FY2018 FINANCIAL RESULTS
ENDED MARCH 31, 2019

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President and CEO
Astellas Pharma Inc.
April 25, 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
FY2018 Consolidated Financial Results
FY2019 Forecasts

II
Initiatives for Sustainable Growth

III
Capital Allocation

FY2018 FINANCIAL RESULTS (CORE BASIS)

(billion yen)	FY17	FY18	Change	FY18 FCST*	Achieve-ment	CER growth
Revenue	**1,300.3**	**1,306.3**	**+0.5%**	**1,300.0**	**100.5%**	+0.8%
Cost of sales	294.2	292.0	-0.7%			
% of revenue	22.6%	22.4%				
SG&A expenses	478.3	490.3	+2.5%			
% of revenue	36.8%	37.5%				
R&D expenses	220.8	208.7	-5.5%	216.0	96.6%	
% of revenue	17.0%	16.0%		16.6%		
Amortisation of intangible assets	35.8	35.2	-1.7%			
Share of profit (loss) of investments accounted for using equity method	- 2.4	- 1.6	-			
Core operating profit	**268.7**	**278.5**	**+3.7%**	**270.0**	**103.2%**	+3.8%
Core profit	**204.3**	**249.3**	**+22.0%**	**221.0**	**112.8%**	
Core EPS (yen)	**100.64**	**129.07**	**+28.2%**	**114.11**	**113.1%**	

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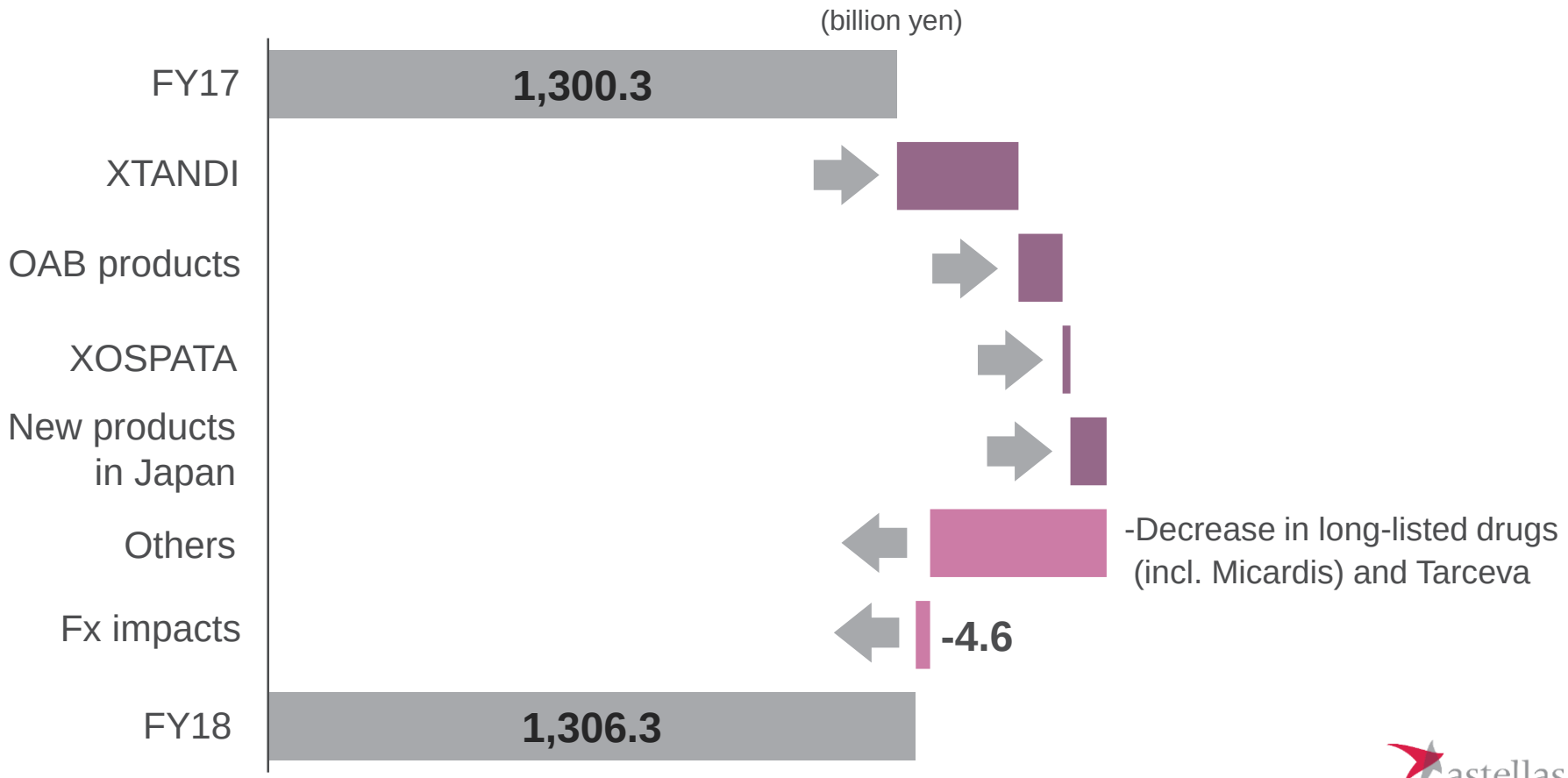
*Announced in Oct. 2018

CER：Constant Exchange Rate

REVENUE ANALYSIS (YEAR ON YEAR)

Sales increase in XTANDI, mirabegron and new products sales



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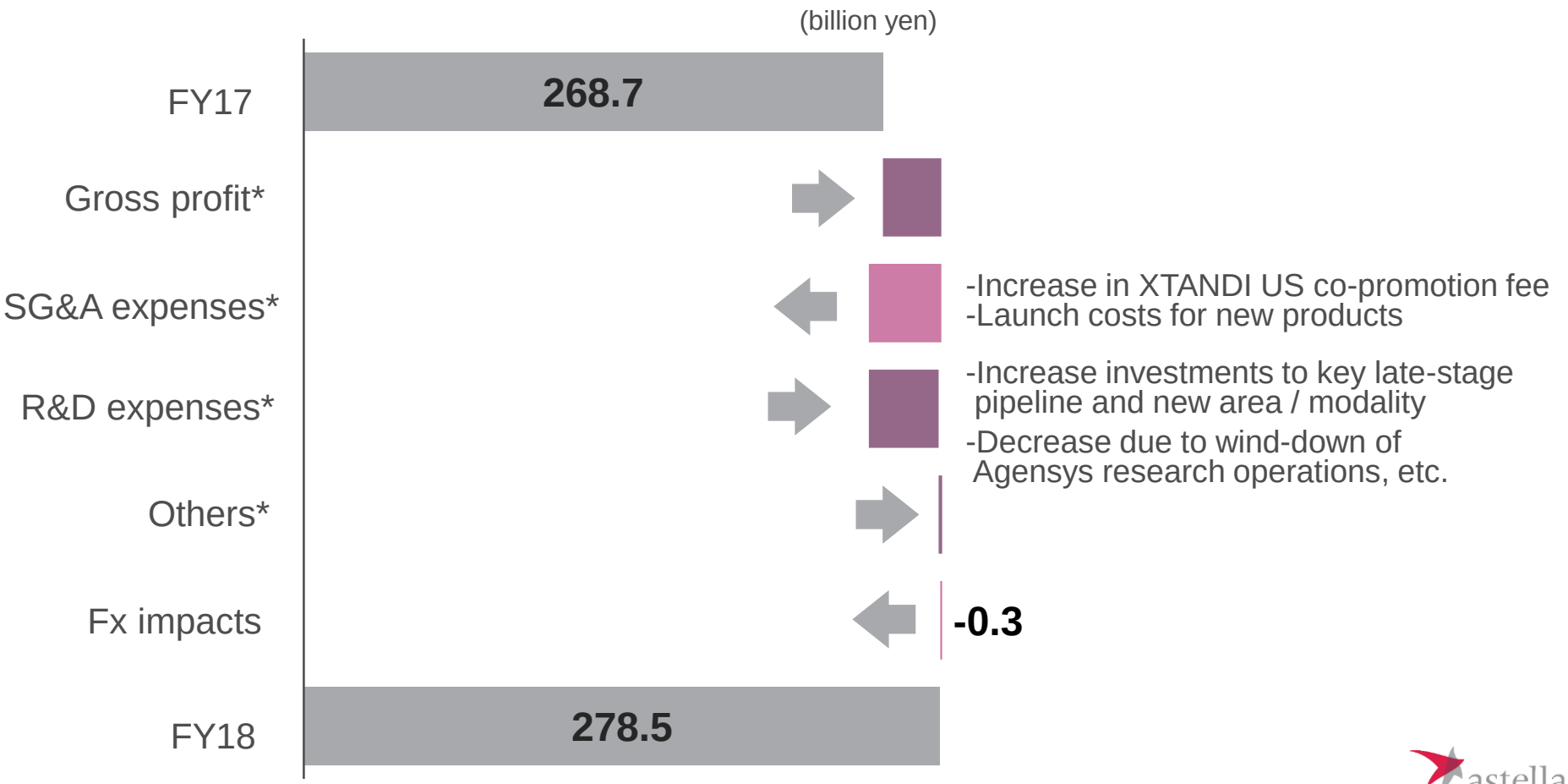
OAB : Overactive bladder　OAB products : Vesicare＋mirabegron (Betanis/Myrbetriq/BETMIGA)
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY)

NHI price revision in Japan
:-17.6 bil.yen

CORE OP ANALYSIS (YEAR ON YEAR)

Increased core OP by 4% through steady growth of main products



*Excluding Fx impacts

FY2018 FINANCIAL RESULTS (FULL BASIS)

(billion yen)	FY17	FY18	Change	FY18 FCST*	Achieve-ment
Core operating profit	**268.7**	**278.5**	**+3.7%**	**270.0**	**103.2%**
Other income	11.9	14.2	+19.2%		
Other expense	67.3	48.8	-27.6%		
Operating profit	**213.3**	**243.9**	**+14.4%**	**234.0**	**104.2%**
Profit before tax	218.1	249.0	+14.1%	236.0	105.5%
Profit	**164.7**	**222.3**	**+35.0%**	**195.0**	**114.0%**
EPS (yen)	**81.11**	**115.05**	**+41.8%**	**100.69**	**114.3%**

Other expense in FY2018

-Expenses related to business restructuring: 23.1**

-Litigation costs: 12.3

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**Including restructuring costs and impairment losses of Nishine plant

*Announced in Oct. 2018

FY2019 FORECASTS

(billion yen)	FY18 ACT	FY19 FCST	Change
Revenue	**1,306.3**	**1,224.0**	**-6.3%**
R&D expenses	208.7	211.0	+1.1%
% of revenue	16.0%	17.2%	+1.2ppt
Core operating profit	**278.5**	**240.0**	**-13.8%**
Core profit	**249.3**	**194.0**	**-22.2%**
Core EPS (yen)	**129.07**	**102.87**	**-20.3%**
Operating profit	**243.9**	**229.0**	**-6.1%**
Profit	**222.3**	**182.0**	**-18.1%**
EPS (yen)	**115.05**	**96.51**	**-16.1%**

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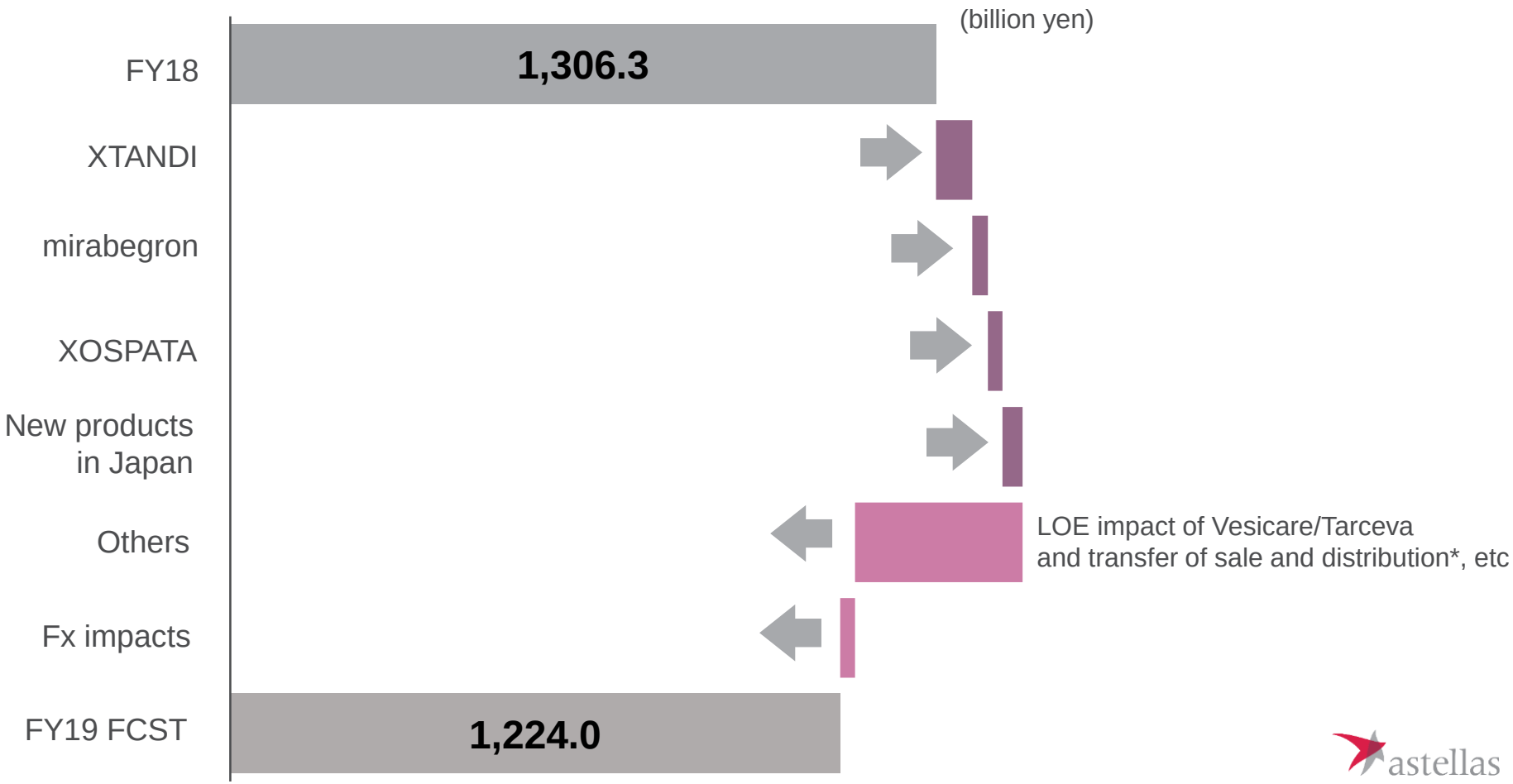
FY2019 FORECASTS: REVENUE

Revenue to decrease due to LOE of major products.
Main products continue to grow and new products contribute throughout the year

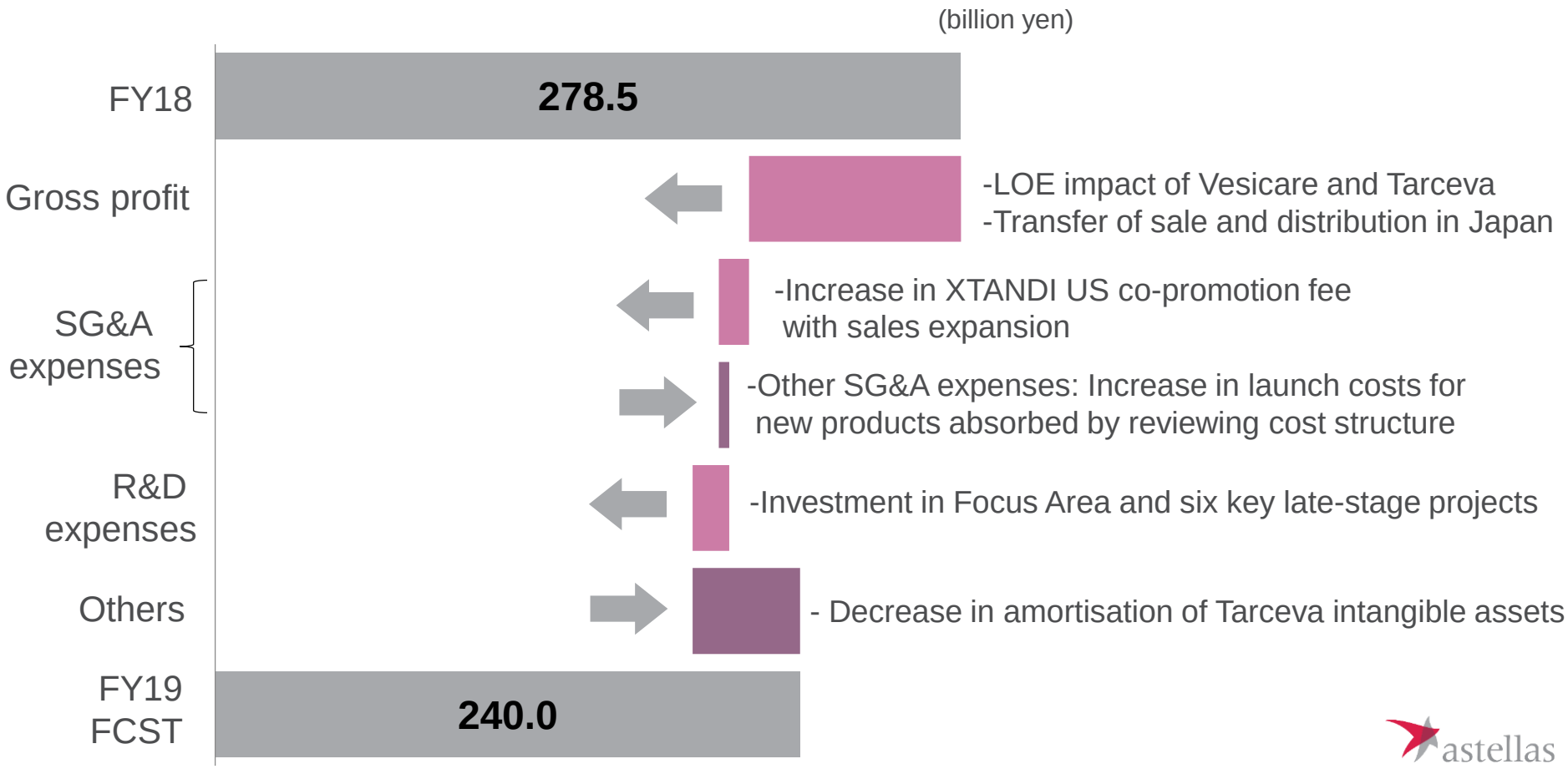


LOE: Loss of exclusivity
mirabegron (Betanis/Myrbetriq/BETMIGA)
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

*Termination of sale and distribution for Symbicort and KM bio products

FY2019 FORECASTS: CORE OP

Securing investments to maximize product VALUE while reviewing cost structure



LOE: Loss of exclusivity

PROGRESS TOWARDS THE STRATEGIC PLAN 2018 GUIDANCE

(billion yen)

Indicators	FY17 ACT	FY18 ACT	FY19 FCST	FY20 Guidance
Revenue	1,300.3	1,306.3	**1,224.0**	**FY2017 level**
R&D investment	220.8	208.7	**211.0**	**More than 200.0 billion yen**
Core OP	268.7 20.7%	278.5 21.3%	**240.0** **19.6%**	**Core OP margin 20%**
Core EPS	100.64 yen	129.07 yen	**102.87 yen**	**Exceed FY2017**

AGENDA

I FY2018 Consolidated Financial Results

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REVIEW OF FY2018

Initiatives aiming at 3 Strategic Goals advancing as planned

Strategic Goal 1

Maximizing Product VALUE and Operational Excellence

Maximizing Product VALUE

- Steady top line growth in XTANDI and OAB products as planned
- Launches of XOSPATA in Japan and US
- Continued launches of new products in Japan
- 6 post-POC projects: Achieved important milestones as planned

Operational Excellence

- Restructuring of operations in Europe/Japan*
  Succession of Nishine plant

*Applicant for early retirement program: Approx. 700 employees

Strategic Goal 2

Evolving How We Create VALUE -With Focus Area Approach-

- Progress of early stage pipeline in identified Primary Focus
- Acquiring external innovation aligned with our strategy
  -Acquitisions:
  Quethera
  Potenza
  -Collaborations:
  Juventas
  Gene Therapy Research Institution
- Construction of new research, development and manufacturing facilities for drugs using innovative modalities/technologies

Strategic Goal 3

Developing Rx+^{TM}programs

- Build connections and networks with technology and knowledge from various fields
  -Established US basis for Rx+^{TM} business
  -Collaboration with venture capitals
- Progress on multiple Rx+^{TM} programs

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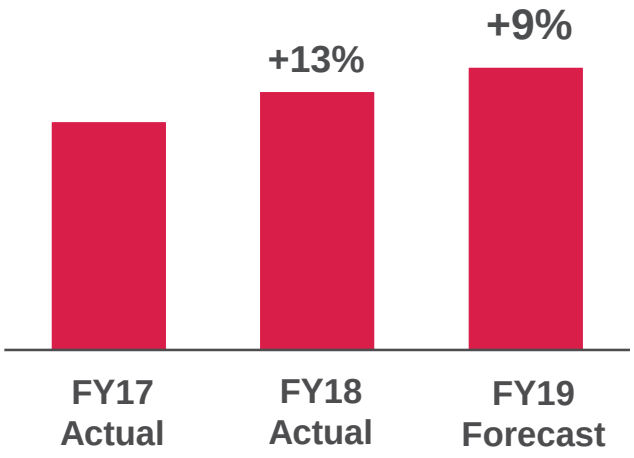
Strategic Goal 1

Maximizing Product VALUE and Operational Excellence

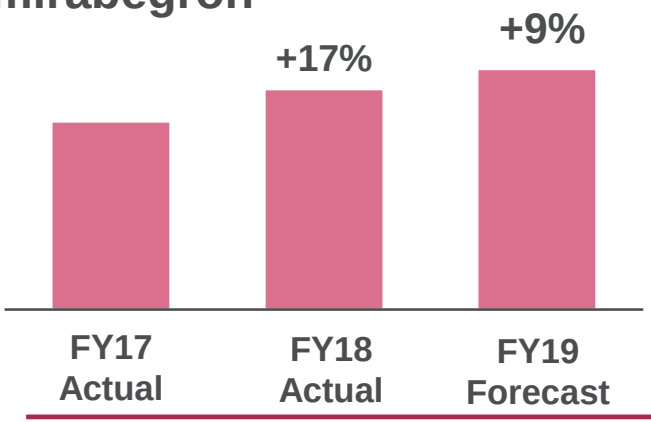
MAIN GROWTH DRIVERS: XTANDI AND MIRABEGRON

XTANDI



- FY2018: XTANDI revenue increased in all regions due to penetration in earlier stage of prostate cancer
- FY2019: Enhance market access and further penetration of urologists in the M0 CRPC indication
  FY2019 forecast：364.2 billion yen
- Regulatory decision to be expected in FY2019
  (Filed in Mar 2018)

mirabegron



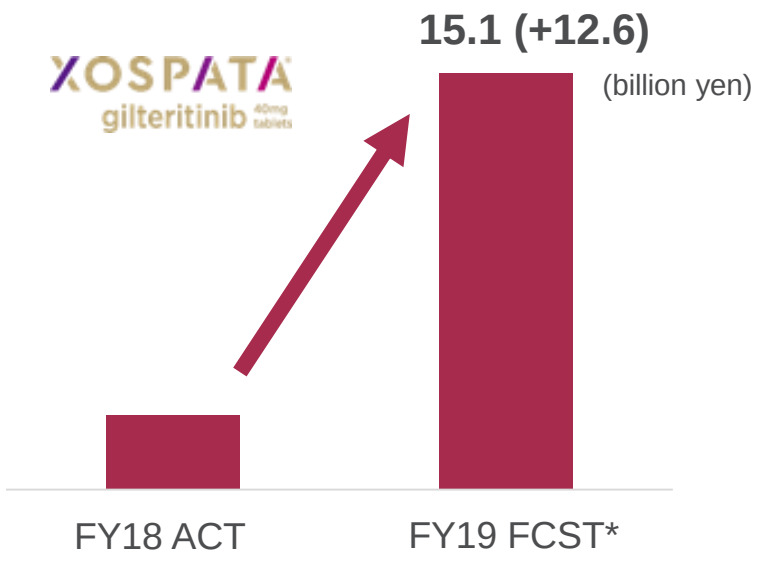
- FY2018: Double digit growth in each region by expanding share in approved markets
- FY2019: Continue to expand OAB market through ongoing disease awareness activities globally
  FY2019 forecast: 160.6 billion yen
- Launched in China in May 2018. Enhance efforts to improve drug adherence, consultation and diagnosis rate

M0 CPRC: Non-metastatic castration-resistant prostate cancer
mirabegron (Betanis/Myrbetriq/BETMIGA)

NEW PRODUCT: XOSPATA
FIRST FLT3 INHIBITOR FOR R/R AML WITH FLT3 MUTATION

Launched in Japan and US as new treatment option for AML

- Patients with AML with activating FLT3 mutations have short survival and high relapse rates. No standard of care established for R/R AML with FLT3 mutation.
- The NCCN guidelines included XOSPATA within days of FDA approval. Secured patient access through broad payer coverage.
- Many doctors experienced remarkably effective responses in target patients identified by companion diagnostics and the reaction from the prescribers is favorable. High rates of XOSPATA awareness post launch.
- Now initiating launch preparations in Europe.
- Educate around importance of FLT3 mutation testing and promote XOSPATA's characteristics for highly specialized hematologists/oncologists.



* Total of JP, US

FLT3: FML-like tyrosine kinase 3, R/R AML: Relapsed or refractory acute myeloid leukemia,
NCCN: National Comprehensive Cancer Network

NEW PRODUCTS IN JAPAN

Sales increase due to launch of new products and additional indications

Strategic plan 2018 Guidance: Exceed 100.0 billion yen in early 2020's

Repatha (evolocumab) injection 140 mg/mL
Launched in Mar. 2019

Suglat®
Additional indication Dec. 2018

Linzess (linaclotide) capsules
Additional indication Aug. 2018

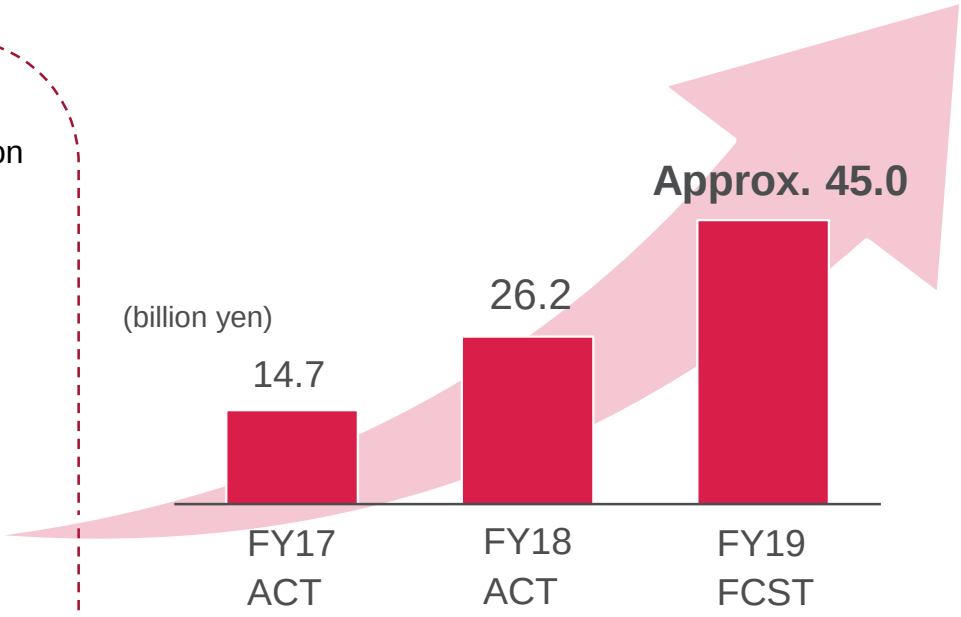
SUJANU®
Launched in May 2018

Dafclir®
Launched in Sep. 2018

BLINCYTO®
Launched in Nov. 2018

EVENITY (romosozumab) injection
Launched in Mar. 2019

Smyraf®
Approved in Mar. 2019



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NEW COMMERCIAL STRUCTURE AS OF APRIL 2019

New sales and marketing structure aims to maximize product VALUE on a global basis

- **Reorganization from the 4 unit commercial structure to 5 unit structure**
  - In addition to US as single division, independence of China where further market expansion to be expected
  - Bring regions and countries with similar payer systems and business practices into one division

Past

- Japan
- Americas
- EMEA
- Asia/Oceania

From April 2019

- Japan
- United States
- Greater China*
- Established Market*
- International*

- **Enhancing strategic planning and execution capabilities for priority products by expanding global marketing functions**
  - Brand General Managers (BGM) for six key late-stage projects build/promote consistent, effective and efficient product strategies on a global basis
  - Enhance collaboration with medical and development functions through leadership of BGM to more accurately reflect market needs to product profiles
  - Reinforce market access functions to secure drug access in each country

*Greater China: China, Hong Kong, Taiwan

*Established Market: Europe, Canada, Australia
*International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea

ENHANCEMENT OF INITIATIVES IN CHINA (1)

Expecting further market expansion by promoting innovation in addition to economic growth

External environment and business opportunities

- Continued market growth from rising income levels due to economic growth and aging society
- Potential for accelerated approval of innovative drugs through deregulation
- Improving patient accessibility by increasing access opportunity to the National Health Insurance Reimbursed Drug List (NRDL)
- Changing healthcare environment such as the rise of digital health thanks to rapid evolution of ICT

ICT: Information and communication technology

ENHANCEMENT OF INITIATIVES IN CHINA (2)

Invest sufficient resources to accelerate development of innovative medicines in top-tier market

Enhancement of development and regulatory functions

- Establishing drug development capabilities similar to other top-tier market like Japan, US and Europe
- Enhancing capabilities in medical affairs, regulatory affairs and other functions
- Allocating sufficient resources to multiple key late-stage projects

Late-stage projects

enzalutamide (XTANDI)	M1 CRPC Filed in Mar. 2018 Regulatory decision to be expected in FY2019
gilteritinib (XOSPATA)	R/R AML P3 study ongoing
enfortumab vedotin	Metastatic urothelial cancer Development plan under discussion
zolbetuximab	Gastric and GEJ adenocarcinoma Plan to join in P3 studies in FY2019
fezolinetant	MR-VMS Plan to initiate P3 studies in FY2019
peficitinib	Rheumatoid arthritis P3 study ongoing

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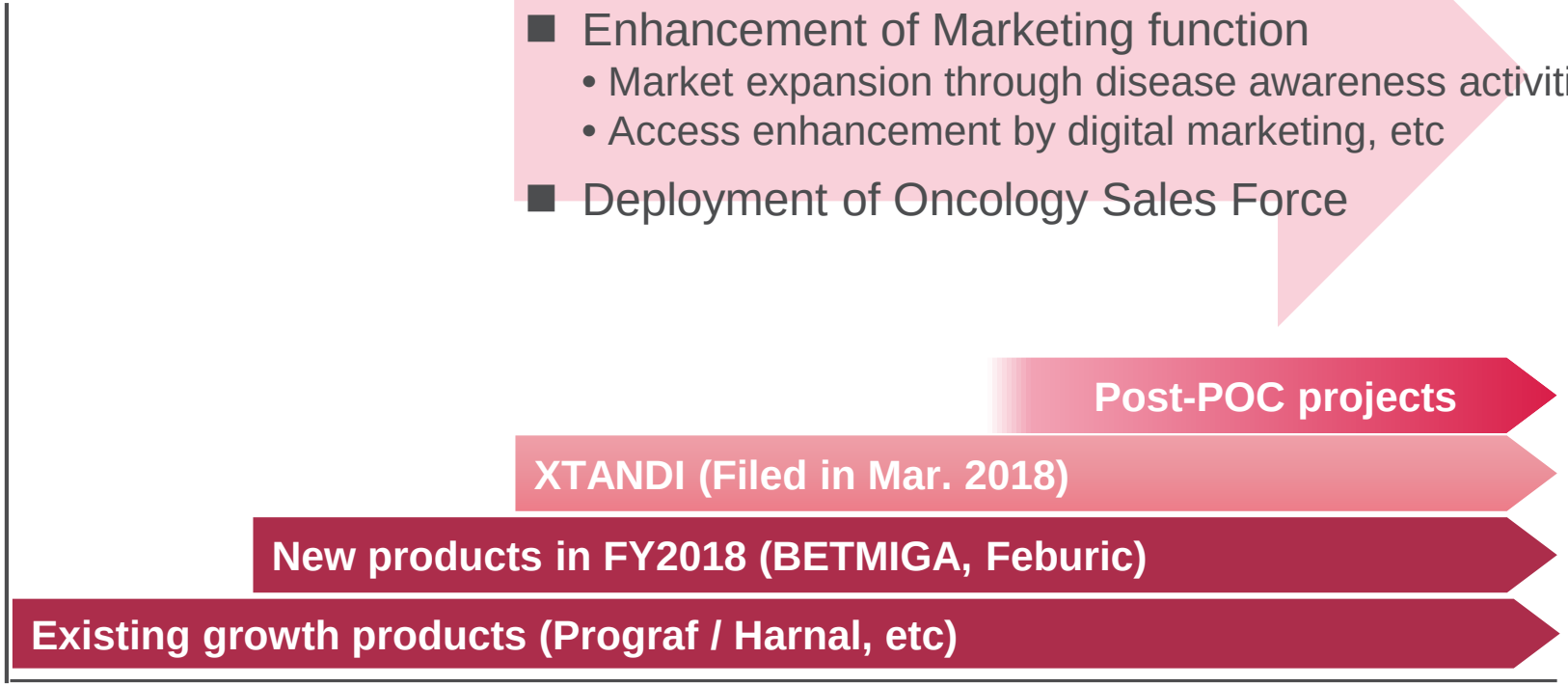
M1: Metastatic, CRPC: Castration resistant prostate cancer
AML: Acute myeloid leukemia
GEJ: Gastroefophafeal junction
MR-VMS: Menopause-related vasomotor symptom

ENHANCEMENT OF INITIATIVES IN CHINA (3)

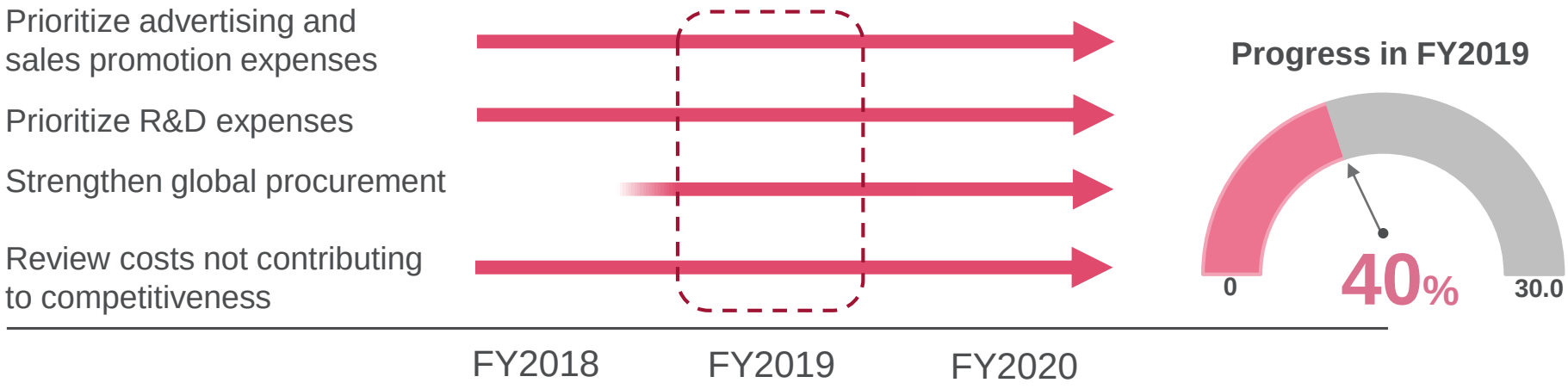
Enhancement of commercial functions to support continuous launch of new products into growth market

- Enhancement of Government affairs function
- Enhancement of Marketing function
  - Market expansion through disease awareness activities
  - Access enhancement by digital marketing, etc
- Deployment of Oncology Sales Force



PURSUE OPERATIONAL EXCELLENCE

Progress as planned against profit improvement plan of over 30.0 billion yen announced in Strategic plan 2018

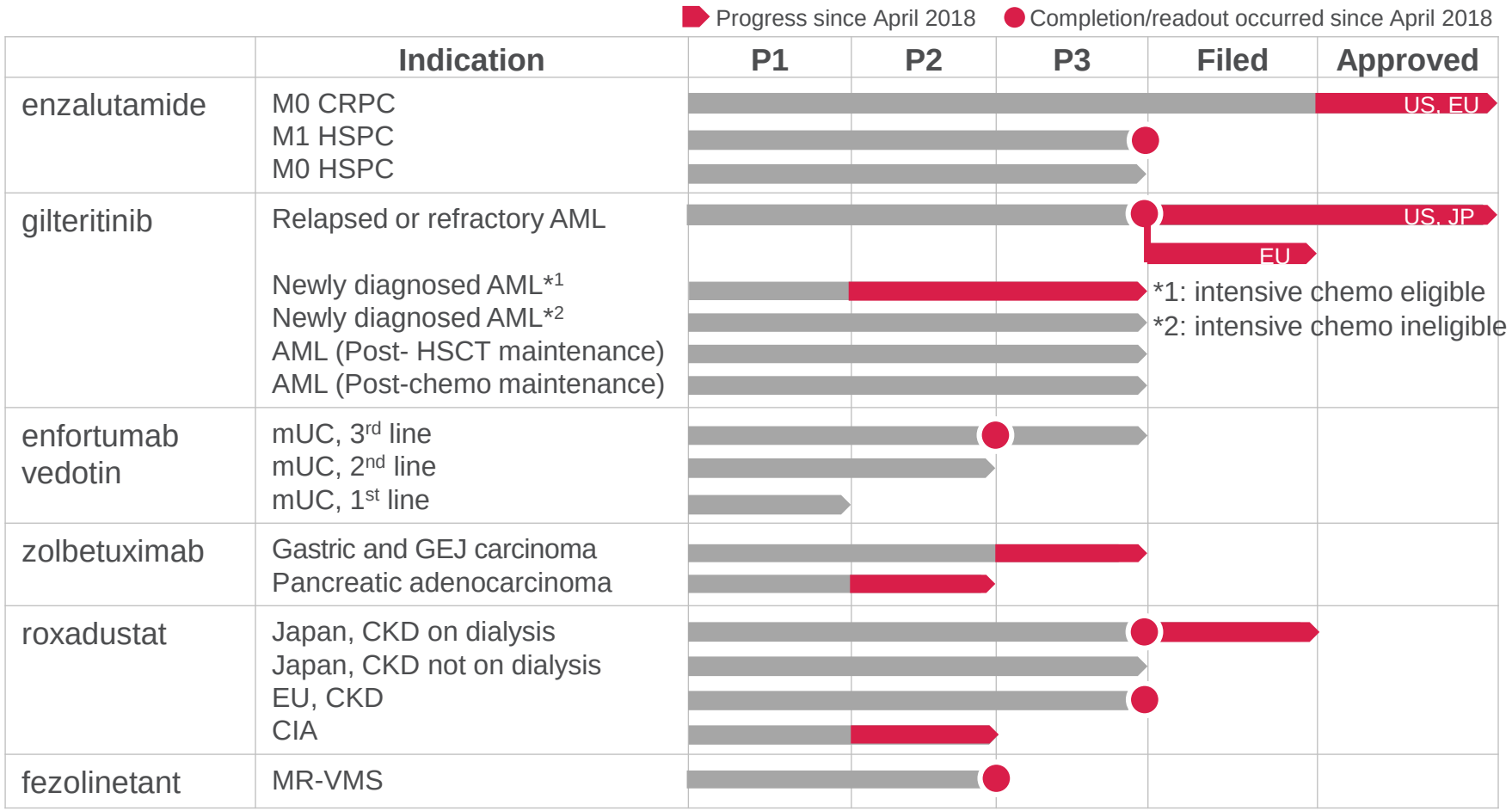


Contributing to mid- to long-term cost structure reform in FY2020 onward along with implemented initiatives

- Wind-down of Agensys research operations
- Reorganization of R&D and sales & marketing functions in EMEA
- Restructuring of domestic group company/ early retirement program in Japan
- Business transfers (Nishine Plant, etc.)

CONTINUED PROGRESS ON 6 POST-POC PROJECTS SINCE APR 2018

Development advancing as intended in Strategic Plan 2018



POC: Proof-of concept, 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, CIA: Chemotherapy-induced anemia, MR-VMS: Menopause-related vasomotor symptoms

FY2018 ACHIEVEMENTS AND STATUS UPDATE
(Underline: Updates since Q3/FY2018 Announcement)

enzalutamide

M0 CPRC
- **US:** Approved in July 2018
- **EU:** Approved in Oct 2018

M1 HSPC
- **ARCHES study:** Results obtained
- Filing planned by mid-2019 in US/EU/Japan

gilteritinib

FLT3 mut+ R/R AML
- **ADMIRAL study:** Results obtained
- **Japan:** Launched in Dec 2018.
  Plan to include OS data in label in 3Q/2019
- **US:** Launched in Dec 2018.
  Submitted sNDA to include OS data in the label in Feb 2019
- **EU:** MAA submitted in Feb 2019

enfortumab vedotin

mUC with prior CPI treatment
- **Cohort 1 in Phase 2 study** (platinum-pretreated): TLR obtained
- BLA submission planned in US in 2019

zolbetuximab

Gastric and GEJ adenocarcinoma
- **SPOTLIGHT study:** FPI in Oct 2018
- **GLOW study:** FPI in Jan 2019

Pancreatic cancer
- Phase 2 to start in 2Q/2019

roxadustat

Anemia associated with CKD
- **EU:** Results obtained from 6 studies.
  MAA planned in 2H/2019
- **JP:** Data readout in 2 studies.
  Filed for patients on dialysis in Sep 2018. For non-dialysis, TLR of the remaining study expected in 2019

Chemotherapy induced anemia
- Phase 2 to start in 2019

fezolinetant

MR-VMS
- **Phase 2b study:** Results obtained
- **Phase 3 study:** Under preparation

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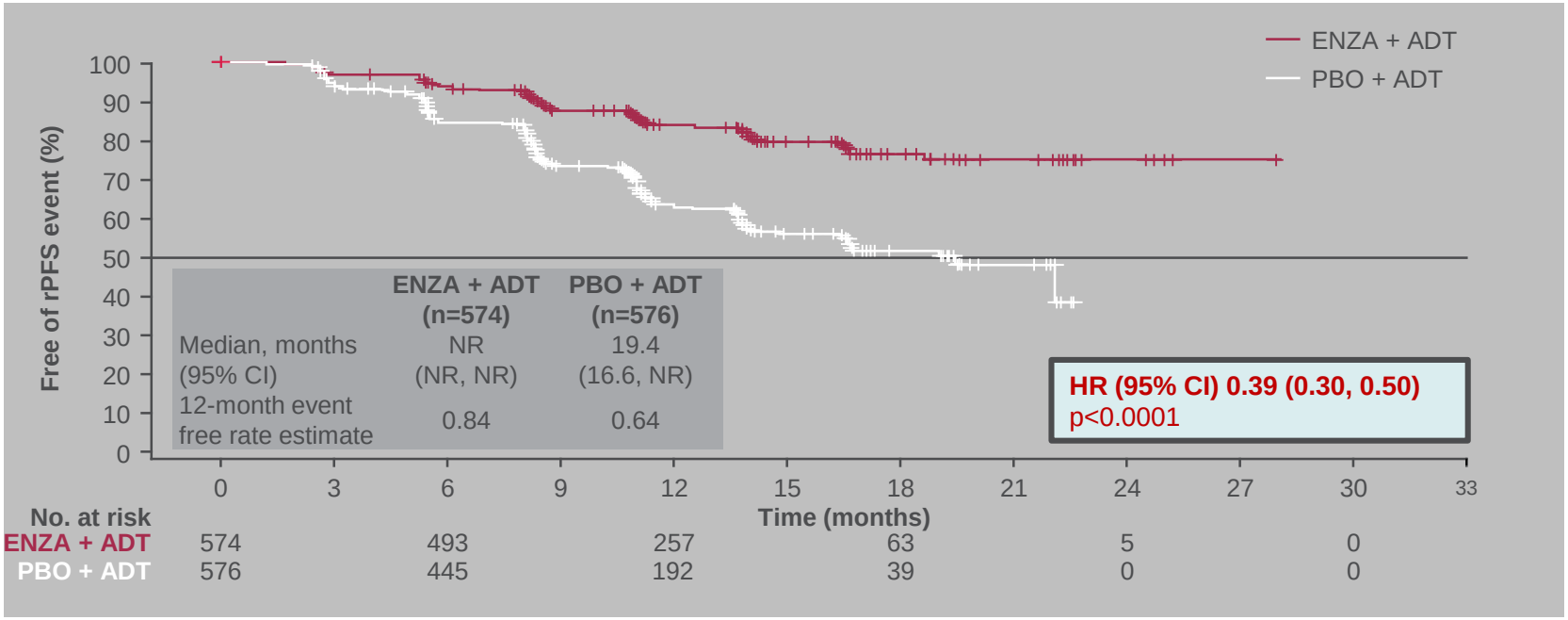
M0 CRPC: Non-metastatic castration-resistant prostate cancer, M1 HSPC: Metastatic hormone-sensitive prostate cancer, FLT3 mut+: Fms-like tyrosine kinase 3 mutation positive, R/R AML: Relapsed/refractory acute myeloid leukemia, OS: Overall survival, sNDA: Supplemental new drug application, MAA: Marketing authorization application, mUC: metastatic urothelial cancer, CPI: Check point inhibitor, TLR: Topline result, BLA: Biologics license application, GEJ: Gastroefophafeal junction, FPI: First patient in, CKD: Chronic kidney disease, MR-VMS: Menopause-related vasomotor symptom

ENZALUTAMIDE: RESULTS OF PHASE 3 ARCHES IN M1 HSPC

Enzalutamide significantly improved rPFS
Filing for M1 HSPC in US/EU/Japan planned by mid-2019



- The preliminary safety analysis appears consistent with the safety profile of XTANDI in previous clinical trials in CRPC

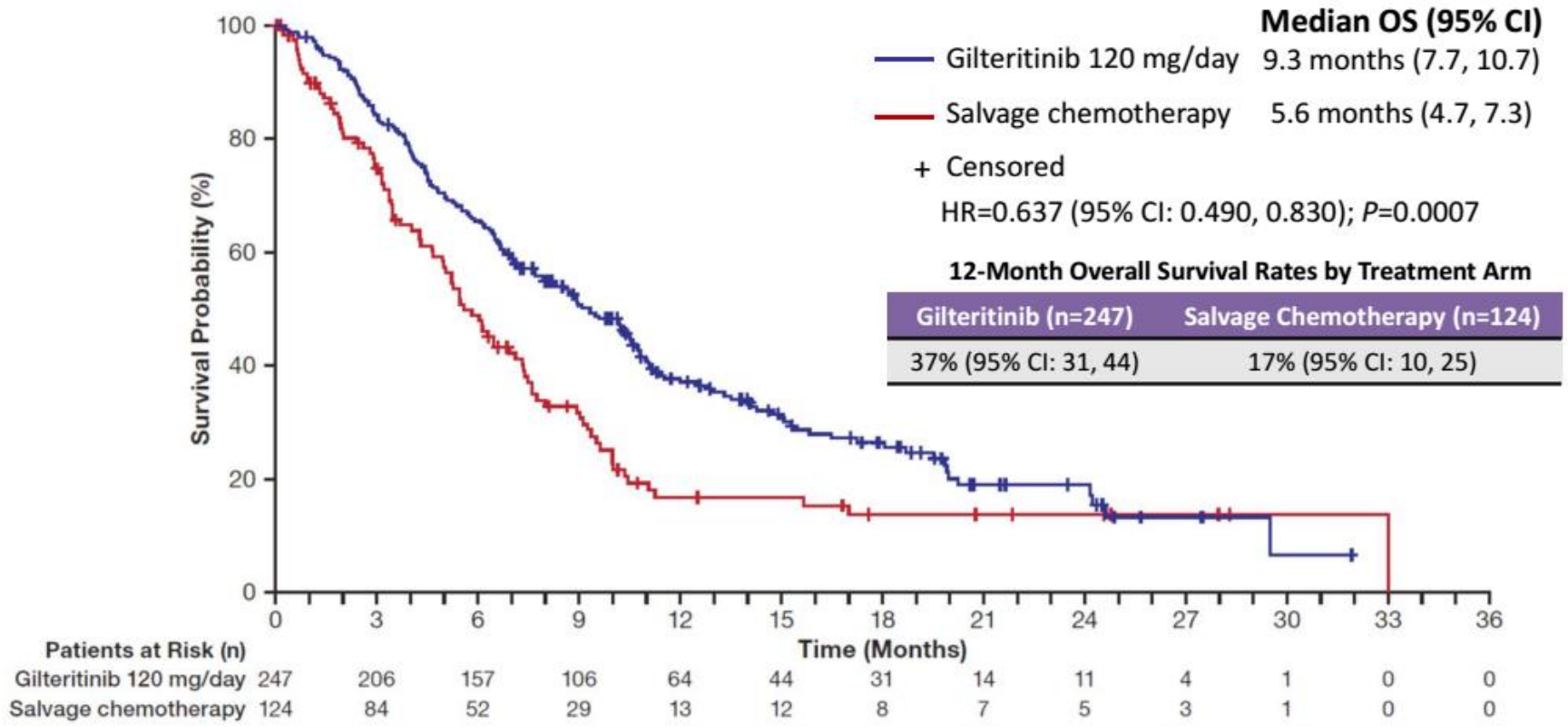
Andrew J. Armstrong *et al*., ASCO-GU 2019

M1 HSPC: Metastatic hormone-sensitive prostate cancer, rPFS: Radiographic progression-free survival, ENZA: enzalutamide, ADT: Androgen deprivation therapy, PBO: Placebo, HR: Hazard ratio, CI: Confidence interval, NR: Not reached, CRPC: Castration-resistant prostate cancer, ASCO-GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium

GILTERITINIB: RESULTS OF PHASE 3 ADMIRAL RESULTS IN R/R AML

Gilteritinib significantly improved survival compared with salvage chemotherapy

US sNDA to include OS and MAA in EU submitted in Feb 2019



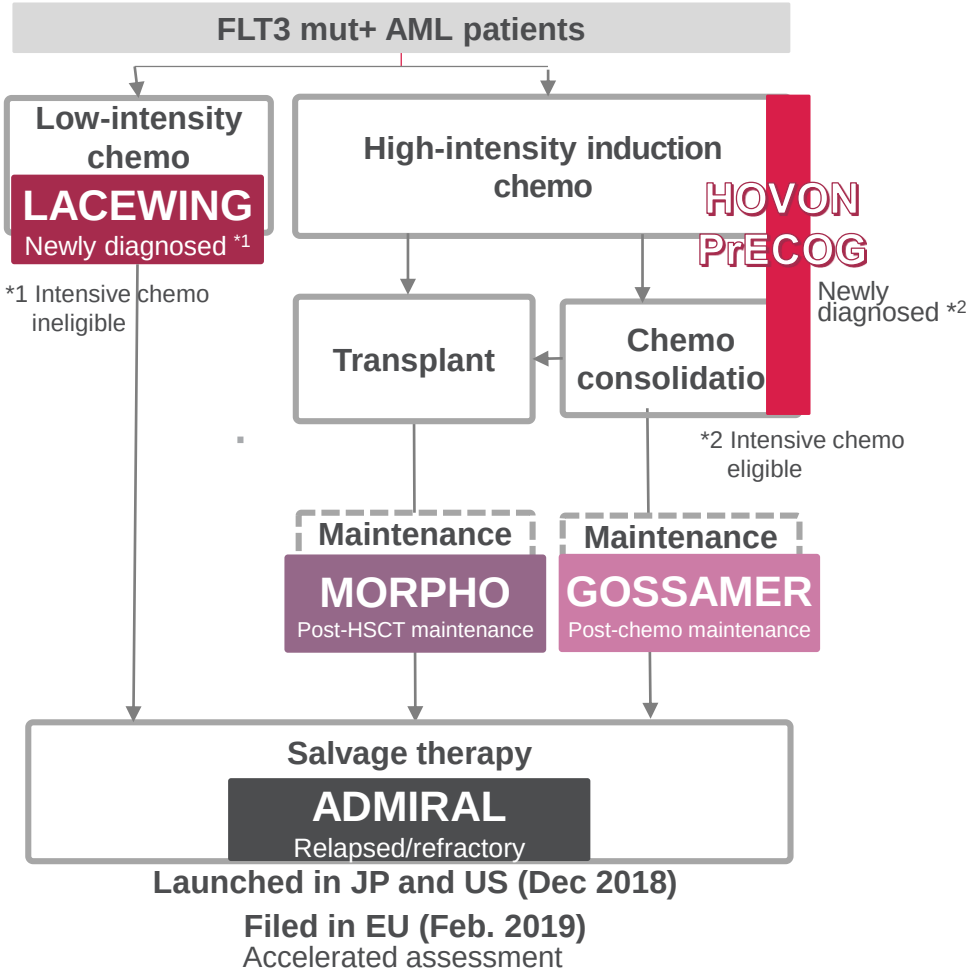
- Compared with salvage chemotherapy, gilteritinib was generally associated with lower toxicity during the first 30 days of treatment, which facilitated outpatient administration of the drug

Alexander E. Perl *et al.,* American Association for Cancer Research 2019

sNDA: Supplemental new drug application, OS, overall survival, MAA: Marketing authorization application, CI: Confidence interval, HR: Hazard ratio

GILTERITINIB

Plan to start 2 head-to-head studies in newly diagnosed patients



- In a Phase 1 study in combination with high intensity chemotherapy, gilteritinib showed a CRc rate of ≥90% in patients with FLT3 mutations **
- Two collaborative studies to be initiated in 3Q/2019
  - Phase 3 study by HOVON primarily in EU
  - Phase 2 study by PrECOG in US
- Head-to-head comparator studies vs midostaurin, in combination with high intensity chemotherapy

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** K. Pratz *et al.*, ASH 2018

FLT3 mut+: Fms-like tyrosine kinase 3 mutation positive, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, ASH: American Society of Hematology

ENFORTUMAB VEDOTIN

Obtained positive results from Cohort 1 of Phase 2 study.
BLA submission in US planned later this year

Characteristics

- First and only ADC targeting Nectin-4, which is highly expressed in bladder cancer and has limited expression on normal tissue
- Breakthrough Therapy designation for CPI-pretreated mUC patients granted by FDA

Unmet medical needs in urothelial cancer

- Approximately 56,000 cases of newly diagnosed or recurrent metastatic bladder cancer annually (US, EU5, JP) *1
- 5-year mortality rate of 4% *2
- Approx. 80% of patients do not respond to PD-1/PD-L1 therapy, requiring further treatment options

Status update

EV-201 study

- Single-arm, pivotal phase 2 study
- Cohort 1 enrolled 128 patients previously treated with a PD-1 or PD-L1 inhibitor and a platinum-containing chemotherapy

Top line results

- 44% ORR (primary endpoint)
- Duration of response was consistent with previous phase 1 study
- The most common treatment-related AEs included fatigue, alopecia, decreased appetite, rash and peripheral neuropathy
- Data to be presented at ASCO in June

Next step

- Intend to submit a BLA to the FDA later this year
- Confirmatory phase 3 study ongoing

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*1: Kantar Health, *2 Cancer Stat Facts: Bladder Cancer by NIH
BLA: Biologics license application, ADC: Antibody-drug conjugate, CPI: Check point inhibitor, mUC: metastatic urothelial cancer,
FDA: Food and Drug Administration, ORR: Objective response rate, AE: Adverse events, ASCO: American Society of Clinical Oncology, NIH: National Institute of Health

ROXADUSTAT

Readout of all Phase-3 studies ongoing, MAA planned in 2H/2019
Initiated development for additional indication

Characteristics

- Novel mechanism of action
- Orally administered
- Reduces the need for IV iron
- Comparable efficacy to current treatment (i.e. ESAs)
- Erythropoietin levels within or near the physiological range, potentially avoiding the concerns from the existing therapy
- Efficacy in patients with inflammation who have reduced response to existing therapy

Status update

- Obtained TLRs of 6 Phase 3 studies to support EU filing and reimbursement
- Pooled safety analysis planned in 1H/2019
- MAA submission planned in 2H/2019

Maximizing VALUE in chemotherapy-induced anemia (CIA)

Unmet medical needs

- Up to 50% of patients with cancer develop CIA over the course of chemotherapy *1
- 25%-40% of patients are non-responders to existing ESAs *2

Next step

- Phase 2 study in non-myeloid malignancies with anemia due to chemotherapy to start in 2019 (Study sponsor: FibroGen)

FibroGen

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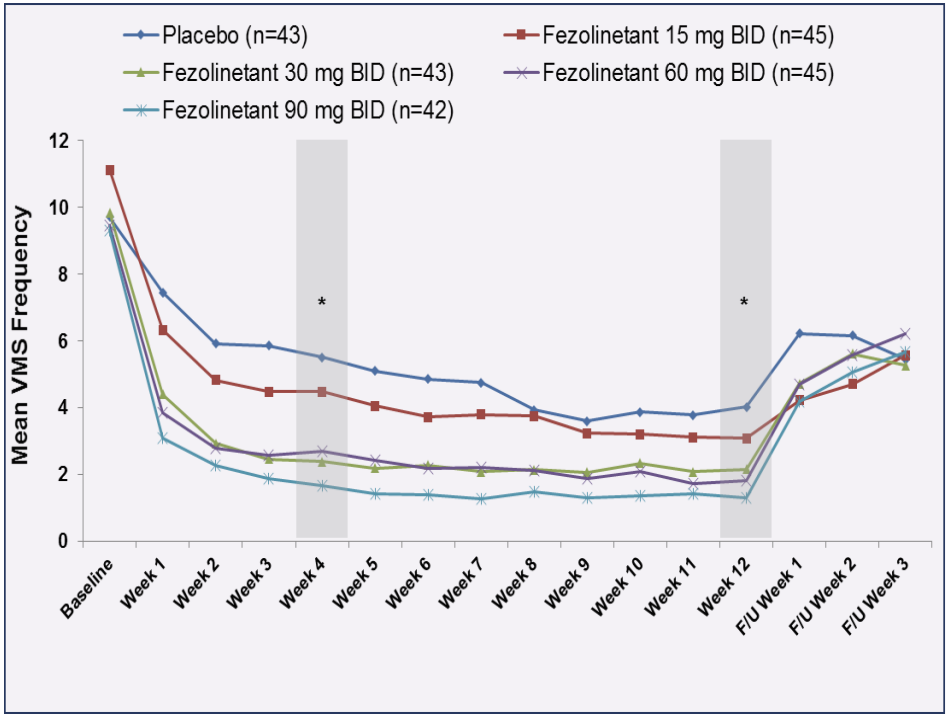
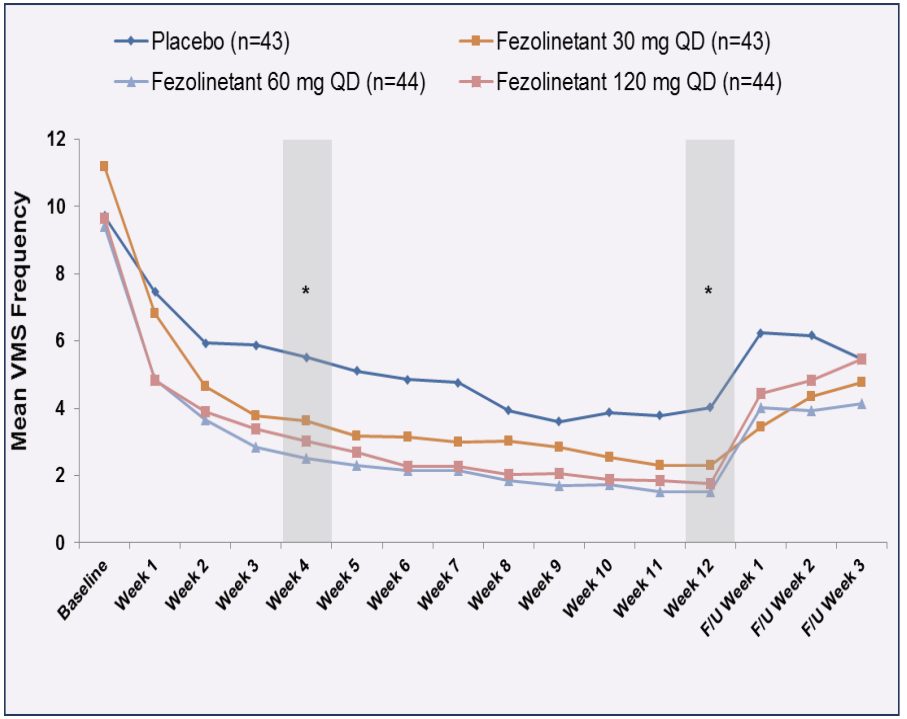
*1: Eur J Cancer 2004; 40: 2293-2306, *2: Cancer Manag Res. 2016; 8: 1-10
MAA: Marketing authorization application, IV: Intravenous, ESA: Erythropoietin-stimulating agent, TLR: Topline result

FEZOLINETANT: EFFICACY IN PHASE 2B

Statistically significant improvement across all four co-primary endpoints in most cohorts; comparable efficacy and treatment effect size for BID and QD

Frequency of moderate and severe VMS per 24 hours with fezolinetant BID/QD





*P<0.05 for all pairwise comparisons of fezolinetant vs placebo at weeks 4 and 12, with no adjustments for multiplicity

BID: Twice daily, QD: Once daily, VMS: Vasomotor symptom, ENDO: Endocrine Society's Annual Meeting

FEZOLINETANT: SAFETY IN PHASE 2B AND NEXT STEP

Fezolinetant was generally well tolerated; Phase 3 preparation ongoing

Safety

- Overall TEAE rates were similar across cohorts; TEAEs were mostly mild or moderate.
- There were no treatment-related serious TEAEs or deaths
- 9 patients (less than 3%) treated with higher doses had transient increases in the liver enzymes ALT and AST; No cases of bilirubin greater than two times the upper limit of normal; Patients returned to baseline levels after discontinuation of dosing

Status update

- End of Phase 2 Meeting is being held with FDA; incorporating their feedback into the planned Phase 3 program
- Plan to also consult with other regulatory authorities

Next step

- Plan to initiate Phase 3 in 2H/2019
- Plan to conduct multiple Phase 3 studies including long term safety studies in Western and Asian populations

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TEAE: Treatment emergent adverse event, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, FDA: Food and Drug Administration

EXPECTED KEY EVENTS IN FY2019

Continued progress on important milestones for 6 post-POC projects

Regulatory decisions	enzalutamide	M1 CRPC (China)
	gilteritinib	Relapsed/refractory AML (EU) Label update to include OS data (US)
	roxadustat	Anemia associated with CKD, dialysis (Japan)
Regulatory submissions*	enzalutamide	M1 HSPC (US/EU/Japan)
	enfortumab vedotin	mUC, CPI-pretreated/platinum-pretreated (US)
	roxadustat	Anemia associated with CKD, dialysis/non-dialysis (EU)
Data readouts	roxadustat	Pooled safety analysis P3 study in Japanese CKD patients, 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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POC: Proof of concept, M1: Metastatic, CRPC: Castration-resistant prostate cancer, AML: Acute myeloid leukemia, OS: Overall survival, CKD: Chronic kidney disease, HSPC: Hormone sensitive prostate cancer, mUC: metastatic urothelial cancer, CPI: Checkpoint inhibitor

Strategic Goal 2

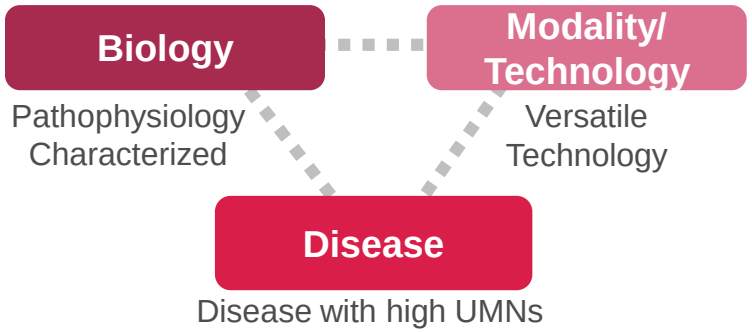
Evolving How We Create VALUE
-With Focus Area Approach-

FOCUS AREA APPROACH

Focusing on the areas to turn innovative science to VALUE for patients

Focus Area approach

- Exploring multiple sets of combinations of Biology, Modality/Technology and Disease



- Primary Focus is selected from Focus Areas based on;
  - -Scientific evidence
  - -Identified lead program
  - -Potential follow-on programs

Our efforts in current and potential Primary Focus

Primary Focus

- Prioritize investment in 4 Primary Focus

Regeneration & blindness	**Immuno-oncology**
ASIM biology	**Mitochondria biology**

Potential future Primary Focus

- Explore the components and connections of Biology, Modality/Technology and Disease further and identify a lead program
- Exploring Genetic regulation and other areas

ASIM: Antigen-specific immuno-modulation

ACQUIRING AND PARTNERING EXTERNAL CAPABILITIES

Incorporate game changing technology and cutting-edge science

Primary Focus

Regeneration & blindness	ocata THERAPEUTICS, Universal Cells, * Quethera, Clinical Innovation CLINO CO., Harvard Medical School
Immuno-oncology	* POTENZA therapeutics, 鳥取大学 Tottori University
ASIM biology	IMMUNOMIC THERAPEUTICS, Affinivax
Mitochondria biology	mitobridge

Potential future Primary Focus

Genetic regulation	* Gene Therapy Research Institution, * Juventas THERAPEUTICS

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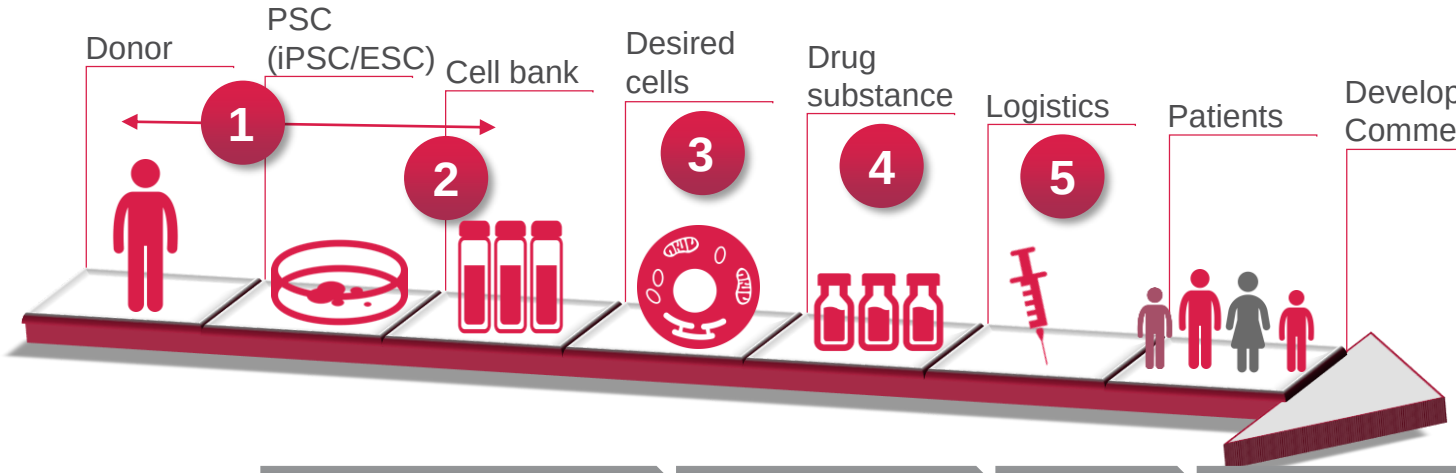
Note) This chart Includes M&As, license agreements and research collaborations related to Primary Focus
* Agreements executed or updated in FY2018
ASIM: Antigen-specific immuno-modulation, M&A: Merger and acquisition

REGENERATION & BLINDNESS (1/2)

Established research and manufacturing platform for cell therapy



	Research				Manufacturing				Supply chain		Development			Commercial
	PSC sourcing ❶	UDC ❷	Gene-editing ❷	Differentiation ❸	Standardization ❹	QA ❹	Facility ❹	Freeze-thaw tech.	Formulation	Operation ❺	RA	IMT regimen	Specialized platform	Business model
Post-Ocata Acquisition	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Post-UCells Acquisition		●	●											
Current AIRM	●	●	●	●	●	●	●	●	●	●	●	●	●	●

●: Established, ●: Underway, ●: Not Established / To be considered

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PSC: Pluripotent stem cell, iPSC: Induced pluripotent stem cell, ESC: Embryonic stem cell, UDC: Universal donor cell, QA: Quality assurance, RA: Regulatory affairs, IMT: Immunosuppressant, AIRM: Astellas Institute for Regenerative Medicine

REGENERATION & BLINDNESS (2/2)

Building a portfolio of cell therapy, gene therapy and other approaches to address blindness

Strategy

- Provide therapy to regain lost sight or prevent blindness by cell therapy and gene therapy in intractable ophthalmic diseases
- Leverage UDC technology to enrich cell therapy pipeline, including non-ocular indications, and build cell therapy platform throughout value chain

Clinical program

ASP7317
Dry age-related macular degeneration
Recruitment for Phase 1b/2 ongoing

ASP7317 overview

Previous cell line (MA09-hRPE)

- 38 patients were successfully transplanted with hESC-derived RPE cells.
- The cells were well tolerated at all doses up to 4 years post–transplantation.
- Initial gains in vision followed by gradual loss in patients with late stage AMD

Established new cell line (ASP7317)

- Compliant to latest FDA guideline
- Developed a new cell line and an improved formulation with an extended shelf life
- Phase 1b/2 (dose-escalation and POC) study is ongoing; first patient treated in US.

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UDC: Universal donor cell, RPE: Retinal pigment epithelium, hESC: Human embryonic stem cell, AMD: Age-related macular degeneration, FDA: Food and Drug Administration, POC: Proof of concept

IMMUNO-ONCOLOGY

Building a portfolio of novel immuno-oncology programs

Strategy

- Harnessing the immune system to treat intractable cancers

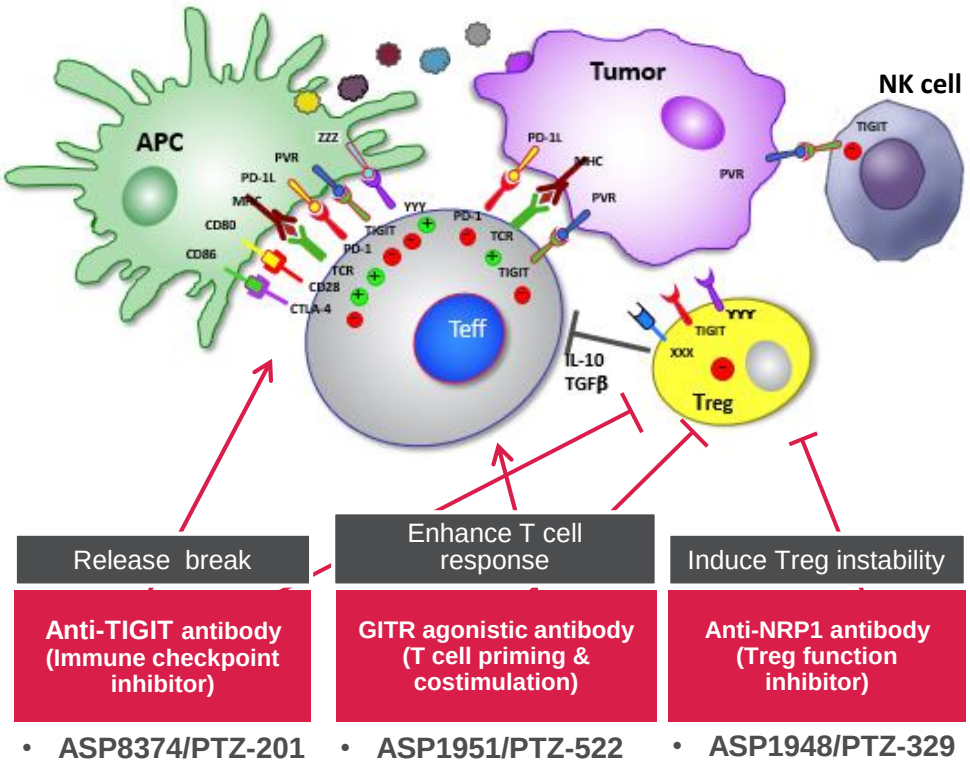
Clinical program

Projects from Potenza
- Started collaboration in 2015
- Acquired the company in Dec 2018

3 projects are in Phase 1 stage
- ASP8374/PTZ-201
- ASP1948/PTZ-329
- ASP1951/PTZ-522

ASP9801 (oncolytic virus)
- Entered into Phase 1 stage

3 clinical projects targeting patients non-responsive to existing therapies



ASIM BIOLOGY AND MITOCHONDIRA BIOLOGY

Exploring potential of multiple clinical programs

ASIM biology

- Exploring LAMP-Vax platform as a potential approach to develop immune tolerance in allergic individuals
- Explore new platform which can prevent serious infectious diseases

Clinical program

LAMP-Vax vaccine
- ASP0892 for peanut allergy
  Phase 1 ongoing
- ASP2390 for house dust mite allergy
  Preparing clinical trial

MAPS vaccine
- ASP3772 for pneumococcal disease
  Phase 1 ongoing

Mitochondria biology

- Develop mitochondria biology-based therapies to address various diseases related to mitochondrial dysfunction

Clinical program

ASP1128/MA-0217
- Acute kidney injury
  Entered into Phase 2 stage

ASP0367/MA-0211
- Duchenne muscular dystrophy
  Phase 1 ongoing

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ASIM: Antigen-specific immuno-modulation, MAPS: Multiple antigen presenting system

Strategic Goal 3

Developing Rx+™ Programs

Rx+™ PROGRAM: ACHIEVEMENTS IN FY2018

- Established US basis for Rx+™ business
- Collaborations with venture capitals digiTx PARTNERS strategic healthcare investment partners
- Progress on multiple programs

	Progress in FY18	Expected key events in FY19
Exercise therapy	• Exercise support application: Executed an agreement with BANDAI NAMCO Entertainment Inc. • Exercise therapy: Clinical research ongoing	• Exercise support application: Plan to conduct a clinical research
Image-guided precision surgery	• ASP5354; first compound as the image-guided precision surgery to identify ureter: Started Phase 1 study	• ASP5354: Plan to initiate POC study • Second compound enabling identification of cancer for surgically removal: Plan to initiate Phase 1 study
Theranostics* with radioisotope-labeled antibodies*		• PET imaging material: Plan to initiate clinical trial

* Concept combining “therapeutic” and “diagnostic”

AGENDA

I FY2018 Consolidated Financial Results

FY2019 Forecasts

II Initiatives for Sustainable Growth

III Capital Allocation

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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

Shareholder return

Aiming for steady dividend increase during FY2018-FY2020

Flexible share buybacks

	FY2017 ACT	FY2018 ACT	FY2019 FCST
Dividend	36 yen	38 yen (planned)	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

FY2018 ACT: REVENUE BY REGION

(billion yen)	FY17 ACT	FY18 ACT	Change
Japan	**421.2**	**396.6**	-5.8%
Americas	**433.3**	**461.5**	+6.5%
EMEA	**343.8**	**340.3**	-1.0%
Asia/Oceania	**102.0**	**107.9**	+5.8%

FY2018: SALES OF MAIN PRODUCTS

(billion yen)	FY17 ACT	FY18 ACT	Change	CER growth	FY18 FCST*	Achieve-ment
XTANDI	**294.3**	**333.1**	**+13.2%**	**+13.6%**	**325.9**	**102.2%**
XOSPATA	**-**	**2.5**	**-**	**-**		
OAB products	**228.1**	**242.2**	**+6.2%**	**+6.5%**	**245.7**	**98.6%**
Vesicare	102.3	95.0	-7.2%	-6.8%	96.1	98.8%
Mirabegron	125.7	147.2	+17.0%	+17.2%	149.6	98.4%
Prograf	**198.5**	**195.7**	**-1.4%**	**-0.7%**	**196.0**	**99.8%**

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

*Announced in Oct. 2018

FY2019 FCST: REVENUE BY REGION

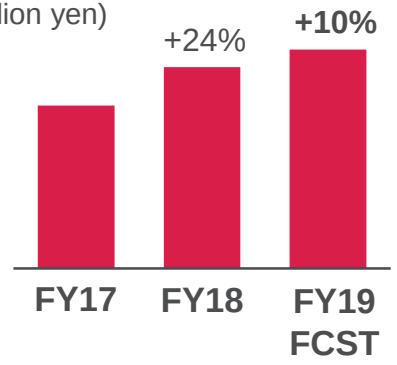
(billion yen)	FY18 ACT	FY19 FCST	Change
Japan	**369.5**	**316.8**	-14.3%
United States	**421.6**	**404.7**	-4.0%
Established Market	**300.0**	**286.8**	-4.4%
Greater China	**62.4**	**70.9**	+13.6%
International	**122.7**	**124.4**	+1.4%

Greater China: China, Hong Kong, Taiwan
Established Market: Europe, Canada, Australia
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea

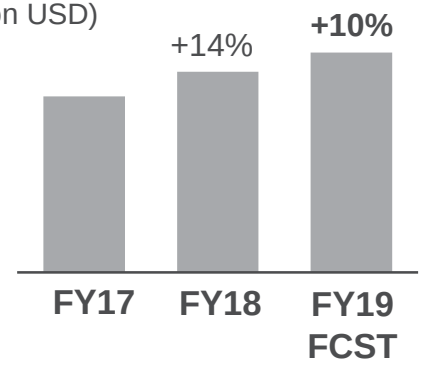
FY2019 FCST: XTANDI SALES BY REGION

Sales by region

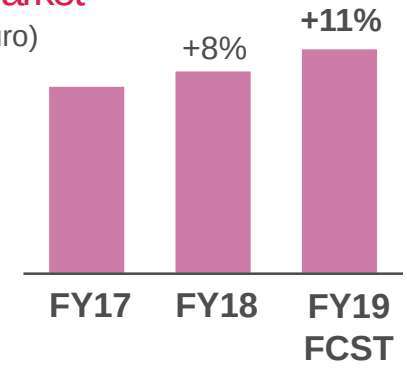
Japan
(billion yen)



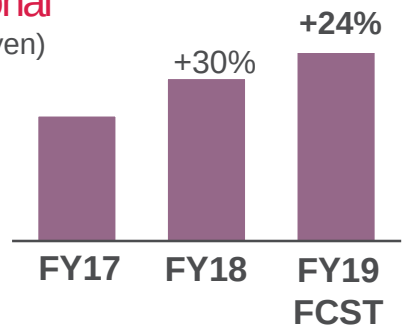
US
(million USD)



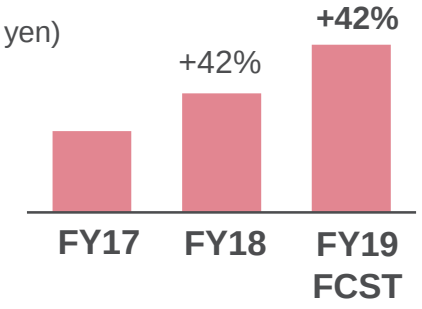
Established Market
(million euro)



International
(billion yen)



Greater China
(billion yen)

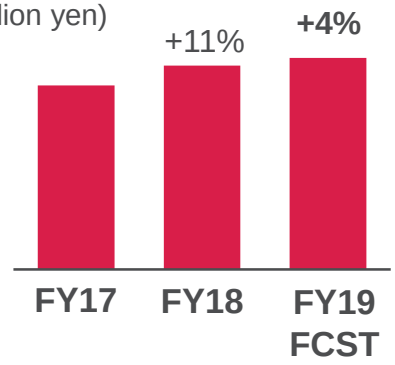


Greater China: China, Hong Kong, Taiwan
Established Market: Europe, Canada, Australia
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea

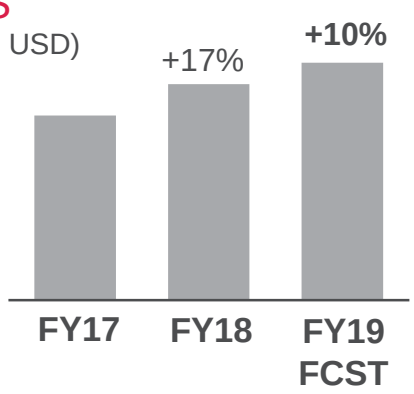
FY2019 FCST: MIRABEGRON SALES BY REGION

Sales by region

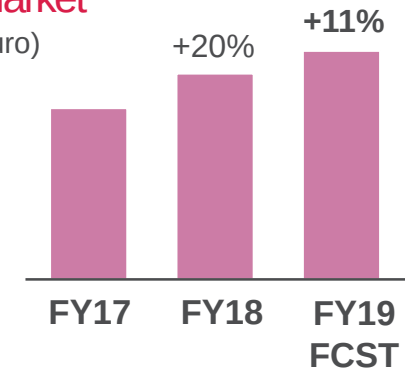
Japan
(billion yen)



US
(million USD)

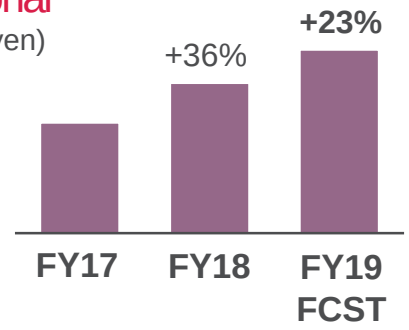


Established Market
(million euro)

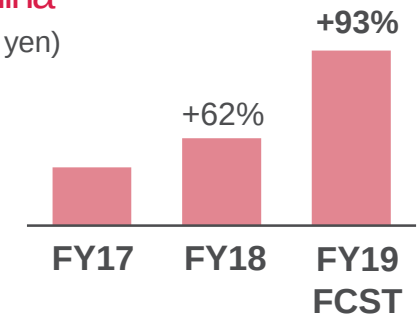


Q3/FY18

International
(billion yen)



Greater China
(billion yen)



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Greater China: China, Hong Kong, Taiwan
Established Market: Europe, Canada, Australia
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea

FX RATE (ACTUAL)

Average rate for the period

Currency	FY17	FY18	change
USD	111 yen	111 yen	+0 yen
EUR	130 yen	128 yen	-1 yen

Change in closing rate from PY end

Currency	FY17	FY18
USD	-6 yen	+5 yen
EUR	+11 yen	-6 yen

Fx impact on elimination of unrealized gain: COGs ratio -0.1 ppt

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 FY2018 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)	FY17 end	FY18 end
Total assets	1,858.2	1,897.6
Cash and cash equivalents	331.7	311.1
Total equity attributable to owners of the parent	1,268.3	1,258.4
Equity ratio (%)	68.3%	66.3%

(billion yen)	FY17	FY18
Cash flows from operating activities	312.6	258.6
Cash flows from investing activities	-121.8	-41.8
Free cash flows	190.8	216.9
Cash flows from financing activities	-203.4	-233.7
Acquisition of treasury shares	-130.7	-160.4
Dividends paid	-71.6	-72.1

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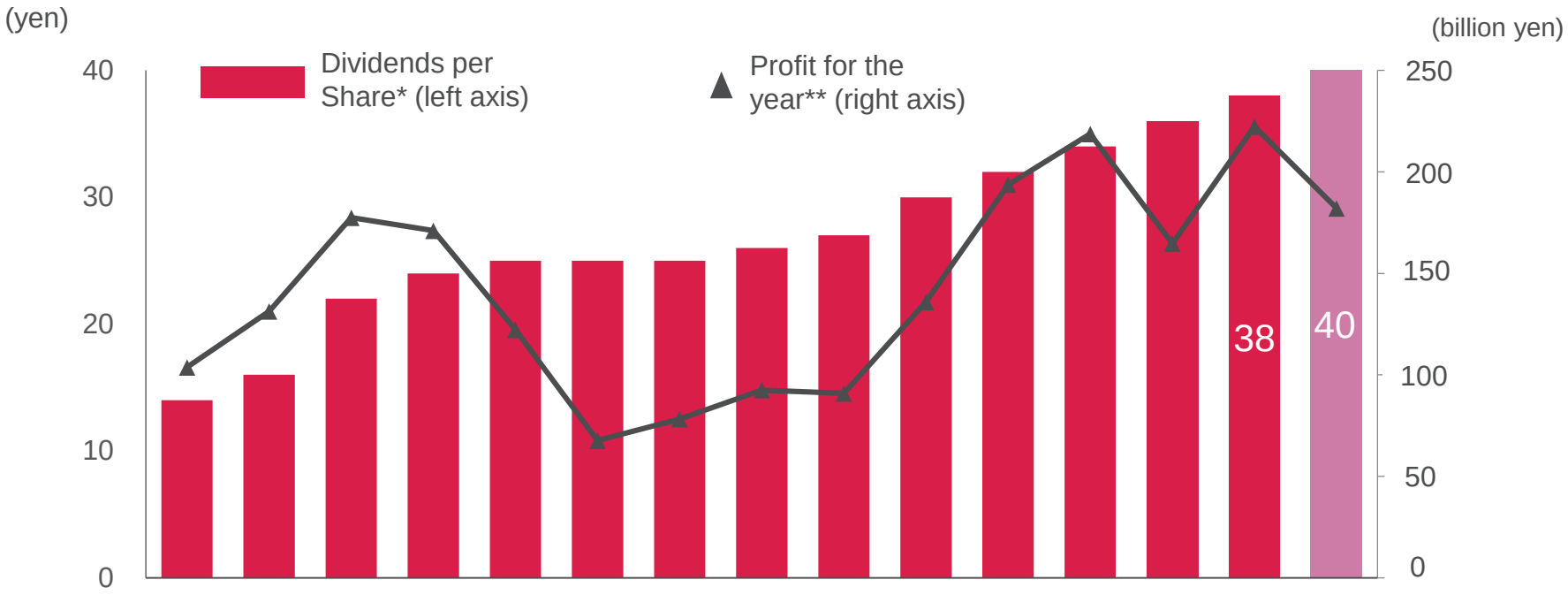
Details of shareholder returns



(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 (including filed pipeline)

enzalutamide M0 CRPC	✓✓✓
gilteritinib R/R AML JP/US EU	✓✓✓ ✓✓
roxadustat Anemia associated with CKD Dialysis (JP)	✓✓

FY2019-2020

enzalutamide M1 HSPC	✓
enfortumab vedotin Metastatic urothelial cancer	✓
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

*Subject to internal assessment, decision and regulatory consultation, as appropriate.
**Filing timing in the first country/region within US/EU/JP. If the project is regional specific (i.e. development right only in JP/Asia), the region is specified in the column.

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
- ASP0892
- ASP0367/MA-0211
- MucoRice-CTB
- ASP3772

Phase 2

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

Phase 3

- enzalutamide (M0 HSPC, M1 HSPC)
- gilteritinib (R/R AML: China, Other AML)
- enfortumab vedotin (Urothelial cancer)
- zolbetuximab (Gastric and gastroesophageal junction adenocarcinoma)
- peficitinib (Rheumatoid arthritis, China)
- mirabegron (Pediatric OAB & NDO)
- roxadustat (Anemia associated with CKD, EU: Non-dialysis/dialysis, JP: non-dialysis)

Filed

- enzalutamide (M1 CRPC, China)
- gilteritinib (R/R AML, EU)
- solifenacin* (Pediatric NDO, US)
- roxadustat (Anemia associated with CKD in dialysis, JP)
- evolocumab (Statin intolerant hypercholesterolemia, JP)
- fidaxomicin (*Clostridium difficile* infection in pediatric patients, EU)

*Received Complete Response Letter from FDA in Aug 2017.

Oncology | Immunology, Muscle disease, Ophthalmology | Urology, Nephrology | Others

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

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

PROGRESS IN OVERALL PIPELINE

Phase 1 entry to filing, since Q3/FY2018 financial results announcement in Jan 2019

Phase 1 Entry	Phase 2 Entry	Phase 3 Entry	Filing
ASP9801 Cancer	**roxadustat** Chemotherapy-induced anemia		**gilteritinib** Relapsed or Refractory acute myeloid leukemia: EU **fidaxomicin** *Clostridium difficile* infection in pediatric patients: EU

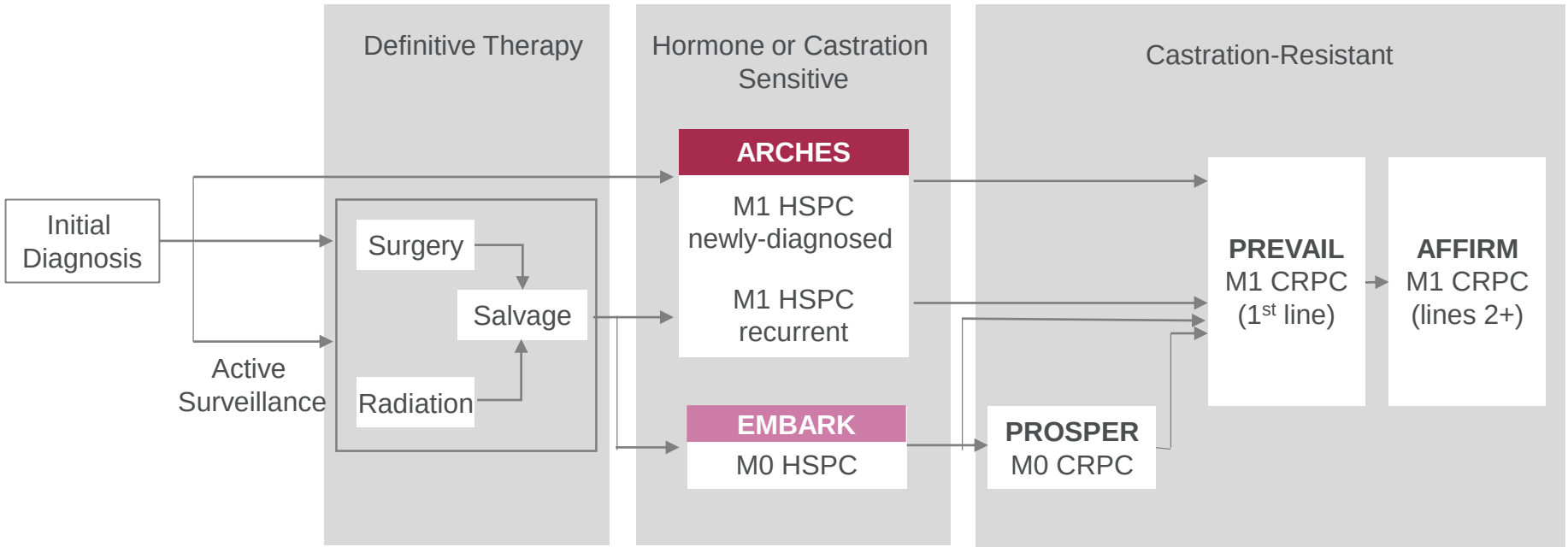
Discontinuation

ASP5094: Rheumatoid arthritis (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

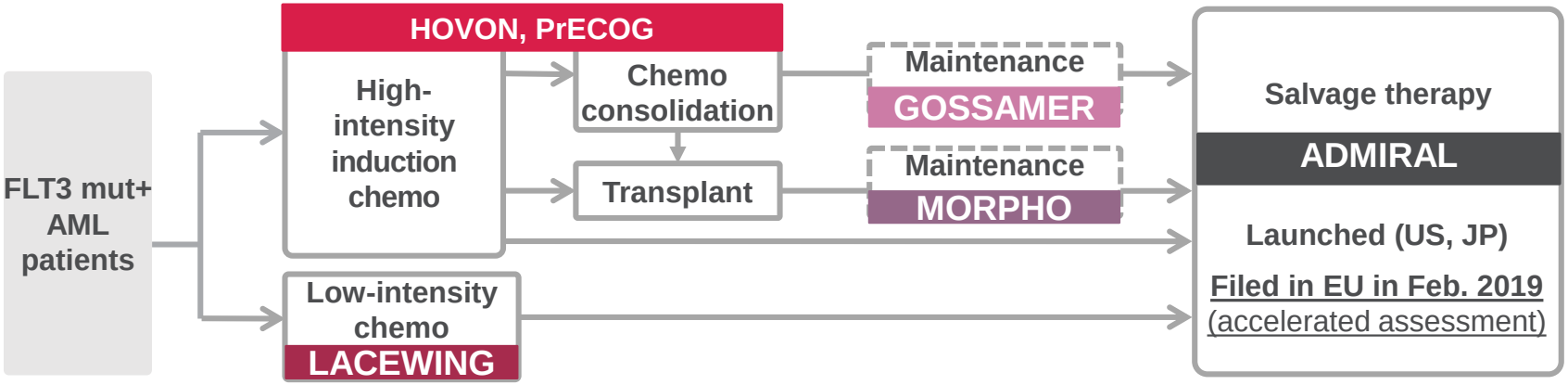
ENZALUTAMIDE



P3: ARCHES	**M1 HSPC**	vs. placebo, combination with ADT, n=1,150	Data presented at ASCO-GU Filing planned in US/EU/Japan by mid-2019
P3: EMBARK	**M0 HSPC**	vs. placebo, combination with ADT, n=1,068	Enrollment completed

Underline indicates the changes from the previous announcement on Jan 31, 2019.
M1: Metastatic, M0: Non-metastatic, HSPC: Hormone-sensitive prostate cancer, CRPC: Castration resistant prostate cancer,
ADT: Androgen deprivation therapy, ASCO-GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium

GILTERITINIB

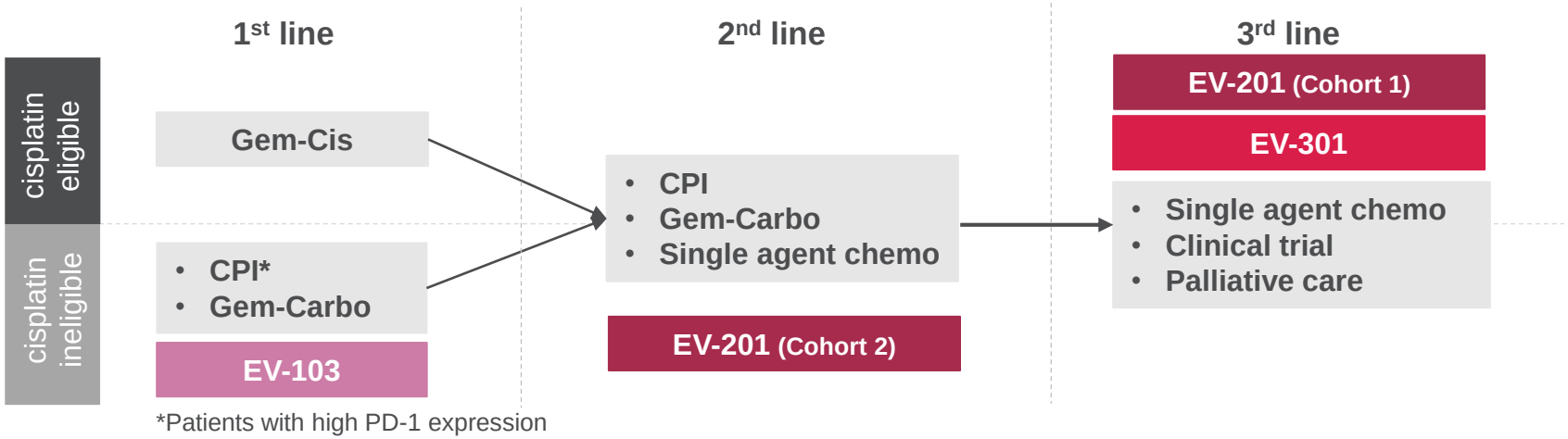


Relapsed or refractory	**P3: ADMIRAL**	Monotherapy vs salvage chemo (2:1), n=371		MAA submitted in Feb 2019 Label update to include OS data US: sNDA submitted Feb 2019 (RTOR pilot program) JP: Planned in 3Q/2019
Newly diagnosed (intensive chemo eligible)	**P3: HOVON**	Combo with high intensity chemo gilteritinib vs midostaurin (1:1)	n=768	FPI planned in: 3Q2019 (Sponsor: HOVON)
	P2: PrECOG		n=179	FPI planned in: 3Q2019 (Sponsor: PrECOG, LLC.)
Newly diagnosed (intensive chemo ineligible)	**P3: LACEWING**	Combo with azacitidine vs azacitidine alone (2:1), n=323		First Patient in: Nov 2016
Post-HSCT maintenance	**P3: MORPHO**	Monotherapy vs placebo (1:1), n=346		First Patient In: Jul 2017 Collaborating with BMT-CTN
Post-chemo maintenance	**P3: GOSSAMER**	Monotherapy vs placebo (2:1), n=354		First Patient In: Apr 2017

Underline indicates the changes from the previous announcement on Jan 31, 2019.
FLT3 mut+: Fms-like tyrosine kinase 3 mutation positive, AML: Acute myeloid leukemia, OS: Overall survival, sNDA: Supplemental new drug application, RTOR: Real-time oncology review, FPI: First patient in, 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	Pts with prior CPI treatment (platinum-pretreated)	n=550	First Patient In: Jul 2018
	P2: EV-201	Pts with prior CPI treatment Cohort 1: Platinum-pretreated Cohort 2: Platinum naïve/cisplatin ineligible	n=200	First Patient In: Oct 2017 Cohort 1: <u>TLR obtained</u> Cohort 2: Recruiting
	P1b: EV-103	Combination with CPI <u>and/or platinum</u>	n=159	First Patient In: 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 with prior CPI treatment	n= 215	Renal insufficiency cohort: Recruiting Other cohorts: Completed enrollment <u>Matured data presented at ASCO-GU</u>

SeattleGenetics astellas

Underline indicates the changes from the previous announcement on Jan 31, 2019.
Gem-Carbo: Gemcitabine and carboplatin, CPI: Checkpoint inhibitor, Pts: Patients, TLR: Topline result, mUC: metastatic urothelial cancer, NSCLC: Non-small cell lung carcinoma, ASCO-GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium

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]

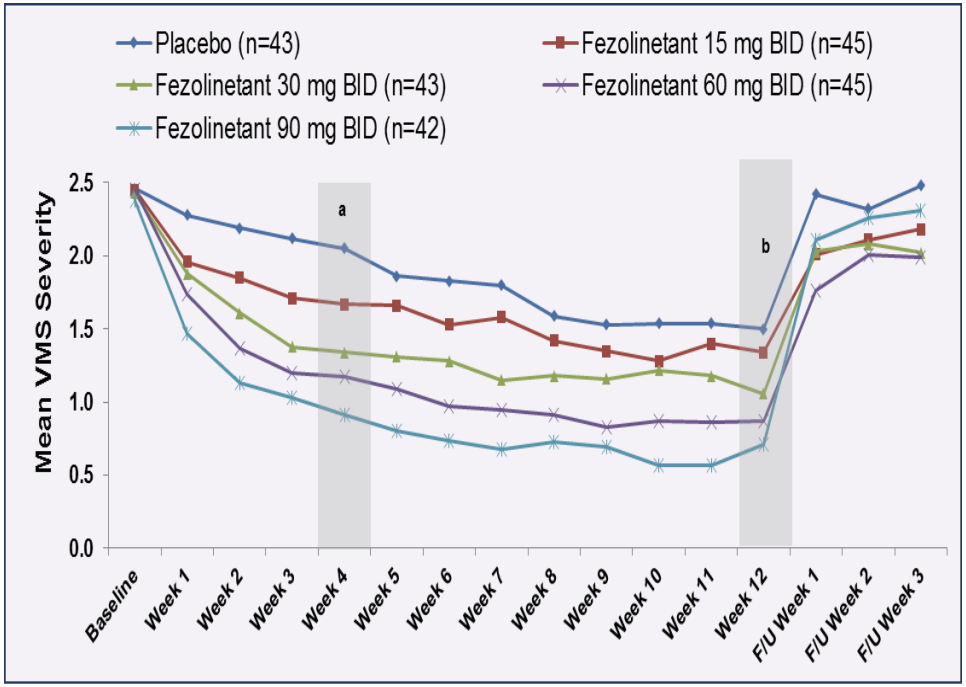
	Gastric and GEJ adenocarcinoma	**P3: SPOTLIGHT**	Combination with mFOLFOX6	vs. placebo, n=550	First Patient In: Oct 2018
		P3: GLOW	Combination with CAPOX	vs. placebo, n=500	First Patient In: Jan 2019
		P2: ILUSTRO	Monotherapy, Combination with mFOLFOX6	n=102	First Patient In: Sep 2018
	Pancreatic adenocarcinoma	**P2**	Combination with nab-paclitaxel and gemcitabine	vs. placebo, n=141	Study initiation planned in 2Q/2019

astellas

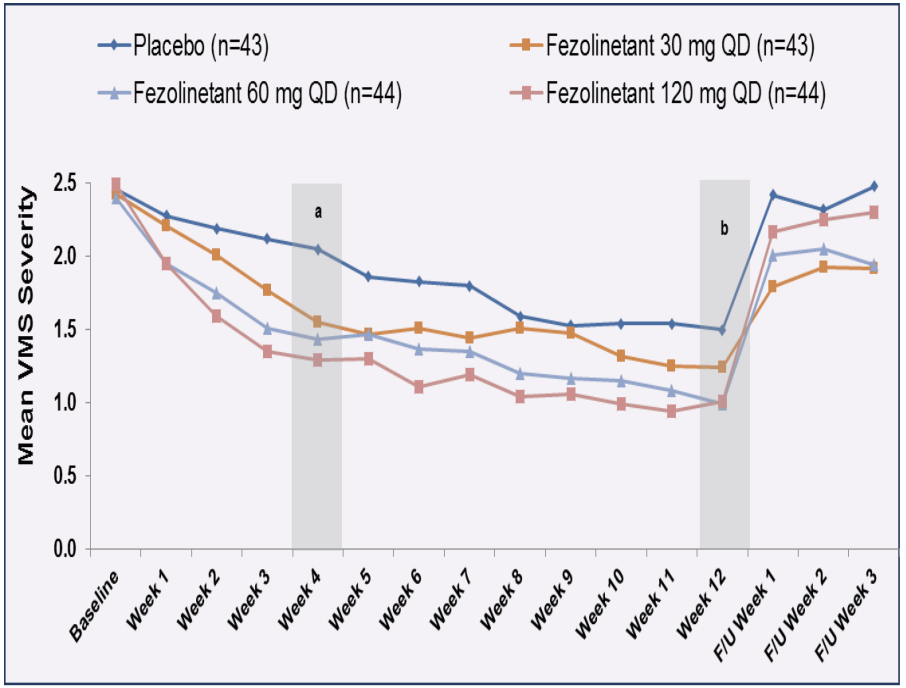
Underline indicates the changes from the previous announcement on Jan 31, 2019.
*1: Al-Batran *et al*. ASCO2016, *2: Pennathur *et al*. 2013, *3: Sahin *et al*. 2008, *4: 2017 RDPAC survey, *5: Iizumi, S *et al*. 2018
NSCLC: Non-small cell lung cancer, OS: Overall survival, CAPOX: Capecitabine and oxaliplatin, mFOLFOX6: 5-FU, leucovorin and oxaliplatin

FEZOLINETANT: EFFICACY IN PHASE 2B

Mean severity of moderate and severe VMS per 24 hours with fezolinetant QD



[a] Week 4: P<0.05 for all pairwise comparisons of fezolinetant doses vs placebo, without adjustments for multiplicity.
[b] Week 12: P<0.05 for fezolinetant 60 mg BID and 90 mg BID vs placebo, based on pairwise comparisons without adjustment for multiplicity.



[a] Week 4: P<0.05 for all pairwise comparisons of fezolinetant doses vs placebo, without adjustments for multiplicity.
[b] Week 12: P<0.05 for fezolinetant 60 mg QD vs placebo, based on pairwise comparisons without adjustments for multiplicity.

astellas

VMS: Vasomotor symptom, QD: Once daily, BID: Twice daily, ENDO: Endocrine Society's Annual Meeting

ON THE FOREFRONT OF HEALTHCARE CHANGE