Q1/FY2016 FINANCIAL RESULTS
ENDED JUNE 30, 2016

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Senior Corporate Executive, Chief Financial Officer
Astellas Pharma Inc.
July 29, 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 Q1/FY2016 Financial Results

II Initiatives to Build Resilience for Sustainable Growth

III Profit Distribution Policy

Q1/FY2016 FINANCIAL RESULTS (CORE BASIS)

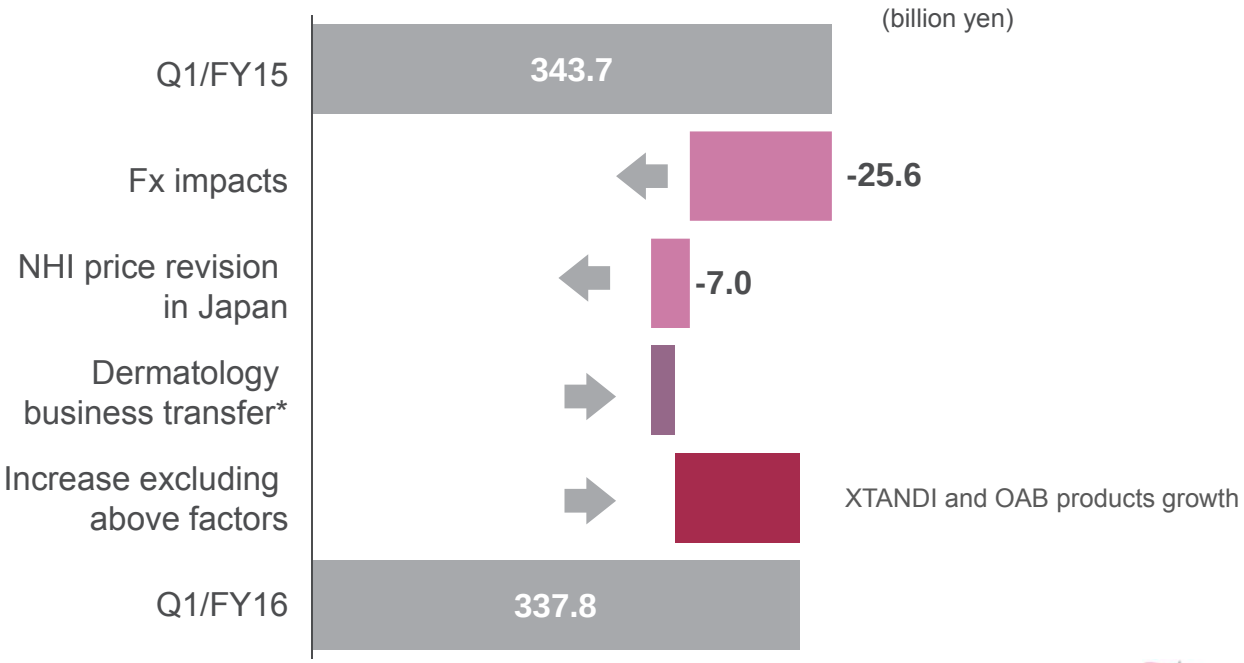
(billion yen)	Q1/FY15	Q1/FY16	Change	FY16 FCST*	Achieve-ment	(ref) CER** growth
Net sales	**343.7**	**337.8**	**-1.7%**	**1,350.0**	**25.0%**	+6%
Cost of sales	90.1	71.5	-20.7%			
% of sales	26.2%	21.2%	-5.1 ppt			
SG&A expenses	118.7	111.9	-5.7%			
% of sales	34.5%	33.1%	-1.4 ppt			
R&D expenses	56.0	51.0	-8.9%	231.0	22.1%	
% of sales	16.3%	15.1%	-1.2 ppt	17.1%		
Amortisation of intangibles	10.9	9.0	-17.5%			
Share of associates/JVs losses	-0.2	-0.4	-			
Core operating profit	**67.8**	**94.0**	**+38.5%**	**270.0**	**34.8%**	+38%
Core profit for the period	**45.0**	**67.1**	**+49.1%**	**199.0**	**33.8%**	

[Exchange rate (yen)]***	Q1/FY15	Q1/FY16	Change	FY16FCST
USD: Average for the period	121	108	-13	110
EUR: Average for the period	134	122	-12	125
USD: Change from PY end	+2	-10		
EUR: Change from PY end	+7	-13		

Fx impacts		
	Net sales:	-25.6
	Core OP:	+0.4

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

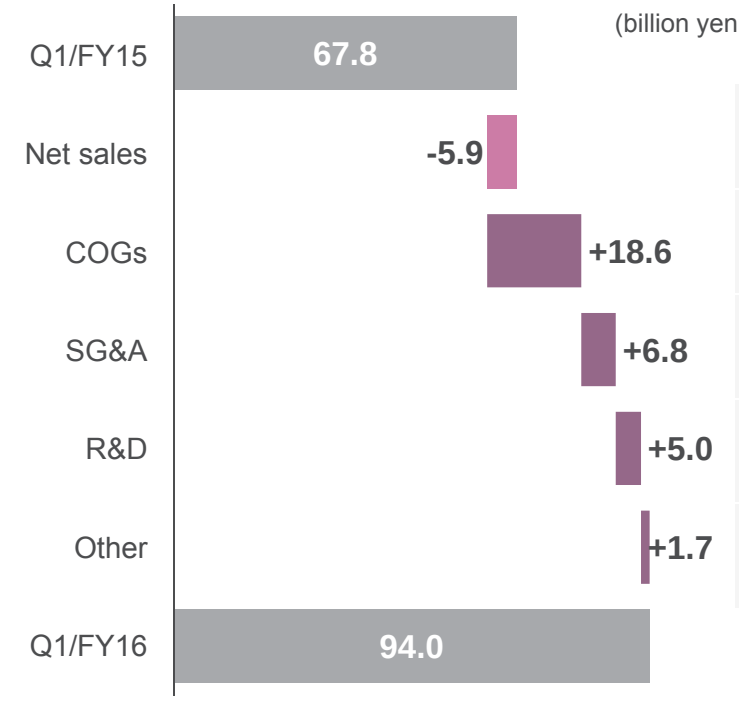
SALES ANALYSIS



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

CORE OP ANALYSIS

(Positive/negative signs show impacts on OP)



XTANDI and OAB products growth Negative impacts by Fx, NHI price revision in Japan (CER growth +6%)
COGs ratio decrease: -5.1ppt Product mix change, etc: -2.2ppt Fx impacts on unrealized profit elim.: -2.9ppt
SG&A decrease due to Fx (Increase on a CER basis)
R&D decrease mainly due to Fx (Development Projects steadily progress)
Amorisation decrease: -1.9 Share of associates/JVs losses: -0.2

FINANCIAL RESULTS (FULL BASIS)

(billion yen)	Q1/FY15	Q1/FY16	Change	FY16FCST*	Achievement
Net sales	**343.7**	**337.8**	**-1.7%**	**1,350.0**	**25.0%**
Core operating profit	**67.8**	**94.0**	**+38.5%**	**270.0**	**34.8%**
Other income	1.3	0.2			
Other expenses	7.2	1.3			
Operating profit	**61.9**	**92.9**	**+50.0%**	**267.0**	**34.8%**
Financial income	6.0	1.2			
Financial loss	0.3	0.9			
Profit before tax	67.7	93.2	+37.7%	268.0	34.8%
Profit for the period	**44.6**	**66.6**	**+49.3%**	**197.0**	**33.8%**

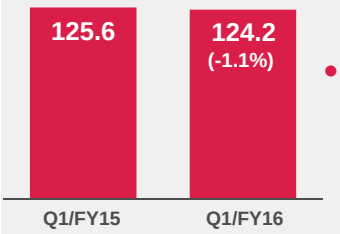
Q1/FY15 (PY) Other expenses: Impairment loss of tangible assets recorded
Q1/FY15 (PY) Financial income: Gain on sale of financial assets recorded

*Announced in May 2016

SALES BY REGION (LOCAL CURRENCY BASIS)

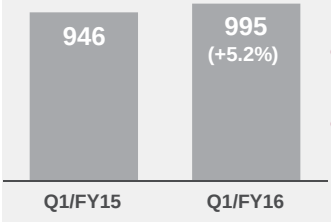
Steady growth in Americas, EMEA and Asia/Oceania on a local currency basis

Japan (billion yen)



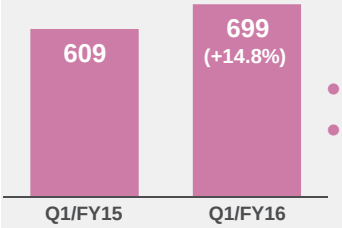
- Sales in Japanese market: 114.8 (-6%) Decrease due to NHI price revision, etc

Americas (million USD)



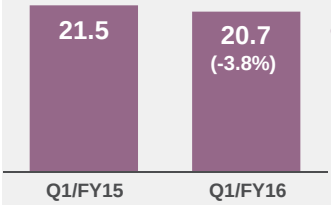
- XTANDI and OAB products growth
- Lexiscan and CRESEMBA contribution

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



- XTANDI growth
- Prograf increase

Asia/Oceania (billion yen)



- +15% 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

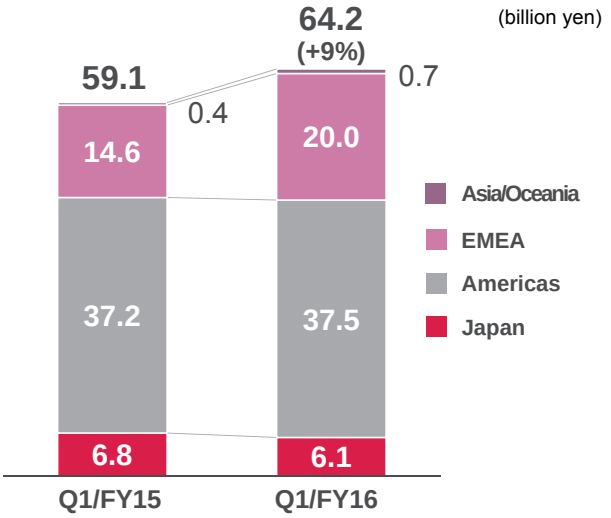
(billion yen)	Q1/FY15	Q1/FY16	Change	(ref) CER growth
Oncology	**77.6**	**79.1**	**+2%**	+13%
XTANDI	59.1	64.2	+9%	+20%
OAB in Urology	**53.5**	**54.0**	**+1%**	+10%
Vesicare	35.4	30.4	-14%	-6%
Betanis/Myrbetriq/BETMIGA	18.1	23.6	+30%	+41%
Transplantation	**50.4**	**49.4**	**-2%**	+7%

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

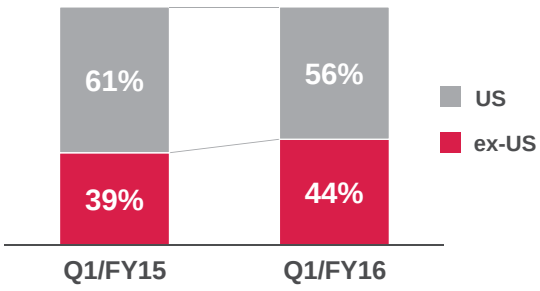
XTANDI

Pursue further penetration in chemo-naive mCRPC

Sales by region



Sales composition by region



Year-on-Year sales growth

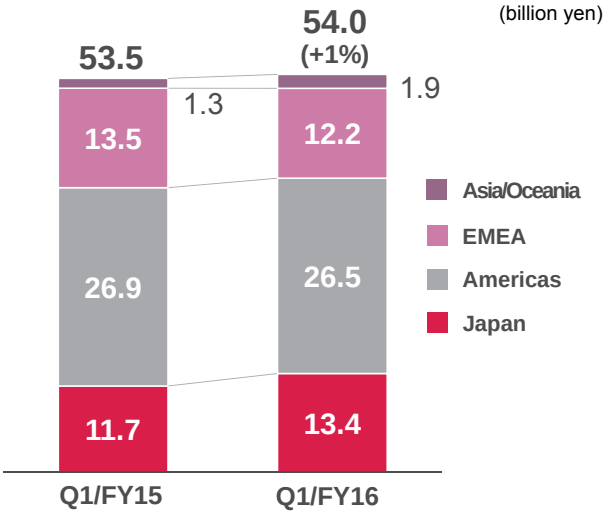
Japan: -11%
Americas: +13% (USD basis)
EMEA: +51% (EUR basis)
Asia/Oceania: +90% (CER basis)

mCRPC: metastatic castration-resistant prostate cancer

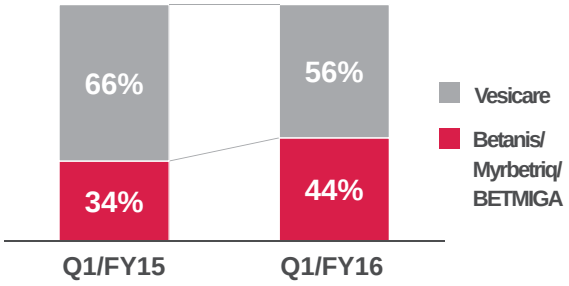
OAB FRANCHISE IN UROLOGY

Betanis/Myrbetriq/BETMIGA penetration enhances OAB Franchise

Sales by region



Sales composition ratio by product



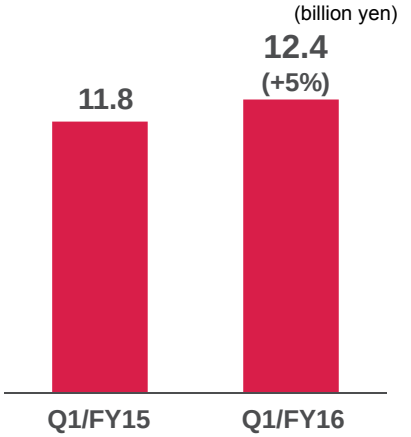
Year on Year sales growth

Japan: +14%
EMEA: -1% (EUR basis)
Americas: +11% (USD basis)
Asia/Oceania: +66% (CER basis)

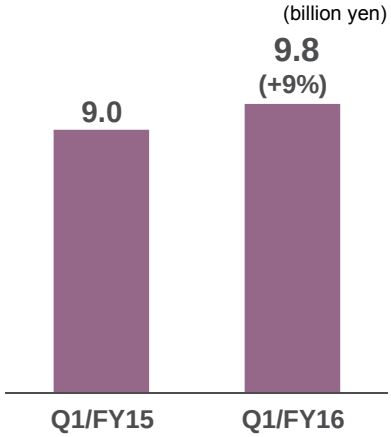
SALES IN JAPANESE MARKET

Sales in Japanese market decrease by 6% due to NHI price revision, etc
Key products sales are on track

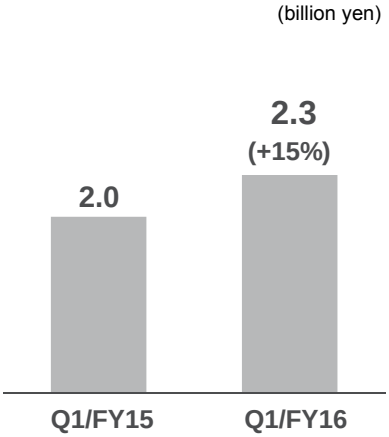
Celecox



Symbicort



Suglat



FY2016 FULL YEAR FORECAST

Keep initial forecasts* unchanged taking into account both various variable factors

Business is on track toward initial forecasts.

<Major variable factors to initial forecasts>

Positive	Amortisation of deferred revenue from divesture of global dermatology business to exceed the initial forecast
Negative	Negative impacts of foreign exchange rates assuming current yen's appreciation to continue throughout the year

*Announced in May 2016

AGENDA

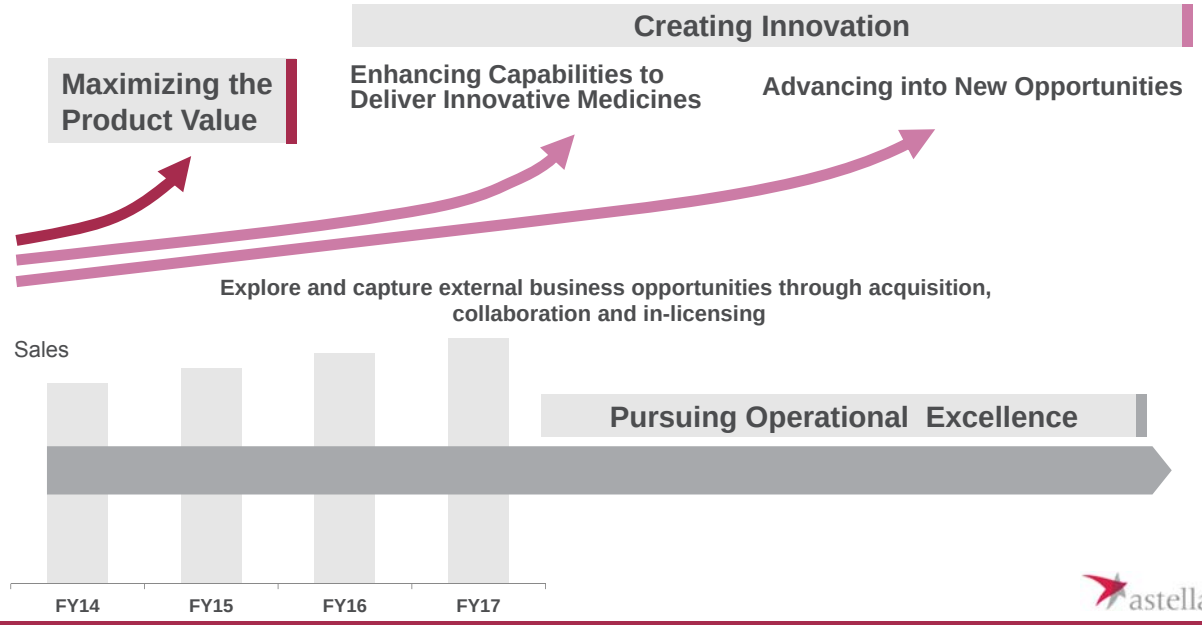
I Q1/FY2016 Financial Results

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



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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]

- P3 Entry:
  - Enzalutamide (TNBC, Global)
  - Ipragliflozin (Type 1 diabetes, JP)
  - Linaclotide (Chronic constipation, JP)

[New initiative]

- Expansion of collaboration with Cytokinetics, Inc.

Muscle Diseases

- Research collaboration for biomarker database on healthy adults with Takeda and Daiichi-Sankyo
- Launch of DigiTx Partners, a digital health investment company, in partnership with MPM Capital
- Collaboration for rice-based oral vaccine with the Institute of Medical Science, the University of Tokyo

Pursue Operational Excellence

[Continually enhance organization structure]

- Establishment of affiliate in Colombia

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TNBC: Triple-negative breast cancer

MAXIMIZE THE PRODUCT VALUE

CONTINUOUS INTRODUCTION OF NEW PRODUCTS

EMEA

[Status of XTANDI and BETMIGA]

XTANDI
- Post-chemo indication: Launched in 37 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 13 countries
- Chemo-naive indication: Launched in 11 countries

Myrbetriq:
- Launched in 6 countries

[FY2016 Progress]

XTANDI
- Post-chemo indication: Launched in Colombia and Bolivia
- Chemo-naive indication: Launched in Colombia, Chile, and Paraguay

Myrbetriq:
- Launched in Brazil

Asia/Oceania

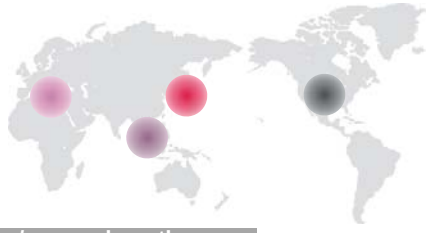
[Status of XTANDI and BETMIGA]

XTANDI
- Post-chemo indication: Launched in 7 countries/areas
- Chemo-naive indication: Launched in 4 countries/areas

BETMIGA:
- Launched in 8 countries/areas

[FY2016 Progress]

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



No. of countries/areas where the following have been launched:
XTANDI: Approx. 60
Betanis / Myrbetriq / BETMIGA: Approx. 50

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CREATE INNOVATION
PROGRESS OF PIPELINE

ROBUST PIPELINE OF ASTELLAS

Phase 1

- Enfortumab vedotin (ASG-22ME)
- ASG-15ME
- ASP5878
- AGS67E
- ASP4132
- Gilteritinib (NSCLC)
- AGS62P1
- ASP2205
- ASP6282
- YM311 (JP)
- ASP7398
- ASP6294
- Bleselumab (ASKP1240) (JP)
- ASP5094
- ASP3662 (Alzheimer's)
- ASP4345
- ASP4070
- ASP0819
- ASP8062
- ASP7266
- ASP0892

Phase 2

- Enzalutamide (Breast cancer, HCC)
- AGS-16C3F (Renal cell carcinoma)
- Blinatumomab (AMG 103) (Acute lymphoblastic leukemia)
- YM311 (FG-2216) (Renal anemia, EU)
- ASP8232 (Diabetic nephropathy)
- ASP0113 (VCL-CB01) (CMV SOT)
- Bleselumab (ASKP1240) (rFSGS, US)
- Peficitinib (ASP015K) (Rheumatoid arthritis, US/EU)
- ASP3662 (PDPN)
- ASP7962 (Osteoarthritis)
- ASP1707 (Endometriosis, rheumatoid arthritis)
- ASP8232 (Diabetic macular edema)
- ASP7373 (Influenza H5N1, 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)
- Quetiapine (BP-D, JP)
- 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)
- Bixalomer (Granule formulation, 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.

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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 MAY TO JULY

*Regions show where studies are performed

P1 Entry

ASP0892
Peanut allergy

AGS62P1
Acute myeloid leukemia

P2 Entry

Bleselumab (ASKP1240)
Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients*

ASP1707
Rheumatoid arthritis

Blinatumomab
Acute lymphoblastic leukemia

P3 Entry

Enzalutamide
Triple-negative breast cancer
(US/Europe/ Japan/Asia)

Ipragliflozin
Type 1 diabetes mellitus (Japan)

Linaclotide
Chronic constipation (Japan)

Filing

Enzalutamide
Withdrew sNDA for tablet
(US)

Regulatory Decision

Solifenacin
Pediatric OAB
Received a notification for end of procedure for the type 2 variation. The indication was not approved but pediatric information was included in the label to enable patent extension of 6 months.
(EU)

*Previous target was prevention of organ transplant rejection. We have decided to focus on this target for future development.

ONCOLOGY PIPELINE

	Project	Target Cancer	Characteristics	Stage in the most advanced territory: 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
Small molecule	Degarelix	Prostate cancer	GnRH antagonist	3-month: JP
Small molecule	Gilteritinib	Acute myeloid leukemia, Non-small cell lung cancer	FLT3/AXL inhibitor	AML / NSCLC
Small molecule	ASP8273	Non-small cell lung cancer	Mutant-selective irreversible EGFR inhibitor	
Small molecule	ASP5878	Solid tumors	FGFR inhibitor	
Small molecule	ASP4132	Advanced cancer		
Antibody	AGS-16C3F	Renal cell carcinoma	Antibody utilizing ADC (target: ENPP3)	
Antibody	Blinatumomab	Acute lymphoblastic leukemia	Anti-CD19 BiTE	
Antibody	Enfortumab vedotin (ASG-22ME)	Solid tumors, Urothelial cancer	Antibody utilizing ADC (target: Nectin-4)	Presented at ASCO
Antibody	ASG-15ME	Urothelial cancer	Antibody utilizing ADC (target: SLITRK6)	Presented at ASCO
Antibody	AGS67E	Lymphoid malignancy	Antibody utilizing ADC (target: CD37)	
Antibody	AGS62P1	Acute myeloid leukemia	Antibody utilizing ADC (target: FLT3)	

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

ENZALUTAMIDE: DEVELOPMENT PROGRESS

*The region where the study is performed, updated underlined items from the 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: Mar. 2015		
	P2 US/EU	**HER2 positive** Advanced, androgen receptor-positive, HER2 positive breast cancer	Open-label, n=80	First Patient In: Sept. 2014		
HCC	P2 US/EU/Asia	**Hepatocellular carcinoma**	Placebo-controlled, n=144	First Patient In: Jan. 2016		

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

ENZALUTAMIDE: TRIPLE-NEGATIVE BREAST CANCER

Triple-Negative Breast Cancer*

Three subsets in breast cancer

- Approx. 75% are positive for the ER/PgR receptors and are treated with hormones (initially)
- Approx. 15% have amplification of the growth factor receptor HER2 and are treated with anti-HER2 (throughout)
- Approx. 20% are TNBC and are treated with cytotoxic agents

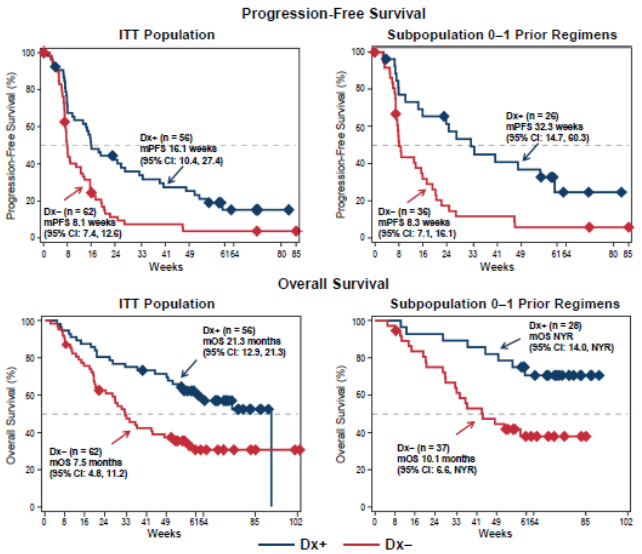
AR expression

- >75% of ER+ express AR
- 50-65% of HER2+ express AR
- 10-30% of TNBC express AR

Diagnostic-positive patients

- In the Phase 2 study, approx. half of TNBC tissues evaluated from enrolled patients (AR IHC>0%) tested diagnostic positive

Phase 2 Data analyzed by Gene Expression Profile Presented at SABCS2015**



These data are supportive of further clinical trials of enzalutamide in patients with TNBC who test positive for the gene expression profile reflecting androgen-driven biology. *Note: This is a retrospective analysis and there is no control group for assessment of treatment effect*

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* L. Collins *et al*., Mod Pathol 2011; 24 (7): 924-31, B. Lehman *et al*., J Pathol 2014: 232 (2): 142-50, A. Goldhirsche St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2011

** K. Miller *et al*, San Antonio Breast Cancer Symposium, Dec. 2015

GILTERITINB: DEVELOPMENT PROGRESS

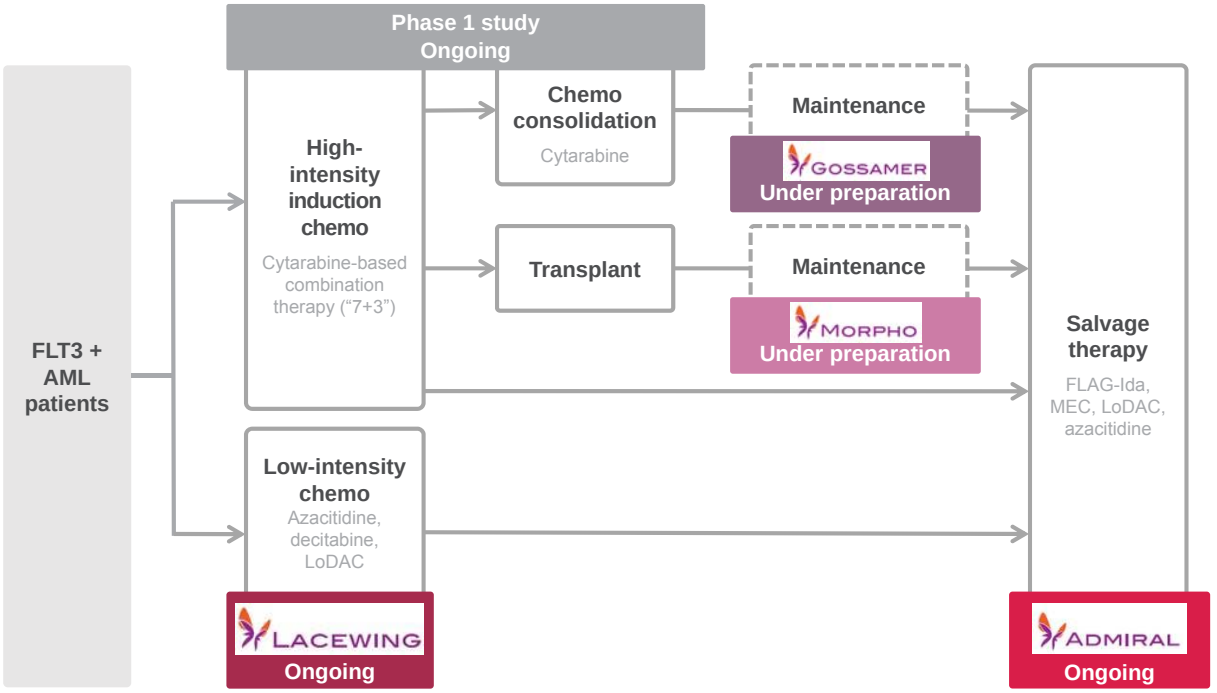
*The region where the study is performed, updated underlined items from previous disclosure

	Phase/Region*	Population	Design	P1	P2	P3
AML	P3 Global ADMIRAL	**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	**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	**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 H1/FY2016**		
	P3 Global MORPHO	**HSCT maintenance** FLT3-ITD positive	-	**Under preparation** Collaborating with Blood and Marrow Transplant – Clinical Trial Network (BMT-CTN)		
	P3 Global GOSSAMER	**Post-chemo maintenance** FLT3-ITD positive	-	**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**		

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

GILTERITINB: TREATMENT LANDSCAPE IN AML



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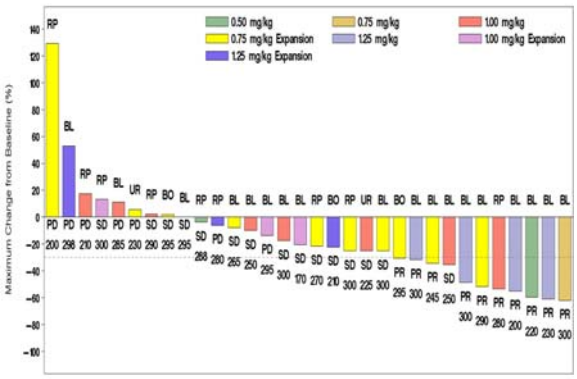
7+3: Cytarabine + idarubicin or daunorubicin, LoDAC: Low dose cytarabine, FLAG-Ida: Fludarabine + cytarabine + G-CSF + idarubicin, MEC: Mitoxantrone + etoposide + cytarabine

AGENSYS PROGRAMS: DATA PRESENTED AT ASCO2016

J. E. Rosenberg *et al.*, ASCO2016

Enfortumab Vedotin (ASG-22ME): Phase 1 in Metastatic Urothelial Cancer

Change from Baseline in Tumor Burden by Best Overall Response

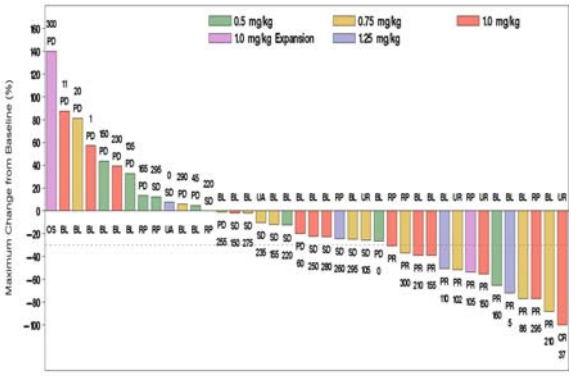


- Enfortumab vedotin is well tolerated in metastatic urothelial patients.
- Enfortumab vedotin shows anti-tumor activity with 10 PRs (ORR = 27.8%). It shows anti-tumor activity in subjects with liver metastases (4/10=40%) and those previously treated with checkpoint inhibitors (3/12=25%).

D.P. Petrylak *et al.*, ASCO2016

ASG-15ME: Phase 1 in Metastatic Urothelial Cancer

Waterfall Plot of Maximum Change from Baseline in Total Tumor Burden by Best Overall Response to Date



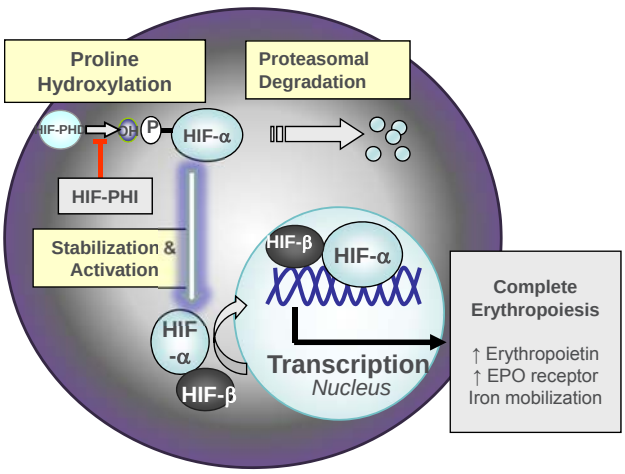
- ASG-15ME is well tolerated in metastatic urothelial patients.
- ASG-15ME shows anti-tumor activity with 1 CR and 13 PRs (ORR=33%). ASG-15ME shows anti-tumor activity in subjects with liver metastases (4/13=31%) and those previously treated with checkpoint inhibitors (5/14=36%).

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Best overall response was determined according to RECIST 1.1: CR= complete response, PR = partial response, SD = stable disease, PD = progressive disease The H score is shown above or below the best overall response. Note: The endpoint of maximum change from baseline in tumor burden is based only on radiography evaluation of measurable disease Tumor Type: BL = Bladder, RP = Renal Pelvis, UR = Ureter, UA = Urethra, OS = Other Site, BO = Bladder, other histology

ROXADUSTAT: DEVELOPMENT PROGRESS

Mechanism of Action*



Progress of Japanese Program

- Initiated 3 Japanese Phase 3 studies for treatment of anemia in patients with chronic kidney disease on dialysis.

Ongoing Phase 3 studies in Japan

Target Population	Design
Dialysis (HD), correction	Open-label, 2 arms
Dialysis (PD), correction/conversion	Open-label, 3 arms
Dialysis (HD), conversion	Open-label, single arm

Phase 3 studies in Japan under preparation

Target Population	Design
Dialysis (HD), conversion	Double-blind,darbepoetin-controlled, 2 arms
Non-dialysis, correction	Open-label, 2 arms
Non-dialysis, conversion	Open-label, darbepoetin-controlled, 3 arms

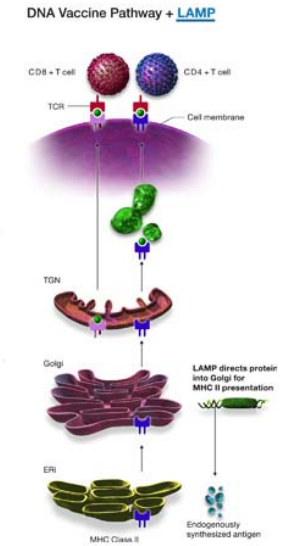
FIBROGEN

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*Ivan *et al. Science* 2001, 292:464-8, Jaakkola *et al. Science* 2001, 292:468-7
HD: Hemodialysis, PD: Peritoneal dialysis

ASP0892: DEVELOPMENT PROGRESS ~P1 ENTRY~

ASP0892: New DNA Vaccine



- DNA vaccine [LAMP-vax Technology]
- Aims to modulate the immune response, without systemic exposure to the allergen
- Consist of Ara h1, h2, and h3, the three major peanut allergens

Unmet Medical Need in Peanut Allergy

Condition

- Number one cause of fatal food-related anaphylaxis
- Trace exposure can induce life-threatening anaphylaxis

Prevalence

- Prevalence in the US is about 0.6% of the population.*1
- Some studies show peanut allergy affects more than 1% of children in countries including the US and UK.*2
- Accidental exposure rates with 15-40% of peanut allergic patients each year*3

Unmet medical need

- There is no currently approved treatment for preventing dangerous peanut-induced allergic reactions in the event of accidental ingestion.
- Currently patients manage their condition by strict allergen avoidance and carrying epinephrine auto-injectors for use in case of accidental exposure.
- In the case of children, this vigilance must also be maintained by parents, schools, and other guardians.

IMMUNOMIC Therapeutics, Inc.

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*1 J Allergy Clin. immunol 2010: 126(6) S1-S58
*2 J Allergy Clin Immunol. 2011 Mar;127(3):594-602.
*3 Sheikh 2013

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-months formulation (Japan)

Romosozumab
Osteoporosis (Japan)

Quetiapine
BP-D (Japan)

Fidaxomicin
CDI (Japan)

Regulatory Decisions

Enzalutamide
TERRAIN/STRIVE (US)
Tablet (EU)

Solifenacin
Pediatric OAB (EU)

Bixalomer
Granule formulation (Japan)

Linaclotide
IBS-C (Japan)

ASP7374
Seasonal influenza (Japan)

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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

NEW INITIATIVE (1/3)

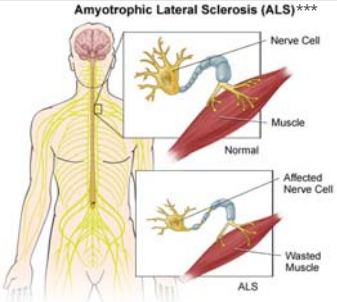
Expansion of collaboration with Cytokinetics, Inc.

- Expanded scope of collaboration in skeletal muscle activators including CK-2127107

  Neuromuscular indications
  - Spinal Muscular Atrophy (SMA): Phase 2
  - **Amyotrophic Lateral Sclerosis (ALS): Preparing Phase 2** ← **Added**

  Non-neuromuscular indications
  - Chronic obstructive pulmonary disease (COPD): Phase 2
- Obtained an option right to collaboratively develop and commercialize tirasemtiv*
- Extend joint research focused on the discovery of additional next-generation skeletal muscle activators through 2017

About ALS:**
- ALS is a progressive neurodegenerative disease that afflicts approximately 30,000 people in the US and a comparable number of patients in Europe. Approximately 6,000 new cases of ALS are diagnosed each year in the US.
- The average life expectancy of an ALS patient is approximately 3 to 5 years after diagnosis and only 10% of patients survive for more than 10 years.
- Few treatment options exist for these patients, resulting in a high unmet need for new therapies to address functional deficits and disease progression.



Cytokinetics

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*tirasemtiv: first-in-class skeletal muscle activator currently in Phase 3 for ALS by Cytokinetics

**Source: *ALSA Media Facts (http://www.alsa.org/news/media/quick-facts.html)*
ALSA Facts You Should Know (http://www.alsa.org/about-als/facts-you-should-know.html)

***R.A.A.I.D. (http://weishendopublications.com/)*

NEW INITIATIVE (2/3)

Research collaboration on establishing biomarker database on healthy adults with Takeda and Daiichi-Sankyo

Comprehensively acquire and analyze fundamental biomarker data on healthy adult volunteers in order to optimize and accelerate the development of innovative medicines

- Astellas will mainly utilize the analysis results in the therapeutic areas of focus
- Samples will be acquired at a clinical research organization associated with Leiden University

Launch of DigiTx Partners, a digital health investment company, in partnership with MPM Capital

Explore the business opportunities in the growing field of digital health and extend our knowledge in the area through investment activities

- DigiTx Partners will invest in the digital health space broadly, with a special focus on companies which create solutions that improve patient outcomes and provide substantial synergy with a broader pharma business
- Although the emphasis will be on earlier stage companies, investments will be made in both start-ups and growth stage companies

NEW INITIATIVE (3/3)

Collaborative development agreement for rice-based oral vaccine with the Institute of Medical Science, the University of Tokyo (IMSUT)

Develop vaccines against infectious diseases affecting developing countries and hope to address Access to Health issues

- MucoRice is a rice-based oral vaccine expressing cholera toxin B subunit (CTB) in the intrinsic storage protein of rice using genetic engineering
- Expected to meet the unmet medical needs of existing cholera vaccines such as the need for the cold chain and the ineffectiveness against enterotoxigenic *E coli*
- Under the contract:
  - IMSUT provides clinical trial materials and trial data, etc. which are necessary for the phase 1 and phase 2 trials of MucoRice for cholera and enterotoxigenic *E coli.*, and
  - Astellas is responsible for conducting and managing the clinical trials

AGENDA

I Q1/FY2016 Financial Results

II Initiatives to Build Resilience for Sustainable Growth

III Profit Distribution Policy

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

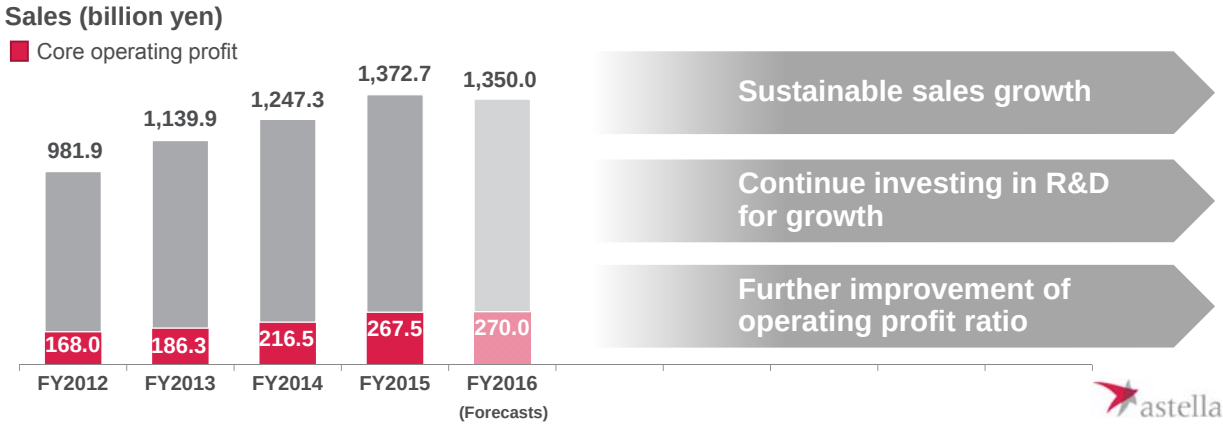
	FY2014	FY2015	FY2016 (Forecast)
Core EPS	69.37 yen	92.12 yen	93.65 yen
Dividends per Share	30 yen	32 yen	34 yen (planned)
ROE	10.5%	15.0%	-
DOE	5.1%	5.4%	-
Share Buybacks*	38 million shares (58.2 billion yen)	68 million shares (119.3 billion yen)	Implemented in a flexible manner
Cancellation of Treasury 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

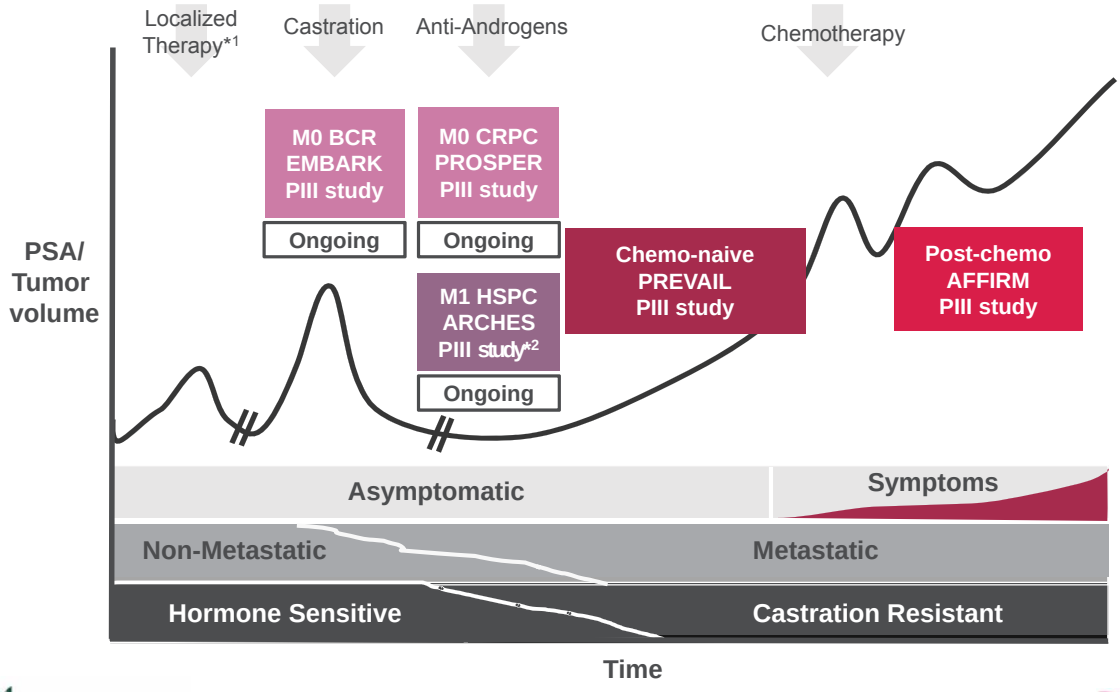
- Business goes favorably, driven by XTANDI and OAB products
- Continue investing in R&D for creating innovation that is source of future growth
- Work toward higher quality and efficiency of operations through optimization of resources and enhancement of organizational structure



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APPENDIX

MAXIMIZING THE VALUE OF ENZALUTAMIDE FOR PROSTATE CANCER PATIENTS



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

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

PSA: Prostate-specifc antigen

RECONCILIATION OF FULL BASIS TO CORE BASIS

(billion yen)

	FY15 APR. - JUN.			FY16 APR. - JUN.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Sales	**343.7**	**-**	**343.7**	**337.8**	**-**	**337.8**
Cost of sales	90.1	-	90.1	71.5	-	71.5
Gross profit	**253.6**	**-**	**253.6**	**266.3**	**-**	**266.3**
SG&A expenses	118.7	-	118.7	111.9	-	111.9
R&D expenses	56.0	-	56.0	51.0	-	51.0
Amortisation of intangible assets	10.9	-	10.9	9.0	-	9.0
Share of losses of associates and joint ventures	-0.2	-	-0.2	-0.4	-	-0.4
Other income *1	1.3	-1.3	-	0.2	-0.2	-
Other expense *1	7.2	-7.2	-	1.3	-1.3	-
Operating profit	**61.9**	**5.9**	**67.8**	**92.9**	**1.1**	**94.0**
Finance income *2	6.0	-5.5	0.6	1.2	-0.7	0.6
Finance expense *2	0.3	-0.2	0.1	0.9	-0.3	0.6
Profit before tax	**67.7**	**0.6**	**68.3**	**93.2**	**0.7**	**93.9**
Income tax expense	23.0	0.2	23.3	26.6	0.2	26.8
Profit for the period	**44.6**	**0.4**	**45.0**	**66.6**	**0.5**	**67.1**

*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.

ON THE FOREFRONT OF HEALTHCARE CHANGE

