



Q3/FY2017 FINANCIAL RESULTS

ENDED DECEMBER 31, 2017



Chikashi Takeda
Chief Financial Officer
Astellas Pharma Inc.
January 31, 2018

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

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I

Q3/FY2017 Financial Results

II

Initiatives to Build Resilience for
Sustainable Growth

III

Profit Distribution Policy

Q3/FY2017 FINANCIAL RESULTS (CORE BASIS)

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On-track toward FY2017 FCST

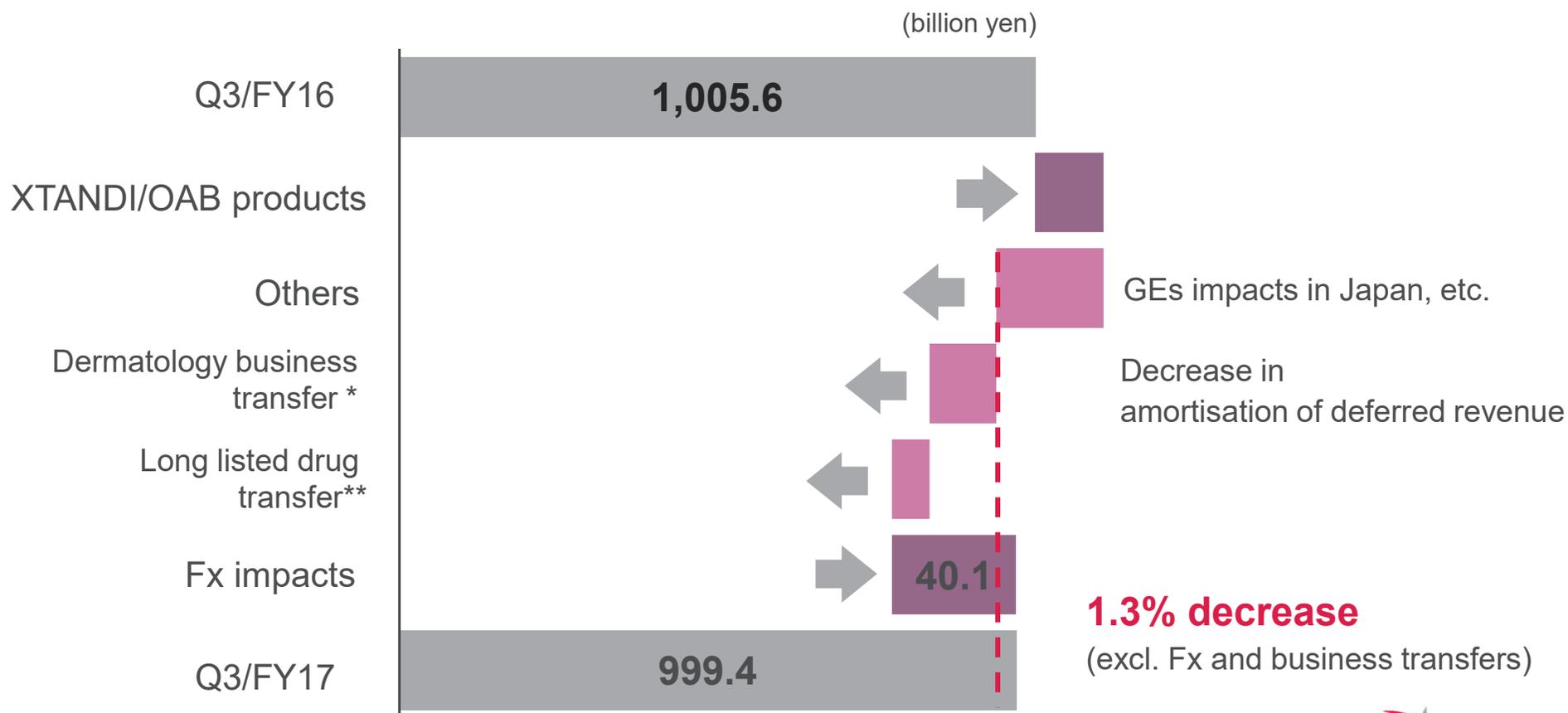
(billion yen)	Q3/FY16	Q3/FY17	Change	FY17 FCST*	Achieve- ment	Excl impacts from Fx and business transfer
Net sales	1,005.6	999.4	-0.6%	1,297.0	77.1%	-1.3%
Cost of sales	250.8	238.9	-4.7%			
% of sales	24.9%	23.9%				
SG&A expenses	336.7	350.0	+4.0%			
% of sales	33.5%	35.0%				
R&D expenses	148.3	161.6	+9.0%	218.0	74.1%	
% of sales	14.7%	16.2%		16.8%		
Amortisation of intangible	26.7	27.0	+0.9%			
Share of associates/JVs losses	- 1.3	- 1.4	-			
Core operating profit	241.8	220.5	-8.8%	258.0	85.4%	-2.6%
Core profit for the period	177.2	167.9	-5.3%	201.0	83.5%	



* Revised in Oct. 2017

SALES ANALYSIS (YEAR ON YEAR)

*Growth drivers in good shape,
slight decrease in net sales due to GEs impacts in Japan*



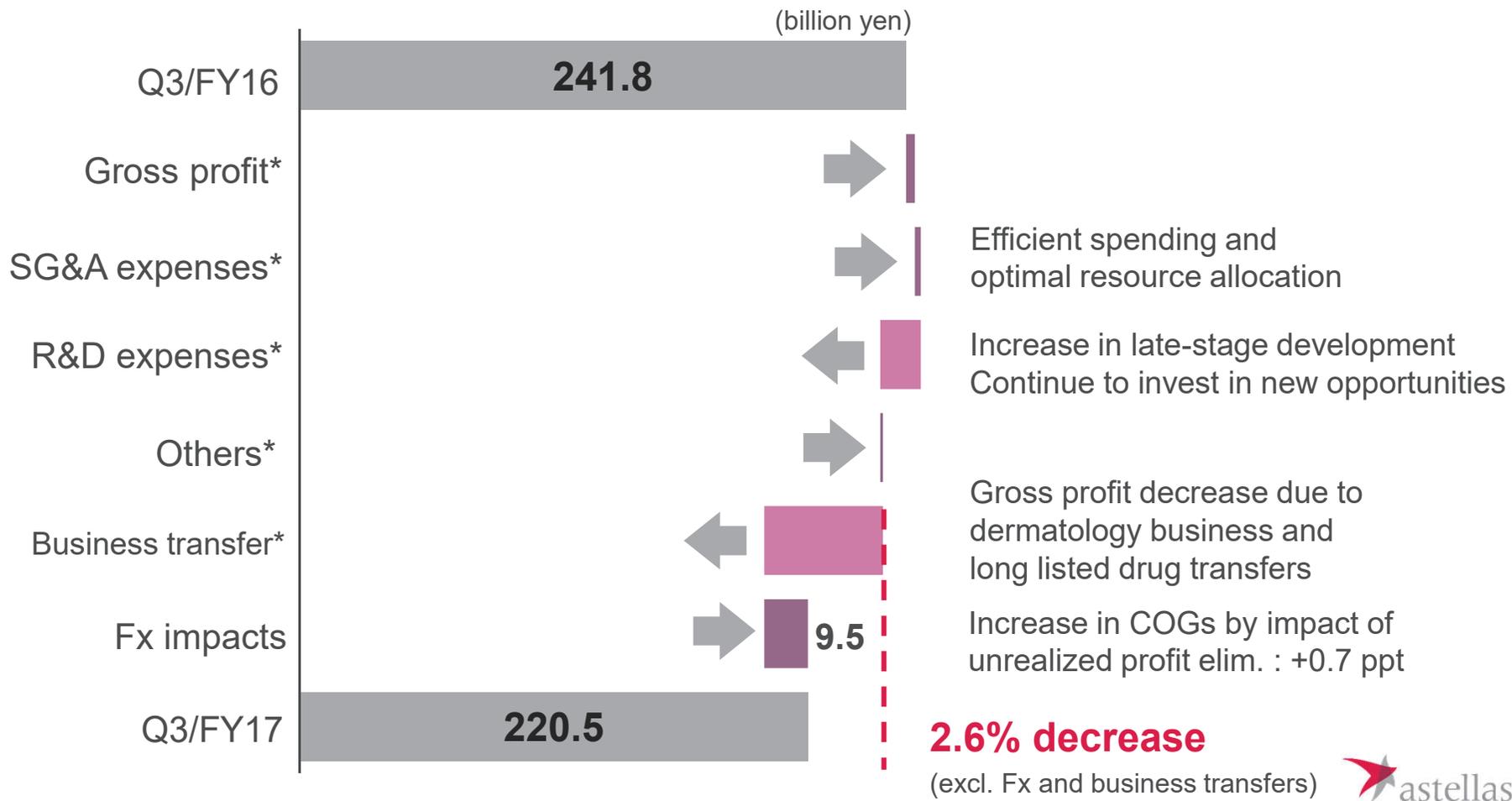
*Dermatology business transfer: Decrease in amortisation of deferred revenue

**Long listed drug transfer: Amortisation of deferred revenue in Q3/FY17 – Sales of transferred products in Q3/FY16

OAB: Overactive bladder,
OAB products: Vesicare+
Betanis/Myrbetriq/BETMIGA

CORE OP ANALYSIS (YEAR ON YEAR)

Development costs for late-stage projects, etc. increased



*Fx impacts excluded from each item



Q3/FY2017 FINANCIAL RESULTS (FULL BASIS)

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On-track toward FY2017 FCST

(billion yen)	Q3/FY16	Q3/FY17	Change	FY17FCST*	Achievement
Core operating profit	241.8	220.5	-8.8%	258.0	85.4%
Other income	6.6	10.4	+58.8%		
Other expenses	17.1	51.2	+198.7%		
Operating profit	231.3	179.8	-22.3%	222.0	81.0%
Financial income	14.0	6.1	-56.9%		
Financial loss	1.4	1.2	-16.0%		
Profit before tax	243.9	184.6	-24.3%	228.0	81.0%
Profit for the period	178.8	142.6	-20.2%	180.0	79.2%
EPS (yen)	84.38	69.84	-17.2%	88.44	79.0%



* Revised in Oct. 2017

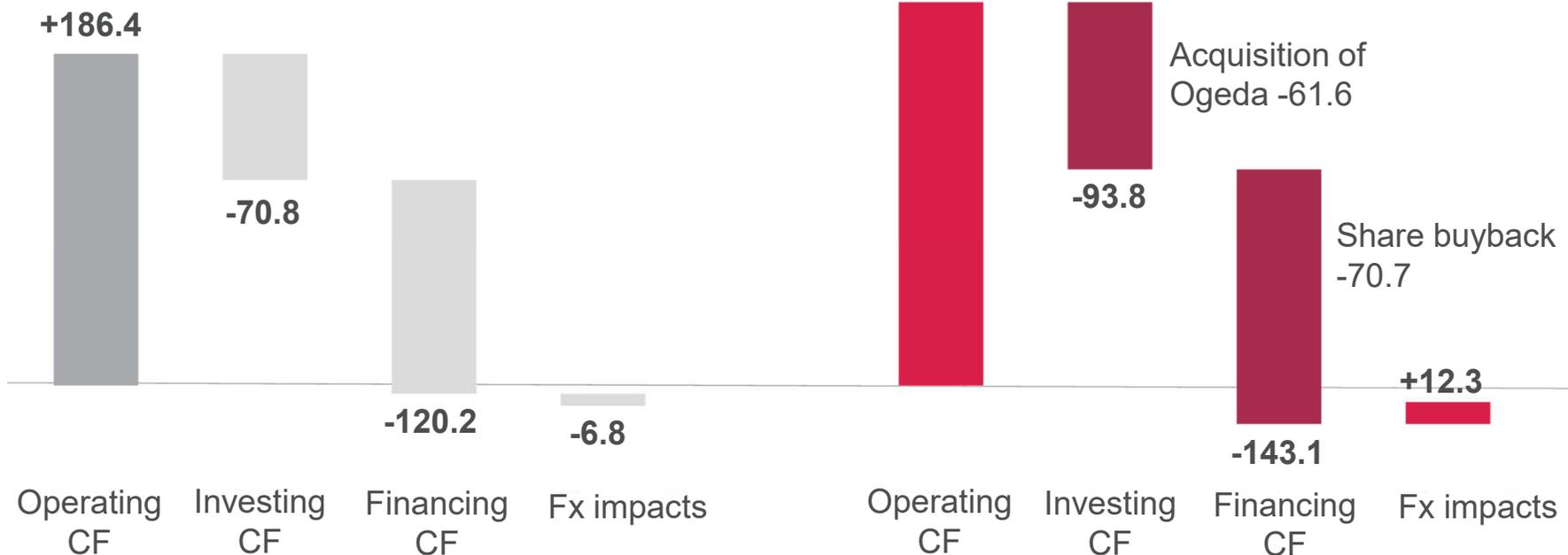
CASH FLOW ANALYSIS

*Cash flows from operating activities increased by 16% (YoY)
 Implemented active business investment and flexible shareholder return*

Q3/FY16

Q3/FY17

(billion yen)



SALES IN THREE KEY AREAS

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XTANDI, OAB franchise increase on a global basis

(billion yen)	Q3/FY16	Q3/FY17	Change	CER growth
Oncology	232.3	260.8	+12.3%	+6.2%
XTANDI	189.2	219.9	+16.2%	+9.9%
OAB in Urology	160.9	171.6	+6.6%	+2.1%
Vesicare	89.3	78.5	-12.1%	-16.0%
Betanis/Myrbetriq/BETMIGA	71.6	93.1	+30.0%	+24.7%
Transplantation	142.2	150.2	+5.6%	+0.2%



Oncology: XTANDI, Tarceva, Eligard and Gonax
 Transplantation: Prograf, Advagraf/Graceptor/ASTAGRAF XL

CER: Constant Exchange Rate



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Sustainable Growth

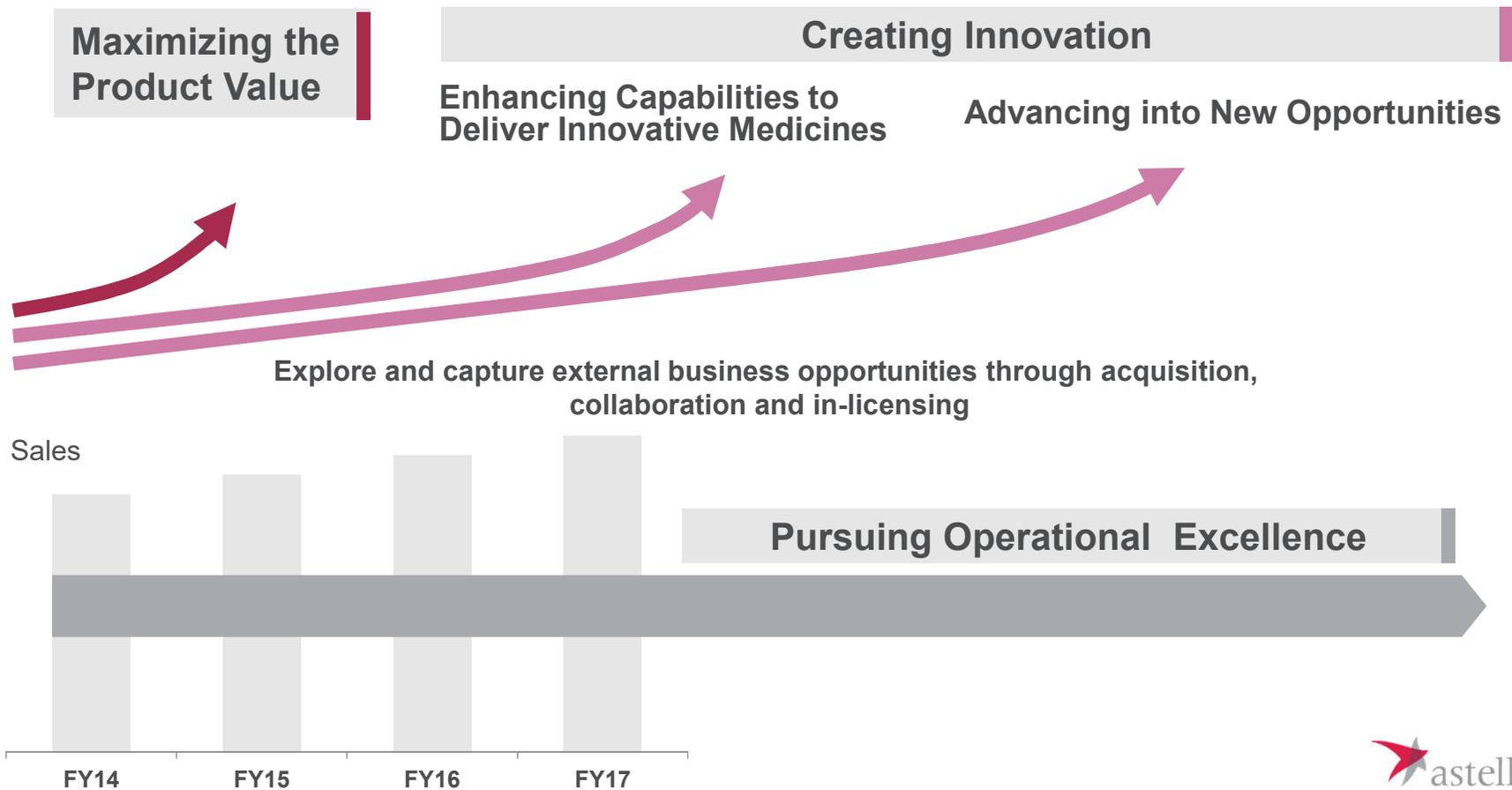
III

Profit Distribution Policy

ACHIEVING SUSTAINABLE GROWTH

(same as Strategic Plan 2015-2017 slide)

*New products will drive mid-term growth;
Sustainable growth will be reinforced by continuous selective investment in
innovation and strengthening of the business foundation*





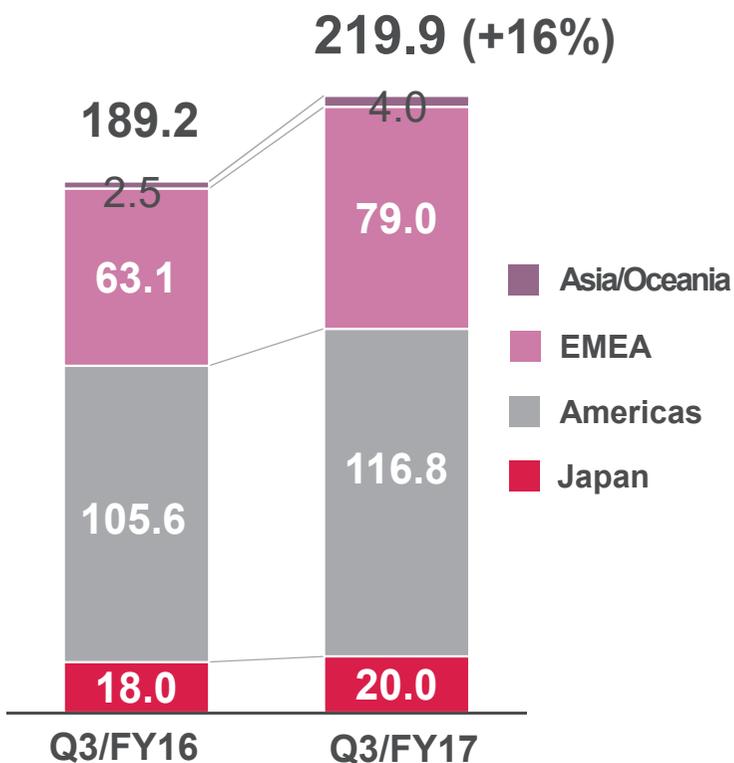
MAXIMIZE THE PRODUCT VALUE

XTANDI

Record-high quarterly sales in each region

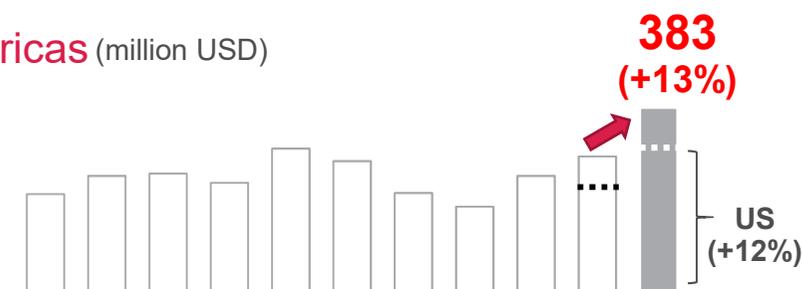
Sales by region

(billion yen)

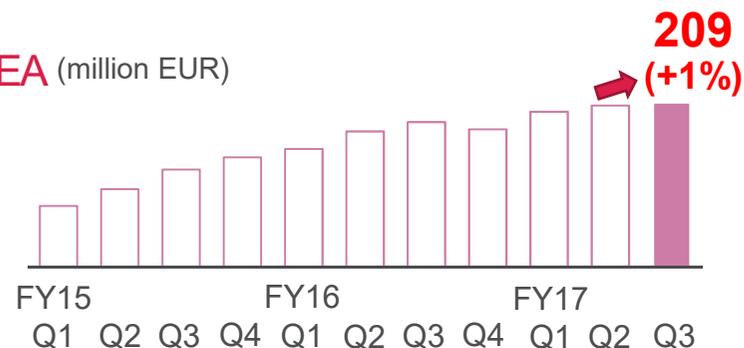


Quarterly sales (local currency)

Americas (million USD)



EMEA (million EUR)



- Further penetration in earlier treatment within current indications
- Expansion to new markets: launched in >70 countries

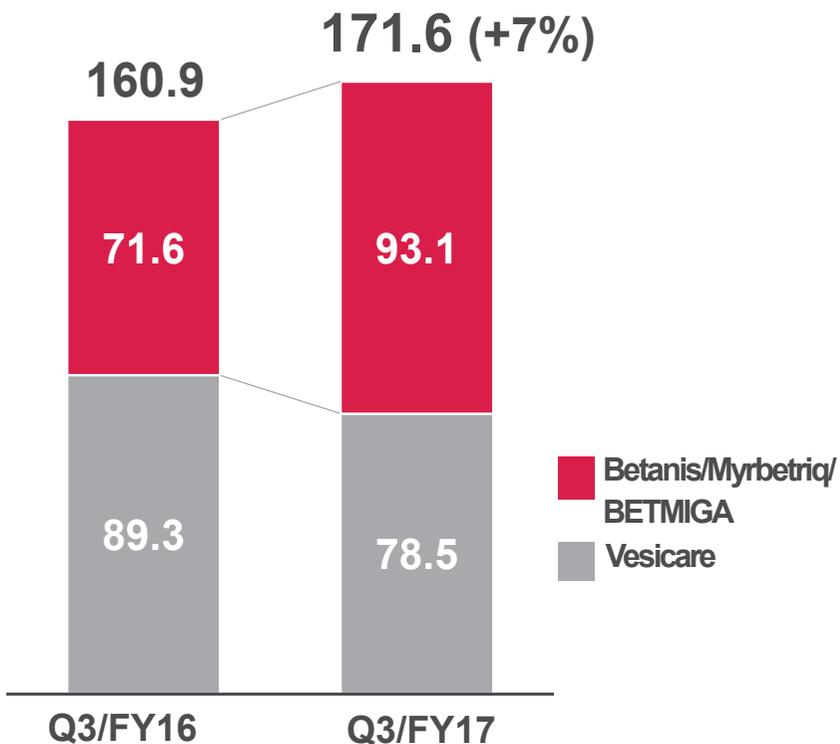


OAB FRANCHISE IN UROLOGY

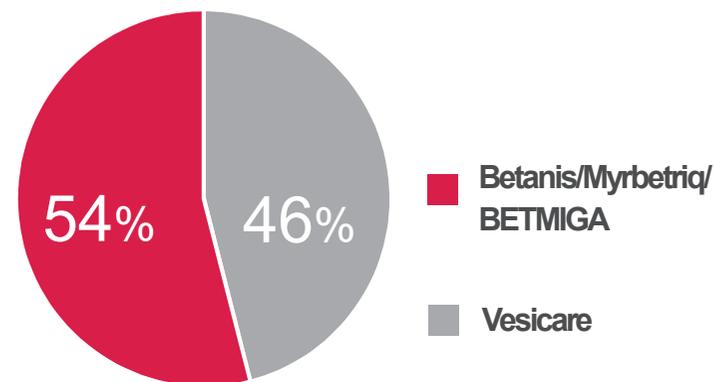
Betanis/Myrbetriq/BETMIGA growth enhances OAB Franchise

Sales by product

(billion yen)



Sales composition ratio by product (yen basis)



- The market share of Betanis/Myrbetriq/BETMIGA continuously increased

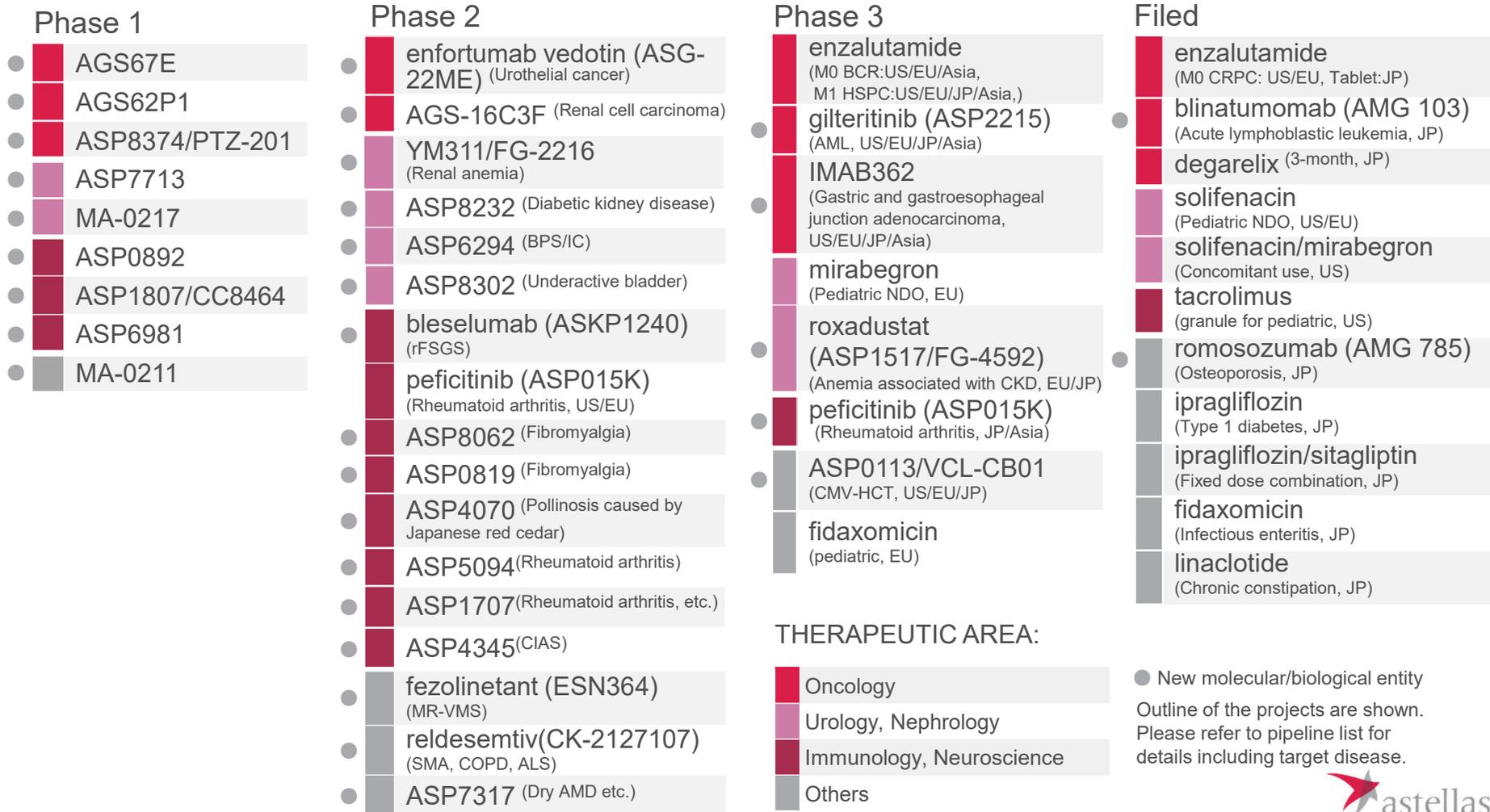


CREATE INNOVATION

PIPELINE

ROBUST PIPELINE OF ASTELLAS

Evaluating ~30 new molecular/biological entities as potential drivers of future growth



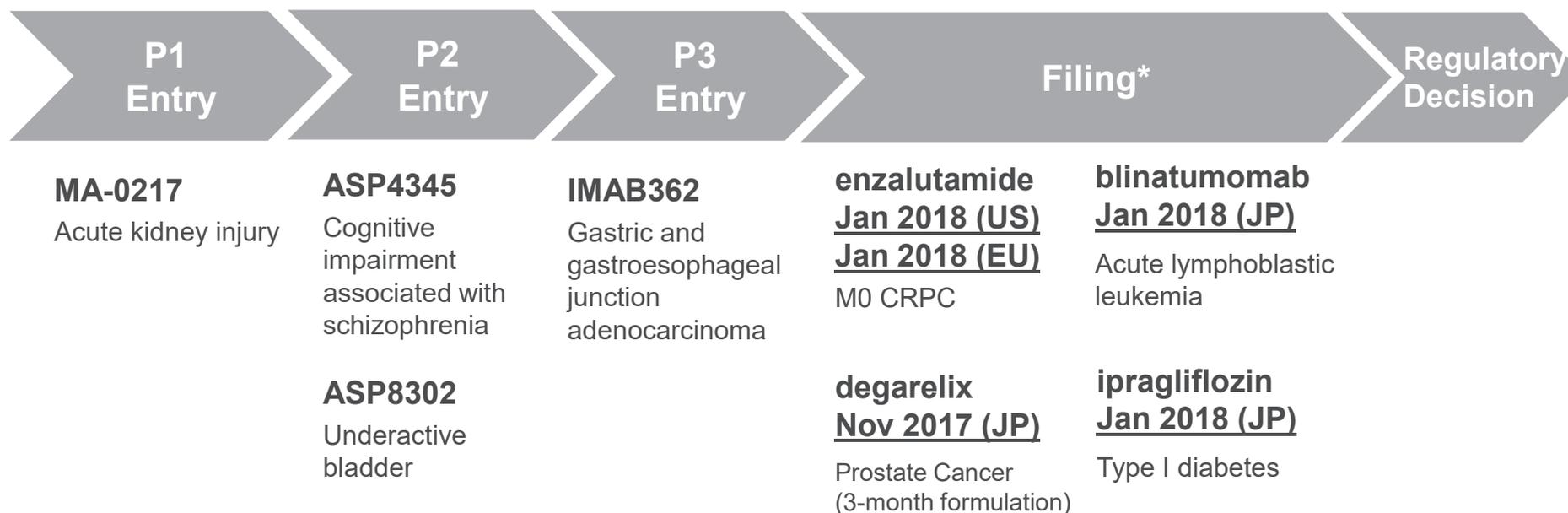
BPS/IC: Bladder pain syndrome/Interstitial cystitis, rFSGS: Recurrence of focal segmental glomerulosclerosis, MR-VMS: Menopause-related vasomotor symptoms, CIAS: Cognitive impairment associated with schizophrenia, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, ALS: Amyotrophic lateral sclerosis, AMD: Age-related macular degeneration, M0 CRPC: Non-metastatic castration-resistant prostate cancer, M0 BCR: Non-metastatic biochemical recurrence, M1 HSPC: Metastatic hormone sensitive prostate cancer, AML: Acute myeloid leukemia, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, CMV: Cytomegalovirus, HCT: Hematopoietic cell transplant

STEADY PROGRESS IN DEVELOPMENT

SUMMARY OF PROGRAM PROGRESS FROM OCT 2017 TO JAN 2018

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Steady progression of pipeline



**Discontinuation
(in a part of
indications) etc.**

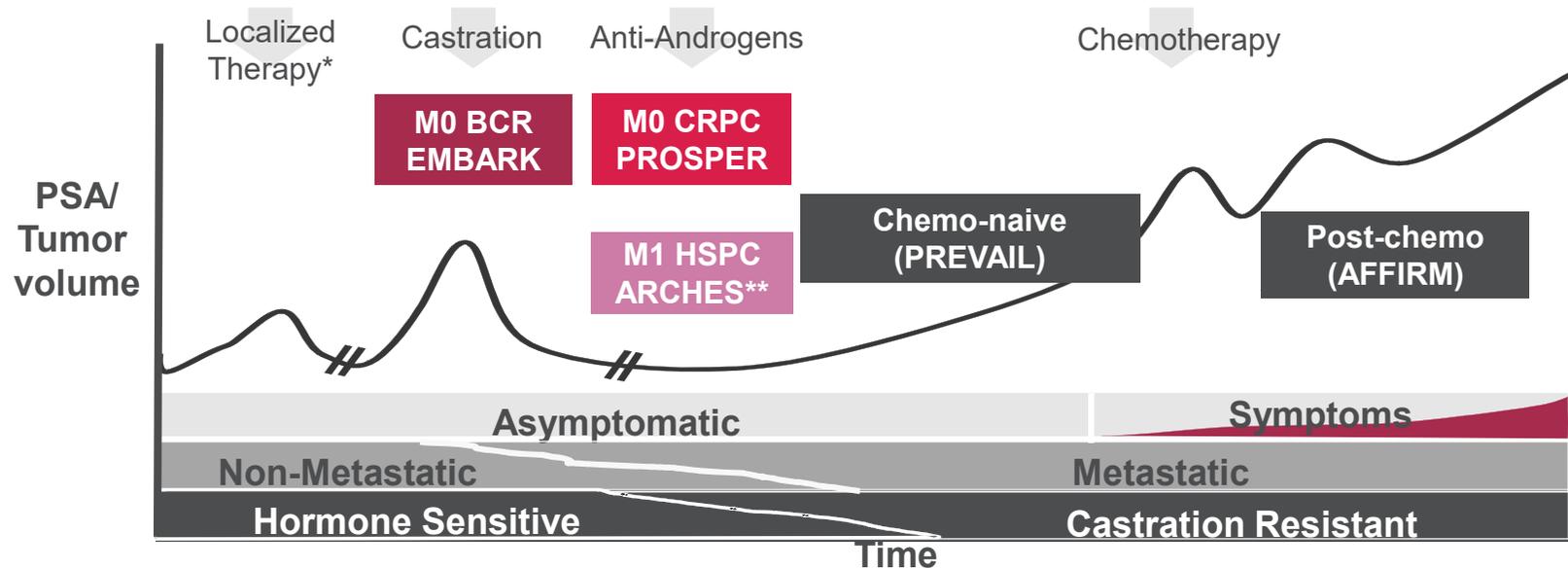
enzalutamide: Hepatocellular carcinoma (P2)
ASP7962: Osteoarthritis (P2)
ASP7398: Nocturia (P1)
ASP6282: Underactive bladder (P1)



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.

ENZALUTAMIDE: MAXIMIZE THE VALUE FOR PROSTATE CANCER PATIENTS

Application for marketing approval submitted to FDA and EMA for M0 CRPC. PROSPER study data will be presented at ASCO-GU 2018



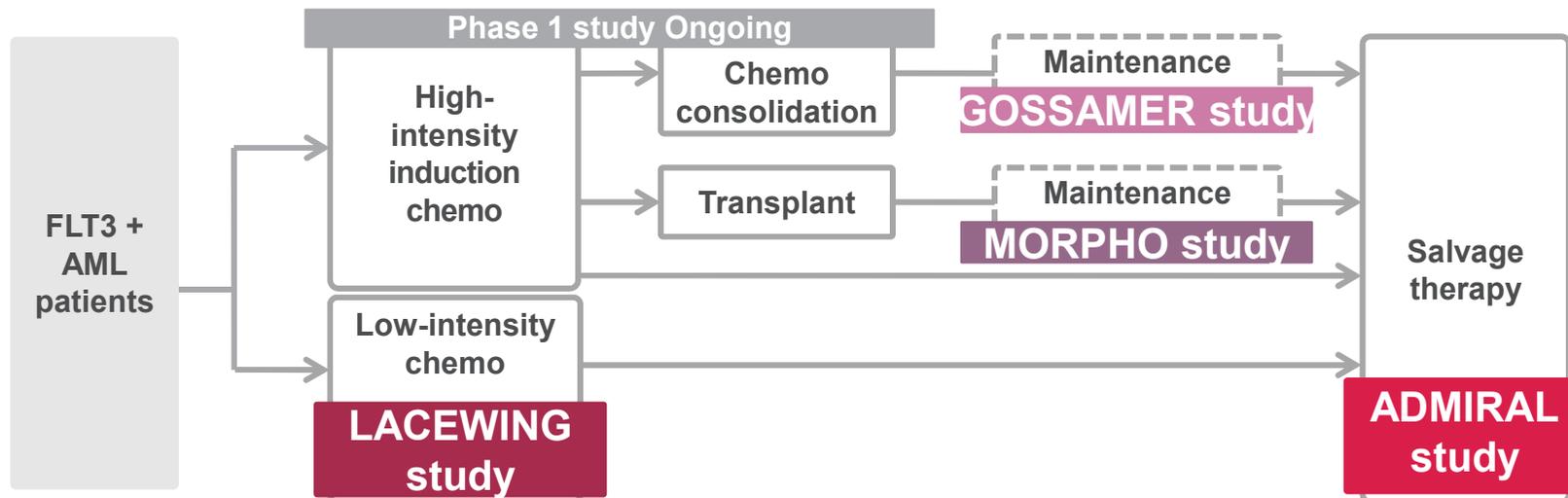
	PROSPER study P3	M0 CRPC Non-metastatic CRPC	Placebo-controlled, combination with ADT, n=1,440	<u>Application submitted (US/EU)</u>
	EMBARK study P3	M0 BCR Non-metastatic prostate cancer, biochemical recurrence	To compare with ADT and combination, n=1,860	First Patient In: Jan. 2015
	ARCHES study P3	M1 HSPC Metastatic hormone-sensitive prostate cancer	Placebo-controlled, combination with ADT, n=1,100	First Patient In: Mar. 2016



P. Mulders *et al.* EAU2012, modified by Astellas * Radiotherapy, prostatectomy, ** Metastatic at the time of diagnosis
PSA: Prostate-specific antigen, ASCO-GU: American Society of Clinical Oncology, Genitourinary

GILTERITINIB: TREATMENT LANDSCAPE IN AML

European Commission granted orphan designation to gilteritinib for the treatment of acute myeloid leukemia (AML)



ADMIRAL study P3	Relapsed or refractory 1 st relapsed or refractory, FLT3 mutation positive	Open-label, randomized, monotherapy vs salvage chemo (2:1), n=369	First Patient In: Oct. 2015
LACEWING study P2/3	1st line intensive chemo ineligible Newly diagnosed, FLT3 mutation positive	Open-label, randomized, 3 arms (monotherapy, combo with azacitidine and azacitidine alone), n=528	First Patient in: Nov. 2016
GOSSAMER study P3	Post-chemo maintenance FLT3-ITD positive	Double-blind, randomized, monotherapy vs placebo (2:1), n=354	First Patient In: Apr. 2017
MORPHO study P3	Post-HSCT maintenance FLT3-ITD positive	Double-blind, randomized, monotherapy vs placebo (1:1), n=346	First Patient In: July 2017 Collaborating with BMT-CTN

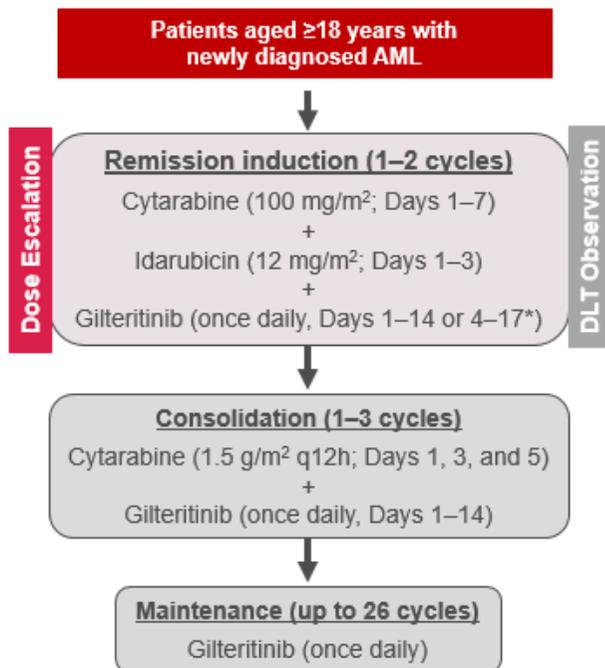


GILTERITINIB: PHASE 1 STUDY IN NEWLY DIAGNOSED AML

Encouraging data from on-going Phase 1 study in the FLT3 mutation positive, newly diagnosed AML patients was presented at ASH2017

Study design:

- Multicenter, open-label, 3+3 design
- Dose-escalation cohorts: 40, 80, 120 mg/day



*Gilteritinib was initially administered on Days 1–14, but the schedule was later changed to administration on Days 4–17 due to DLTs in the 40 mg/day dose cohort.

Conclusion:

- Preliminary results suggest that gilteritinib can be safely combined with intensive induction chemotherapy
- All evaluable FLT3^{Mut+} patients achieved CRc with gilteritinib in combination with intensive frontline chemotherapy

Response Parameter*, n (%)	FLT3 ^{Mut+} (n=21) [†]	FLT3 ^{WT} (n=23) [†]
CR	19 (90.5)	9 (39.1)
CRp	1 (4.8)	0
CRi	1 (4.8)	5 (21.7)
PR	0	3 (13.0)
CRc [‡]	21 (100)	14 (60.9)

*Response parameters were defined according to the International Working Group Criteria for AML (Cheson B, et al. *J Clin Oncol.* 2003;12(24):4642–4649).

[†]Two patients were excluded from the response analysis population: one patient was excluded due to favorable cytogenetic status and one patient was excluded due to refusal to undergo a bone marrow biopsy and withdrawal of consent.

[‡]CRc included patients who achieved CR, CRp, and CRi.



IMAB362: PHASE 3 PROGRAM

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Global Phase 3 studies to support global registration for first-line gastric and gastroesophageal junction adenocarcinoma indication

Phase 3: Combination with mFOLFOX6

Study design:

- multicenter, double-blind, randomized
- vs placebo, combination with mFOLFOX6

Patient population:

- CLDN18.2-positive, HER2-negative, metastatic adenocarcinomas of the stomach or the gastroesophageal junction

Planned enrollment: approx. 550 patients

Primary endpoint: Progression free survival

Secondary endpoint (key): Overall survival

Study region: global (US, EU, JP, Asia, etc)

Phase 3: Combination with CAPOX

Study design:

- multicenter, double-blind, randomized
- vs placebo, combination with CAPOX

Patient population:

- CLDN18.2-positive, HER2-negative, metastatic adenocarcinomas of the stomach or the gastroesophageal junction

Planned enrollment: approx. 420 patients

Primary endpoint: Progression free survival

Secondary endpoint (key): Overall survival

Study region: global (US, EU, JP, Asia, etc)



ROXADUSTAT: ROBUST PHASE 3 PROGRAM TO SUPPORT FILING AND REIMBURSEMENT IN EUROPE AND JAPAN

Steady progress of Phase 3 program in dialysis and non-dialysis patients

	Dialysis	Non-dialysis
Global	HIMALAYAS: Incident dialysis, vs epoetin alfa 	DOLOMITES , vs darbepoetin Enrollment completed 
	SIERRAS: Stable dialysis, vs epoetin alfa 	ALPS , vs placebo Study completed Data readout planned in 1Q/2018 
	PYRENEES: Stable dialysis, vs epoetin alfa or darbepoetin Enrollment completed 	ANDES , vs placebo Enrollment completed 
Japan 	HD: Conversion , vs darbepoetin Enrollment completed	Conversion, vs darbepoetin
	HD: Conversion , long-term Study completed Data readout planned in 1Q/2018	
	HD: Correction (ESA-naïve) Study completed Data readout planned in 1Q/2018	Correction
	PD: Study completed TLR obtained in Oct/2017	

EXPECTED KEY PIPELINE EVENTS IN FY2017

Important milestones from POC through registration

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

Data Readouts

Phase 2 (POC) study

enzalutamide

Breast Cancer (HER2+)

ASP4070

(JRC2-LAMP-vax)

Pollinosis caused by Japanese red cedar

ASP1707

Rheumatoid Arthritis (MTX-IR)

reldesemtiv

(CK-2127107)

Spinal Muscular Atrophy

ASP7962

Osteoarthritis

Phase 3 study

enzalutamide

M0 CRPC (PROSPER)

roxadustat

Non-dialysis pts (ALPS)

Hemodialysis: Conversion, long-term (Japan)

Peritoneal dialysis (Japan)

ASP0113

Hematopoietic Cell Transplantation

peficitinib

RA pts with MTX-IR

RA pts with DMARD-IR

Filing*

solifenacin/mirabegron

Concomitant use of solifenacin and mirabegron (US)

linaclotide

Chronic constipation (Japan)

evolocumab

Cardiovascular outcome study (Japan)

ipragliflozin/sitagliptin

Fixed dose combination (Japan)

Regulatory Decisions

enzalutamide

Tablet (EU)

Tablet (Japan)

romosozumab

Osteoporosis (Japan)

quetiapine

BP-D (Japan)

solifenacin

Pediatric NDO (US)

Pediatric NDO (EU)

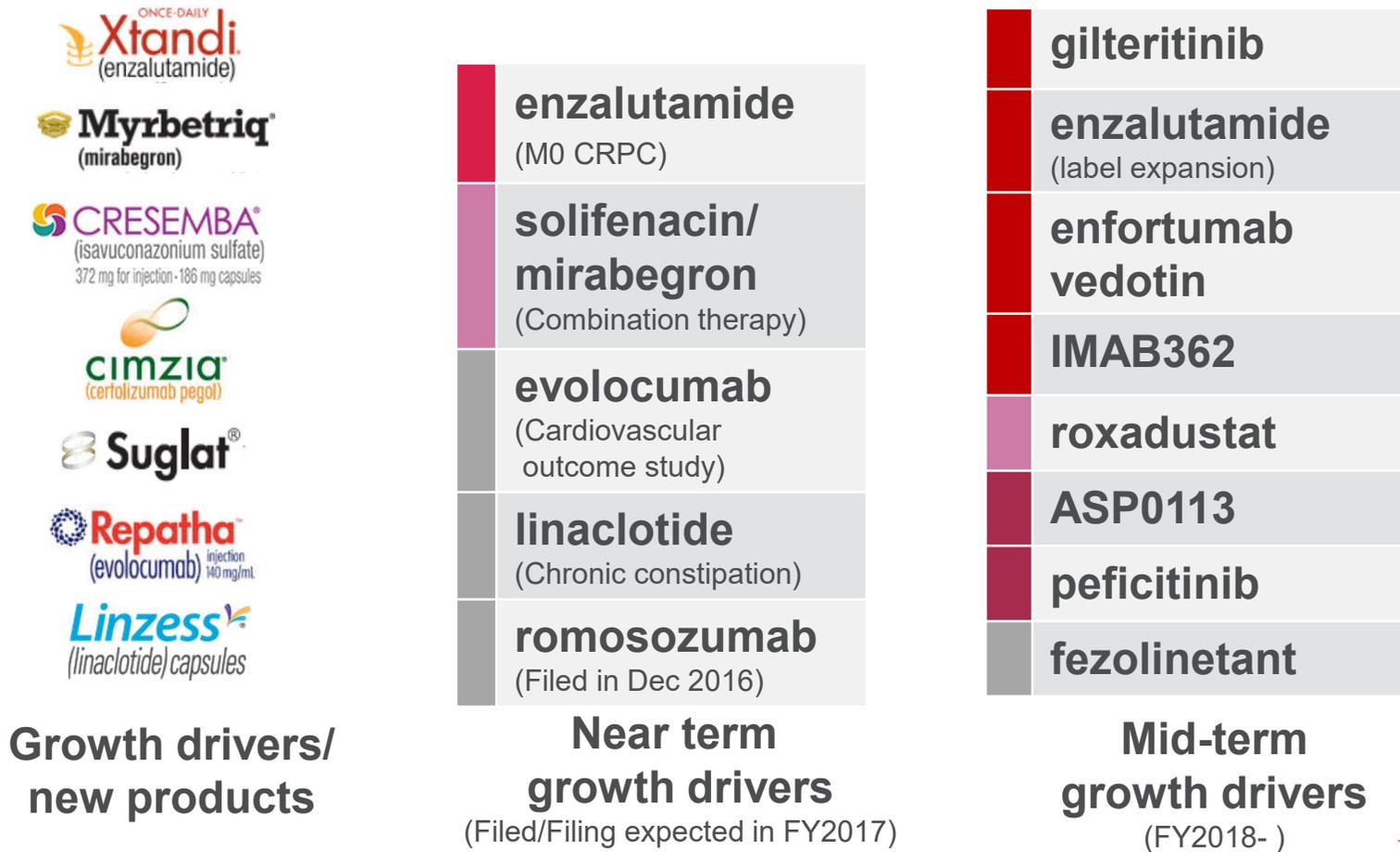


*Light gray items indicate completed events.

MTX-IR: Methotrexate inadequate response, RA: Rheumatoid arthritis, DMARD-IR: Disease-modifying antirheumatic drugs inadequate response, BP-D: Depressive symptoms associated with bipolar disorder, NDO: Neurogenic detrusor overactivity

POTENTIAL GROWTH DRIVERS

Future growth driven by compounds that already have achieved POC



Subject to internal assessment, decision and regulatory consultation, as appropriate

POC; Proof of Concept

■ Oncology, ■ Urology, Nephrology, ■ Immunology, Neuroscience, ■ Others





CREATE INNOVATION

NEW INITIATIVES

BIOLOGY: ACQUISITION OF MITOBRIDGE

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Reinforce the discovery and development of novel drugs that target Mitochondrial functions

Programs:

MA-0211

- Phase 1 ongoing for duchenne muscular dystrophy

MA-0217

- Phase 1 ongoing for acute kidney injury

Several other INDs expected in the next few years

Transaction Summary:

Up-front payment

USD 225 million*

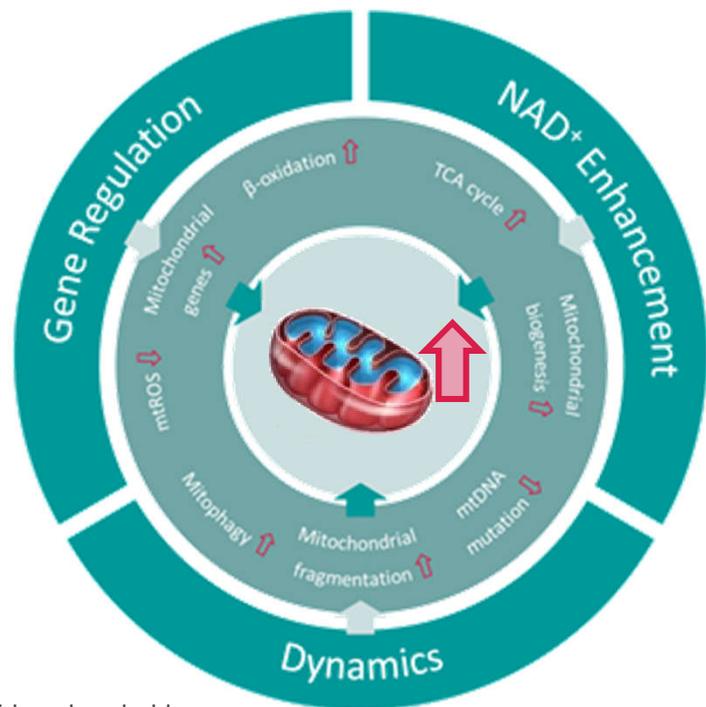
Earn-outs

Up to USD 225 million*, depending on the progress of various programs in clinical development

*As Astellas is a shareholder in Mitobridge, the followings are actual payment to Mitobridge shareholders;
Up-front payment: \$161.7 million, Earn-outs: \$165.5 million



Approaches to mitochondrial function



TCA: TriCarboxylic Acid
NAD: Nicotinamide Adenine Dinucleotide

CREATE SOCIAL VALUE: INITIATIVES FOR ACCESS TO HEALTH

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Resolve social issues and enhance our enterprise value over the long-term



Moving NCD Care Forward

Participation in
Access Accelerated



Global Health Innovative Technology Fund

GHIT Fund replenishment



Collaborative development
agreement for rice-based
oral vaccine



Support of Action on Fistula



Development of pediatric
formulation for schistosomiasis



Collaborative research
agreement to discover
anti-tuberculosis drugs



Screening collaboration
agreement to discover
antimalarial drugs

Recent activities

- Collaborative research agreement aiming at the practical application of the rice-based oral vaccine “MucoRice”

Designated as a project under CiCLE and supported by AMED



CiCLE: Cyclic Innovation for Clinical Empowerment)

AMED: Japan Agency for Medical Research and Development



PURSUE OPERATIONAL
EXCELLENCE

INITIATIVES TO CONTINUOUS STRENGTHENING OF MANAGEMENT FOUNDATION

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Resource allocation from scratch responding to environment changes

Investment priority

- Investment in growth areas and withdrawal from non-growth areas
- Sufficient investment to deal with new risks

Capability, organization / structure

- Optimization of organization / structure
- Identify core capabilities and form strategic partnerships

Cost structure

- Cost reduction through strategic procurement activities
- Further focus on appropriate expenses use

Initiatives in FY2017

- ✓ Transfer of long-listed products
- ✓ Enhancement of global management structure
- ✓ Pursuing strategic outsourcing
- ✓ Wind-down of Agensys research operations



AGENDA

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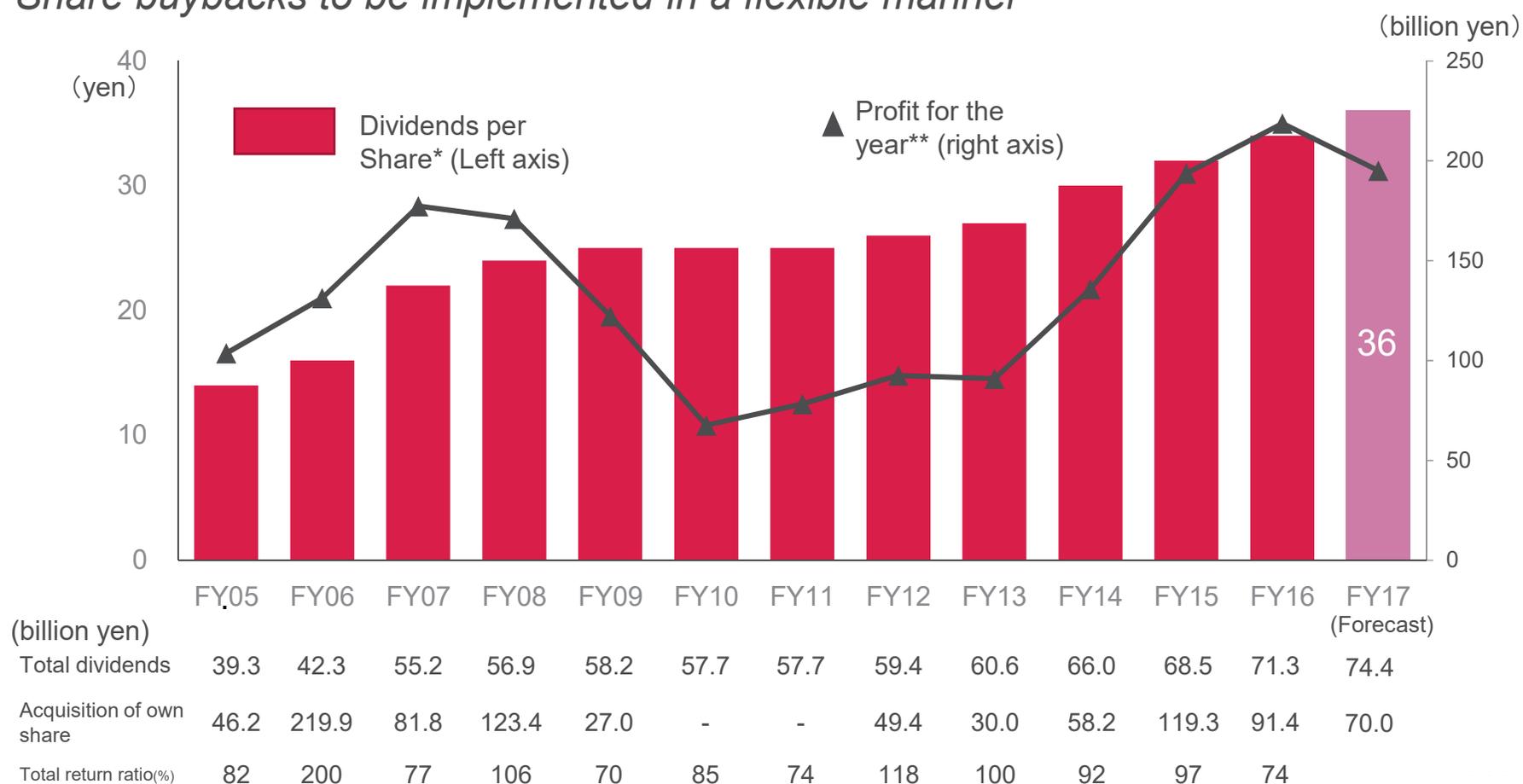
Profit Distribution Policy

PROFIT DISTRIBUTION POLICY

Top priority on investment for growth business

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

Share buybacks to be implemented in a flexible manner

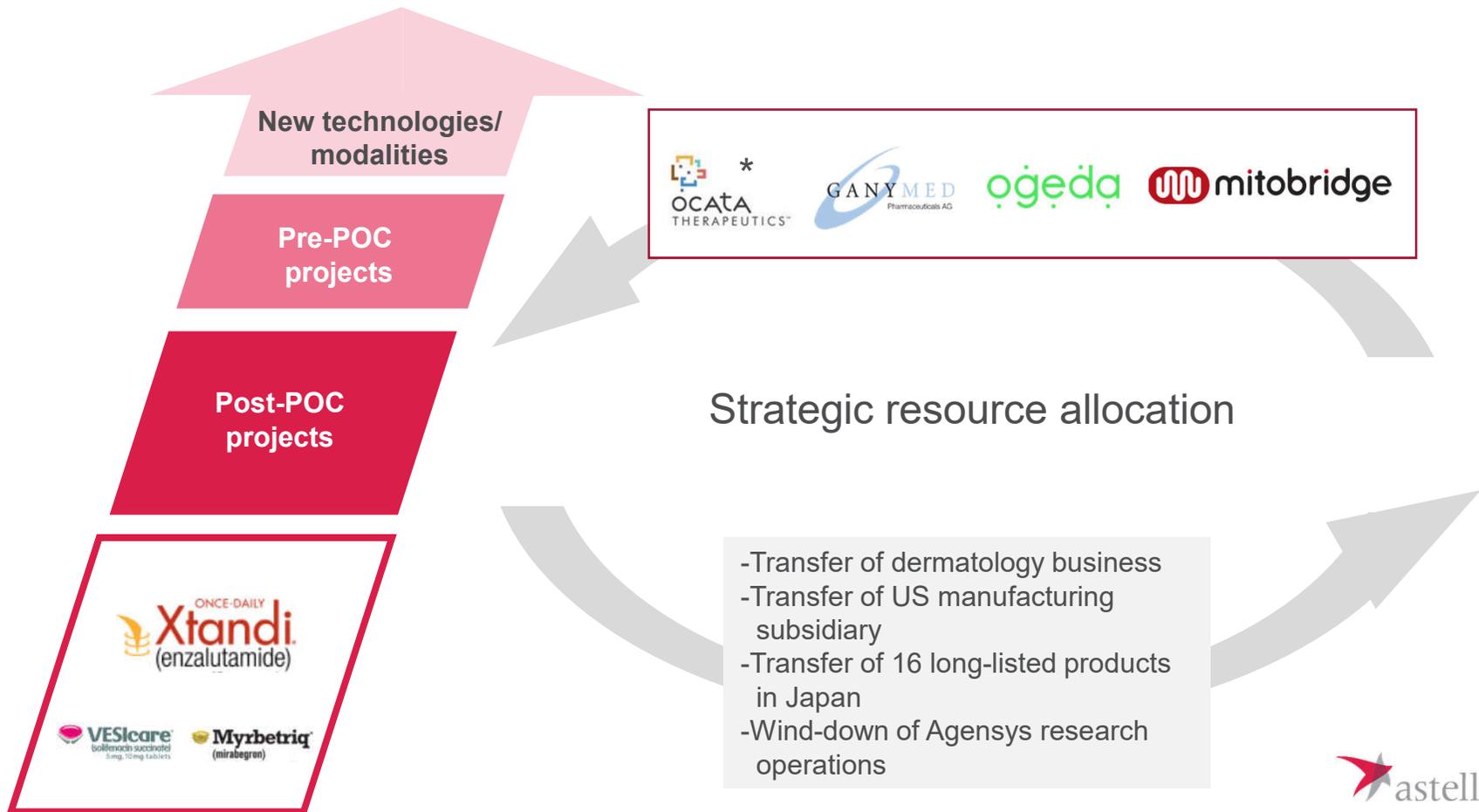


*The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014, Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal 2005.

**From fiscal 2013, figures are in accordance with International Financial Reporting Standards (IFRS).

REALIZE SUSTAINABLE GROWTH

Turn innovative science into value for patients on the forefront of healthcare change



POC: Proof of concept

Company name was changed to the Astellas Institute for Regenerative Medicine.





SCHEDULE

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April 26, 2018: Financial Results for FY2017

May 22, 2018: New Strategic Plan



APPENDIX

Q3/FY2017: SALES BY REGION

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	Q3/FY16	Q3/FY17	Change
Japan (billion yen)	380.1	337.3	-11.3%
of sales in Japanese market	358.2	309.0	-13.7%
Americas (million USD)	2,889	2,926	+1.3%
EMEA (million EUR)	2,143	2,023	-5.6%
Asia/Oceania (billion yen)	64.5	75.3	+16.8%

FX RATE (ACTUAL)

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Average rate for the period

(yen)

Currency	Q3/FY16	Q3/FY17	Change
USD	107	112	+5
EUR	118	129	+11

Change in closing rate from PY end

Currency	Q3/FY16	Q3/FY17
USD	+4	+1
EUR	-5	+15

Exchange rate change +: Yen Weakening, - : Yen Strengthening

FY2017 FCST : FX SENSITIVITY

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**Forecast rates from October 2017 onwards:
110 USD/yen, 130EUR/yen**

Estimated Fx sensitivity (October 2017 and onward) of FY2017 forecasts by 1 yen appreciation*

Currency	Average rate 1 yen higher than assumption		Year-end rate 1 yen higher than assumption
	Net sales	Core OP	Core OP
USD	Approx. -2.4 bil yen	Approx. -0.6 bil yen	Approx. +0.6 bil yen
EUR	Approx. -1.3 bil yen	Approx. -0.5 bil yen	Approx. +0.3 bil yen



*Sensitivity to fluctuation of Fx rates used for consolidation of overseas affiliates' results compared to forecasted rates from October 2017 and onwards

BALANCE SHEET/CASH FLOW HIGHLIGHTS

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(billion yen)	FY2016 end	Dec. 2017
Total assets	1,814.1	1,933.8
Cash and cash equivalents	340.9	331.7
Total net assets	1,271.8	1,366.9
Equity ratio (%)	70.1%	70.7%

(billion yen)	Q3/FY16	Q3/FY17	FY2016
Cash flows from operating activities	186.4	215.3	235.6
Cash flows from investing activities	(70.8)	(93.8)	(73.4)
Free cash flows	115.6	121.5	162.2
Cash flows from financing activities	(120.2)	(143.1)	(166.2)
Acquisition of treasury shares	(46.7)	(70.7)	(92.2)
Dividends paid	(70.1)	(71.6)	(70.1)

PROFIT DISTRIBUTION

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	FY2015	FY2016	FY2017 (forecast)
EPS (yen)	89.75	103.69	88.44
Divided per share (yen)	32	34	36 (forecast)
ROE	15.0%	17.3%	-
DOE	5.4%	5.6%	-
Share buyback	68 million shares 119.3 billion yen	60 million shares 91.4 billion yen	Implemented in a flexible manner 49 million shares 70.0 billion yen (in Jul. - Oct.)
Treasury stock cancellation	38 million shares	68 million shares	85 million shares

ON THE FOREFRONT OF HEALTHCARE CHANGE

