Q1/FY2019 FINANCIAL RESULTS
ENDED JUNE 30, 2019

Chikashi Takeda
Chief Financial Officer
Astellas Pharma Inc.
July 30, 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.

AGENDA

I Q1/FY2019 Consolidated Financial Results

II Initiatives for Sustainable Growth

III Capital Allocation

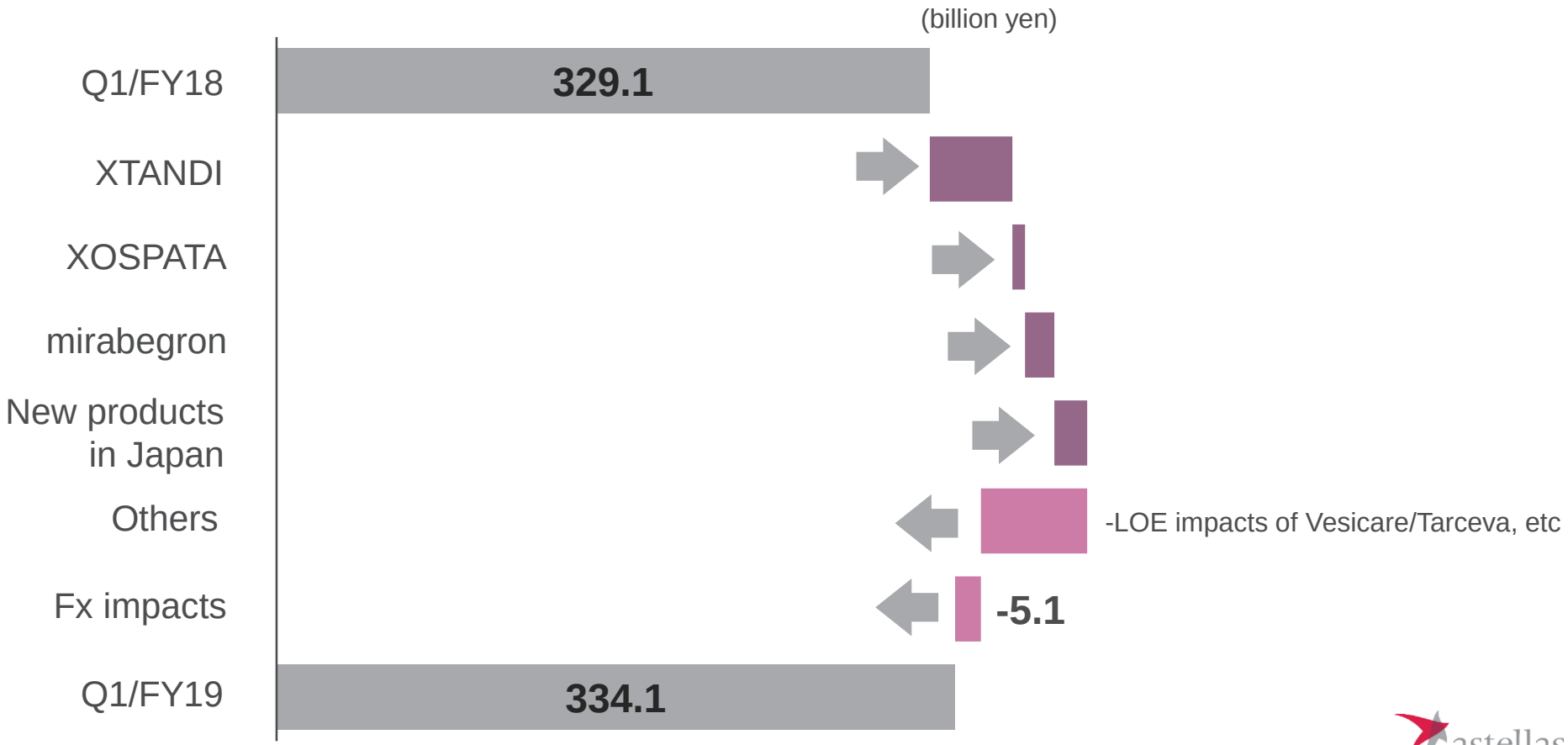
Q1/FY2019 FINANCIAL RESULTS (CORE BASIS)

(billion yen)	Q1/FY18	Q1/FY19	Change	FY19 FCST*	Progress	CER growth
Revenue	**329.1**	**334.1**	**+1.5%**	**1,224.0**	**27.3%**	+3.1%
Cost of sales	70.7	70.5	-0.3%			
% of revenue	21.5%	21.1%				
SG&A expenses	112.9	117.5	+4.1%			
% of revenue	34.3%	35.2%				
R&D expenses	52.1	53.5	+2.6%	211.0	25.4%	
% of revenue	15.8%	16.0%		17.2%		
Amortisation of intangible assets	9.0	7.2	-20.6%			
Share of profit (loss) of investments accounted for using equity method	- 0.3	- 0.7	-			
Core operating profit	**84.0**	**84.7**	**+0.8%**	**240.0**	**35.3%**	+0.4%
Core profit	**70.4**	**67.1**	**-4.6%**	**194.0**	**34.6%**	
Core EPS (yen)	**35.70**	**35.58**	**-0.3%**	**102.87**	**34.6%**	

*Announced in Apr. 2019
CER: Constant Exchange Rate

REVENUE ANALYSIS (YEAR ON YEAR)

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

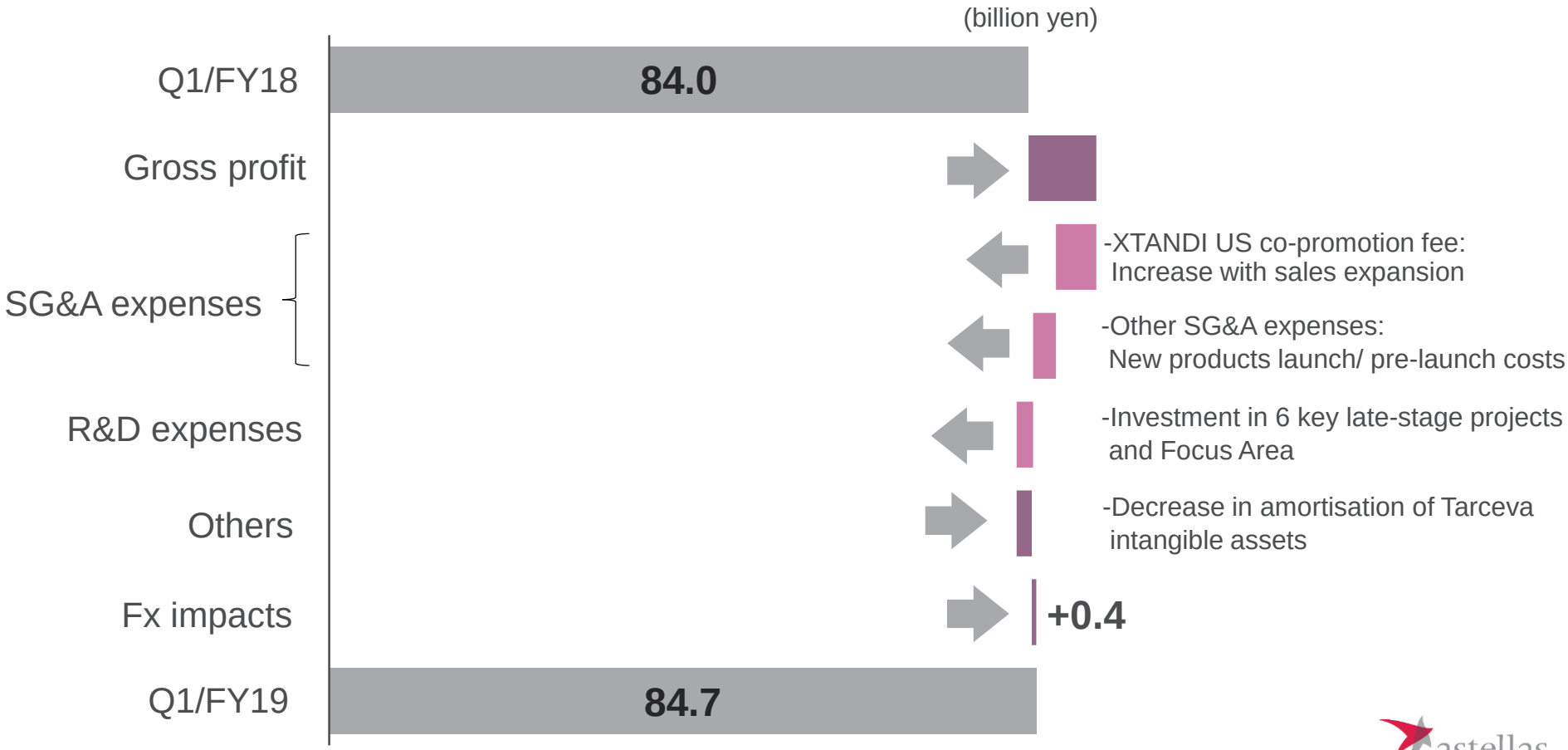


mirabegron (Betanis/Myrbetriq/BETMIGA)
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY)

LOE: Loss of exclusivity

CORE OP ANALYSIS (YEAR ON YEAR)

Steady growth of main products/new products. Resource allocation to growth investment for new product launches and R&D while implementing cost optimization



Q1/FY2019 FINANCIAL RESULTS (FULL BASIS)

(billion yen)	Q1/FY18	Q1/FY19	Change	FY19 FCST*	Progress
Core operating profit	**84.0**	**84.7**	**+0.8%**	**240.0**	**35.3%**
Other income	4.2	4.5	+6.7%		
Other expense	24.7	12.2	-50.8%		
Operating profit	**63.5**	**77.1**	**+21.3%**	**229.0**	**33.7%**
Profit before tax	64.5	76.5	+18.7%	230.0	33.3%
Profit	**54.6**	**58.5**	**+7.3%**	**182.0**	**32.2%**
EPS (yen)	**27.68**	**31.03**	**+12.1%**	**96.51**	**32.2%**

Other expense in Q1/FY19

-Fair value remeasurements on contingent consideration: 11.4 billion yen
(Mainly due to P3 study entry of fezolinetant)

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*Announced in Apr. 2019

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SALES OF MAIN PRODUCTS: XTANDI, XOSPATA, MIRABEGRON

(billion yen)

	Q1/FY18	Q1/FY19	
XTANDI	**81.2**	**96.0 (+18%)**	• *Record quarterly sales* • *Steady growth in all regions due to penetration in earlier stage of prostate cancer* • *M1 HSPC additional indication filed in US and EU*
XOSPATA* **(Launched in Dec. 2018)** * Total of JP, US	**—**	**2.5**	• *Label update to include OS data in May 2019 (US)* • *Many doctors experienced remarkably effective responses in target patients. XOSPATA has been well-accepted thus far*
mirabegron	**34.4**	**39.9 (+16%)**	• *Double-digit growth in all regions* • *Conduct disease awareness activities* • *Increase prescriptions as first choice of therapy due to penetration with mechanism of action and product features*

mirabegron (Betanis/Myrbetriq/BETMIGA)

M1: Metastatic, HSPC: Hormone-sensitive prostate cancer

NEW PRODUCTS IN JAPAN*

Sales doubled with continued launches of new products

(billion yen)	Q1/FY18	Q1/FY19	YoY
Total of New products	**6.3**	**12.8**	**+103%**

EVENITY® Launched in March 2019

- Initial uptake positive thus far (Q1/FY19 actual: 3.5 billion yen)
- EVENITY has dual effects of increasing bone formation and decreasing bone resorption. It reduces the risk of fracture by increasing bone mineral density rapidly and maintaining and improving the micro structure of bone and strengthening it
- Administered once a month for a year, which is expected to improve the convenience for patients
- The adopted facilities exceed our expectations. Steadily increasing the number of prescriptions and the reaction from the prescribers is favorable

Smyraf® Launched in July 2019

- JAK (Janus kinase) inhibitor discovered in Japan
- Confirmed improvement of symptoms in rheumatoid arthritis and suppressive effect of progression of structural damage in joints
- Once daily oral administration
- Two initial doses can be selected depending on the patients' condition and background

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

ENHANCEMENT OF INITIATIVES IN CHINA

Maximize the VALUE of existing growth products/new products and enhance commercial function

(billion yen)	Q1/FY18	Q1/FY19	YoY
Greater China	**13.7**	**14.7**	**+7%** +14% (CER growth)

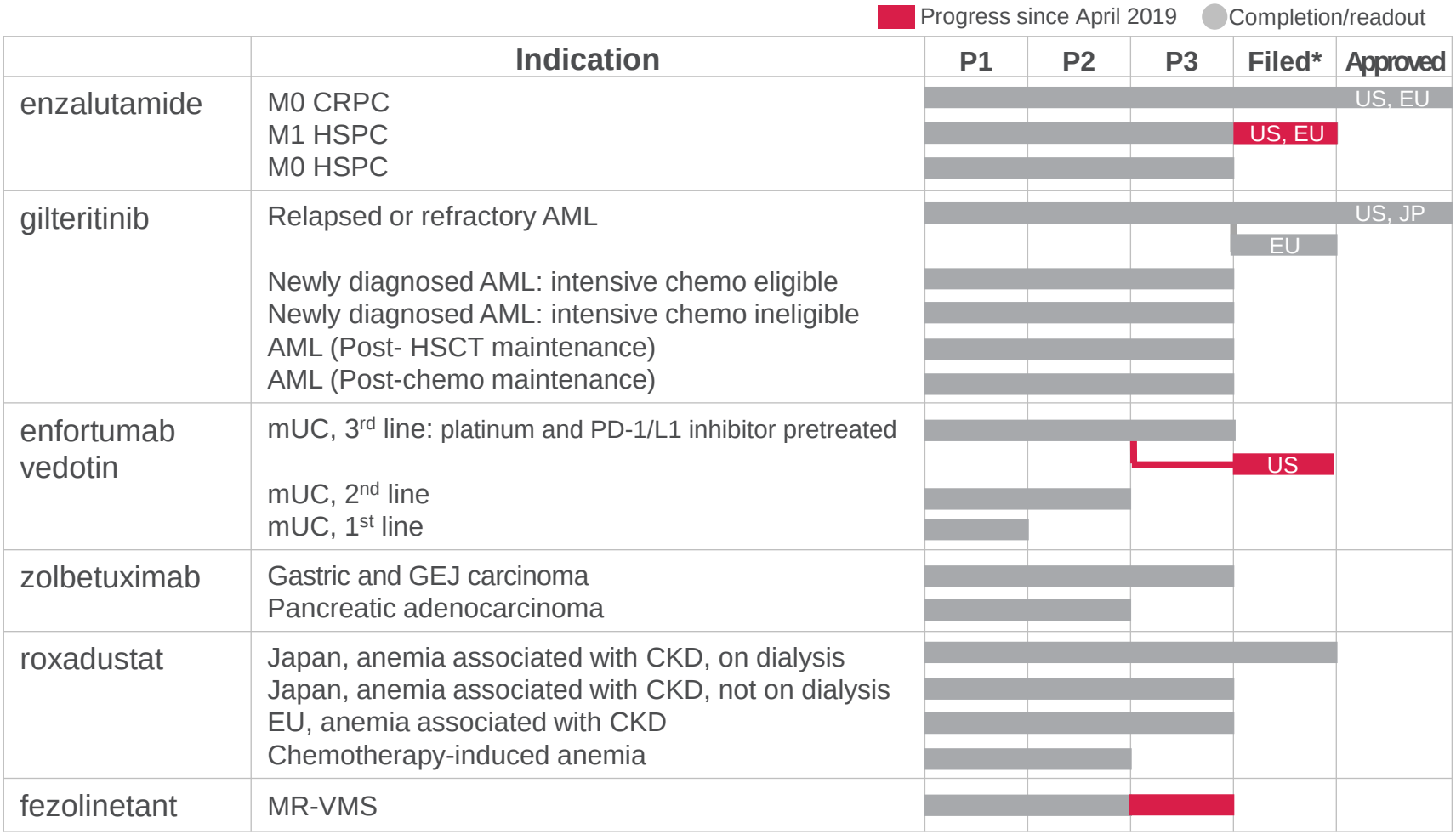
Greater China: China, Hong Kong, Taiwan

<Recent topics in China>

- Expansion of clinical adoption of Advagraf contributing to continued double-digit Prograf sales growth
- Established oncology marketing team to prepare for XTANDI launch
- Established marketing excellence function responsible for Digital Marketing
- Established channel management function responsible for strategy of drugstore channel, which is expected to grow

CONTINUED PROGRESS ON 6 POST-POC PROJECTS SINCE APR 2019

Development advancing as intended in Strategic Plan 2018



*Including submission of application, M0: Non-metastatic, CRPC: Castration-resistant prostate cancer, M1: Metastatic, HSPC: Hormone-sensitive prostate cancer, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, mUC: Metastatic urothelial cancer, GEJ: Gastroesophageal junction, CKD: Chronic kidney disease, MR-VMS: Menopause-related vasomotor symptoms

6 POST-POC PROJECTS: STATUS UPDATE
(Underline: Updates since FY2018 Announcement)

enzalutamide

M1 HSPC

- sNDA submitted in US (Jun 2019) and MAA type II variation filed in EU (Jul 2019)
- ENZAMET: Data presented at ASCO2019

M1 CRPC

- Regulatory decision expected in China in FY2019

gilteritinib

FLT3 mut+ R/R AML

- **US:** sNDA to include OS data approved in May 2019
- **JP:** Plan to update the label in 3Q/2019
- **EU:** MAA submitted in Feb 2019

enfortumab vedotin

mUC (3rd line, platinum and PD-1/L1 inhibitor pretreated)

- **Cohort 1 in Phase 2 study:** Data presented at ASCO2019
- BLA submitted in US in Jul 2019

mUC (1st line)

- Expect to report data from the cohort in combination with pembrolizumab at ESMO2019

zolbetuximab

Gastric and GEJ adenocarcinoma

- **Phase 3 studies - SPOTLIGHT and GLOW:** Recruitment ongoing

Pancreatic cancer

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

roxadustat

Anemia associated with CKD

- **EU:** MAA targeting FY2019
- **JP:** Filed for patients on dialysis in Sep 2018. For non-dialysis, TLR of the remaining study expected in 2019

fezolinetant

MR-VMS

- **Phase 3 program:** Started in US/EU. Development plan under preparation in Japan/China

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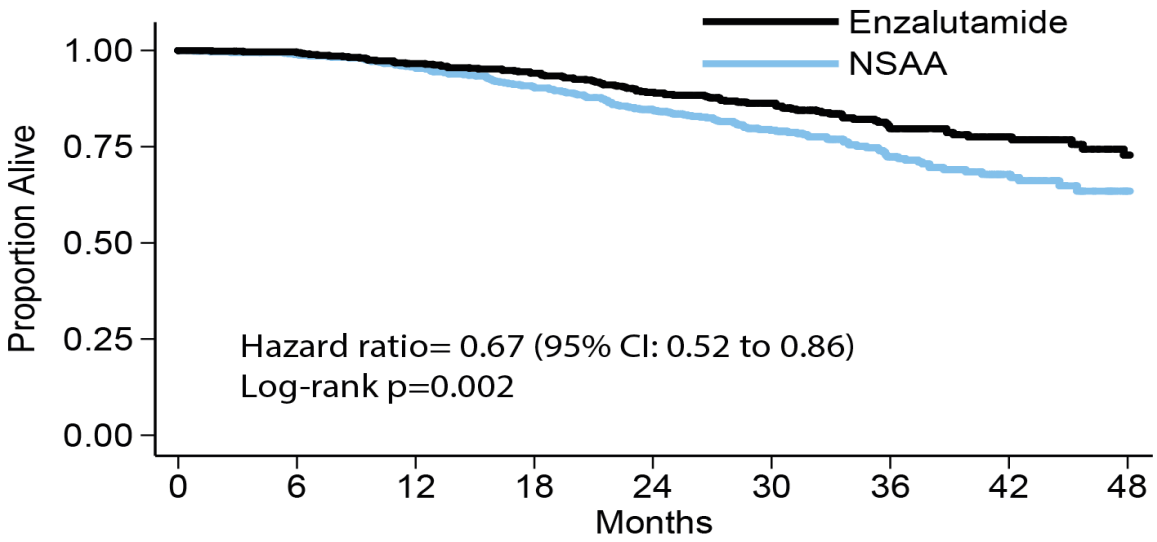
ENZALUTAMIDE: RESULTS OF ENZAMET IN M1 HSPC

Enzalutamide significantly improved OS compared to NSAA

Supporting sNDA/MAA Type II variation for M1 HSPC together with ARCHES

Primary endpoint: Overall survival



Number at risk

NSAA	562	551	531	501	452	311	174	86	32
Enzalutamide	563	558	541	527	480	340	189	106	45

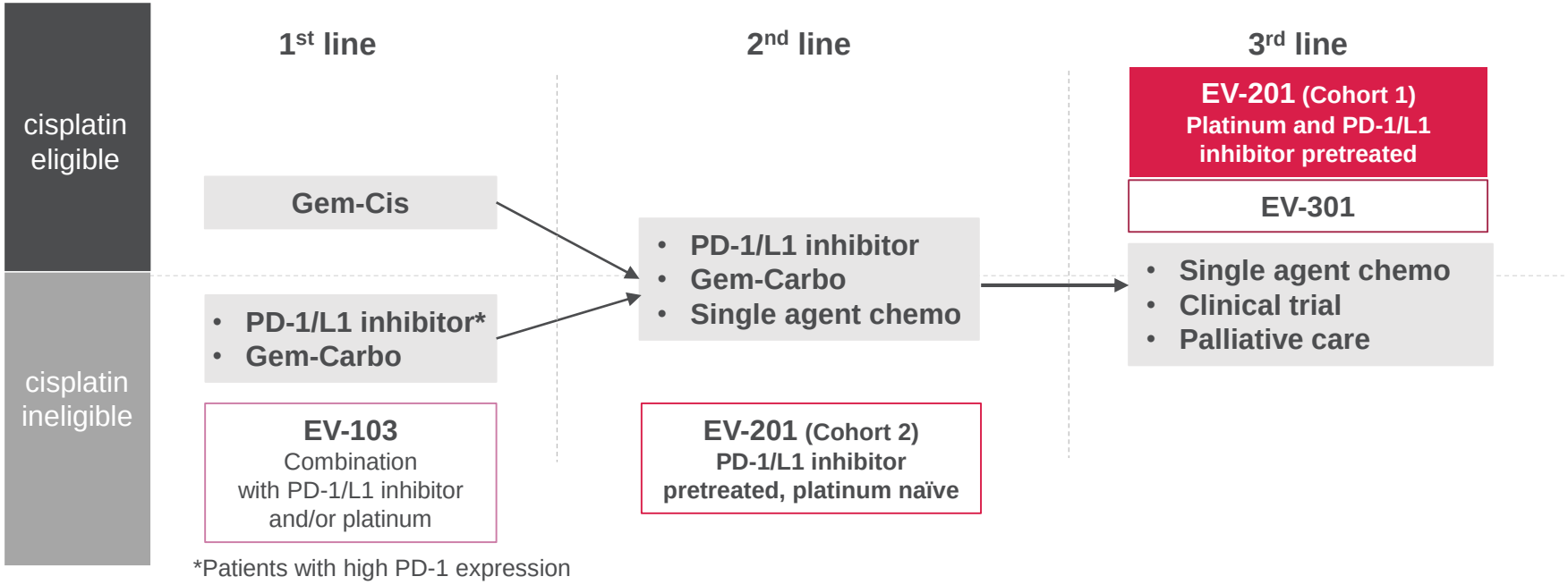
- At 3 years, 36% NSAA vs 64% ENZA were still on their assigned study treatment.
- Safety data was consistent with the safety profile of enzalutamide in previous clinical trials.

Sweeney C, *et al*., ASCO 2019
NSAA: Non-steroidal anti-androgen
ARCHES: Phase 3 study in M1 HSPC comparing enzalutamide plus androgen deprivation therapy (ADT) with placebo with ADT, data presented at ASCO-GU2019

ENFORTUMAB VEDOTIN

BLA submitted to the FDA in July for patients pretreated with platinum and PD-1/L1 inhibitor

- BLA submitted based on Cohort 1 results of EV-201 study for Accelerated Approval
- Annually 56,000 patients are diagnosed with mUC in US, EU and Japan (US: 19K, EU5: 29K, Japan 8K)[1]
- Studies in earlier mUC patients are ongoing



***Overall treatment flow is similar among regions even though the standard of care and approved drugs varies.

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1: Kantar Health incident and newly recurrent patients
Gem-Cis: Gemcitabine and cisplatin, Gem-Carbo: Gemcitabine and carboplatin

ENFORTUMAB VEDOTIN: RESULTS OF COHORT 1 IN PHASE 2

ORR was 44% in platinum and PD-1/L1 inhibitor pretreated patients

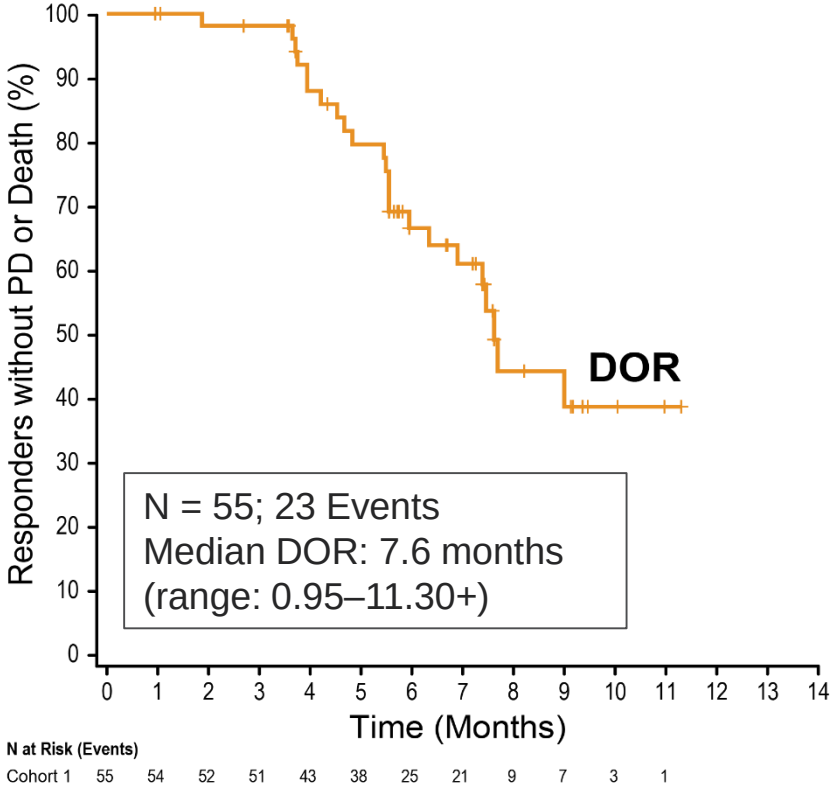
ORR per RECIST v 1.1 assessed by BICR	Patients (N=125) n (%)
Confirmed objective response rate 95% confidence interval[1]	55 (44) (35.1, 53.2)
Best overall response per RECIST v. 1.1, n (%)	
Complete response	15 (12)
Partial response	40 (32)
Stable disease	35 (28)
Progressive disease	23 (18)
Not evaluable[2]	12 (10)

[1] Computed using the Clopper-Pearson method
[2] Includes 10 patients who discontinued study prior to post-baseline response assessment, 1 patient who had uninterpretable post-baseline assessment, and 1 patient whose post-baseline assessment did not meet the minimum interval requirement for stable disease

Petrylak DP, *et al.,* ASCO2019
ORR: Objective response rate, RECIST: Response evaluation criteria in solid tumors, BICR: Blinded independent central review

ENFORTUMAB VEDOTIN: RESULTS OF COHORT 1 IN PHASE 2

DOR was 7.6 months in this heavily pre-treated patient population



EV-201: Cohort 1 Safety data

- The most common TEAEs occurring in more than 40% of patients
  - Fatigue, alopecia, rash, decreased appetite, taste distortion and peripheral neuropathy
- Treatment-related adverse events of interests

  Events categorized based on queries for related MedDRA terms

Peripheral neuropathy: 50% any grade, 3% ≥Grade 3
- 76% had resolution or events ongoing at Grade 1 at last follow-up

Rash: 48% any grade, 12% ≥Grade 3
- 93% resolution or improvement at last follow-up

Hyperglycemia: 11% any grade, 6% ≥Grade 3
- 1 Grade 4 event, resolved, no need for ongoing medication
- 71% resolution or improvement at last follow-up

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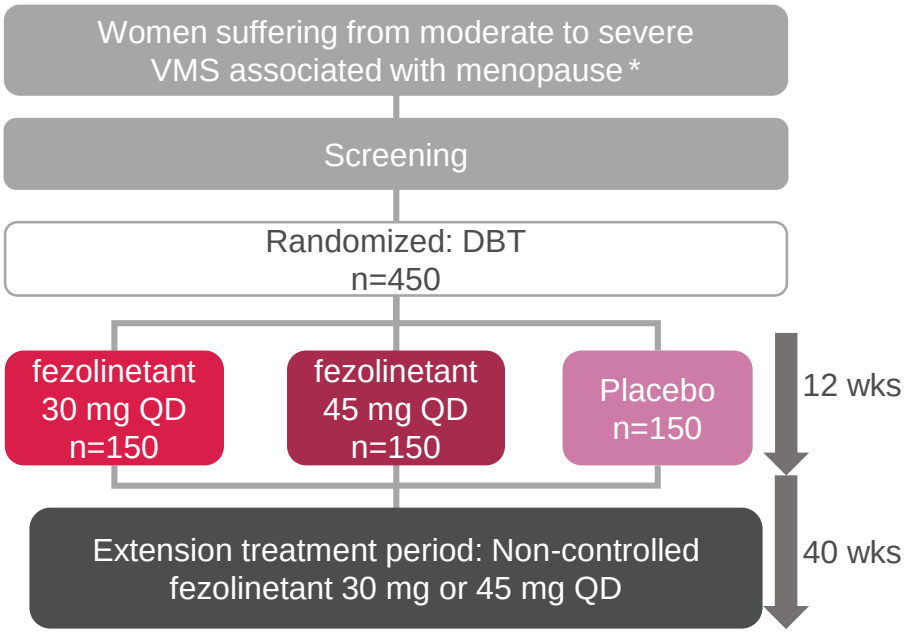
Petrylak DP, *et al.,* ASCO2019

DOR: Duration of response, TEAE: Treatment-emergent adverse event, MedDRA: Medical Dictionary for Regulatory Activities

FEZOLINETANT: PHASE 3 STUDY DESIGN

Initiated three MR-VMS (hot flashes, night sweats) Phase 3 studies in US and EU

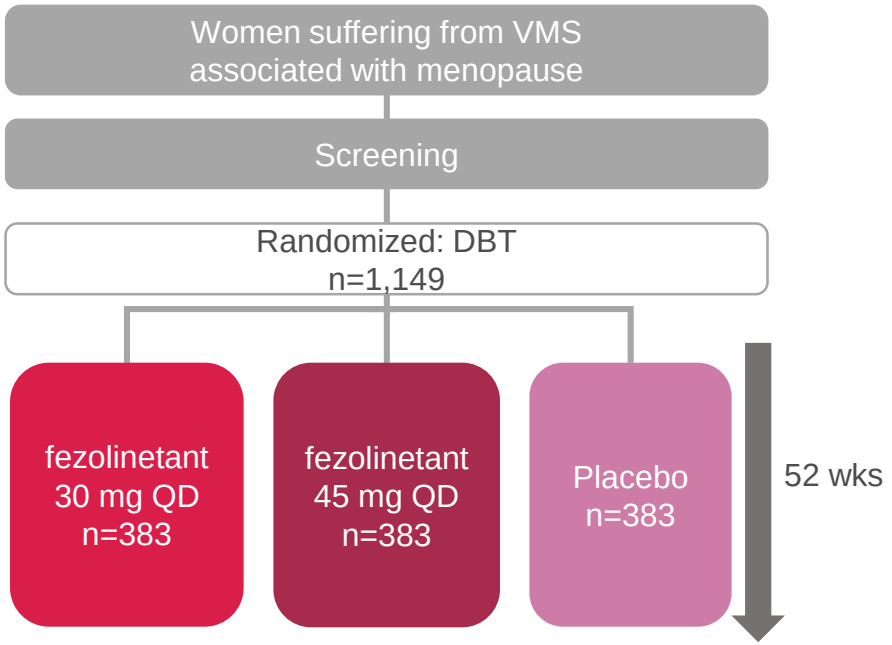
2 Pivotal studies (SKYLIGHT 1, SKYLIGHT 2)



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

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DBT: Double-blind trial, QD: Once daily

* 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

EXPECTED KEY EVENTS IN FY2019

Continued progress on important milestones for 6 post-POC projects

Regulatory decisions	enzalutamide		M1 CRPC (China) M1 HSPC (US/EU)
	gilteritinib		Relapsed/refractory AML (EU) ✓ Label update to include OS data (US) Label update to include OS data (JP)
	roxadustat		Anemia associated with CKD, dialysis (Japan)
Regulatory submissions *	enzalutamide	✓	M1 HSPC (US/EU) M1 HSPC (Japan)
	enfortumab vedotin	✓	mUC, platinum and PD-1/L1 inhibitor pretreated (US)
	roxadustat		Anemia associated with CKD, dialysis/non-dialysis (EU)
Data readouts	roxadustat		P3 study in Japanese patients (anemia associated with CKD, non-dialysis: 1517-CL-0310)

* Subject to study outcome, internal assessment, decision and regulatory consultation, as appropriate
Please refer to R&D pipeline list for details including target disease.

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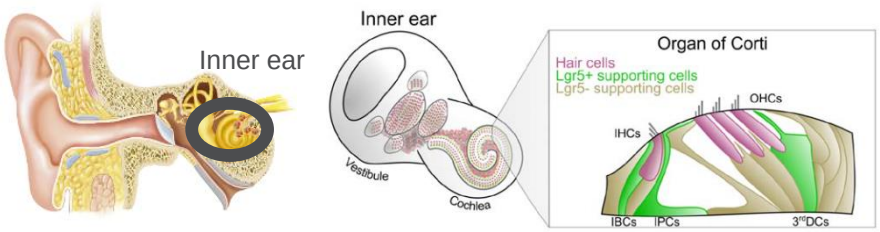
PROGRESS IN FOCUS AREA APPROACH

License agreement[1] for clinical stage program, FX-322

Regeneration

Regenerative therapeutic candidate targeting sensorineural hearing loss

- Globally 15% of adults are estimated to have hearing loss[2] and 90% are affected by sensorineural hearing loss.[3] No approved therapeutic options at present.
- FX-322 is designed to activate dormant inner ear progenitor cells with the aim of inducing hair cell regeneration to stimulate recovery of hearing



Inner ear and hair cells[4]

- Phase 1/2 completed, Phase 2a to start in 4Q/2019

FREQUENCY THERAPEUTICS

Start of Phase 2 part of ASP3772 in Phase 1/2 study

ASIM

Vaccine targeting pneumococcus utilizing Affinivax' Multiple Antigen Presenting System (MAPS) technology

- Penumococcus can cause serious infections, representing global health problem. More than 1.6 million people die from pneumococcal infections.[2] High unmet need exists for innovative vaccine.
- Potential to provide broader protection against invasive disease and to reduce nasopharyngeal colonization (first step in transmission).
- MAPS technology is able to combine protective components – polysaccharides and proteins – in a single vaccine using a much simpler and cost-efficient manufacturing process.
- Phase 1/2 study
  - P1 part: SAD study in adults
  - P2 part: SAD dose-finding study in elderly subjects

Affinivax

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1: Exclusive license agreement to develop and commercialize in ex-US markets, 2: World Health Organization, 3: U.S. National Institutes of Health, 4: McLean WJ, *et al.*, Cell Rep. 2017, IHC: Inner hair cell, OHC: Outer hair cell, IBC: Inner border cell, IPC: Inner pillar cell, DC: Daitels cell, ASIM: Antigen-specific immuno-modulation, SAD: Single ascending dose

ONCOLOGY ASSETS IN EARLY STAGES

Multiple assets in clinical stage including novel immuno-oncology programs

	Modality/MoA	Origin/Partner *	Target cancer	P1	P2
zolbetuximab	Anti-Claudin 18.2 monoclonal antibody	GANYMED	Pancreatic adenocarcinoma		
ASP1650	Anti-Claudin 6 monoclonal antibody	GANYMED	Testicular cancer		
AGS-16C3F	Anti-ENPP3 ADC	Agensys, SeattleGenetics	Renal cell carcinoma		
ASP1235/AGS62P1	ADC	Agensys, Ambrx	Acute myeloid leukemia		
ASP8374/PTZ-201	Anti-TIGIT antibody	POTENZA therapeutics			
ASP1948/PTZ-329	Anti-NRP1 antibody	POTENZA therapeutics			
ASP1951/PTZ-522	GITR agonistic antibody	POTENZA therapeutics			
ASP9801	Oncolytic virus	Tottori University			
ASP7517	Cell therapy (artificial adjuvant vector cells)	RIKEN			

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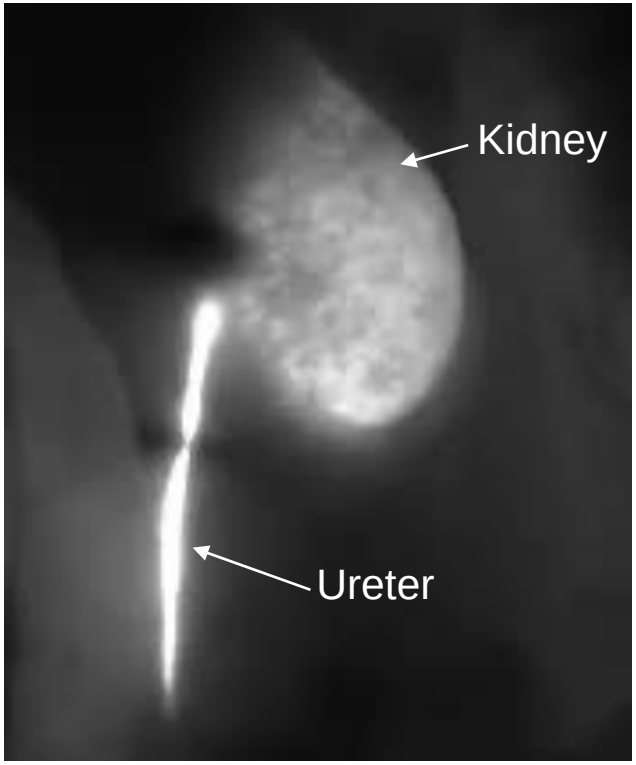
* Incl. programs developed under joint research

UPDATES IN Rx+^{TM} PROGRAM: IMAGE-GUIDED PRECISION SURGERY: ASP5354

Potential to improve surgery outcome by providing rapid time to ureteral visualization with alternative to conventional methods



Ureter imaging with ASP5354 in rats

Business concept and characteristics

- Use established Astellas proprietary pharmaceutical drug development processes to address unmet medical needs in surgery
- Mid-size molecule to specify ureter visualization during surgery
- Alternative to invasive ureteral instrumentation to avoid ureteral injury during abdominal surgery including total hysterectomy

Development progress

Phase 1: Patient observation completed
- Single dose administration in healthy volunteers
- Safety, Tolerability, and Pharmacokinetic Study

Preparing Phase 2 POC Study
- Plan to start in FY2019

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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

License agreement

FREQUENCY THERAPEUTICS

Shareholder return

Aiming for steady dividend increase during FY2018-FY2020

Flexible share buybacks

	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%	-

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APPENDIX

Q1/FY2019: REVENUE BY REGION

(billion yen)	Q1/FY18	Q1/FY19	Change
Japan	**94.1**	**98.5**	+4.6%
United States	**102.7**	**105.3**	+2.5%
Established Markets	**76.9**	**75.8**	-1.4%
Greater China	**13.7**	**14.7**	+7.4%
International	**32.1**	**34.2**	+6.6%

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.

Q1/FY2019: SALES OF MAIN PRODUCTS

(billion yen)	Q1/FY18	Q1/FY19	Change	CER growth	FY19 FCST*	Progress
XTANDI	**81.2**	**96.0**	**+18.2%**	**+20.1%**	**364.2**	**26.4%**
XOSPATA	**-**	**2.5**	**-**	**-**	**15.1**	**16.3%**
OAB products	**59.3**	**53.5**	**-9.8%**	**-8.7%**	**202.4**	**26.4%**
mirabegron	34.4	39.9	+16.1%	+16.8%	160.6	24.9%
Vesicare	24.9	13.6	-45.6%	-44.0%	41.8	32.5%
Prograf	**52.2**	**50.4**	**-3.4%**	**-0.3%**	**187.7**	**26.9%**

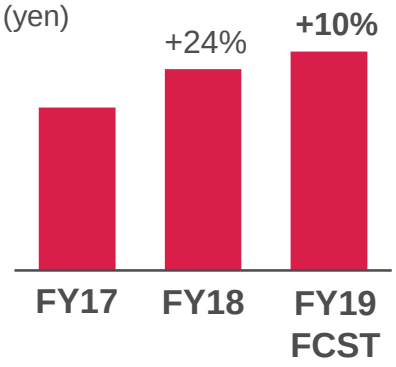
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL
OAB products: Vesicare＋mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)

*Announced in Apr. 2019

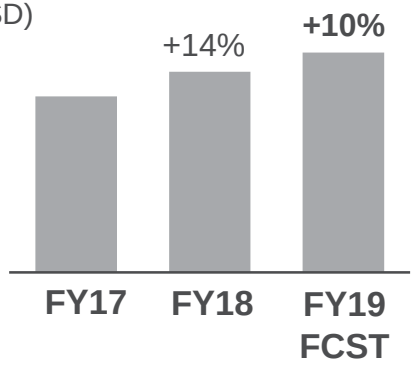
FY2019 FCST: XTANDI SALES BY REGION

Sales by region

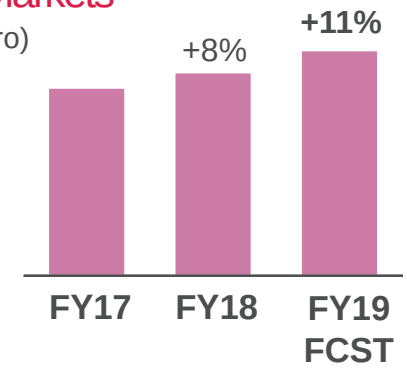
Japan
(yen)



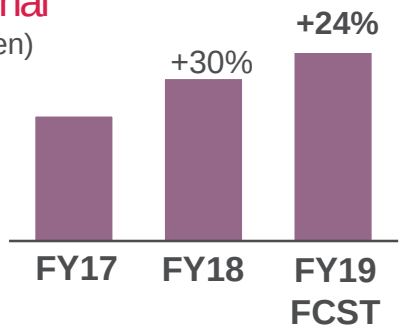
United states
(USD)



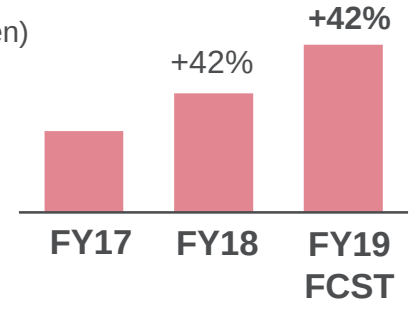
Established Markets
(euro)



International
(yen)



Greater China
(yen)

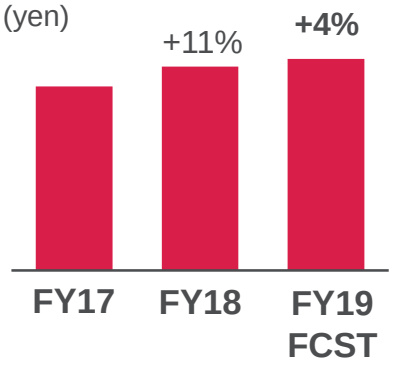


Greater China: China, Hong Kong, Taiwan
Established Markets: Europe, Canada, Australia
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

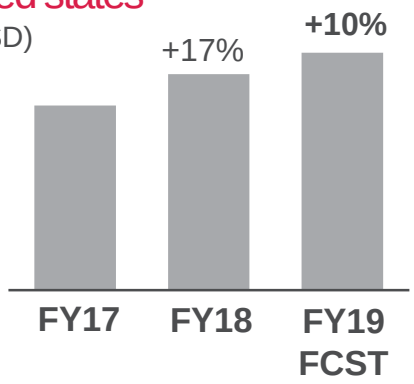
FY2019 FCST: MIRABEGRON SALES BY REGION

Sales by region

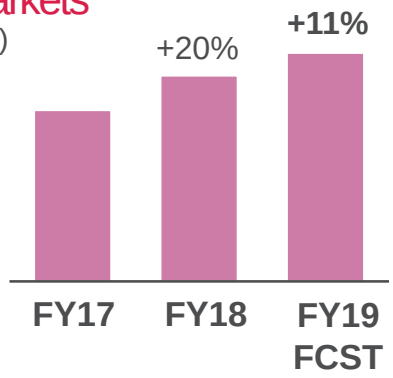
Japan
(yen)



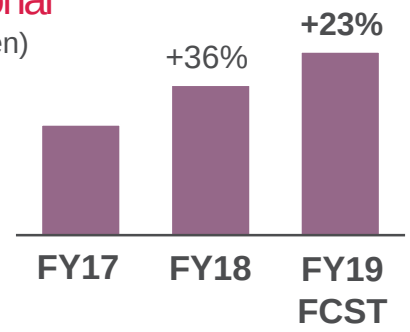
United states
(USD)



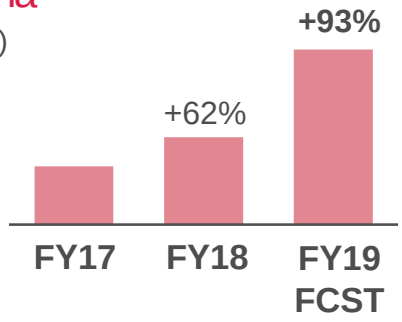
Established Markets
(euro)



International
(yen)



Greater China
(yen)



Greater China: China, Hong Kong, Taiwan
Established Markets: Europe, Canada, Australia
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

FX RATE (ACTUAL)

Average rate for the period

Currency	Q1/FY18	Q1/FY19	change
USD	109 yen	110 yen	+1 yen
EUR	130 yen	123 yen	-7 yen

Change in closing rate from PY end

Currency	Q1/FY18	Q1/FY19
USD	+4 yen	-3 yen
EUR	-3 yen	-2 yen

Fx impact on elimination of unrealized gain: COGs ratio -1.1ppt

FY2019 FCST：FX RATE & FX SENSITIVITY

Average rate for the period

Currency	FY18	FY19 FCST	Change
USD	111 yen	110 yen	-1 yen
EUR	128 yen	125 yen	-3 yen

Change in closing rate from PY end

Currency	FY18	FY19 FCST
USD	+5 yen	-1 yen
EUR	-6 yen	+0 yen

Estimated Fx sensitivity of FY2019 forecasts by 1 yen appreciation

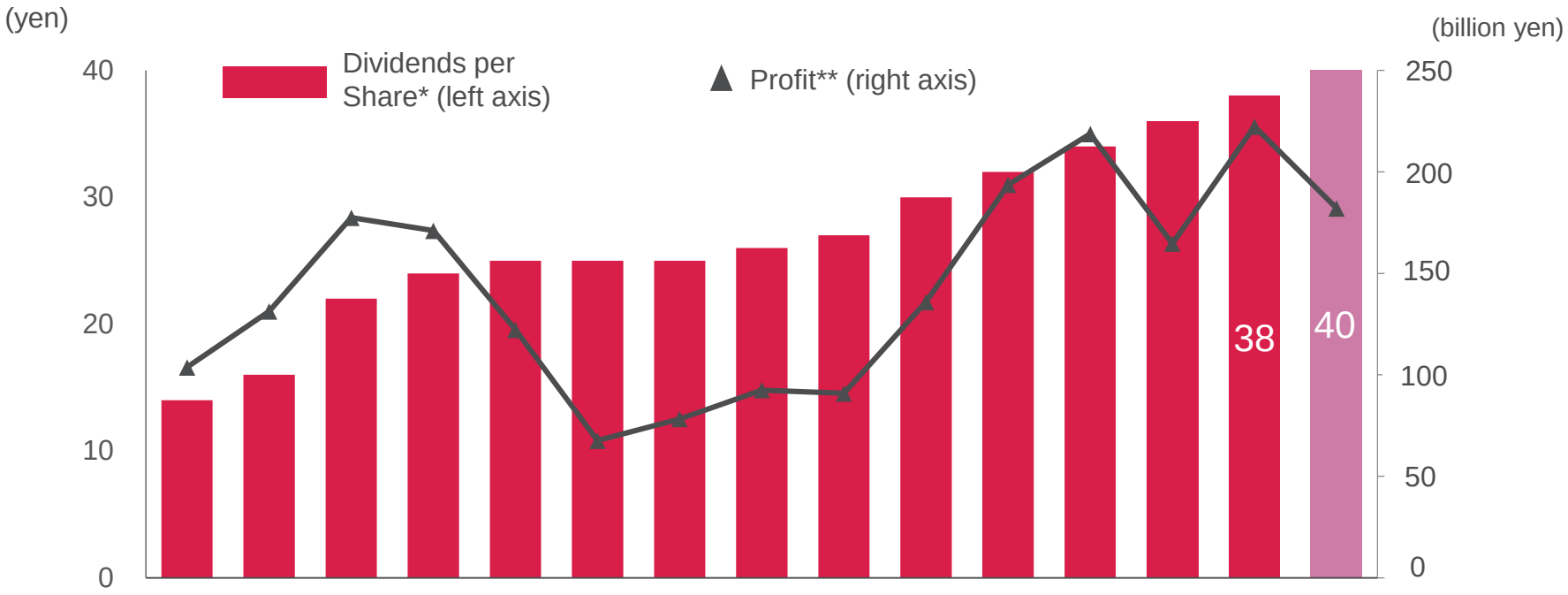
Currency	Average rate 1 yen higher than assumption		Year-end rate 1 yen higher than assumption
	Revenue	Core OP	Core OP
USD	Approx. -5.2 bil yen	Approx. -1.1 bil yen	Approx. +0.6 bil yen
EUR	Approx. -2.6 bil yen	Approx. -1.0 bil yen	Approx. +0.3 bil yen

BALANCE SHEET/CASH FLOW HIGHLIGHTS

(billion yen)	FY18 end	Jun. 2019
Total assets	1,897.6	1,927.0
Cash and cash equivalents	311.1	259.4
Total equity attributable to owners of the parent	1,258.4	1,249.7
Equity ratio (%)	66.3%	64.9%

(billion yen)	Q1/FY18	Q1/FY19	FY18
Cash flows from operating activities	37.2	7.4	258.6
Cash flows from investing activities	2.4	-14.0	-41.8
Free cash flows	39.6	-6.6	216.9
Cash flows from financing activities	-63.3	-404	-233.7
Acquisition of treasury shares	-27.8	-0.0	-160.4
Dividends paid	-35.6	-35.8	-72.1

Details of shareholder returns



(billion yen)	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19 (Forecast)
Total dividends	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	75.6
Acquisition of own share	46.2	219.9	81.8	123.4	27.0	-	-	49.4	30.0	58.2	119.3	91.4	130.0	160.0	
Total return ratio(%)	82	200	77	106	70	85	74	118	100	92	97	74	123	105	

*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

enzalutamide
M0 CRPC ✓✓✓

gilteritinib
R/R AML
JP/US ✓✓✓
EU ✓✓

roxadustat
Anemia associated with CKD
Dialysis (JP) ✓✓

FY2019-2020

enzalutamide
M1 HSPC (US/EU) ✓✓

enfortumab vedotin
Metastatic urothelial cancer platinum and PD-1/L1 inhibitor pretreated (US) ✓✓

roxadustat
Anemia associated with CKD
Non-dialysis (JP)

roxadustat
Anemia associated with CKD
Dialysis/Non-dialysis (EU) ✓

FY2021 or beyond

enzalutamide
M0 HSPC

zolbetuximab
Gastric and gastroesophageal junction adenocarcinoma

gilteritinib
AML (Post-HSCT maintenance)

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, CPRC: Non-metastatic castration-resistant prostate cancer, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, CKD: Chronic kidney disease,
M1: Metastatic, HSPC: Hormone-sensitive prostate cancer, 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
- ASP0892
- ASP0367/MA-0211
- MucoRice-CTB
- ASP8062

Phase 2

- zolbetuximab (Pancreatic adenocarcinoma)
- AGS-16C3F (Renal cell carcinoma)
- ASP1650 (Testicular cancer)
- reldesemtiv (SMA, ALS)
- ASP7317 (Dry AMD, etc.)
- ASP1128/MA-0217 (AKI)
- ASP3772 (Pneumococcal disease)
- bleselumab (rFSGS)
- ASP6294 (BPS/IC)
- ASP8302 (Underactive bladder)
- roxadustat (CIA)
- ASP0819 (Fibromyalgia)
- ASP4345 (CIAS)
- isavuconazole (Pediatric, US)

Phase 3

- enzalutamide (M1 HSPC: JP, M0 HSPC)
- gilteritinib (R/R AML: China, Other AML)
- enfortumab vedotin (UC)
- zolbetuximab (Gastric and GEJ adenocarcinoma)
- peficitinib (Rheumatoid arthritis, China)
- mirabegron (Pediatric OAB & NDO)
- roxadustat (Anemia associated with CKD, EU: Non-dialysis/dialysis, JP: Non-dialysis)
- fezolinetant (MR-VMS)

Filed

- enzalutamide (M1 CRPC, China)
- enzalutamide (M1 HSPC, US/EU)
- gilteritinib (R/R AML, EU)
- enfortumab vedotin (mUC, platinum and PD-1/L1 pretreated, US)
- solifenacin* (Pediatric NDO, US)
- roxadustat (Anemia associated with CKD on dialysis, JP)
- fidaxomicin (*Clostridium difficile* infection in pediatric patients, EU)
- micafungin (Invasive candidiasis in neonates and young infants, US)

*Received Complete Response Letter from FDA in Aug 2017

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

Outline of the projects are shown. Please refer to R&D pipeline list for details including target disease.

astellas

SMA: Spinal muscular atrophy, ALS: Amyotrophic lateral sclerosis, AMD: Age-related macular degeneration, AKI: Acute kidney injury, rFSGS: Recurrence of focal segmental glomerulosclerosis, BPS/IC: Bladder pain syndrome/Interstitial cystitis, CIA: Chemotherapy-induced anemia, CIAS: Cognitive impairment associated with schizophrenia, M1: Metastatic, HSPC: Hormone-sensitive prostate cancer, M0: Non-metastatic, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, UC: Urothelial cancer, GEJ: Gastroesophageal junction, OAB: Overactive bladder, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, MR-VMS: Menopause-related vasomotor symptoms, CRPC: Metastatic castration-resistant prostate cancer, mUC: Metastatic urothelial cancer

PROGRESS IN OVERALL PIPELINE

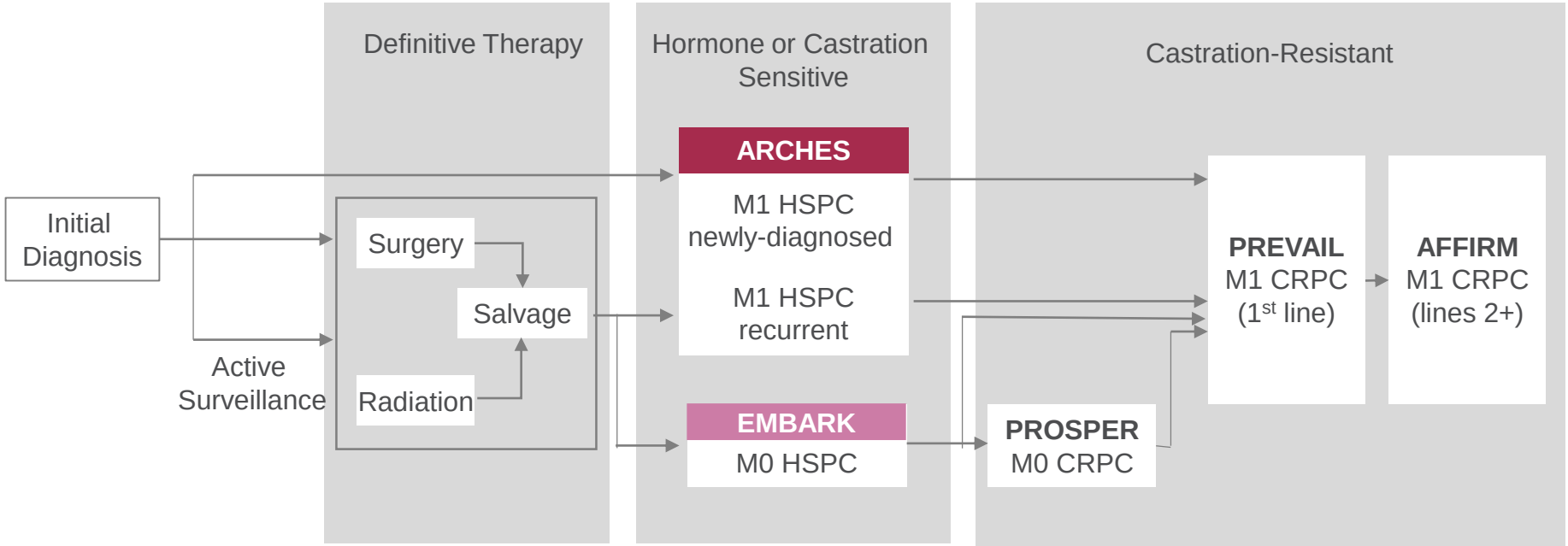
Phase 1 entry to approval, since FY2018 financial results announcement in April 2019

Phase 1 Entry	Phase 2 Entry	Phase 3 Entry	Filing	Approval
ASP7517 Cancer	**ASP3772** Prevention of pneumococcal disease	**fezolinetant** Menopause-related vasomotor symptoms	**enzalutamide** Metastatic hormone-sensitive prostate cancer: US/EU	**evolocumab** Familial hypercholesterolemia or hypercholesterolemia in patients who are not suitable for statin therapy: JP
ASP8062 Substance use disorders			**enfortumab vedotin** Locally advanced or metastatic urothelial cancer in patients who have received prior treatment with a PD-1/PD-L1 inhibitor and platinum-containing chemotherapy: US	
			micafungin Invasive candidiasis in neonates and young infants less than 120 days of life: US	

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

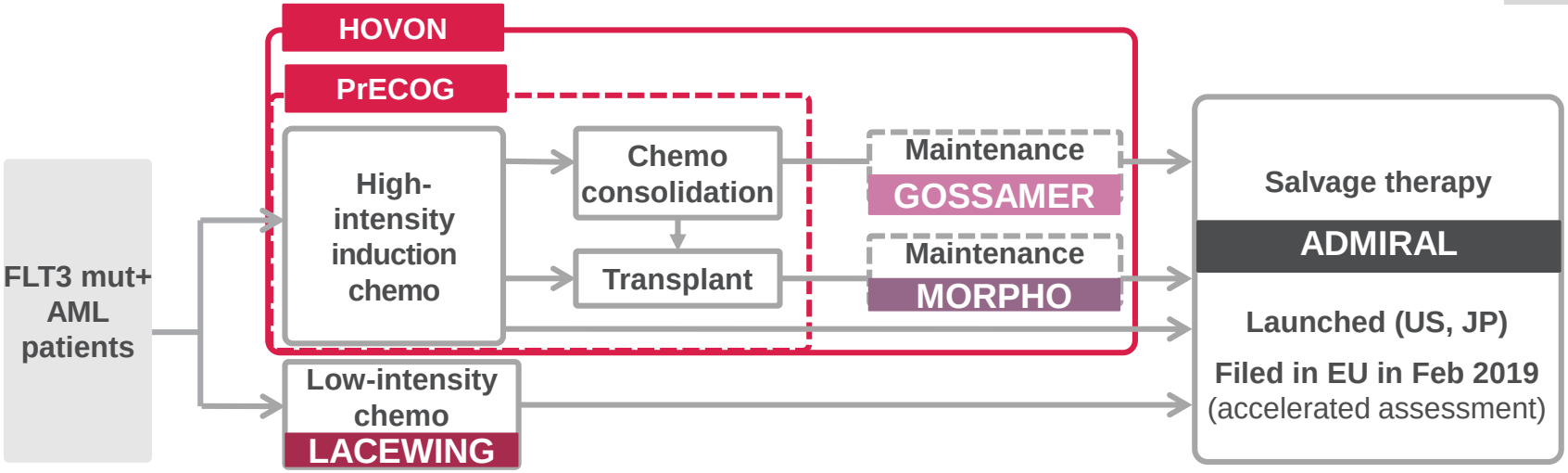
ENZALUTAMIDE



	P3: ARCHES	**M1 HSPC**	vs. placebo, combination with ADT, n=1,150	ENZAMET data presented at ASCO2019 sNDA submitted in US in June 2019 and filed in EU in July 2019 with ARCHES data, supported by ENZAMET
	P3: EMBARK	**M0 HSPC**	vs. placebo, combination with ADT, n=1,068	Enrollment completed

Underline indicates the changes from the previous announcement on Apr 25, 2019.
M1: Metastatic, M0: Non-metastatic, HSPC: Hormone-sensitive prostate cancer, CRPC: Castration resistant prostate cancer, ADT: Androgen deprivation therapy

GILTERITINIB

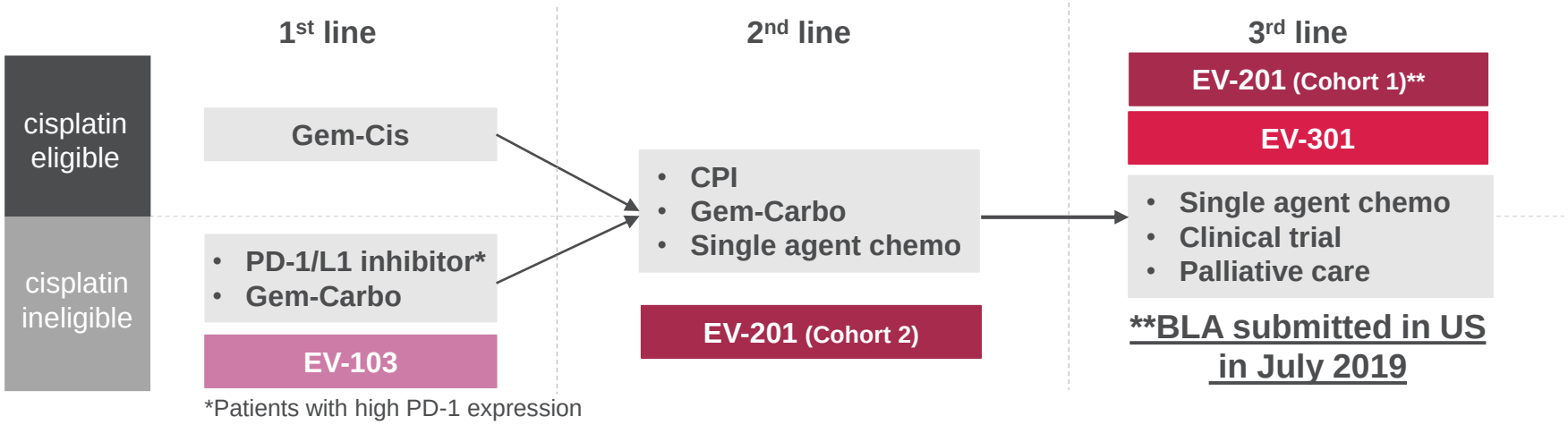


	Relapsed or refractory	**P3: ADMIRAL**	Monotherapy vs salvage chemo (2:1), n=371		MAA submitted in Feb 2019 Label update to include OS data US: sNDA approved in May 2019 JP: Planned in 3Q/2019
	Newly diagnosed (intensive chemo eligible)	**P3: HOVON**	Combo with high intensity chemo gilteritinib vs midostaurin (1:1)	n=768	FSFT planned in: 3Q2019 (Sponsor: HOVON)
		P2: PrECOG		n=179	FSFT planned in: 3Q2019 (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: Jun 2019

Underline indicates the changes from the previous announcement on Apr 25, 2019.
HSCT: Hematopoietic stem cell transplant, BMT-CTN: Blood and Marrow Transplant - Clinical Trial Network

ENFORTUMAB VEDOTIN

Treatment Landscape *Overall treatment flow is similar among regions even though the standard of care and approved drugs varies.



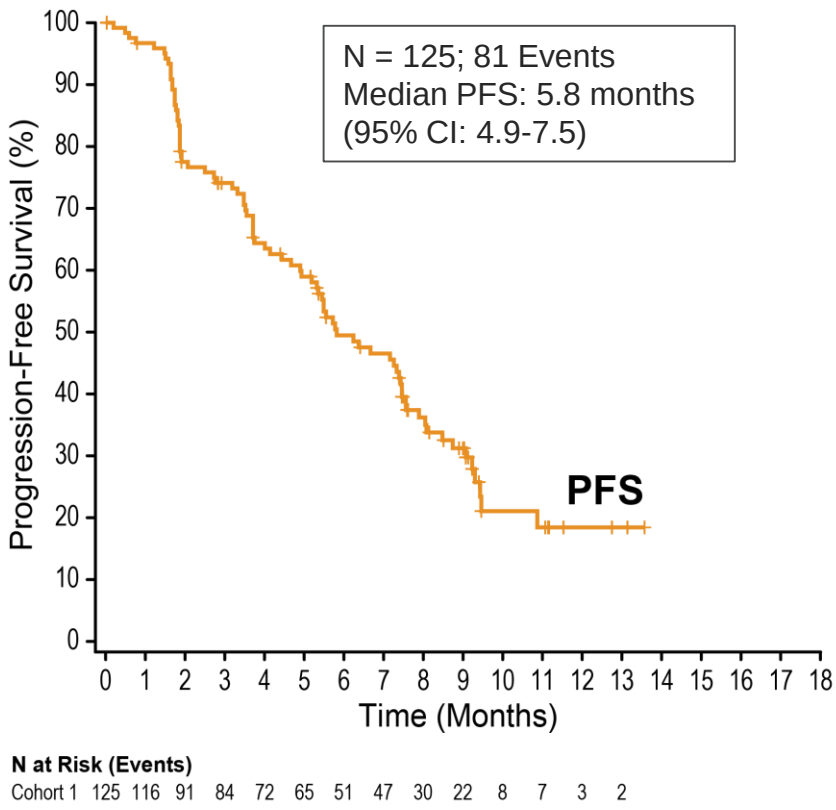
*Patients with high PD-1 expression

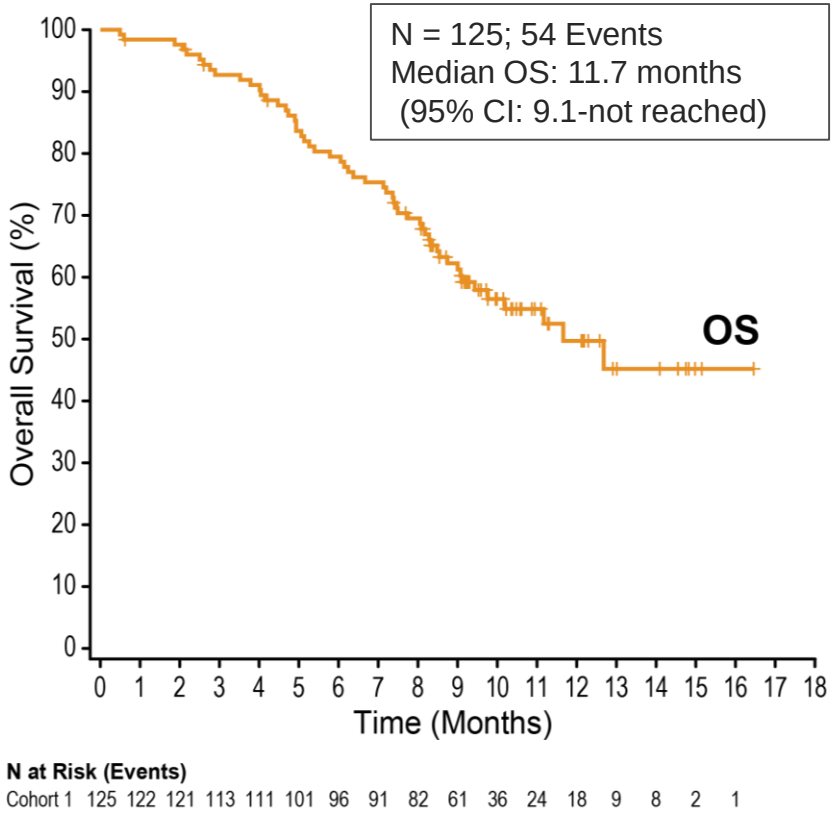
	P3: EV-301	Platinum and PD-1/L1 inhibitor pretreated	n=550	FSFT: Jul 2018
	P2: EV-201	PD-1/L1 inhibitor pretreated Cohort 1: Platinum pretreated Cohort 2: Platinum naïve/cisplatin ineligible	n=200	Cohort 1: Data presented at ASCO2019 Cohort 2: Recruiting
	P1b: EV-103	Combination with PD-1/L1 inhibitor and/or platinum	n=159	FSFT: Nov 2017
	P1: EV-101	Part A: mUC pts Part B: mUC pts with renal insufficiency metastatic NSCLC, metastatic ovarian cancer Part C: mUC pts (PD-1/L1 pretreated)	n= 215	Renal insufficiency cohort: Recruiting Other cohorts: Enrollment completed

SeattleGenetics® astellas

Underline indicates the changes from the previous announcement on Apr 25, 2019.
Gem-Cis: Gemcitabine and cisplatin, Gem-Carbo: Gemcitabine and carboplatin, NSCLC: Non-small cell lung carcinoma

ENFORTUMAB VEDOTIN: RESULTS OF COHORT 1 IN PHASE 2





SeattleGenetics®

astellas

Petrylak DP, *et al.,* ASCO2019

ZOLBETUXIMAB

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
  - ~70-90% biliary duct, pancreatic, gastric and mucinous ovarian cancer[1]
  - ~10% ovarian cancer and NSCLC[1]

Gastric and gastroesophageal junction (GEJ) adenocarcinoma

- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin 18.2 expression
- Fourth leading cause of cancer death worldwide.
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20%[2, 3]
- Median OS for Stage IV gastric cancer is 10-15 months[4, 5]

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

astellas

Underline indicates the changes from the previous announcement on Apr 25, 2019.

1: Al-Batran SE, *et al*., ASCO2016, 2: Pennathur A, *et al*., Lancet. 2013, 3: Sahin U, *et al*., Clin Cancer Res. 2008, 4: 2017 RDPAC survey, 5: Iizumi S, *et al*. 2018

NSCLC: Non-small cell lung cancer, CAPOX: Capecitabine and oxaliplatin, mFOLFOX6: 5-FU, leucovorin and oxaliplatin

ABBREVIATIONS

ADC	Antibody-drug conjugate
AML	Acute myeloid leukemia
ASCO	American Society of Clinical Oncology
BLA	Biologics licensing application
CKD	Chronic kidney disease
ESMO	European Society for Medical Oncology
FDA	Food and Drug Administration
FLT3	Fms-like tyrosine kinase 3
FLT3 mut+	FLT3 mutation positive
FSFT	First Subject First Treatment
GEJ	Gastroesophageal junction
M0 CRPC	Non-metastatic castration-resistant prostate cancer
M0 HSPC	Non-metastatic hormone sensitive prostate cancer
M1 CRPC	Metastatic castration-resistant prostate cancer
M1 HSPC	Metastatic hormone sensitive prostate cancer
MAA	Marketing authorization application
MR-VMS	Menopause-related vasomotor symptoms
mUC	Metastatic urothelial cancer
NDA	New drug application
OS	Overall survival
POC	Proof of Concept
R/R AML	Relapsed or refractory acute myeloid leukemia
sNDA	Supplemental new drug application
TLR	Top line result
UC	Urothelial cancer
VMS	Vasomotor symptoms

ON THE FOREFRONT OF HEALTHCARE CHANGE