	Metastatic UC, Platinum and PD-1/L1 inhibitor pretreated	n=550	FSFT: July 2018
P2: EV-201	Metastatic UC, PD-1/L1 inhibitor pretreated Cohort 1: Platinum pretreated Cohort 2: Platinum naïve/cisplatin ineligible	n=200	Cohort 1: Filed in US in July 2019 (PDUFA Date set in Mar 2020 under Priority Review) Cohort 2: Recruiting
P1b: EV-103	Cohorts A - G (Locally advanced or metastatic UC): Combo with pembrolizumab and other chemotherapy Cohorts H & J (Muscle invasive UC): EV monotherapy (H), Combo with pembrolizumab (J)	n=159	FSFT: Nov 2017 Results from the cohorts in combination with pembrolizumab 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 pretreated)	n= 215	Renal insufficiency cohort: Enrollment completed Other cohorts: Enrollment completed

Underlined: Updates since Q1/FY2019 announcement in July 2019

ADC: Antibody-drug conjugate, mUC: Metastatic urothelial cancer, Gem: Gemcitabine, Cis: Cisplatin, Carbo: Carboplatin, FSFT: First subject first treatment, PDUFA: Prescription Drug User Fee Act, ESMO: European Society for Medical Oncology, NSCLC: Non-small cell lung cancer

ENFORTUMAB VEDOTIN: EV-103 STUDY DESIGN



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}

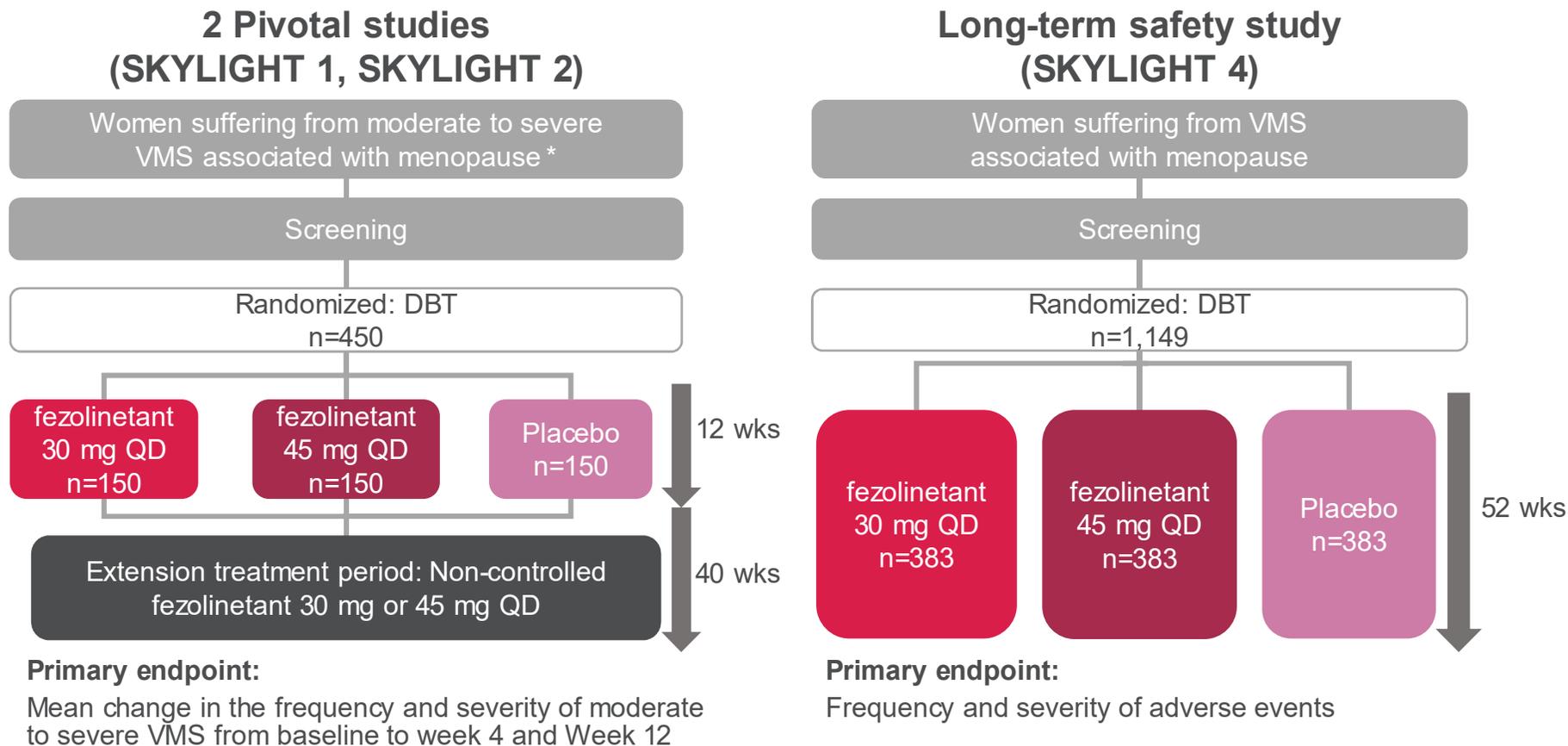
Gastric and GEJ adenocarcinoma	P3: SPOTLIGHT	Combo with mFOLFOX6, vs. placebo	n=550	FSFT: Oct 2018
	P3: GLOW	Combo with CAPOX, vs. placebo	n=500	FSFT: Jan 2019
	P2: ILUSTRO	Monotherapy, Combo with mFOLFOX6	n=102	FSFT: Sep 2018
Pancreatic adenocarcinoma	P2	Combo with nab-paclitaxel and gemcitabine, vs.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



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



* 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

