



Q3/FY2016 FINANCIAL RESULTS

ENDED DECEMBER 31, 2016



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Senior Corporate Executive, Chief Financial Officer
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January 31, 2017

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. 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/FY2016 Financial Results

II

Initiatives to Build Resilience for Sustainable Growth

III

Profit Distribution Policy

Q3/FY2016 FINANCIAL RESULTS (CORE BASIS)

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(billion yen)	Q3/FY15	Q3/FY16	Change	FY16 FCST*	Achievement	(ref) CER growth
Net sales	1,065.7	1,005.6	-5.6%	1,300.0	77.4%	+3%
Cost of sales	270.5	250.8	-7.3%			
% of sales	25.4%	24.9%	-0.4 ppt			
SG&A expenses	362.7	336.7	-7.2%			
% of sales	34.0%	33.5%	-0.6ppt			
R&D expenses	165.0	148.3	-10.1%	216.0	68.7%	
% of sales	15.5%	14.7%	-0.7ppt	16.6%		
Amortisation of intangibles	33.2	26.7	-19.3%			
Share of associates/JVs losses	-0.5	-1.3	-			
Core operating profit	233.9	241.8	+3.4%	274.0	88.3%	+18%
Core profit for the period	169.4	177.2	+4.6%	202.0	87.7%	
Exchange rate (yen)**	Q3/FY15	Q3/FY16	Change	FY16FCST		
USD: Average for the period	122	107	-15	103		
EUR: Average for the period	134	118	-16	117		
USD: Change from PY end	+0	+4				
EUR: Change from PY end	+1	-5				
			Fx impacts	Net sales:	-89.6	
				Core OP:	-33.6	

* Revised in Oct. 2016

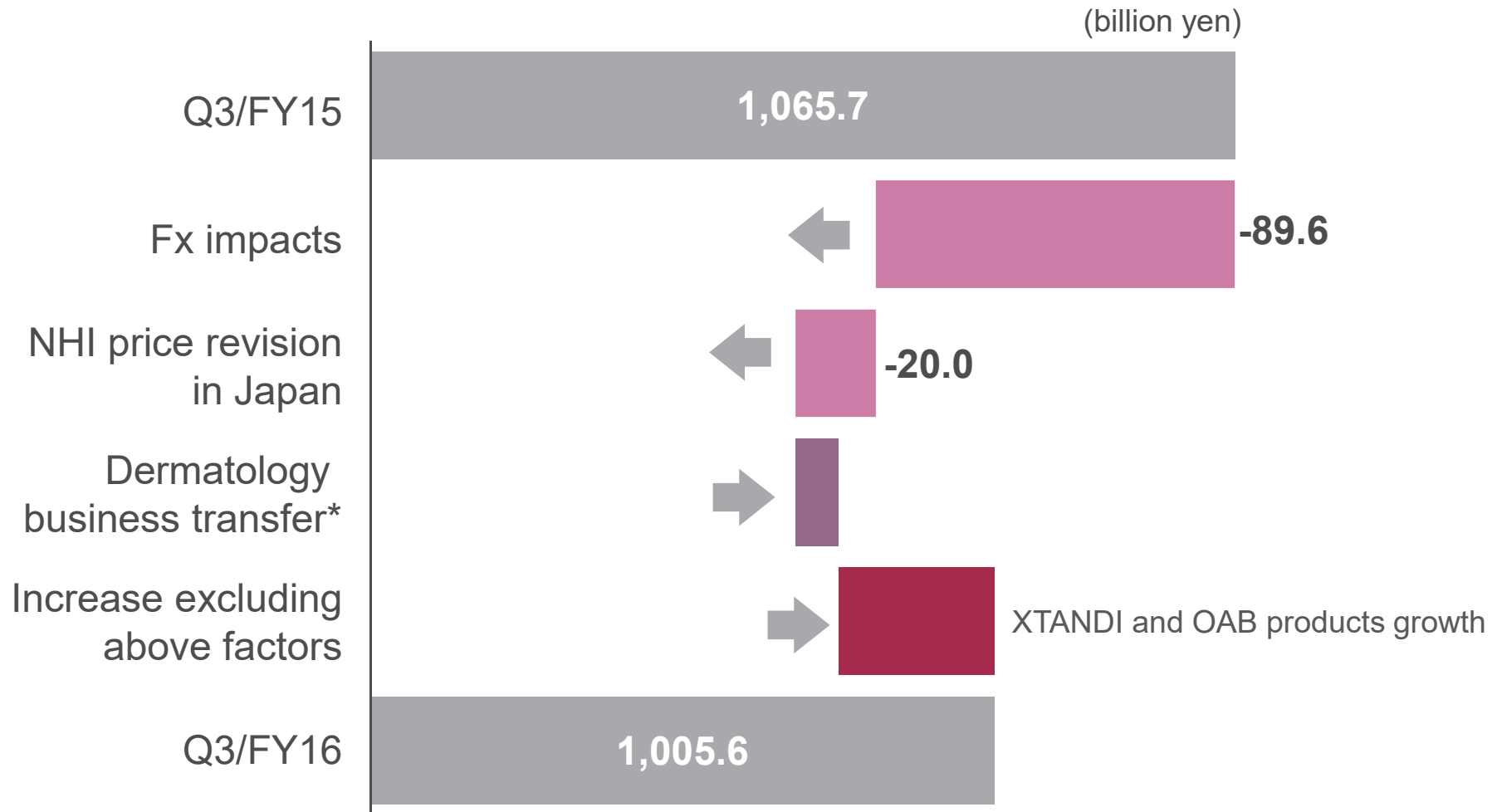
** Exchange rate change +: Yen weakening, -: Yen Strengthening

CER: Constant exchange rate

PY: Previous year



SALES ANALYSIS



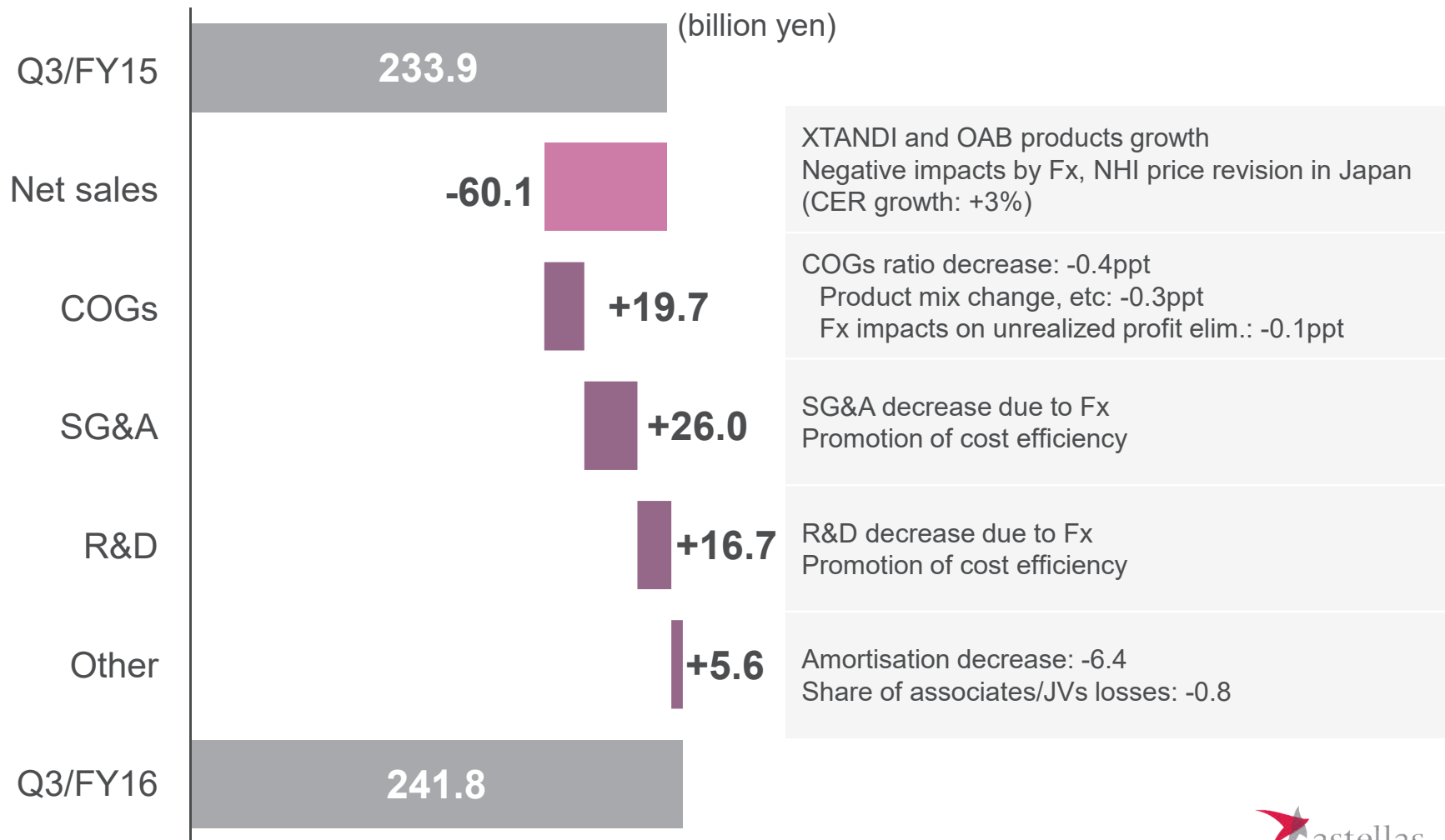
*Dermatology business transfer: Amortisation of deferred revenue - PY sales of transferred products

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

NHI: National health insurance

CORE OPERATING PROFIT ANALYSIS

(Positive/negative signs show impacts on operating profit)



FINANCIAL RESULTS (FULL BASIS)

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(billion yen)	Q3/FY15	Q3/FY16	Change	FY16FCST*	Achievement
Net sales	1,065.7	1,005.6	-5.6%	1,300.0	77.4%
Core operating profit	233.9	241.8	+3.4%	274.0	88.3%
Other income	1.1	6.6			
Other expenses	19.4	17.1			
Operating profit	215.6	231.3	+7.3%	267.0	86.6%
Financial income	13.8	14.0			
Financial loss	0.9	1.4			
Profit before tax	228.5	243.9	+6.8%	268.0	91.0%
Profit for the period	164.5	178.8	+8.7%	198.0	90.3%

Other income:

- Q3/FY16 Foreign exchange gain (4.3 bil. yen) recorded

Other expenses:

- Q3/FY16 Loss on sale and disposal of property, plant and equipment (7.7 bil. yen) and impairment loss of other intangible assets (4.1 bil. yen) recorded
- Q3/FY15 (PY) Loss on sale and disposal of property, plant and equipment (8.8 bil. yen) and foreign exchange losses (7.0 bil. yen) recorded

Financial income:

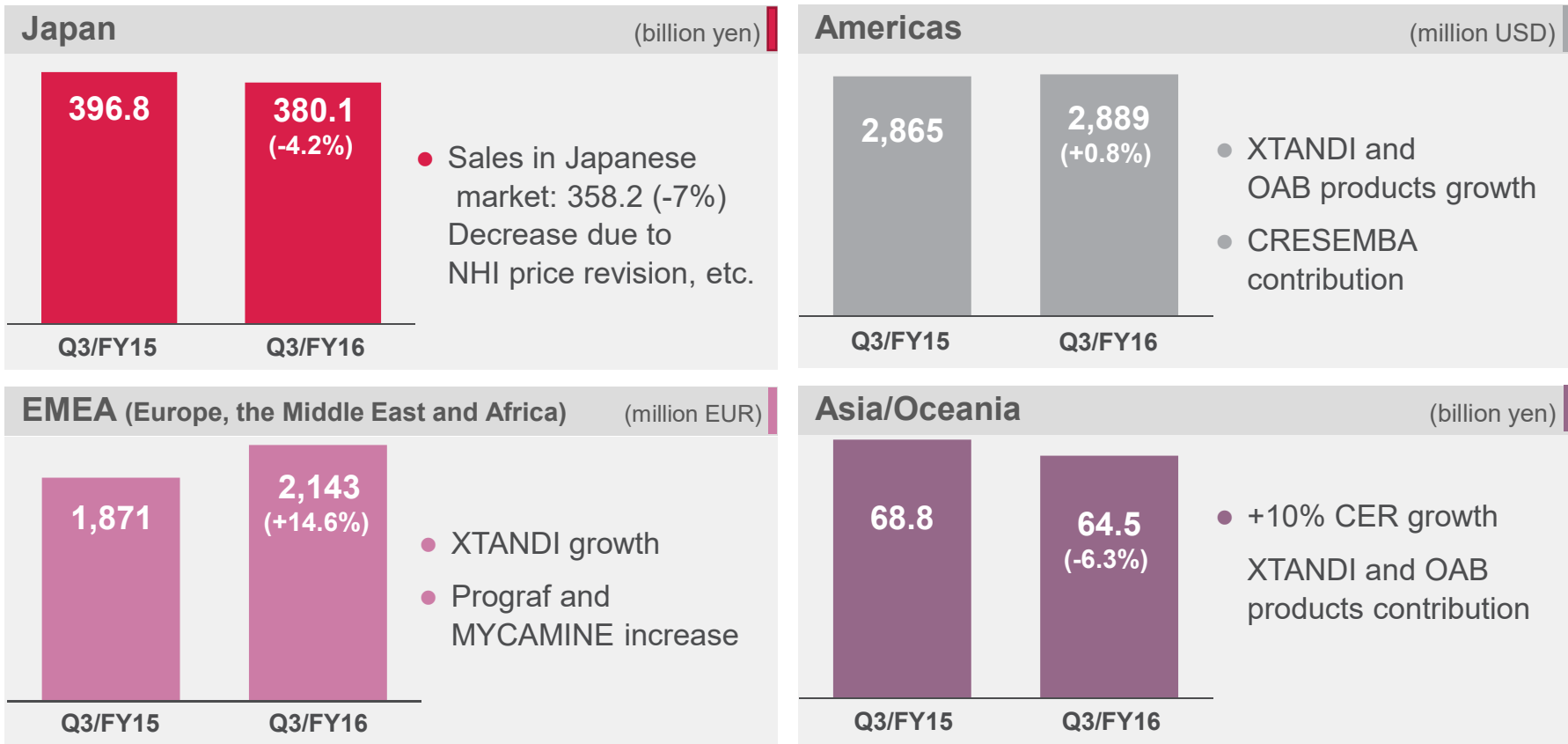
- Q3/FY16 Gain on sale of financial assets (12.7 bil. yen) recorded
- Q3/FY15 (PY) Gain on sale of financial assets (12.1 bil. yen) recorded



*Revised in Oct. 2016

SALES BY REGION (LOCAL CURRENCY BASIS)

Steady growth in Americas, EMEA and Asia/Oceania on a local currency basis



Sales by region: based on the location of the seller

SALES IN THREE KEY AREAS

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Each franchise showed solid performance on a CER basis

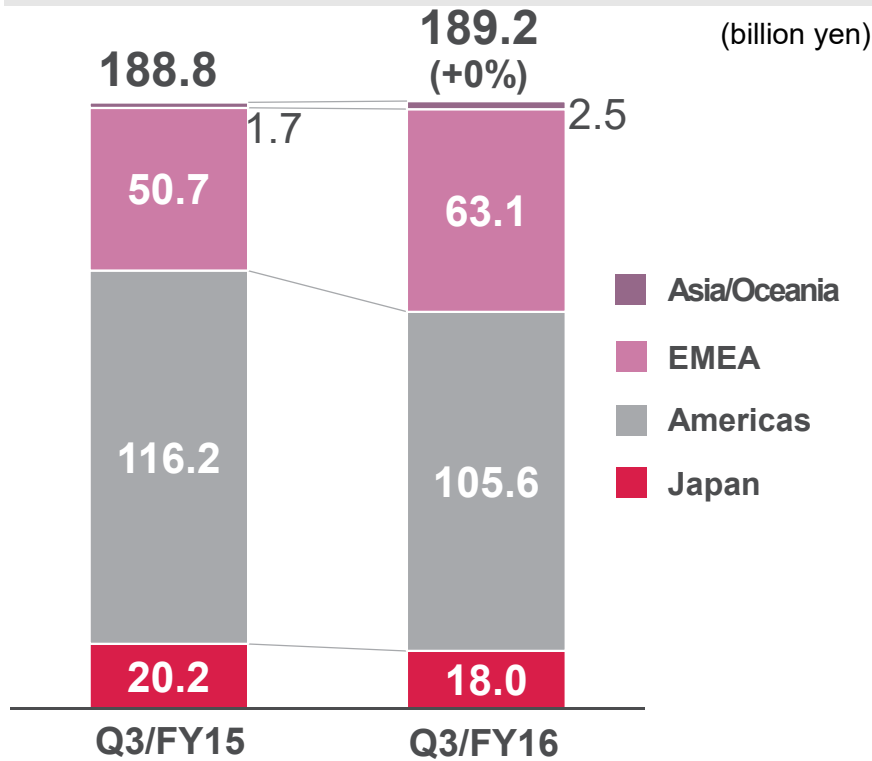
(billion yen)	Q3/FY15	Q3/FY16	Change	(ref) CER growth
Oncology	242.7	232.3	-4%	+8%
XTANDI	188.8	189.2	+0%	+13%
OAB in Urology	164.9	160.9	-2%	+8%
Vesicare	104.8	89.3	-15%	-6%
Betanis/Myrbetriq/BETMIGA	60.1	71.6	+19%	+31%
Transplantation	157.5	142.2	-10%	+0%



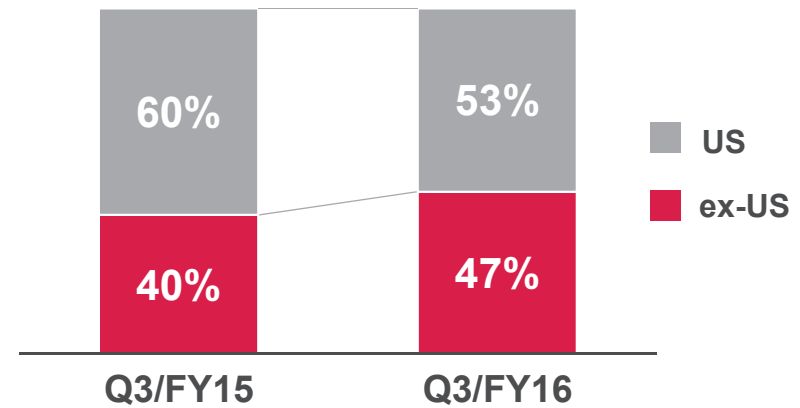
Oncology: XTANDI, Tarceva, Eligard and Gonax
 Transplantation: Prograf, Advagraf/Graceptor/ASTAGRAF XL

Pursue further penetration in chemo-naive mCRPC

Sales by region



Sales composition by region



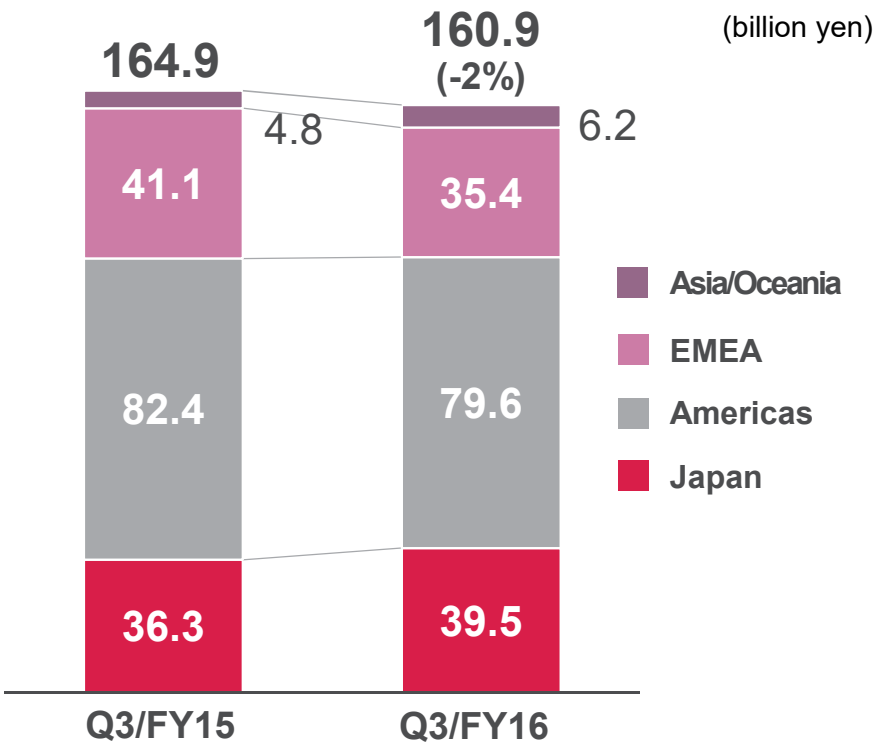
Year-on-Year sales growth

Japan: -11% **Americas:** +4% (USD basis)
EMEA: +42% (EUR basis) **Asia/Oceania:** +68% (CER basis)

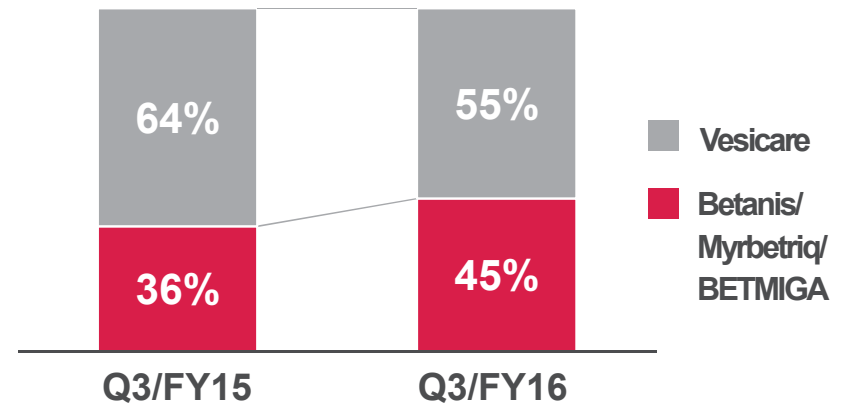


Betanis/Myrbetriq/BETMIGA penetration enhances OAB Franchise

Sales by region



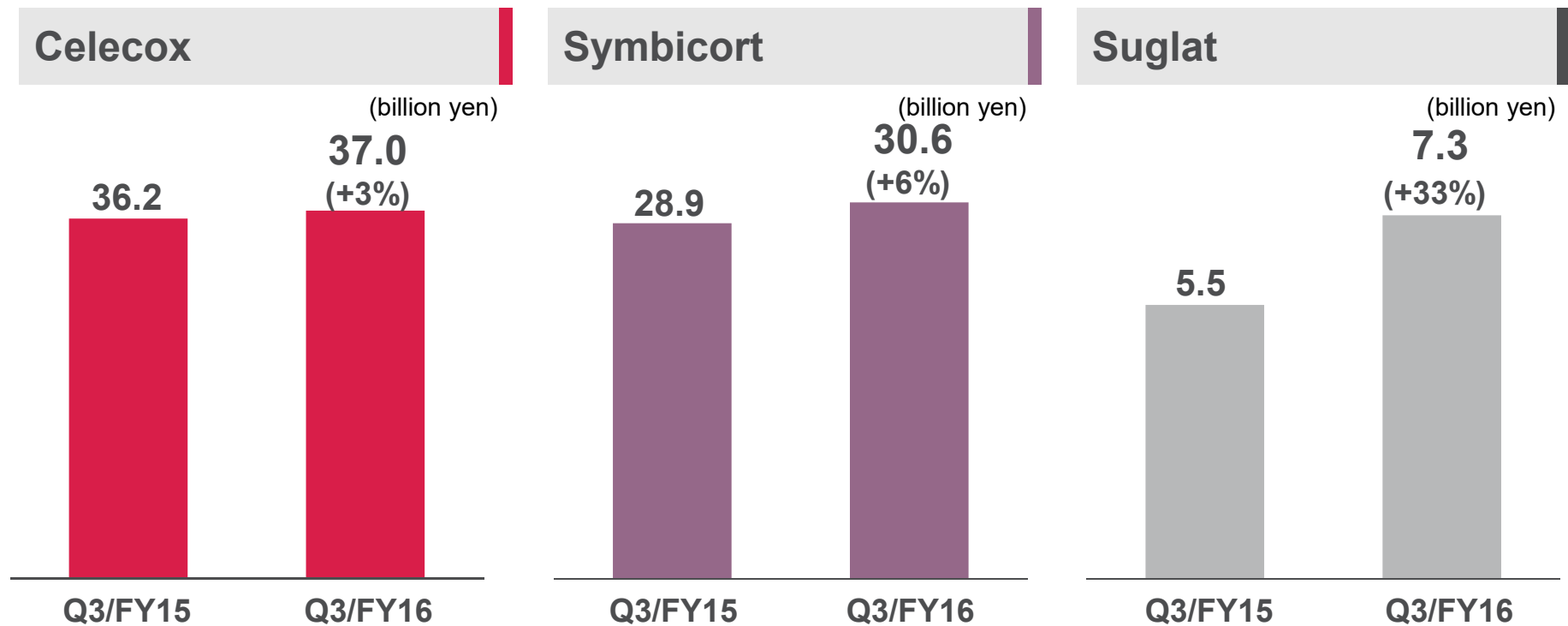
Sales composition ratio by product



Year on Year sales growth

Japan: +9% **Americas: +10%** (USD basis)
EMEA: -2% (EUR basis) **Asia/Oceania: +47%**
(CER basis)

*Sales in Japanese market decreased by 7% due to NHI price revision, etc.
Key products sales steadily expanded*





AGENDA

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Q3/FY2016 Financial Results

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Initiatives to Build Resilience for Sustainable Growth

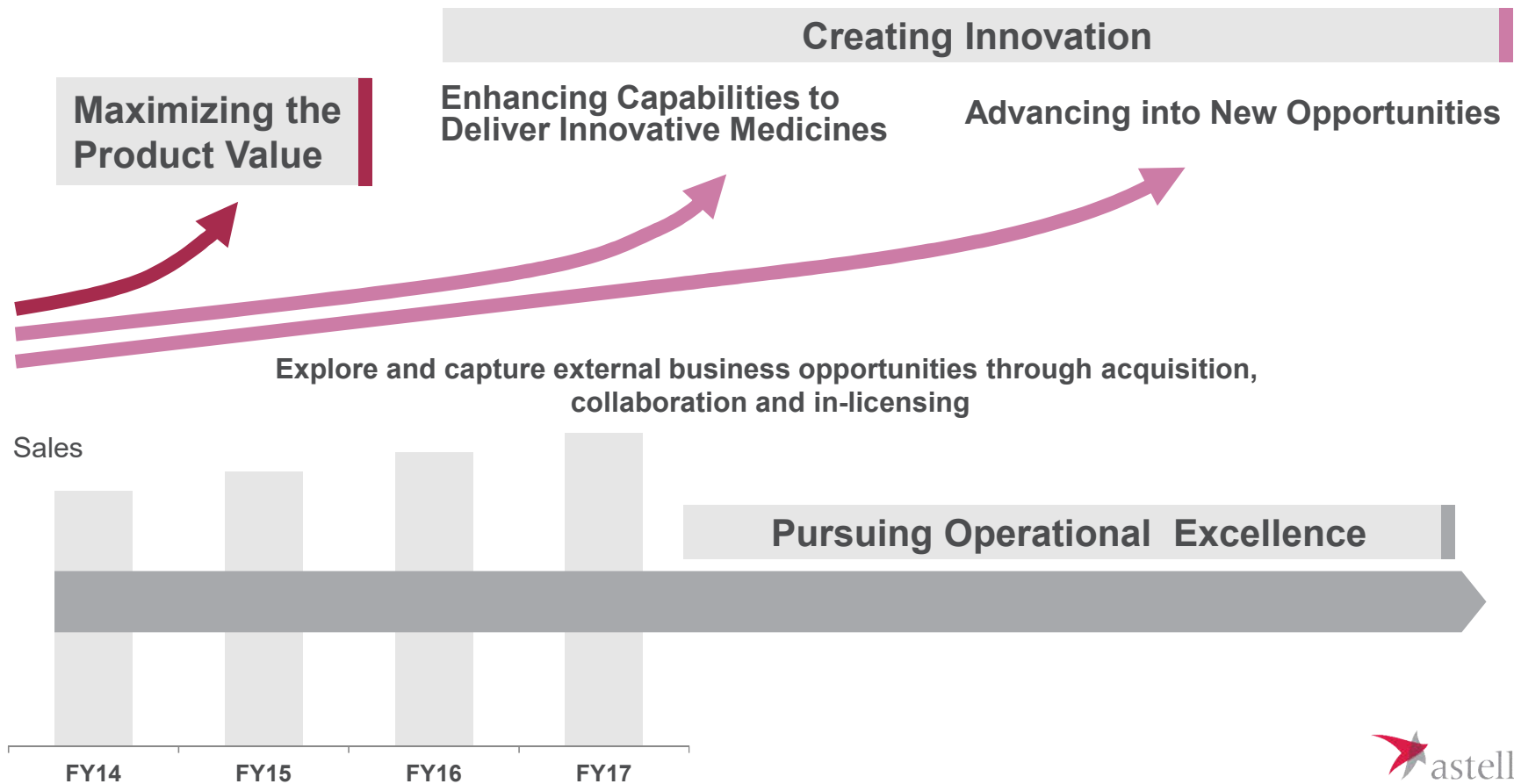
III

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***



STRATEGIC PRIORITIES AND RECENT ACTIVITIES (UPDATE FROM PREVIOUS ANNOUNCEMENT)

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Maximize the Product Value

- Enhance oncology franchise (XTANDI sales growth, label expansion)
- Maximize OAB franchise (expansion of Vesicare + Betanis/ Myrbetriq/BETMIGA)
- New product launches in many countries

Create Innovation

[Progress of pipeline]

- Approval:
 - LINZESS (IBS-C, JP)
- Filing:
 - Romosozumab (JP)
- P3 trials are steadily ongoing

[New initiative]

- Completion of acquisition of Ganymed Pharmaceuticals
- License agreement with Auration for AU-935 to treat chronic tympanic membrane perforations

Pursue Operational Excellence

[Optimal allocation of resources]

- Transfer of Qutenza to Grünenthal

[Continually enhance organization structure]

- Outsourcing of facility and equipment management support in Japan, and dissolution of Astellas Business Service





MAXIMIZE THE PRODUCT VALUE

CONTINUOUS INTRODUCTION OF NEW PRODUCTS

EMEA

[Status of XTANDI and BETMIGA]

XTANDI

- Inclusion of TERRAIN data to SmPC
- Post-chemo indication: Launched in 41 countries
- Chemo-naive indication: Launched in 20 countries

BETMIGA:

- Launched in 34 countries

[FY2016 Progress]

XTANDI

- Chemo-naive indication: Launched in Iceland

Japan

[Status of XTANDI and Betanis]

XTANDI

- Launched

Betanis

- Launched

[FY2016 Progress]

Repatha, Micatrio, Kiklin Granules

- Launched

Americas

[Status of XTANDI and Myrbetriq]

XTANDI

- Post-chemo indication: Launched in 14 countries
- Chemo-naive indication: Launched in 10 countries

Myrbetriq:

- Launched in 6 countries

[FY2016 Progress]

XTANDI

- Inclusion of TERRAIN data to label (US)
- Post-chemo indication: Launched in Colombia, Bolivia and Mexico
- Chemo-naive indication: Launched in Colombia and Chile

Myrbetriq:

- Launched in Brazil

Asia/Oceania

[Status of XTANDI and BETMIGA]

XTANDI

- Post-chemo indication: Launched in 11 countries/areas
- Chemo-naive indication: Launched in 7 countries/areas

BETMIGA:

- Launched in 9 countries/areas

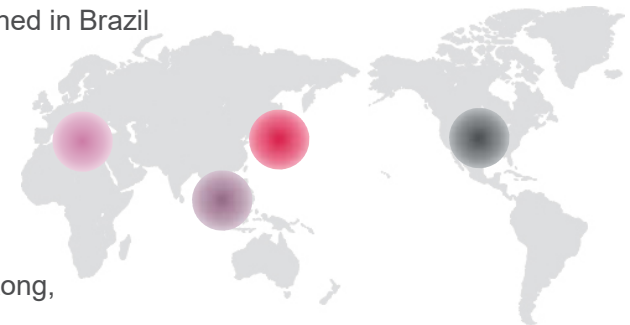
[FY2016 Progress]

XTANDI

- Post-chemo indication: Launched in Taiwan, India, Malaysia, Brunei and Thailand
- Chemo-naive indication: Launched in Taiwan, Hong Kong, Malaysia, Brunei and Thailand

BETMIGA:

- Launched in Indonesia



No. of countries/areas where the following have been launched:
 XTANDI: Approx. 70
 Betanis / Myrbetriq / BETMIGA: Approx. 50



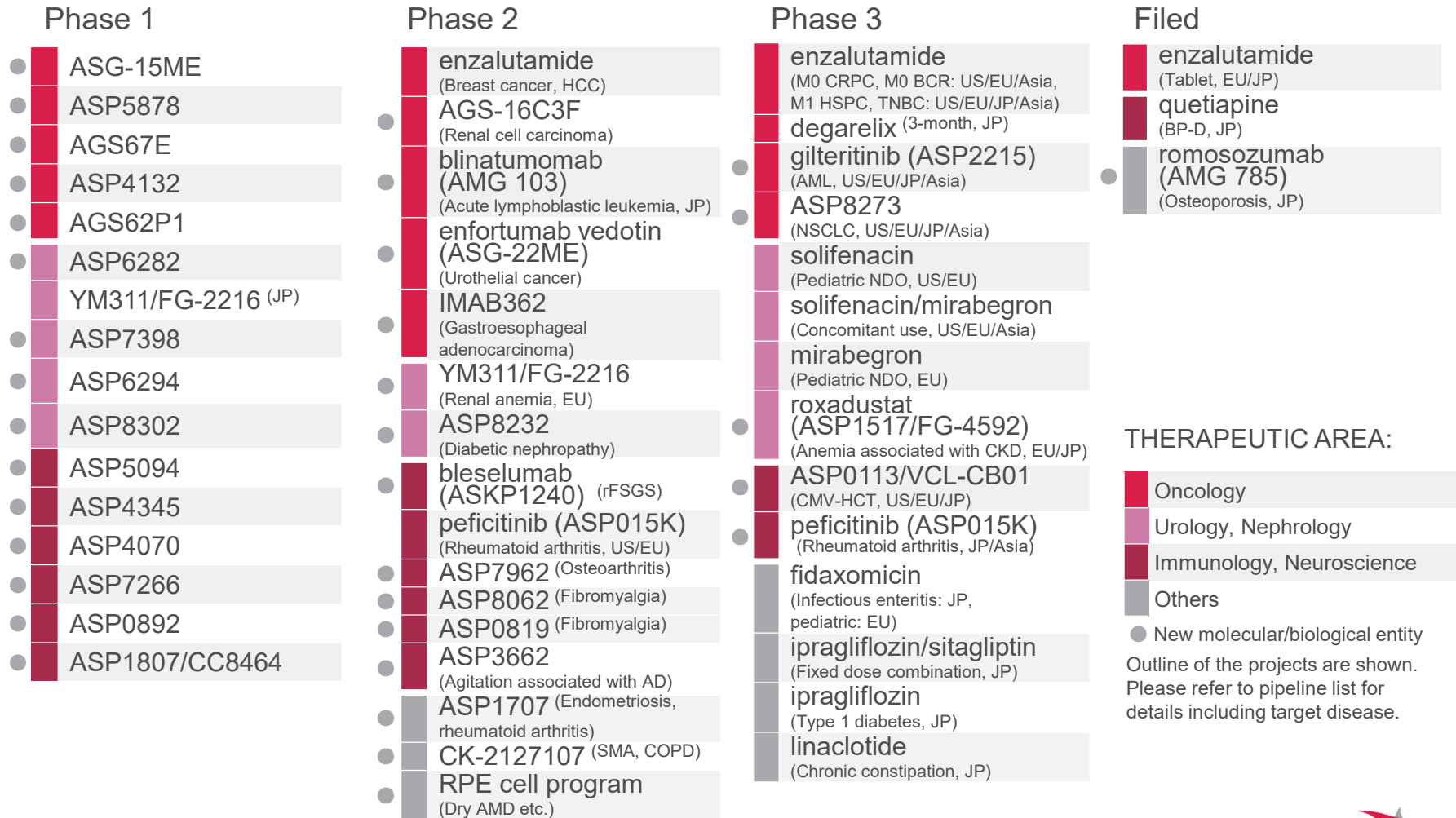
Underlined items show updates from the previous announcement



CREATE INNOVATION

PIPELINE

ROBUST PIPELINE OF ASTELLAS

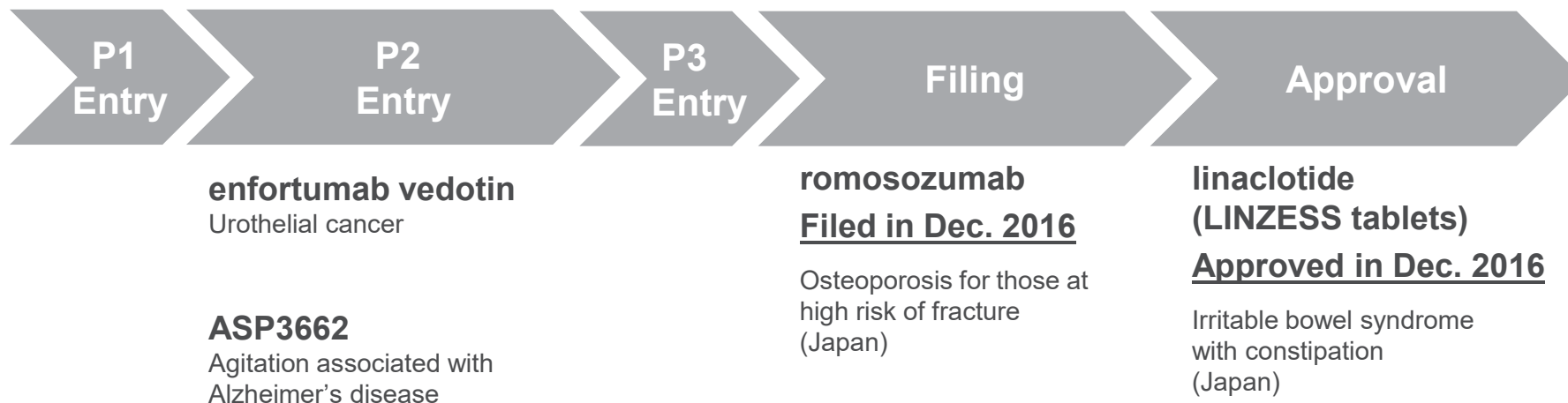


HCC: Hepatocellular carcinoma, rFSGS: Recurrence of focal segmental glomerulosclerosis, AD: Alzheimer's disease, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, AMD: Age-related macular degeneration, M0 CRPC: Non-metastatic castration-resistant prostate cancer, M0 BCR: Non-metastatic biochemical recurrence, M1 HSPC: Metastatic hormone sensitive prostate cancer, TNBC: Triple-negative breast cancer, AML: Acute myeloid leukemia, NSCLC: Non-small cell lung cancer, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, CMV: Cytomegalovirus, HCT: Hematopoietic cell transplant, BP-D: Bipolar disorder depressive episodes

STEADY PROGRESS IN DEVELOPMENT

SUMMARY OF CHANGES FROM OCTOBER 2016 TO JANUARY 2017

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Discontinuation (in a part of indications) etc.

- ASP7374:** Prophylaxis of seasonal influenza (Filed, Japan)
(Exercised the right to terminate the agreement with UMN Pharma.
Withdrew the application for marketing approval based on the comprehensive consideration.)
- ASP7373:** Prophylaxis of H5N1 influenza (P2, Japan)
(Exercised the right to terminate the agreement with UMN Pharma.)
- gilteritinib:** Non-small cell lung cancer (P1)
(The phase 1 study was terminated due to adverse events in combination therapy.)
- ASP2205:** Stress urinary incontinence (P1)

linaclotide

- Top line results obtained from Japanese Phase 3 study in patients with chronic constipation
 - The study met its primary endpoints.
 - Safety profile was consistent with the previous clinical studies.

ASP0892

- Fast track designation granted from FDA for mitigation of severe hypersensitivity reactions due to peanut allergy
- Phase 1 study ongoing

ONCOLOGY PIPELINE

Stage in the most advanced territory

	Project	Target Cancer	Characteristics	P1	P2	P3
Small molecule	enzalutamide	Prostate cancer (M0 CRPC, M0 BCR, M1 HSPC), Breast cancer, Hepatocellular carcinoma	Androgen receptor inhibitor	PC, TNBC		
				BC, HCC		
	degarelix	Prostate cancer	GnRH antagonist	3-month: JP		
	gilteritinib	Acute myeloid leukemia	FLT3/AXL inhibitor			
	ASP8273	Non-small cell lung cancer	Mutant-selective irreversible EGFR inhibitor			
	ASP5878	Solid tumors	FGFR inhibitor			
ASP4132	Advanced cancer					
Antibody	IMAB362	Gastroesophageal adenocarcinoma	Antibody (target: CLDN18.2)			
	AGS-16C3F	Renal cell carcinoma	Antibody utilizing ADC (target: ENPP3)			
	blinatumomab	Acute lymphoblastic leukemia	Anti-CD19 BiTE			
	enfortumab vedotin (ASG-22ME)	Urothelial cancer	Antibody utilizing ADC (target: Nectin-4)			
	ASG-15ME	Urothelial cancer	Antibody utilizing ADC (target: SLITRK6)			
	AGS67E	Lymphoid malignancy	Antibody utilizing ADC (target: CD37)			
	AGS62P1	Acute myeloid leukemia	Antibody utilizing ADC (target: FLT3)			



ADC: Antibody-drug conjugate, PC: Prostate cancer, BC: Breast cancer

ENZALUTAMIDE: DEVELOPMENT PROGRESS

Updated underlined items from previous disclosure

	Phase/Region*	Population	Design	P1	P2	P3
Prostate cancer	P3 US/EU/Asia [PROSPER study]	M0 CRPC Non-metastatic CRPC	Placebo-controlled, combination with ADT, n=1,500	First Patient In: Nov. 2013		
	P3 US/EU/Asia [EMBARC study]	M0 BCR Non-metastatic prostate cancer, biochemical recurrence	To compare with ADT and combination, n=1,860	First Patient In: Jan. 2015		
	P3 US/EU/JP/Asia [ARCHES study]	M1 HSPC Metastatic hormone-sensitive prostate cancer	Placebo-controlled, combination with ADT, n=1,100	First Patient In: Mar. 2016		
Breast cancer	P3 US/EU/JP/Asia [ENDEAR study]	Triple-negative Advanced, diagnostic-positive, triple- negative breast cancer	Combination with paclitaxel or monotherapy, versus placebo with paclitaxel, n=780	Study start on the way		
	P2 US/EU	ER/PR positive Advanced breast cancer that is ER positive or PR positive and HER2 normal	Placebo-controlled, in combination with exemestane, n=240	Last Patient In: Apr. 2015		
	P2 US/EU	HER2 positive Advanced, androgen receptor- positive, HER2 positive breast cancer	Open-label, n=80	Last Patient In: Aug. 2016		
HCC	P2 US/EU/Asia	Hepatocellular carcinoma	Placebo-controlled, n=144	Last Patient In: Dec. 2016		



*The region where the study is performed

ADT: Androgen-deprivation therapy, ER: Estrogen receptor, PR: Progesterone receptor, HER2: Human epidermal growth factor receptor 2

GILTERITINIB: DEVELOPMENT PROGRESS

Updated underlined items from previous disclosure

	Phase/Region*	Population	Design	P1	P2	P3
AML	P3 Global [ADMIRAL study]	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		
	P1/2 US/EU [CHRYSALIS study]	Relapsed or refractory	Dose-escalation and expansion, n=258	Final results presented at ASH2016		
	P1 JP	Relapsed or refractory	Dose-escalation and expansion	Enrollment completed		
	P2/3 Global [LACEWING study]	1 st 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		
	P3 Global [MORPHO study]	HSCT maintenance FLT3-ITD positive	<u>Double-blind, randomized, monotherapy vs placebo (1:1), n=346</u>	Under preparation Collaborating with Blood and Marrow Transplant – Clinical Trial Network (BMT-CTN)		
	P3 Global [GOSSAMER study]	Post-chemo maintenance FLT3-ITD positive	Double-blind, randomized, monotherapy vs placebo (2:1), n=354	Under preparation		
	P1 US	1 st line intensive chemo eligible Newly diagnosed	Combination with induction and consolidation chemo			
	P1 JP	1 st line intensive chemo eligible Newly diagnosed	Combination with induction and consolidation chemo			



*The region where the study is performed

FLT3: FMS-like tyrosine kinase 3, ITD: Internal tandem duplication

ENFORTUMAB VEDOTIN: DEVELOPMENT PROGRESS -PHASE 2 STUDY TO START IN 2017-

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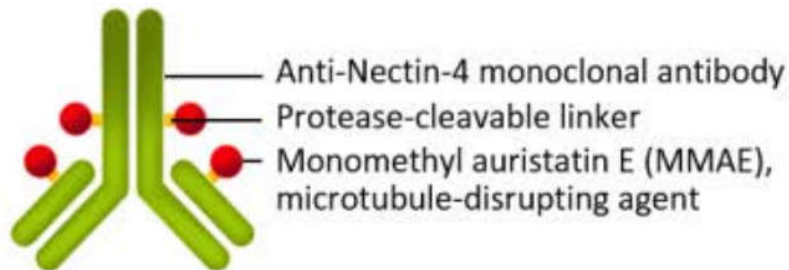
enfortumab vedotin

enfortumab vedotin

Antibody drug conjugate directed against Nectin-4

Target

- Nectin-4 is a type I transmembrane protein that belongs to the Nectin family of adhesion molecules
- Variable, mostly weak or moderate in normal tissue
- Highly expressed in bladder cancer with 83% (434/524) on tissue microarrays were positive, 60% with strong or moderate staining



Development progress

Plan

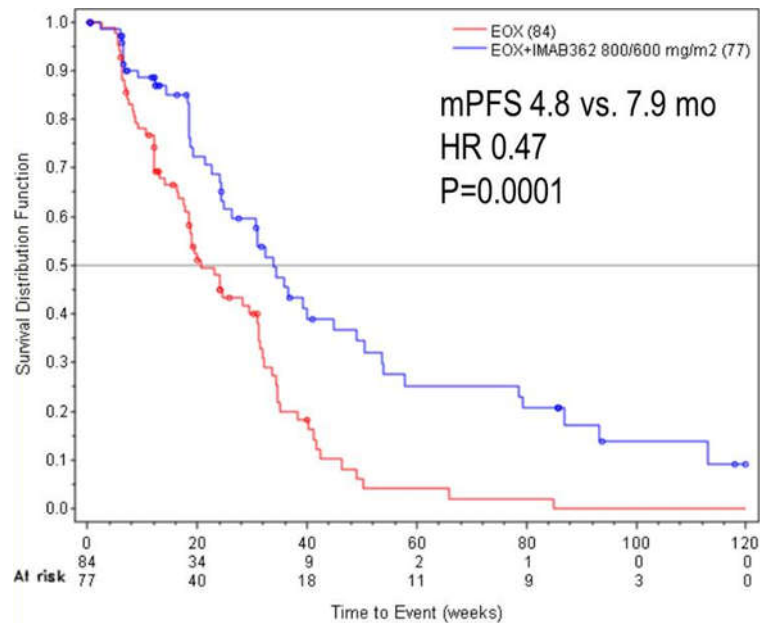
- Consult with regulatory agencies and pursue registrational-directed development plan
- Phase 2 planned in patients who have been exposed to check point inhibitor therapy

Current Phase 1

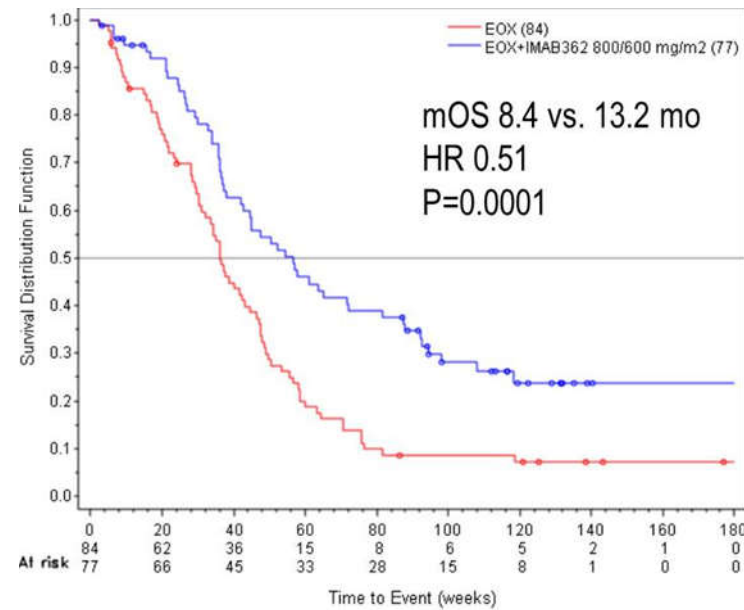
- Continue Phase 1 expansion cohorts in other Nectin 4 expressing solid tumors, including NSCLC and ovarian

IMAB362: Results from Phase 2 FAST Study

Progression-free survival (primary endpoint)



Overall survival



- The most frequent adverse effects observed during the study were vomiting, nausea and neutropenia.



Plan to discuss with regulatory authorities for next steps



FY2016 EXPECTED KEY PIPELINE EVENTS

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

Data Readouts and Phase Transition*

Data readouts**

solifenacin/mirabegron

Phase 3 long term study
(SYNERGY II)

enzalutamide

Phase 2 in ER/PR+
breast cancer

ASP0113

Phase 2 in solid
organ transplants*

ASP3662

Phase 2 in PDPN

ASP8232

Phase 2 in DME

gilteritinib

Phase 1/2 final results in
AML

ASP8273

Phase 1/2 final results in
NSCLC

Phase transition

enzalutamide

TNBC to Phase 3

linaclotide

CC to Phase 3

Filing*

solifenacin

Pediatric OAB (US)

enzalutamide

Tablet (Japan)

degarelix

3-month formulation (Japan)

romosozumab

Osteoporosis (Japan)

quetiapine

BP-D (Japan)

fidaxomicin

CDI (Japan)

Regulatory Decisions

enzalutamide

TERRAIN (US)

enzalutamide

Tablet (EU)

solifenacin

Pediatric OAB (EU)

bixalomer

Granule formulation (Japan)

linaclotide

IBS-C (Japan)

ASP7374***

Seasonal influenza (Japan)

***Exercised the right to terminate
the agreement with UMN Pharma



** Final data readouts or completion of data evaluation
Light gray items indicate completed events

PDPN: Painful diabetic peripheral neuropathy, DME: Diabetic macular edema, AML: Acute myeloid leukemia, NSCLC: Non-small cell lung cancer, TNBC: Triple-negative breast cancer, CC: Chronic constipation, BP-D; Bipolar disorder, depressive episodes, CDI: *Chrostridium difficile* infection, IBS-C, Irritable bowel symptom with constipation



CREATE SOCIAL VALUE

Builds on Company Commitment to improve Access to Health

Access Accelerated:

A global, multi-stakeholder initiative to advance access to non-communicable disease (NCD) prevention, diagnostics and treatment in low-income and lower-middle income countries

Together with 21 other leading pharmaceutical companies and in collaboration with the World Bank Group and the Union for International Cancer Control (UICC), Astellas will seek to find and advance new solutions to address gaps in access for NCDs, and work towards the United Nations Sustainable Development Goal target to reduce premature deaths from NCDs by one-third by 2030.



AGENDA

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Profit Distribution Policy

PROFIT DISTRIBUTION POLICY

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- Top priority on investment for growth of Rx business
- Dividends to be increased continuously based on mid- and long-term growth
- Share buybacks to be implemented in a flexible manner

	FY2014	FY2015	FY2016 (Forecast)
Core EPS	69.37 yen	92.12 yen	95.60 yen
Dividends per Share	30 yen	32 yen	34 yen (planned)
ROE	10.5%	15.0%	-
DOE	5.1%	5.4%	-
Share Buybacks*	38 million shares (58.2 billion yen)	68 million shares (119.3 billion yen)	Implemented in a flexible manner 30 million shares (45.9 billion yen) (in Oct. – Dec.)
Cancellation of Treasury Shares	25 million shares	38 million shares	68 million shares (in Jun.)



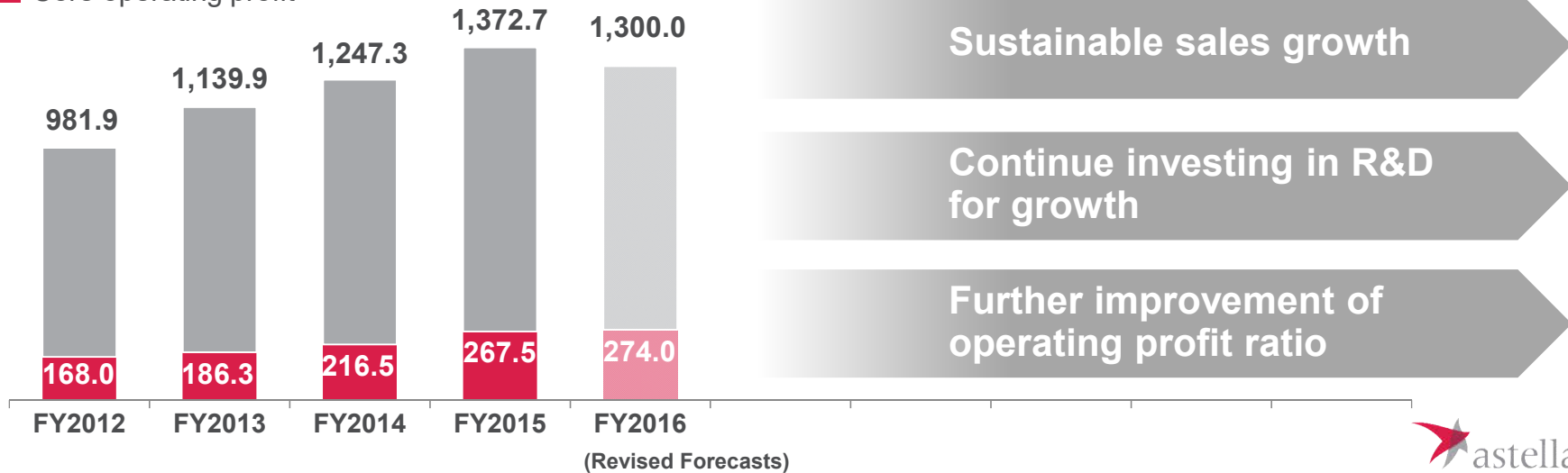
*Excluding amounts for the buyback of shares consisting less than one unit

Resiliently respond to the changing environments and aim for sustainable growth

- Business goes favorably, driven by XTANDI and OAB products
- Continue investing in R&D for creating innovation that is source of future growth
- Work toward higher quality and efficiency of operations through optimization of resources, enhancement of organizational structure and further promotion of cost efficiency

Sales (billion yen)

■ Core operating profit





APPENDIX

RECONCILIATION OF FULL BASIS TO CORE BASIS

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(billion yen)

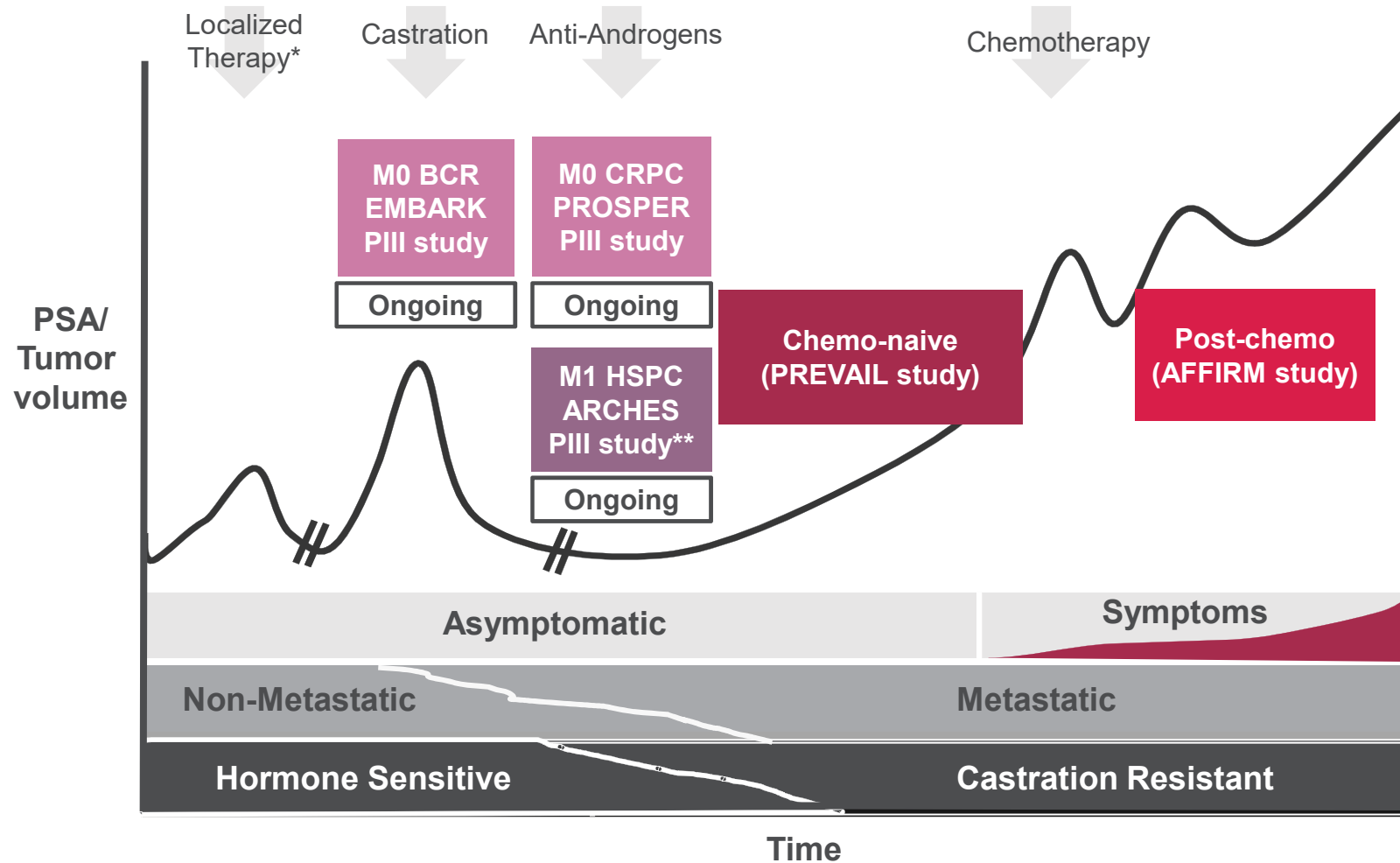
	FY15			FY16		
	APR. - DEC.			APR. - DEC.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Sales	1,065.7	-	1,065.7	1,005.6	-	1,005.6
Cost of sales	270.5	-	270.5	250.8	-	250.8
Gross profit	795.2	-	795.2	754.8	-	754.8
SG&A expenses	362.7	-	362.7	336.7	-	336.7
R&D expenses	165.0	-	165.0	148.3	-	148.3
Amortisation of intangible assets	33.2	-	33.2	26.7	-	26.7
Share of losses of associates and joint ventures	-0.5	-	-0.5	-1.3	-	-1.3
Other income *1	1.1	-1.1	-	6.6	-6.6	-
Other expense *1	19.4	-19.4	-	17.1	-17.1	-
Operating profit	215.6	18.3	233.9	231.3	10.5	241.8
Finance income *2	13.8	-12.1	1.7	14.0	-12.7	1.3
Finance expense *2	0.9	-0.4	0.6	1.4	-0.4	1.0
Profit before tax	228.5	6.6	235.1	243.9	-1.8	242.1
Income tax expense	63.9	1.8	65.7	65.1	-0.2	64.9
Profit for the period	164.5	4.8	169.4	178.8	-1.6	177.2

*1. "Other income" and "Other expense" are excluded from Full basis results.

"Other income" and "Other expense" include gain/loss on sale and disposal of property, plant and equipment, impairment losses for other intangible assets, restructuring costs, litigation costs and net foreign exchange gains/losses, etc.

*2. Gain/loss on sale of available-for-sale ("AFS") and impairment losses of AFS included in "Finance income" and "Finance expense" are excluded from Full basis results.

MAXIMIZE THE VALUE OF ENZALUTAMIDE FOR PROSTATE CANCER PATIENTS



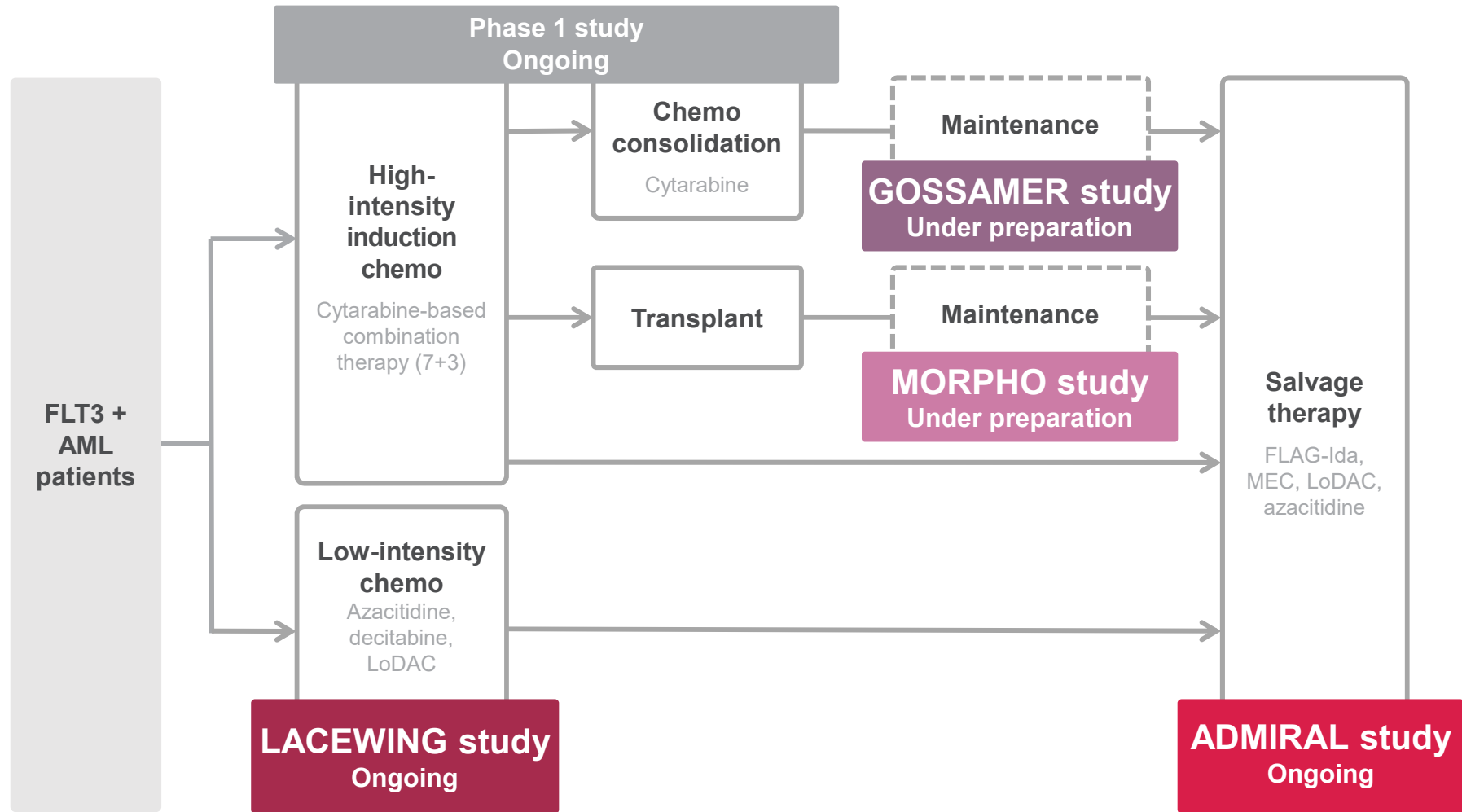
P. Mulders *et al.* EAU2012, modified by Astellas

* Radiotherapy, prostatectomy
 ** Metastatic at the time of diagnosis

PSA: Prostate-specific antigen



GILTERITINIB: TREATMENT LANDSCAPE IN AML



7+3: Cytarabine + idarubicin or daunorubicin, LoDAC: Low dose cytarabine, FLAG-Ida: Fludarabine + cytarabine + G-CSF + idarubicin, MEC: Mitoxantrone + etoposide + cytarabine

ON THE FOREFRONT OF HEALTHCARE CHANGE

