Q2/FY2016 FINANCIAL RESULTS
ENDED SEPTEMBER 30, 2016

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President and CEO
Astellas Pharma Inc.
October 28, 2016

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

I Q2/FY2016 Financial Results

II Initiatives to Build Resilience for Sustainable Growth

III Profit Distribution Policy

Q2/FY2016 FINANCIAL RESULTS (CORE BASIS)

(billion yen)	Q2/FY15	Q2/FY16	Change	FY16 FCST*	Achieve-ment	(ref) CER growth
Net sales	**687.5**	**651.7**	**-5.2%**	**1,350.0**	**48.3%**	+4%
Cost of sales	168.4	146.2	-13.2%			
% of sales	24.5%	22.4%	-2.1 ppt			
SG&A expenses	239.7	220.8	-7.9%			
% of sales	34.9%	33.9%	-1.0 ppt			
R&D expenses	112.0	99.7	-11.0%	231.0	43.1%	
% of sales	16.3%	15.3%	-1.0 ppt	17.1%		
Amortisation of intangibles	21.9	17.7	-19.2%			
Share of associates/JVs losses	-0.3	-0.8	-			
Core operating profit	**145.2**	**166.5**	**+14.7%**	**270.0**	**61.6%**	+23%
Core profit for the period	**103.9**	**120.6**	**+16.0%**	**199.0**	**60.6%**	

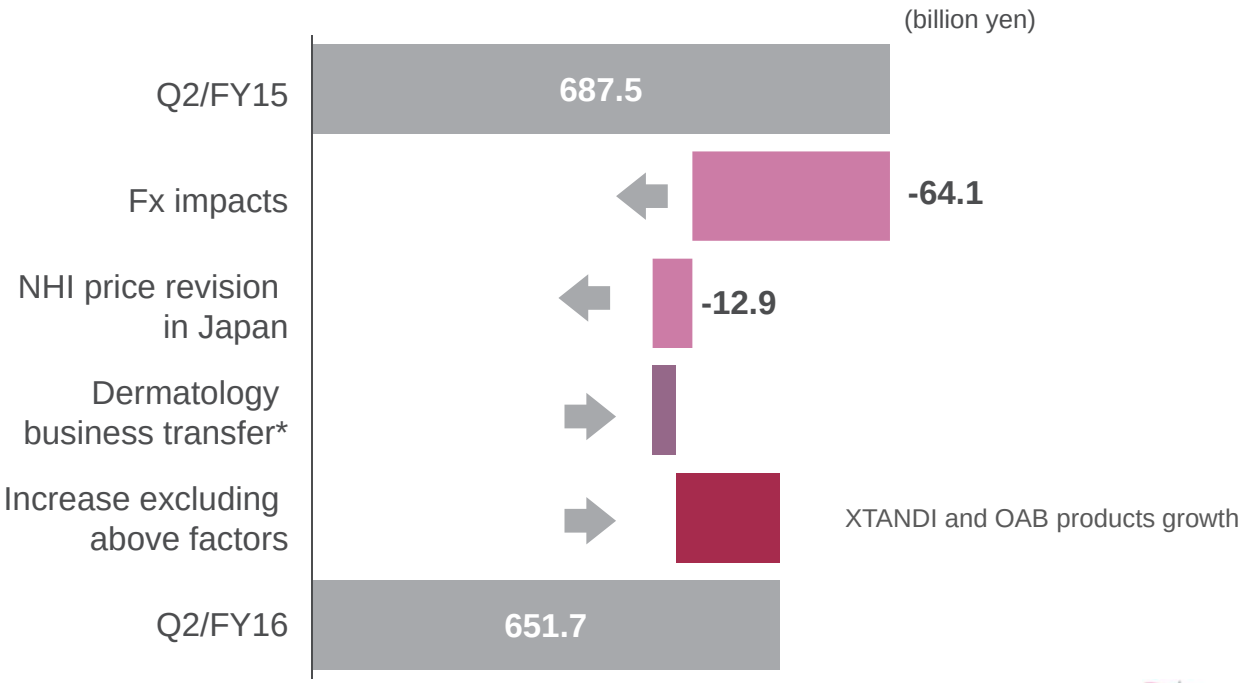
Exchange rate (yen)**	Q2/FY15	Q2/FY16	Change	FY16FCST
USD: Average for the period	122	105	-17	110
EUR: Average for the period	135	118	-17	125
USD: Change from PY end	-0	-12		
EUR: Change from PY end	+5	-14		

Fx impacts		
	Net sales:	-64.1
	Core OP:	+12.5

* Announced in May 2016
** Exchange rate change +: Yen weakening, - : Yen Strengthening

CER: Constant exchange rate
PY: Previous year

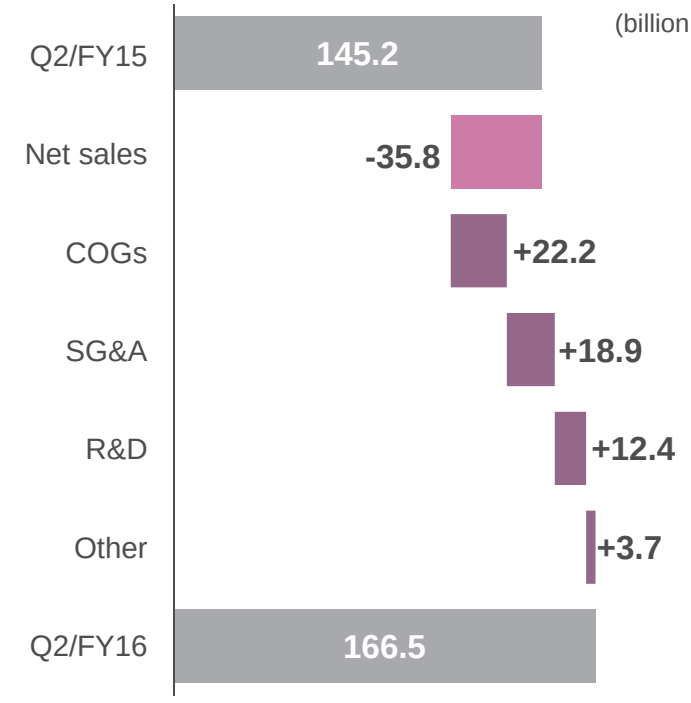
SALES ANALYSIS



*Dermatology business transfer: Amortisation of deferred revenue - PY sales of transferred products
OAB: Overactive bladder, OAB products: Vesicare + Betanis/Myrbetriq/BETMIGA

CORE OPERATING PROFIT ANALYSIS

(Positive/negative signs show impacts on operating profit)



Net sales	XTANDI and OAB products growth Negative impacts by Fx, NHI price revision in Japan (CER growth +4%)
COGs	COGs ratio decrease: -2.1ppt Product mix change, etc: -0.4ppt Fx impacts on unrealized profit elim.: -1.7ppt
SG&A	SG&A decrease due to Fx Increase on a CER basis
R&D	R&D decrease mainly due to Fx
Other	Amorisation decrease: -4.2 Share of associates/JVs losses: -0.5

FINANCIAL RESULTS (FULL BASIS)

(billion yen)	Q2/FY15	Q2/FY16	Change	FY16FCST*	Achievement
Net sales	**687.5**	**651.7**	**-5.2%**	**1,350.0**	**48.3%**
Core operating profit	**145.2**	**166.5**	**+14.7%**	**270.0**	**61.6%**
Other income	0.9	0.4			
Other expenses	13.4	9.8			
Operating profit	**132.6**	**157.1**	**+18.4%**	**267.0**	**58.8%**
Financial income	13.3	2.4			
Financial loss	0.6	1.7			
Profit before tax	145.4	157.8	+8.5%	268.0	58.9%
Profit for the period	**102.9**	**115.1**	**+11.8%**	**197.0**	**58.4%**

Other expenses:
- Q2/FY16 Impairment loss of tangible assets (7.6 bil. yen) recorded (foreign exchange losses: 0.5 bil. yen)
- Q2/FY15 (PY) Impairment loss of tangible assets (6.6 bil. yen) and foreign exchange losses (5.9 bil. yen) recorded

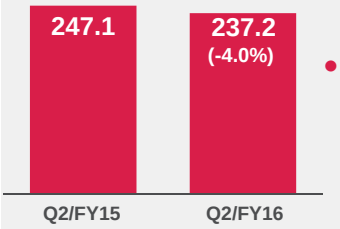
Financial income:
- Q2/FY15 (PY) Gain on sale of financial assets (12.1 bil. yen) recorded

*Announced in May 2016

SALES BY REGION (LOCAL CURRENCY BASIS)

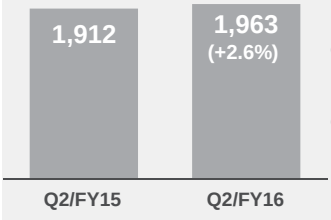
Steady growth in Americas, EMEA and Asia/Oceania on a local currency basis

Japan (billion yen)



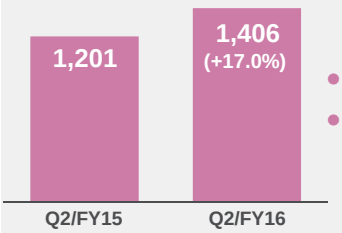
- Sales in Japanese market: 221.8 (-8%) Decrease due to NHI price revision, etc.

Americas (million USD)



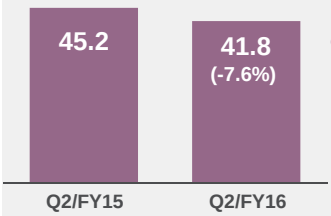
- XTANDI and OAB products growth
- CRESEMBA contribution

EMEA (Europe, the Middle East and Africa) (million EUR)



- XTANDI growth
- Prograf and MYCAMINE increase

Asia/Oceania (billion yen)



- +10% CER growth

  XTANDI and OAB products contribution

Sales by region: based on the location of the seller

SALES IN THREE KEY AREAS

Each franchise showed solid performance on a CER basis

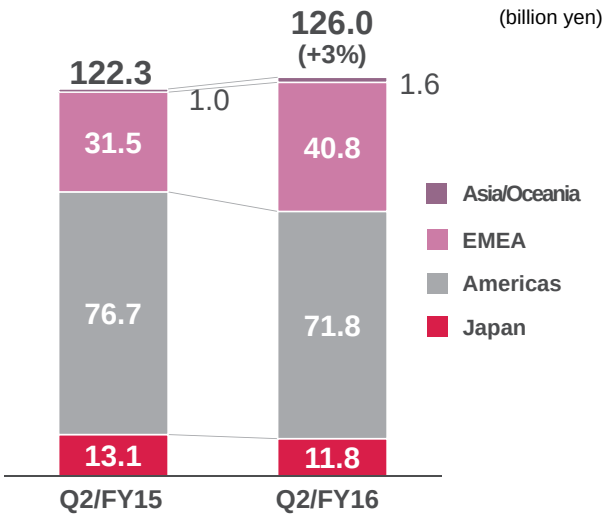
(billion yen)	Q2/FY15	Q2/FY16	Change	(ref) CER growth
Oncology	**158.6**	**153.9**	**-3%**	+10%
XTANDI	122.3	126.0	+3%	+17%
OAB in Urology	**107.8**	**106.5**	**-2%**	+9%
Vesicare	69.7	59.8	-14%	-4%
Betanis/Myrbetriq/BETMIGA	38.1	45.7	+20%	+34%
Transplantation	**104.6**	**94.2**	**-10%**	+1%

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

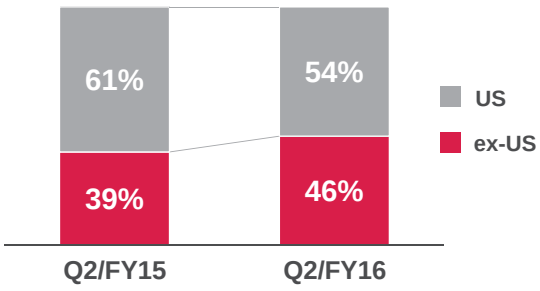
XTANDI

Pursue further penetration in chemo-naive mCRPC

Sales by region



Sales composition by region



Year-on-Year sales growth

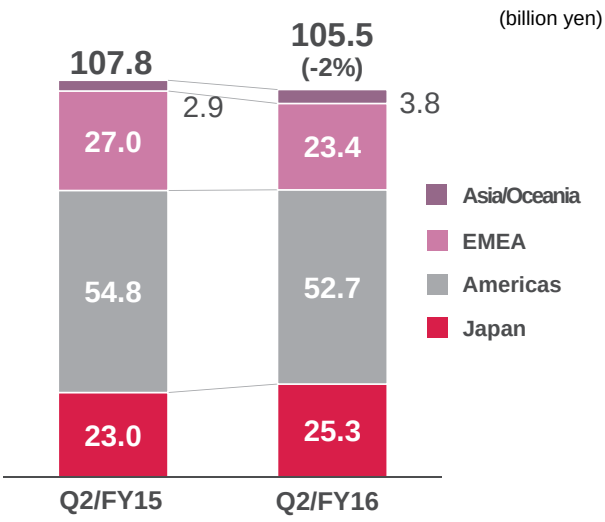
Japan: -10%
Americas: +8% (USD basis)
EMEA: +48% (EUR basis)
Asia/Oceania: +79% (CER basis)

mCRPC: metastatic castration-resistant prostate cancer

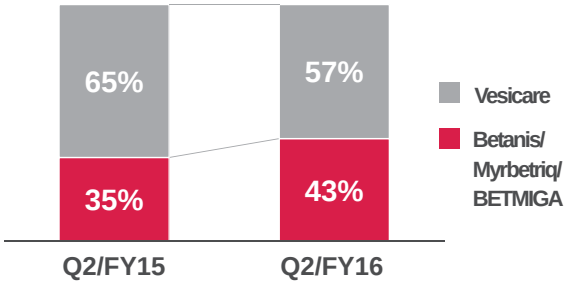
OAB FRANCHISE IN UROLOGY

Betanis/Myrbetriq/BETMIGA penetration enhances OAB Franchise

Sales by region



Sales composition ratio by product



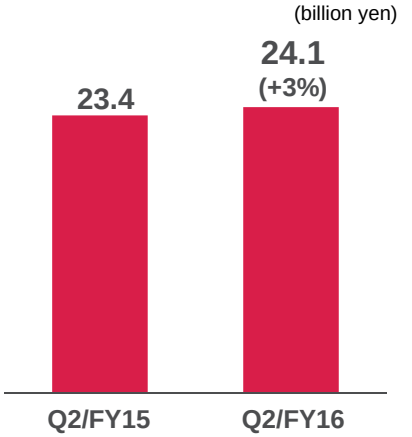
Year on Year sales growth

Japan: +10%
Americas: +11% (USD basis)
EMEA: -1% (EUR basis)
Asia/Oceania: +53% (CER basis)

SALES IN JAPANESE MARKET

Sales in Japanese market decreased by 8% due to NHI price revision, etc.
Key products sales steadily expanded

Celecox



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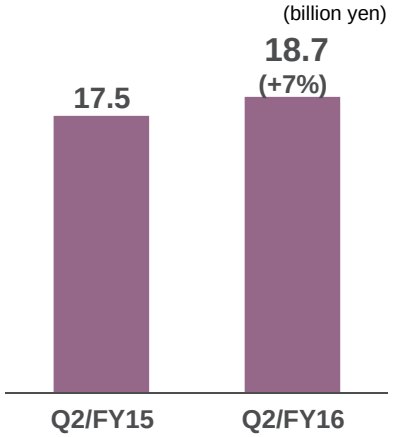

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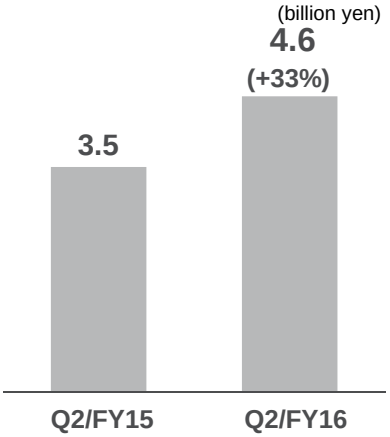


REVISED FORECASTS FOR FY2016 (CORE BASIS)

Revised initial forecasts, based on Q2/FY2016 results and Fx trend

(billion yen)	FY2016 Initial Forecasts	FY2016 Revised Forecasts	Change
Net sales	**1,350.0**	**1,300.0**	**-50.0**
R&D expenses	231.0	216.0	-15.0
as % of sales	17.1%	16.6%	-0.5 ppt
Core operating profit	**270.0**	**274.0**	**+4.0**
Core profit for the year	**199.0**	**202.0**	**+3.0**
Core EPS (YEN)	**93.65**	**95.07**	

Exchange rate (yen) Average for the period	Initial Forecasts	Revised Forecasts
USD	110	103
EUR	125	117

Forecasted rates from Q3/FY2016 onwards:
100 USD/YEN, 115 EUR/YEN

Downward revision of forecast for net sales:
Fx impact (-56.8 billion yen)
Upward revision of profit from dermatology business transfer

Upward revision of forecast for core operating profit

Gross profit: Lower than initial expectation
- Downward revision of forecast for net sales
- COGs ratio: Slightly lower than initial expectation

SG&A: Lower than initial expectation due to Fx impact

R&D Expenses: Lower than initial expectation mainly due to Fx impact

Fx impact on initial forecasts (billion yen)
- Sales: -56.8
- Core operating profit: -10.0

Estimated Fx sensitivity (Q3 and onward) of FY2016 forecasts by 1 yen appreciation*

Currency	Change	Net sales	Core OP
USD	1 yen	Approx. -2.4 bil	Approx. -0.2 bil
EUR	1 yen	Approx. -1.4 bil	Approx. -0.3 bil

*Sensitivity to fluctuation of Fx rates used for consolidation of overseas affiliates' results compared to forecasted rates from Q3/FY2016 and onwards

REVISED FORECASTS FOR FY2016 (FULL BASIS)

Revised initial forecasts, based on Q2/FY2016 results and Fx trend

(billion yen)	FY2016 Initial Forecasts	FY2016 Revised Forecasts	Change
Net sales	**1,350.0**	**1,300.0**	**-50.0**
R&D expenses	231.0	216.0	-15.0
as % of sales	17.1%	16.6%	-0.5 ppt
Operating profit	**267.0**	**267.0**	**-**
Profit before tax	**268.0**	**268.0**	**-**
Profit for the year	**197.0**	**198.0**	**+1.0**
EPS (YEN)	**92.71**	**93.19**	

Maintain forecast for operating profit
Expected other income / expense: -7.0 billion yen

AGENDA

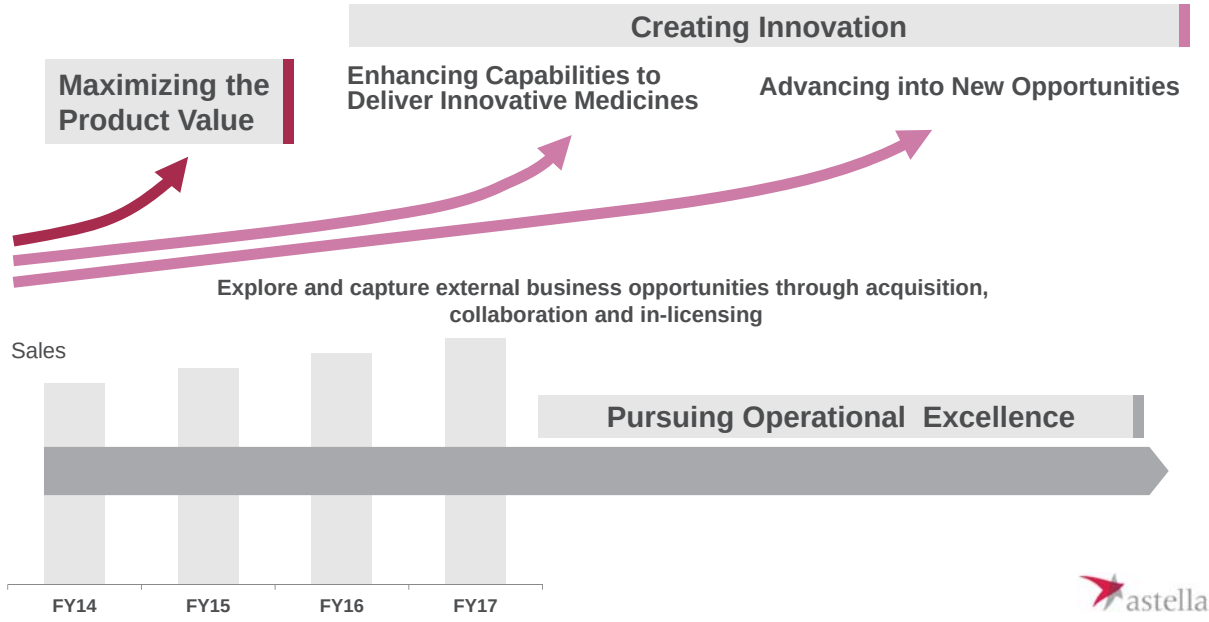
I Q2/FY2016 Financial Results

II 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)

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:
  - Bixalomer granules (JP)
- Filing:
  - Enzalutamide tablet (JP)
  - Quetiapine extended-release tablet (improvement of depressive symptoms associated with bipolar disorder, JP)
- P3 trials are steadily ongoing

[New initiative]

- Acquisition of Ganymed Pharmaceuticals

Pursue Operational Excellence

[Continually enhance organization structure]

- Transfer of US manufacturing subsidiary to Avara

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MAXIMIZE THE PRODUCT VALUE

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CONTINUOUS INTRODUCTION OF NEW PRODUCTS

EMEA

[Status of XTANDI and BETMIGA]

XTANDI
- 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 in post-chemo indication and chemo-naive indication

Betanis
- Launched

[FY2016 Progress]

Repatha
- 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
- Approval for including 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]

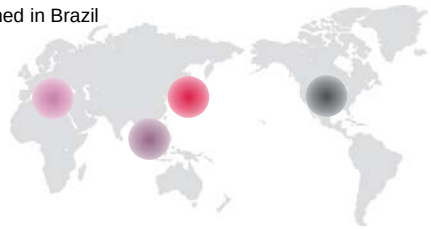
XTANDI
- Post-chemo indication: Launched in 9 countries/areas
- Chemo-naive indication: Launched in 5 countries/areas

BETMIGA:
- Launched in 9 countries/areas

[FY2016 Progress]

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

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

Phase 1

- enfortumab vedotin (ASG-22ME)
- ASG-15ME
- ASP5878
- AGS67E
- ASP4132
- gilteritinib (NSCLC)
- AGS62P1
- ASP2205
- ASP6282
- YM311/FG-2216 (JP)
- ASP7398
- ASP6294
- ASP8302
- ASP5094
- ASP3662
- ASP4345
- ASP4070
- ASP7266
- ASP0892
- ASP1807/CC8464

Phase 2

- enzalutamide (Breast cancer, HCC)
- AGS-16C3F (Renal cell carcinoma)
- blinatumomab (AMG 103) (Acute lymphoblastic leukemia, JP)
- YM311/FG-2216 (Renal anemia, EU)
- ASP8232 (Diabetic nephropathy)
- bleselumab (ASKP1240) (rFSGS)
- peficitinib (ASP015K) (Rheumatoid arthritis, US/EU)
- ASP7962 (Osteoarthritis)
- ASP8062 (Fibromyalgia)
- ASP0819 (Fibromyalgia)
- ASP1707 (Endometriosis, rheumatoid arthritis)
- ASP7373 (H5N1 influenza, JP)
- CK-2127107 (SMA, COPD)
- RPE cell program (Dry AMD etc.)

Phase 3

- enzalutamide (M0 CRPC, M0 BCR: US/EU/Asia, M1 HSPC, TNBC: US/EU/JP/Asia)
- degarelix (3-month, JP)
- gilteritinib (ASP2215) (AML, US/EU/JP/Asia)
- ASP8273 (NSCLC, US/EU/JP/Asia)
- solifenacin (Pediatric NDO, US/EU)
- solifenacin/mirabegron (Concomitant use, US/EU/Asia)
- mirabegron (Pediatric NDO, EU)
- roxadustat (ASP1517/FG-4592) (Anemia associated with CKD, EU/JP)
- ASP0113/VCL-CB01 (CMV-HCT, US/EU/JP)
- peficitinib (ASP015K) (Rheumatoid arthritis, JP/Asia)
- romosozumab (AMG 785) (Osteoporosis, JP)
- fidaxomicin (Infectious enteritis: JP, pediatric: EU)
- ipragliflozin/sitagliptin (Fixed dose combination, JP)
- ipragliflozin (Type 1 diabetes, JP)
- linaclotide (Chronic constipation, JP)

Filed

- enzalutamide (Tablet, EU/JP)
- quetiapine (BP-D, JP)
- ASP7374 (Seasonal influenza, JP)
- linaclotide (ASP0456) (IBS-C, JP)

THERAPEUTIC AREA:

- Oncology
- Urology, Nephrology
- Immunology, Neuroscience
- Others

● New molecular/biological entity

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

NSCLC: Non-small cell lung cancer, HCC: Hepatocellular carcinoma, CMV: Cytomegalovirus, SOT: Solid organ transplant, rFSGS: Recurrence of focal segmental glomerulosclerosis, PDPN: Painful diabetic peripheral neuropathy, 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, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, HCT: Hematopoietic cell transplant, BP-D: Bipolar disorder depressive episodes, IBS-C: Irritable bowel syndrome with constipation

STEADY PROGRESS IN DEVELOPMENT
SUMMARY OF CHANGES FROM AUGUST TO OCTOBER

P1 Entry	P2 Entry	P3 Entry	Filing	Approval
ASP1807/ CC8464 Neuropathic pain **ASP8302** Underactive bladder	**ASP8062** Fibromyalgia **ASP0819** Fibromyalgia		**enzalutamide** **Filed in Sept. 2016 (New formulation)** Tablet (Japan) **quetiapine** **Filed in Aug. 2016** Improvement of depressive symptoms associated with bipolar disorder (Extended-release tablet) (Japan)	**bixalomer Kiklin Granules** **Approved in Sept. 2016 (New formulation)** Treatment of hyperphosphatemia in patients with chronic kidney disease (Japan)

Indication change

Tarceva (US): Metastatic NSCLC (Tarceva is no longer indicated for maintenance therapy or second or greater line treatment* in patients whose tumors do not harbor an EGFR mutations** based on the IUNO trial.)

Discontinuation in a part of indications

P2 projects:

ASP0113/VCL-CB01: Cytomegalovirus infection or reactivation in solid organ transplant recipients (The phase 2 study did not meet its primary endpoint.)

ASP8232: Diabetic macular edema (The phase 2 study did not meet its primary endpoint.)

ASP3662: Painful diabetic peripheral neuropathy (The phase 2 study was terminated due to futility analysis for efficacy.)

* After progression following at least one prior chemotherapy regimen.

** Exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

EGFR: Epidermal growth factor receptor, NSCLC: Non-small cell lung cancer

ONCOLOGY PIPELINE

Stage in the most advanced territory

	Project	Target Cancer	Characteristics	P1	P2	P3	Filed
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, Non-small cell lung cancer	FLT3/AXL inhibitor	AML			
				NSCLC			
	ASP8273	Non-small cell lung cancer	Mutant-selective irreversible EGFR inhibitor				
	ASP5878	Solid tumors	FGFR inhibitor				
	ASP4132	Advanced cancer					
Antibody	**AGS-16C3F**	Renal cell carcinoma	Antibody utilizing ADC (target: ENPP3)				
	blinatumomab	Acute lymphoblastic leukemia	Anti-CD19 BiTE				
	enfortumab vedotin (ASG-22ME)	Solid tumors, 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 [EMBARK 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	**First Patient In: Expected in 2016**		
	P2 US/EU	**ER/PgR positive** Advanced breast cancer that is ER positive or PgR 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	**First Patient In: Jan. 2016**		

FDA approved an sNDA to update the US labeling to include data from the TERRAIN study.

*The region where the study is performed
ADT: Androgen-deprivation therapy, ER: Estrogen receptor, PgR: Progesterone receptor, HER2: Human epidermal growth factor receptor 2
FDA: Food and Drug Administration, sNDA: Supplemental New Drug Application

GILTERITINIB: DEVELOPMENT PROGRESS

Updated underlined items from previous disclosure

	Phase/Region*	Population	Design	P1	P2	P3
AML	**P3 Global [ADMIRAL study]**	**Relapsed or refractory** 1st 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	**Enrollment completed**		
	P1 JP	**Relapsed or refractory**	Dose-escalation and expansion	**Enrollment completed**		
	P2/3 Global [LACEWING study]	**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: Expected in FY2016**		
	P3 Global [MORPHO study]	**HSCT maintenance** FLT3-ITD positive	-	**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	**1st line intensive chemo eligible** Newly diagnosed	Combination with induction and consolidation chemo			
	P1 JP	**1st line intensive chemo eligible** Newly diagnosed	Combination with induction and consolidation chemo			
NSCLC	**P1/2 US/JP**	EGFR activating mutation-positive, resistant to an EGFR inhibitor	Dose-escalation and expansion, combination with erlotinib, n=90	**First Patient In: Sept. 2015**		

*The region where the study is performed

FLT3: FMS-like tyrosine kinase 3, ITD: Internal tandem duplication, EGFR: Epidermal growth factor receptor

ASP8062 AND ASP0819: DEVELOPMENT PROGRESS -P2 STUDIES TO START IN 1H/2017-

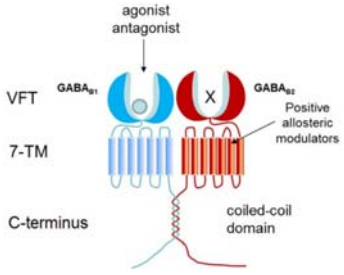
Fibromyalgia

Fibromyalgia
- Chronic pain disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep disturbance, and memory and mood issues
- Significantly decreased quality of life in affected patients, including the ability to work and perform everyday activities
- Pathophysiology is not well understood. Dysregulation of excitatory and inhibitory signals is thought to cause central amplification of pain, resulting in allodynia and hyperalgesia

Prevalence
- Common disorder with prevalence of approx. 2-3%, increasing with age*
- The vast majority of patients are female
- Onset usually occurs between the ages of 20 and 55

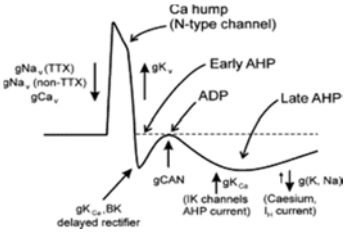
New Molecular Entities

ASP8062
- $GABA_B$ receptor positive allosteric modulator (PAM)
- Expected to achieve analgesia by ameliorating imbalance of inhibitory and excitatory neurotransmission



$GABA_B$ receptor**

ASP0819
- Calcium^{2+}-activated K^+ channel (K_{Ca} 3.1 / IK1) opener
- Potential first-in-class approach, modulating abnormal nerve firing



Action potential and afterpotentials in neurons***

* Queiroz LP, Curr Pain Headache Rep. 2013;17(8):356.
** Xu C, et al., Front Pharmacol. 2014; 11(5):12.
*** Furness JB et al., Prog Neurobiol. 2004; 72(2):143.

FY2016 EXPECTED KEY PIPELINE EVENTS

*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/PgR+ 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)

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** 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 INNOVATION

NEW INITIATIVE

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Acquisition Would Expand Astellas' Oncology Pipeline with Antibody in Late-Stage

Transaction Summary

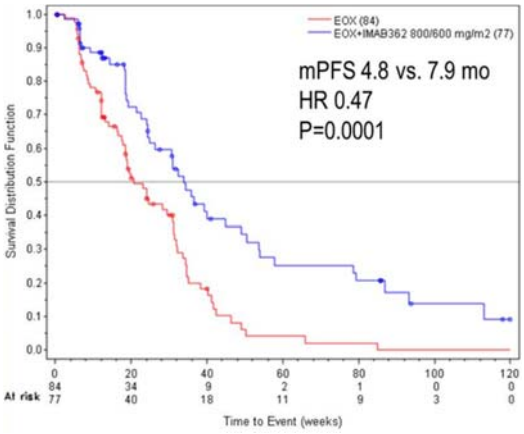
- Acquisition: 100% Equity in Ganymed
- Up-front payment: EUR 422 million
- Earnouts: Up to EUR 860 million in further contingent payments based on progress in the development of IMAB362
- Payment: Cash on hand
- Closing: Expected in the next several weeks
  *Subject to customary regulatory approvals

Overview of Ganymed Pharmaceuticals

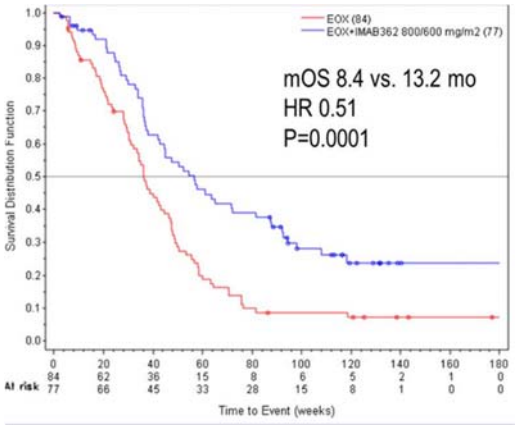
- Privately-held biopharmaceutical company which focuses on the development of antibodies against cancer
- Based in Mainz, Germany
- Founded in 2001
- Number of employees: 85
- Most advanced program: IMAB362
  - ✓ A new investigational antibody drug that is specific for the tight junction protein Claudin18.2
  - ✓ Its mechanism of action includes activation of antibody-dependent cell-mediated cytotoxicity (ADCC), complement-dependent cytotoxicity (CDC) and -in combination with chemotherapy- T-cell infiltration and modulation of the tumor microenvironment
  - ✓ Disease and development stage:
    - Gastroesophageal cancer (GEC) (Phase 2b data available)
    - Pancreatic cancer (preclinical)
  - ✓ Received orphan drug designation in the US and Europe for gastric and pancreatic cancer

In Phase 2b study (FAST) in gastroesophageal cancer patients positive for Claudin18.2, PFS (primary endpoint) and OS were extended in IMAB362 arm.

PFS (primary endpoint)



OS



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

EOX: Epirubicin, Oxaliplatin, Capecitabine

Salah-Eddin Al-Batran and et al. 2016 ASCO Annual Meeting

CREATE SOCIAL VALUE

CREATE SOCIAL VALUE: NEW INITIATIVE

A global agreement with the World Anti-Doping Agency (“WADA”) to partner on the prevention of misuse and abuse of medicines for doping in sports

As the first Japan-based company to partner with WADA, Astellas will cooperate with WADA to;

- identify compounds developed by Astellas with the potential for sport-related doping abuse,
- share relevant information to aid WADA to develop detection methods for these compounds, and
- minimize the risk of misuse of compounds with doping potential during clinical trials to avoid opportunities for abuse.

WORLD ANTI-DOPING AGENCY

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AGENDA

I Q2/FY2016 Financial Results

II Initiatives to Build Resilience for Sustainable Growth

III Profit Distribution Policy

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PROFIT DISTRIBUTION POLICY

- 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

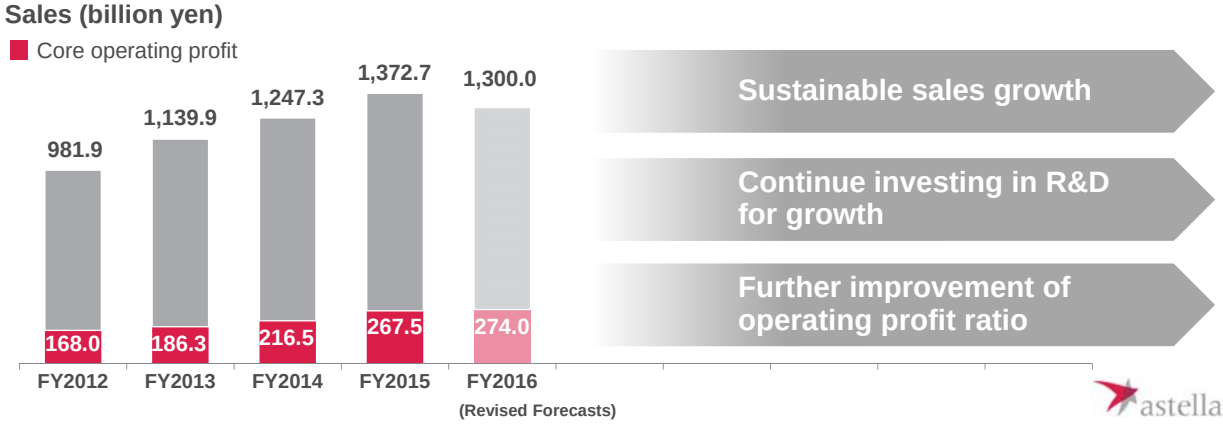
	FY2014	FY2015	FY2016 (Forecast)
Core EPS	69.37 yen	92.12 yen	95.07 yen
Dividends per Share	30 yen	32 yen	34 yen (planned)
ROE	10.5%	15.0%	-
DOE	5.1%	5.4%	-
Share Buybacks*	38 million shares (58.2 billion yen)	68 million shares (119.3 billion yen)	Implemented in a flexible manner
Cancellation of Treasury Shares	25 million shares	38 million shares	68 million shares (in June)

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

REALIZE SUSTAINABLE GROWTH

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 and enhancement of organizational structure



R&D Meeting

Date & Time:
Thursday, December 8, 2016
1 pm – 3:30 pm

Venue: Hall on 4th floor, Astellas HQs, Tokyo

APPENDIX

RECONCILIATION OF FULL BASIS TO CORE BASIS

(billion yen)

	FY15 APR. - SEP.			FY16 APR. - SEP.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Sales	**687.5**	**-**	**687.5**	**651.7**	**-**	**651.7**
Cost of sales	168.4	-	168.4	146.2	-	146.2
Gross profit	**519.1**	**-**	**519.1**	**505.5**	**-**	**505.5**
SG&A expenses	239.7	-	239.7	220.8	-	220.8
R&D expenses	112.0	-	112.0	99.7	-	99.7
Amortisation of intangible assets	21.9	-	21.9	17.7	-	17.7
Share of losses of associates and joint ventures	-0.3	-	-0.3	-0.8	-	-0.8
Other income *1	0.9	-0.9	-	0.4	-0.4	-
Other expense *1	13.4	-13.4	-	9.8	-9.8	-
Operating profit	**132.6**	**12.5**	**145.2**	**157.1**	**9.4**	**166.5**
Finance income *2	13.3	-12.1	1.3	2.4	-1.6	0.8
Finance expense *2	0.6	-0.3	0.3	1.7	-0.4	1.3
Profit before tax	**145.4**	**0.7**	**146.2**	**157.8**	**8.2**	**166.0**
Income tax expense	42.5	-0.3	42.2	42.7	2.7	45.4
Profit for the period	**102.9**	**1.0**	**103.9**	**115.1**	**5.5**	**120.6**

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

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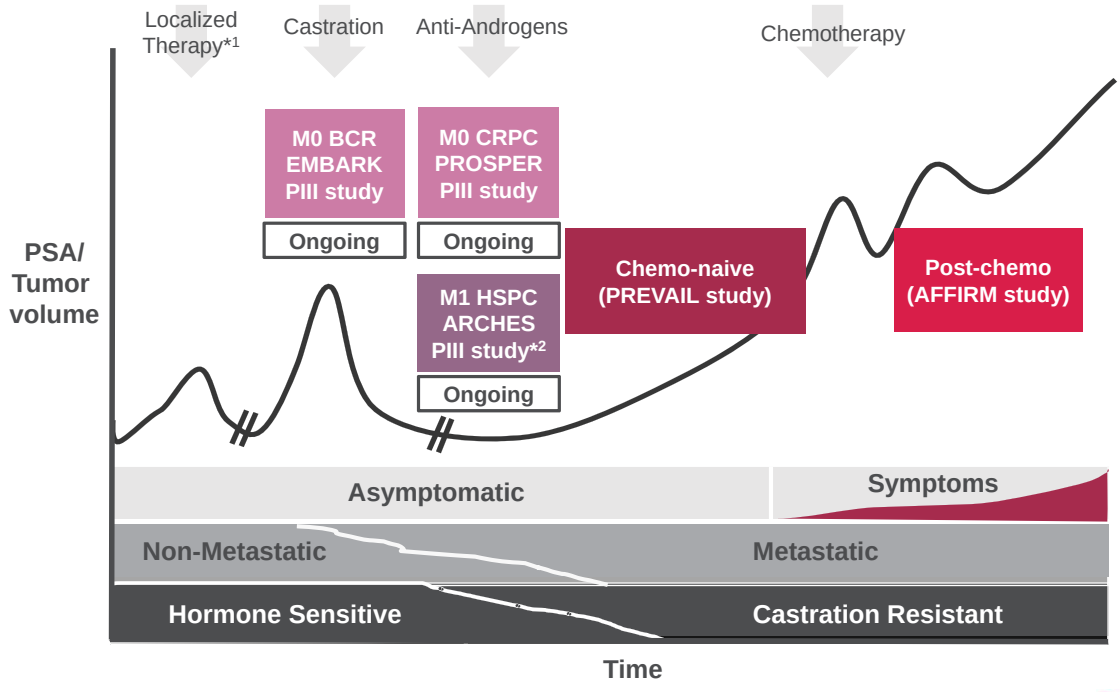
MAXIMIZE THE VALUE OF ENZALUTAMIDE FOR PROSTATE CANCER PATIENTS



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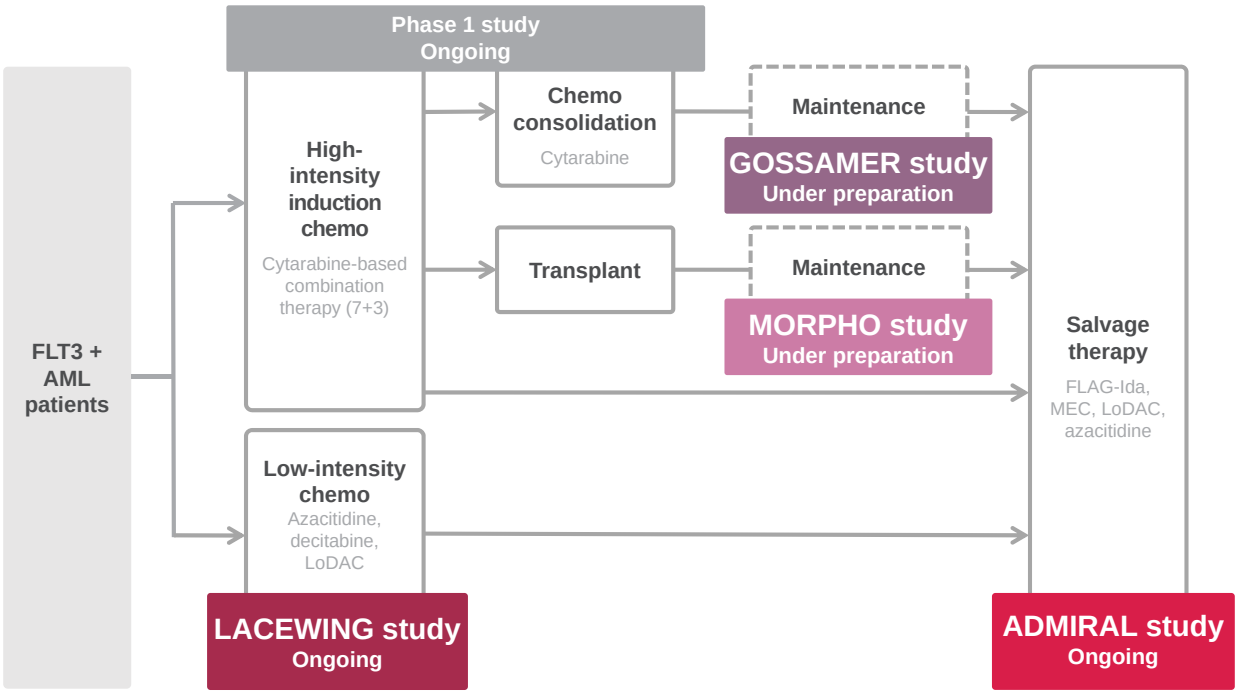
P. Mulders *et al. EAU2012,* modified by Astellas

*1 Radiotherapy, prostatectomy
*2 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