Q1/FY2017 FINANCIAL RESULTS
ENDED JUNE 30, 2017



July 28, 2017
Chikashi Takeda
Chief Financial Officer
Astellas Pharma Inc.

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/FY2017 Financial Results

II Initiatives to Build Resilience for Sustainable Growth

III Profit Distribution Policy

Q1/FY2017 FINANCIAL RESULTS (CORE BASIS)

On-track toward FY2017 FCST

(billion yen)	FY16/Q1	FY17/Q1	Change	FY17 FCST*	Achieve-ment	Excl impacts from Fx and business transfer
Net sales	**337.8**	**322.6**	**-4.5%**	**1,279.0**	**25.2%**	-1%
Cost of sales	71.5	79.3	+10.9%			
% of sales	21.2%	24.6%	+3.4ppt			
SG&A expenses	111.9	112.3	+0.4%			
% of sales	33.1%	34.8%	+1.7ppt			
R&D expenses	51.0	56.5	+10.7%	218.0	25.9%	
% of sales	15.1%	17.5%	+2.4ppt	17.0%		
Amortisation of intangible	9.0	9.0	-0.1%			
Share of associates/JVs losses	- 0.4	-0.4	-			
Core operating profit	**94.0**	**65.1**	**-30.7%**	**254.0**	**25.6%**	-8%
Core profit for the period	**67.1**	**51.9**	**-22.7%**	**195.0**	**26.6%**	

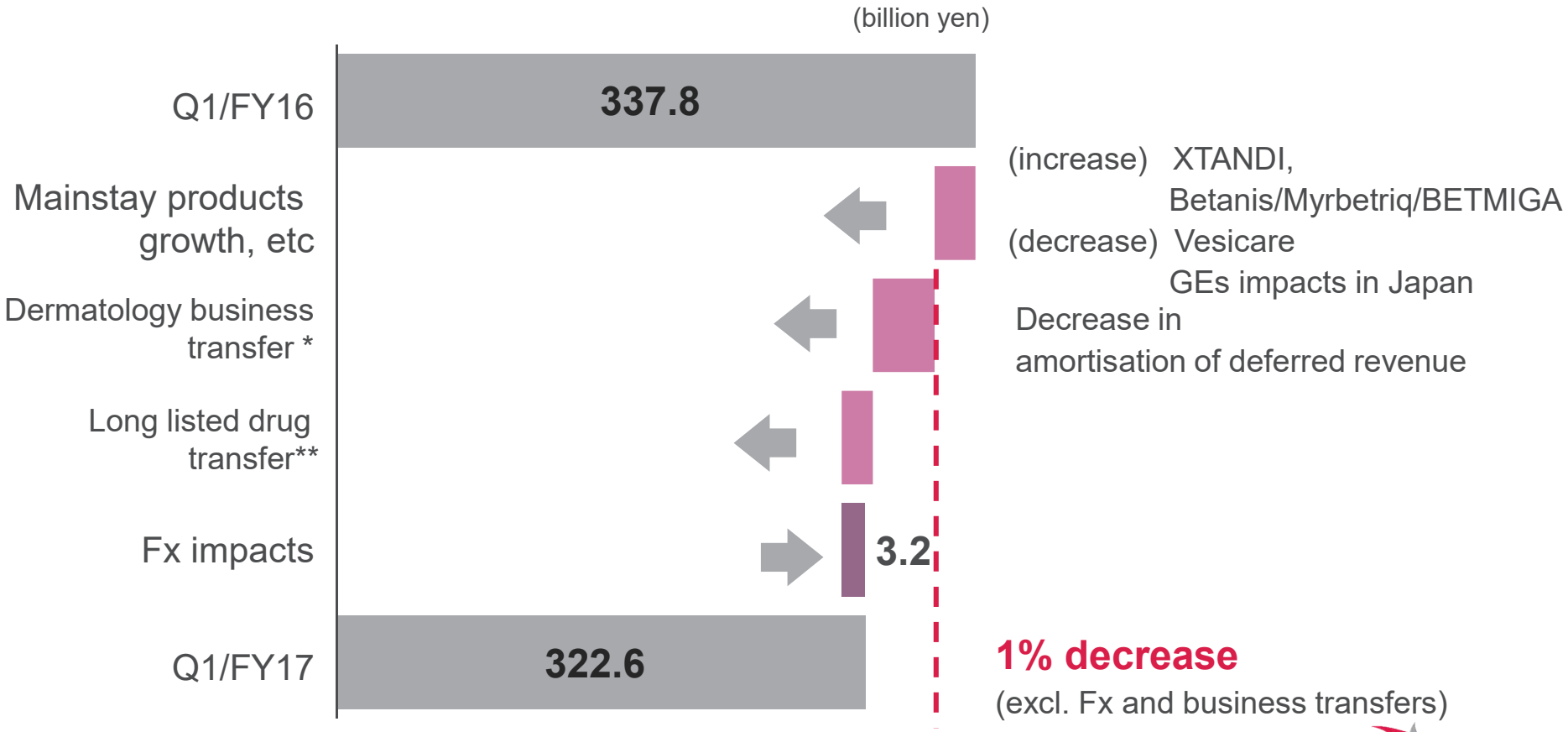
USD: Average	16/Q1: 108yen	17/Q1: 111yen (+3yen) /FY17FCST: 110yen
End rate change	16/Q1: -10yen	17/Q1: -0yen
EUR: Average	16/Q1: 122yen	17/Q1: 122yen (+0yen) /FY17FCST: 120yen
End rate change	16/Q1: -13yen	17/Q1: +8yen

Fx impacts		
	Net Sales:	+3.2
	Core OP:	-11.5

*Announced in April 2017

SALES ANALYSIS (YEAR ON YEAR)

Slight decrease excluding impacts of Fx and business transfers

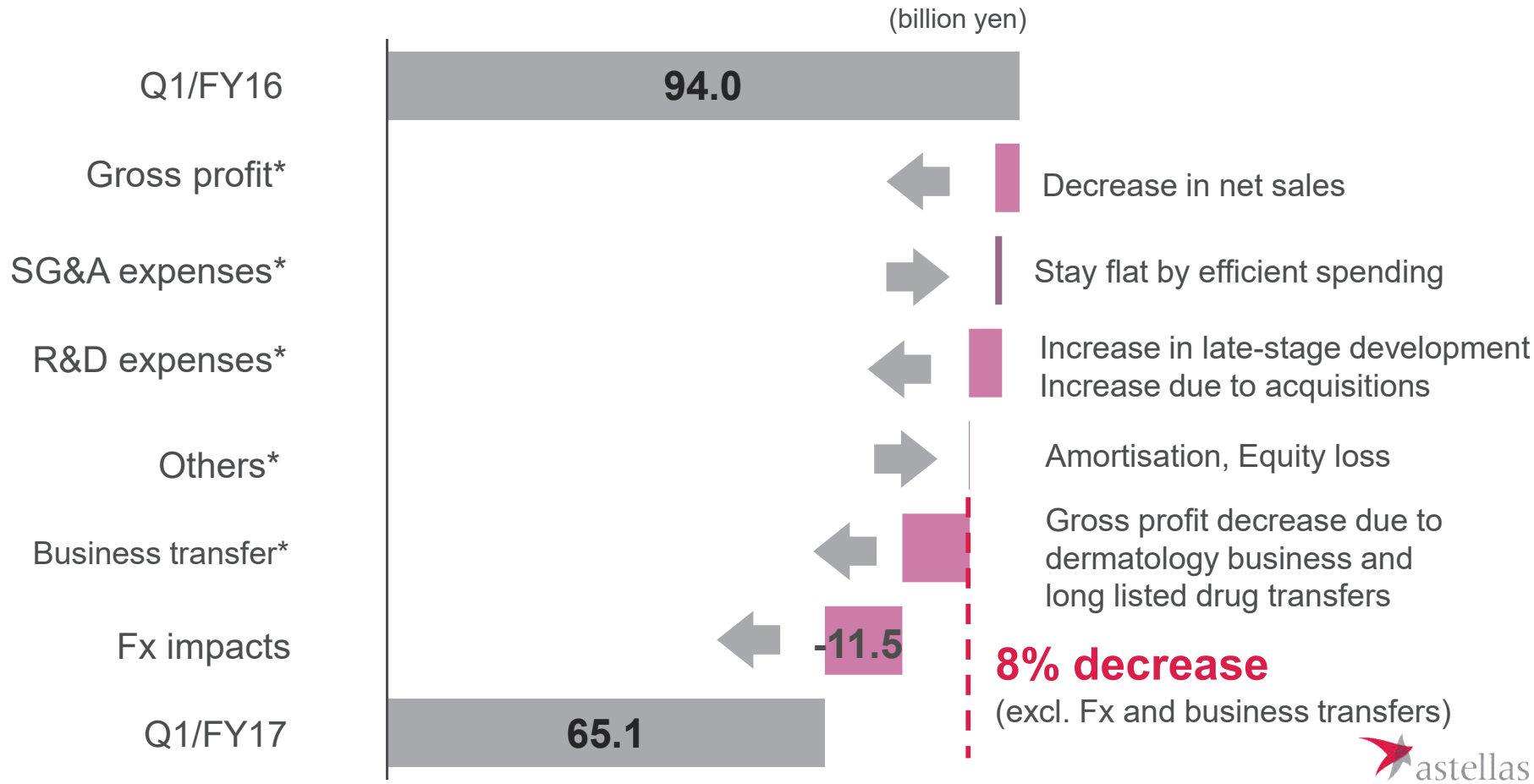


*Dermatology business transfer: Decrease in amortisation of deferred revenue

**Long listed drug transfer: Amortisation of deferred revenue – Sales of transferred products in Q1/FY16

CORE OP ANALYSIS (YEAR ON YEAR)

Development cost for late-stage projects increased



*Fx impacts excluded from each item

Q1/FY2017 FINANCIAL RESULTS (FULL BASIS)

Other income/expenses for IMAB362 development plan review

(billion yen)	Q1/FY16	Q1/FY17	Change	FY17FCST*	Achieve-ment
Core operating profit	**94.0**	**65.1**	**-30.7%**	**254.0**	**25.6%**
Other income	0.2	9.7	-		
Other expenses	1.3	31.3	-		
Operating profit	**92.9**	**43.5**	**-53.1%**	**254.0**	**17.1%**
Financial income	1.2	5.2	+328.9%		
Financial loss	0.9	0.3	-68.8%		
Profit before tax	93.2	48.5	-48.0%	260.0	18.6%
Profit for the period	**66.6**	**42.5**	**-36.2%**	**198.0**	**21.4%**
EPS (yen)	**31.35**	**20.57**	**-34.4%**	**95.88**	**21.5%**

In Q1/FY2017
Other income/expenses for IMAB362 development plan review
Impairment loss 26.0, Fair value remeasurements on contingent consideration (Other income) 9.2
Fx loss (Other expenses) 5.1
Gain from sale of financial assets (Financial income) 4.7

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*Announced in April 2017

SALES IN THREE KEY AREAS

XTANDI increase on a global basis

(billion yen)	Q1/FY16	Q1/FY17	Change	CER growth
Oncology	**79.1**	**81.8**	**+3.4%**	**+2%**
XTANDI	64.2	67.9	+5.8%	+4%
OAB in Urology	**54.0**	**51.8**	**-4.0%**	**-6%**
Vesicare	30.4	24.6	-19.2%	-20%
Betanis/Myrbetriq/BETMIGA	23.6	27.2	+15.6%	+14%
Transplantation	**49.4**	**49.4**	**+0.0%**	**-1%**

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

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

CER：Constant Exchange Rate

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ACHIEVING SUSTAINABLE GROWTH
(same as Strategic Plan 2015-2017 slide)

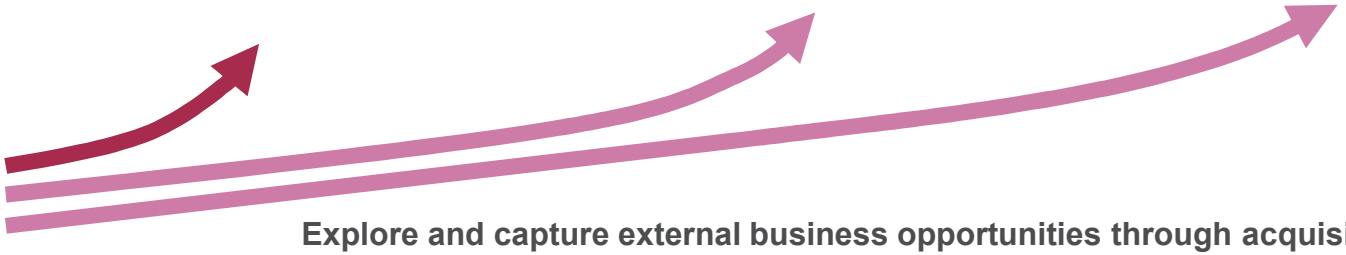
New products will drive mid-term growth;
Sustainable growth will be reinforced by continuous selective investment in innovation and strengthening of the business foundation

Maximizing the Product Value

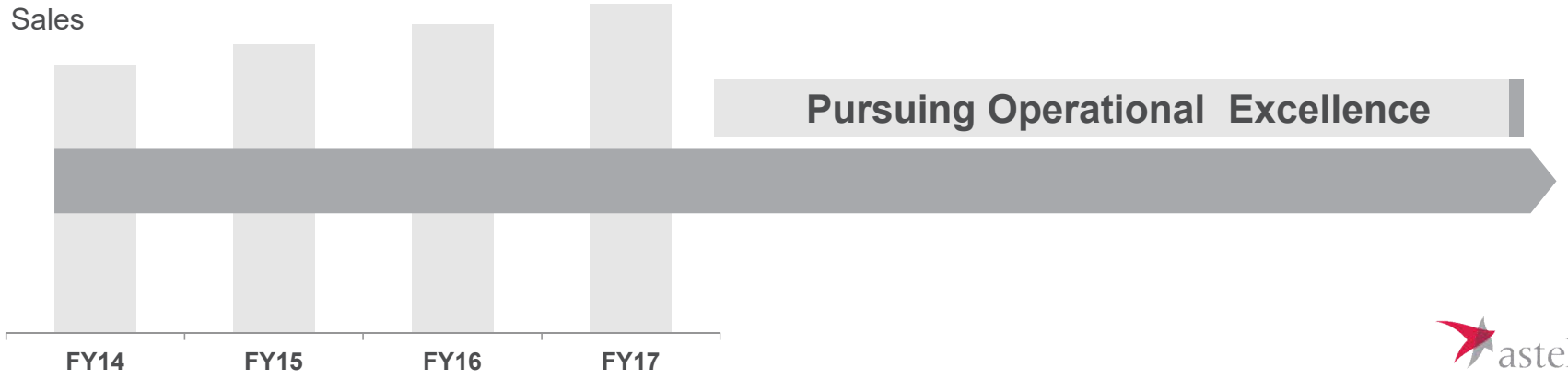
Creating Innovation

Enhancing Capabilities to Deliver Innovative Medicines

Advancing into New Opportunities



Explore and capture external business opportunities through acquisition, collaboration and in-licensing



Pursuing Operational Excellence

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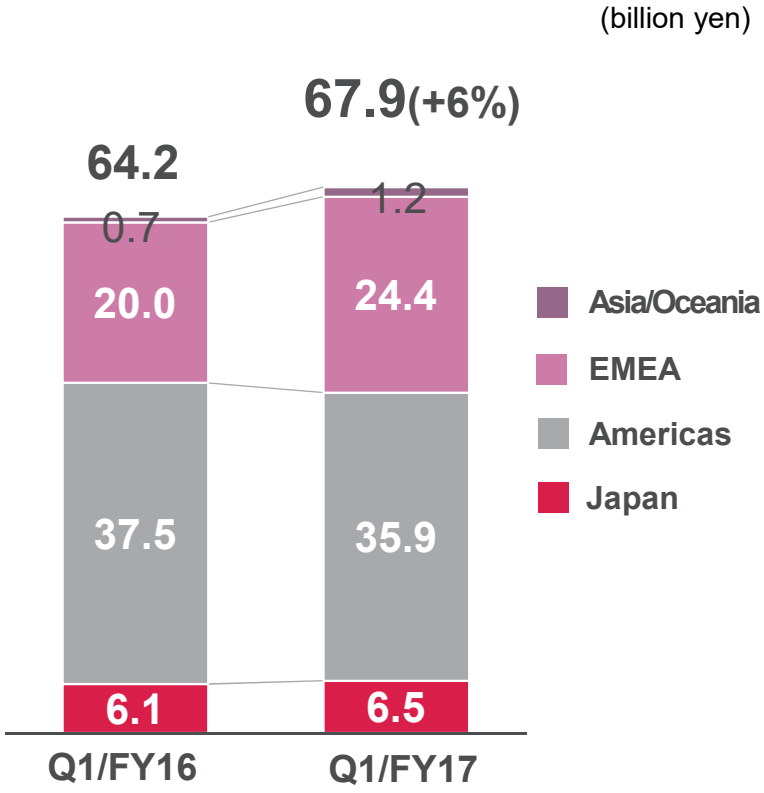
MAXIMIZE THE PRODUCT VALUE

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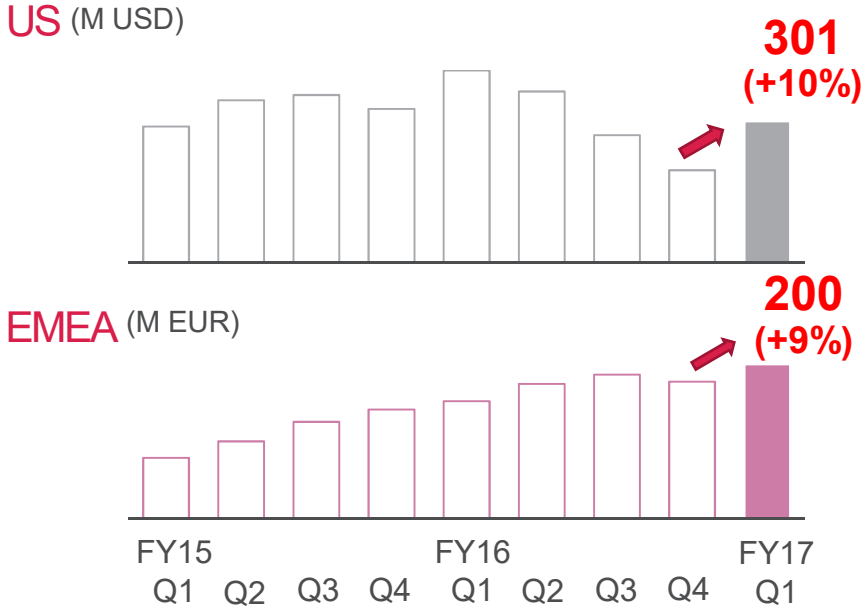
XTANDI

Global sales on-track. All-time high quarterly sales in EMEA

Sales by region



Quarterly sales (local currency)



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

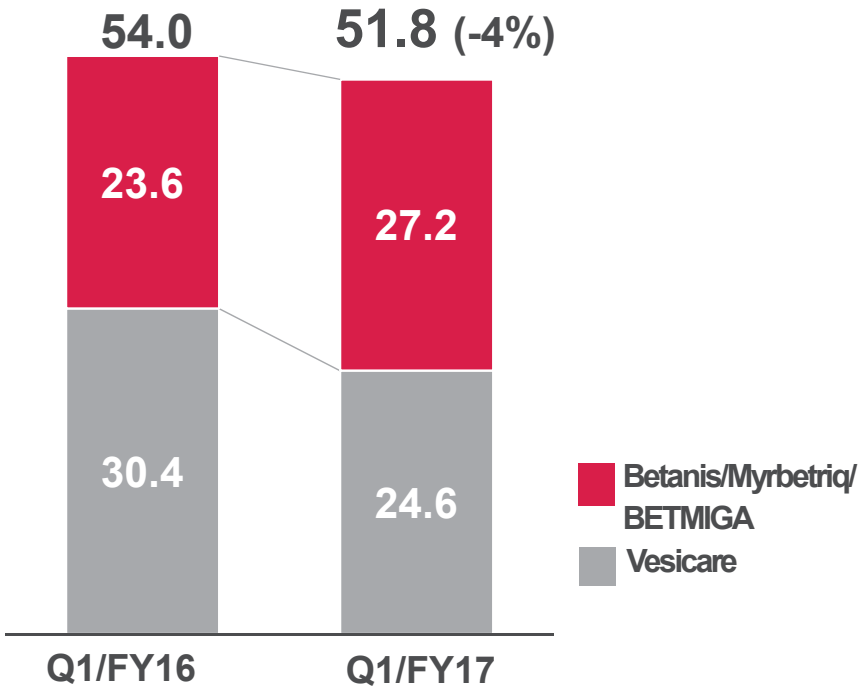
New drug application in China for Chemo-naive mCRPC was temporarily withdrawn (expect to resubmit within FY2017).

OAB FRANCHISE IN UROLOGY

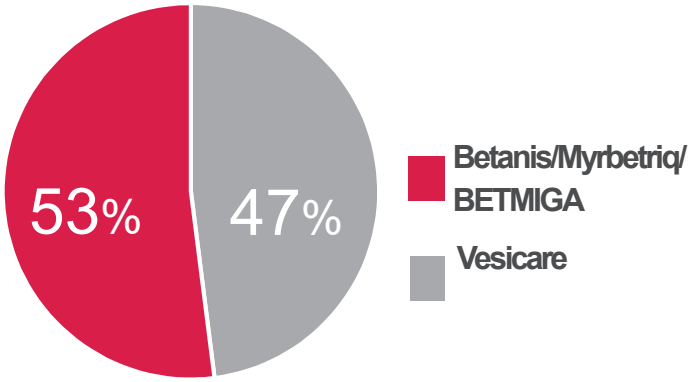
Betanis/Myrbetriq/BETMIGA showed steady sales

Sales by product

(billion yen)



Sales composition ratio by product (JPY basis)



- Negative impacts of such as price adjustments related to PY in the US
- Total OAB sales increased on a volume basis

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CREATE INNOVATION

PIPELINE

ROBUST PIPELINE OF ASTELLAS

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

Phase 1

- ASG-15ME
- AGS67E
- ASP4132
- AGS62P1
- ASP6282
- ASP8302
- ASP7398
- ASP7713
- ASP4345
- ASP0892
- ASP1807/CC8464
- ASP6981
- MA-0211

Phase 2

- enzalutamide (HCC)
- AGS-16C3F (Renal cell carcinoma)
- blinatumomab (AMG 103) (Acute lymphoblastic leukemia, JP)
- enfortumab vedotin (ASG-22ME) (Urothelial cancer)
- IMAB362 (Gastroesophageal adenocarcinoma)
- YM311/FG-2216 (Renal anemia)
- ASP8232 (Diabetic nephropathy)
- ASP6294 (BPS/IC)
- bleselumab (ASKP1240) (rFSGS)
- peficitinib (ASP015K) (Rheumatoid arthritis, US/EU)
- ASP7962 (Osteoarthritis)
- ASP8062 (Fibromyalgia)
- ASP0819 (Fibromyalgia)
- ASP4070 (Pollinosis caused by Japanese red cedar)
- ASP1707 (Rheumatoid arthritis etc)
- ASP5094 (Rheumatoid arthritis)
- fezolinetant (ESN364) (MR-VMS)
- CK-2127107 (SMA, COPD, ALS)
- ASP7317 (RPE cell program) (Dry AMD etc.)

Phase 3

- enzalutamide (M0 CRPC, M0 BCR:US/EU/Asia, M1 HSPC:US/EU/JP/Asia,)
- degarelix (3-month, JP)
- gilteritinib (ASP2215) (AML, US/EU/JP/Asia)
- mirabegron (Pediatric NDO, EU)
- roxadustat (ASP1517/FG-4592) (Anemia associated with CKD, EU/JP)
- peficitinib (ASP015K) (Rheumatoid arthritis, JP/Asia)
- ASP0113/VCL-CB01 (CMV-HCT, US/EU/JP)
- fidaxomicin (Infectious enteritis:JP, pediatric:EU)
- ipragliflozin (Type 1 diabetes, JP)
- linaclotide (Chronic constipation, JP)

Filed

- enzalutamide (Tablet, EU/JP)
- solifenacin (Pediatric NDO, US/EU)
- solifenacin/mirabegron (Concomitant use, US)
- tacrolimus (granule for pediatric, US)
- romosozumab (AMG 785) (Osteoporosis, JP)
- ipragliflozin/sitagliptin (Fixed dose combination, 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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HCC: Hepatocellular carcinoma, BPS/IC: Bladder pain syndrome/Interstitial cystitis, rFSGS: Recurrence of focal segmental glomerulosclerosis, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, ALS: Amyotrophic lateral sclerosis, RPE: Retinal pigment epithelium, AMD: Age-related macular degeneration, M0 CRPC: Non-metastatic castration-resistant prostate cancer, M0 BCR: Non-metastatic biochemical recurrence, M1 HSPC: Metastatic hormone sensitive prostate cancer, AML: Acute myeloid leukemia, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, CMV: Cytomegalovirus, HCT: Hematopoietic cell transplant, MR-VMS:Menopause-related vasomotor symptoms

CONSISTENT ACHIEVEMENT ON FILING/APPROVAL

Commitment to steady progress and achievement for filing and approval

Filing

solifenacin/mirabegron

- Combination use for OAB (US)
- Filed in June 2017
- To provide a new treatment option. Continuous focus on maximizing OAB franchise.

ipragliflozin/sitagliptin

- FDC for Type 2 diabetes (JP)
- Filed in May 2017
- To provide additive glucose-lowering effect by combining 2 different MoA drugs. FDC is expected to improve the patient adherence and better glycemic control by reducing number of tablets which leads to patient convenience.

tacrolimus granule

- Granule formulation in pediatric use for prevention of rejection after organ Tx (US)
- Filed in July 2017
- Allows for more accurate dose preparation of tacrolimus for pediatric administration.

Approval

quetiapine fumarate (extended release tablet)*

- Indication: Improvement of depressive symptoms associated with bipolar disorder
- Approved on July 3, 2017
- Astellas filed application per request from MHLW as “Unapproved or Off-labeled Drugs with High Medical Needs”.

enzalutamide tablet

- Tablet formulation for mCRPC (EU)
- Obtained CHMP positive opinion on July 24, 2017.
- To provide a new formulation with reduced size compared to currently marketed capsule formulation to help address the needs of patients who have difficulty swallowing.

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*Distribution and promotion by Kyowa Pharmaceutical Industry Co., Ltd., mCRPC: Metastatic castration-resistant prostate cancer
OAB: Overactive bladder, FDC: Fixed dose combination, MoA: Mode of action, MHLW: Ministry of Health, Labour, Welfare, Tx: transplantation

STEADY PROGRESS IN DEVELOPMENT
SUMMARY OF PROGRAM PHASE TRANSITION FROM APR 2017 TO JULY 2017

Steady progression of pipeline

P1 Entry	P2 Entry	P3 Entry
ASP6981 Cognitive impairment associated with schizophrenia	**ASP5094** Rheumatoid arthritis	
MA-0211 Duchenne muscular dystrophy		

Discontinuation (in a part of indications) etc.

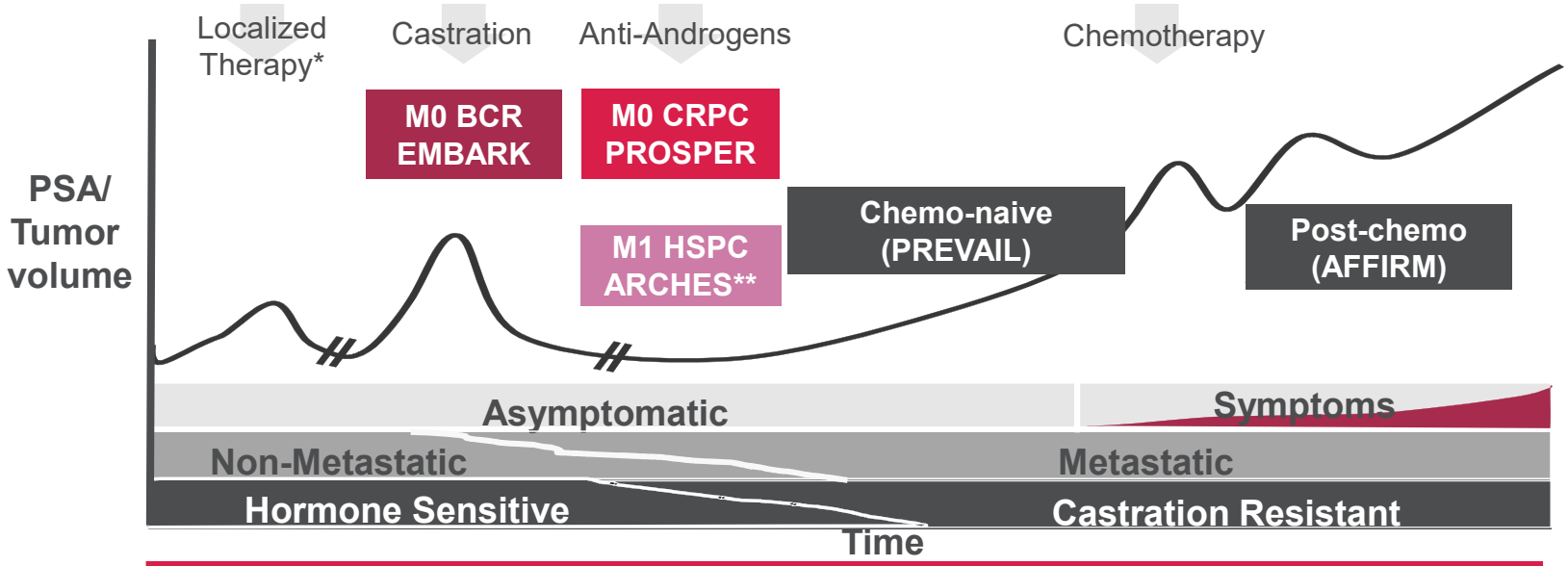
enzalutamide: Breast Cancer (P3: Triple-negative, P2: ER/PR positive, HER2 positive)
(Due to the comprehensive assessment based on discussion with Pfizer including competitive landscape change, need for further diagnostic development and new Phase 2 data.)
ASP8273: Non-small cell lung cancer (P3)
(Due to the comprehensive assessment of patient's benefit and risks following IDMC recommendation.)
ASP3662: Agitation associated with Alzheimer's disease (P2)
(Due to the comprehensive consideration including strategic prioritization.)
ASP5878: Cancer (P1)
ASP7266: Severe asthma (P1)

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Note: Phase transition is defined by company decision.
ER/PR: Estrogen/progesterone, IDMC: Independent data monitoring committee

ENZALUTAMIDE: MAXIMIZE THE VALUE FOR PROSTATE CANCER PATIENTS

Data readout of PROSPER study is planned in 2017.

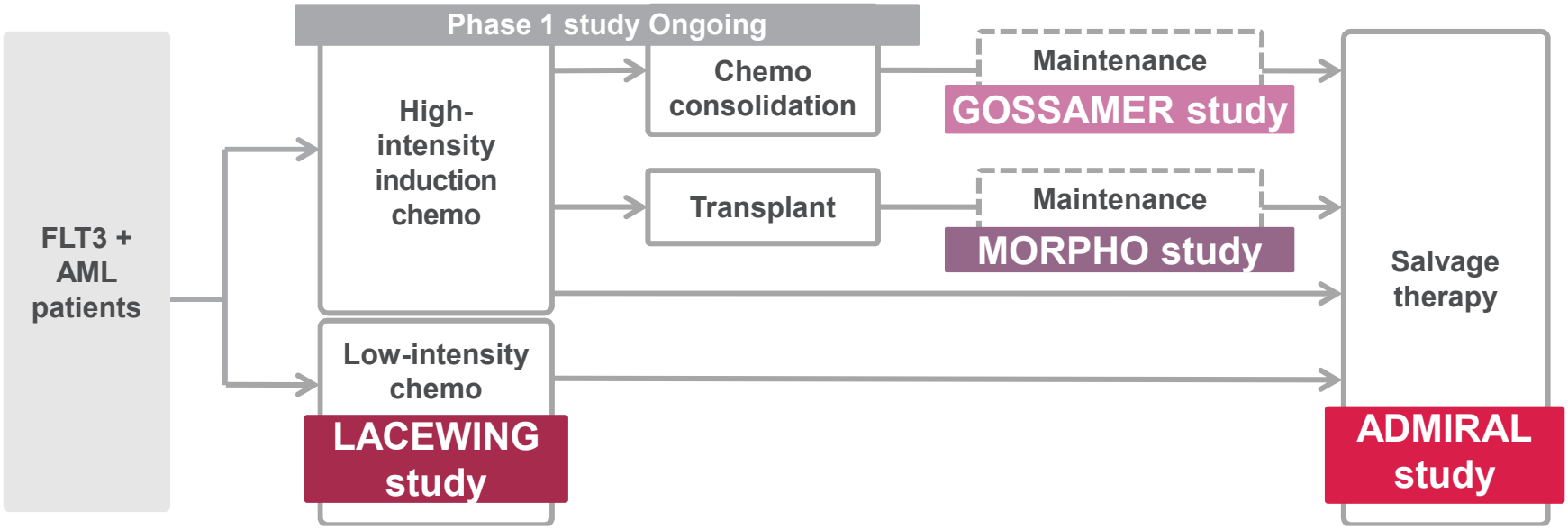


	PROSPER study P3	M0 CRPC Non-metastatic CRPC	Placebo-controlled, combination with ADT, n=1,440	Enrollment completed Jun 2017
	EMBARK study P3	M0 BCR Non-metastatic prostate cancer, biochemical recurrence	To compare with ADT and combination, n=1,860	First Patient In: Jan. 2015
	ARCHES study P3	M1 HSPC Metastatic hormone-sensitive prostate cancer	Placebo-controlled, combination with ADT, n=1,100	First Patient In: Mar. 2016

P. Mulders *et al. EAU2012,* modified by Astellas * Radiotherapy, prostatectomy, ** Metastatic at the time of diagnosis,
PSA: Prostate-specific antigen

GILTERITINIB: TREATMENT LANDSCAPE IN AML

FDA granted orphan drug designation to gilteritinib for AML



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

AML: Acute myeloid leukemia, HSCT: Hematopioetic Stem Cell Transplant, BMT-CTN: Blood and Marrow Transplant – Clinical Trial Network
ITD: Internal tandem duplication

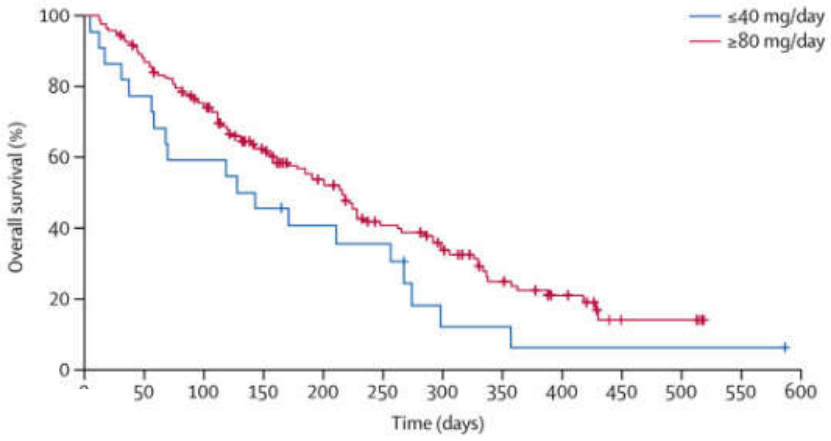
GILTERITINIB: PUBLICATION IN THE LANCET ONCOLOGY

The Lancet Oncology publishes anti-leukemic activity and safety data from Phase 1/2 CHRYSALIS study

THE LANCET Oncology

Selective inhibition of FLT3 by gilteritinib in relapsed or refractory acute myeloid leukaemia: a multicentre, first-in-human, open-label, phase 1–2 study

Overall survival of patients receiving gilteritinib ≤ 40mg/day vs ≥ 80mg/day



Key findings:

- Gilteritinib monotherapy was well tolerated, generated a high proportion of responses, and showed durable responses and promising survival results in patients with FLT3^{mut+} R/R AML, including those with both ITD mutations in FLT3 and point mutations in codon D835.
- Gilteritinib at 120 mg/day is being tested in phase 3 trials.

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Perl AE, *et al*., The Lancet Oncology 2017 Jun 20. pii: S1470-2045(17)30416-3
R/R: Relapsed or refractory, ITD: Internal tandem duplication

ENFORTUMAB VEDOTIN: ROBUST UPDATED DATA OF PHASE 1 STUDY IN METASTATIC UROTHELIAL CANCER

Registrational Phase 2 study initiation planned in 2017 in mUC patients with prior checkpoint inhibitor supported by the robust data of Phase 1 study in mUC patients

ASCO2017: Updated analysis in mUC patients from on-going Phase 1 study

Efficacy: Investigator-assessed Response in mUC Patients

	All mUC patients		Prior CPI Treatment	
	1.25mg/kg (n=30)	All Doses (n=71)	1.25mg/kg (n=17)	All Doses (n=32)
CR,n (%)	1 (3)	3 (4)	0	1 (3)
PR, n (%)	15 (50)	26 (37)	8 (47)	13 (41)
SD, n (%)	6 (20)	22 (31)	5 (29)	9 (28)
ORR (95% CI) (unconfirmed)	**53 (34.3, 71.7)**	**41 (29.3, 53.2)**	**47 (23.0, 72.2)**	**44 (26.4, 62.3)**
DCR (95% CI)	73 (54.1, 87.7)	72 (59.9, 81.9)	77 (50.1, 93.2)	72 (53.3, 86.3)

Safety:

- In patients with mUC, enfortumab vedotin was well tolerated.
- Nausea, pruritus, and fatigue were the most commonly reported treatment-related AEs.
- UTI and hypophosphatemia were the most common grade ≥3 AEs.

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Petrylak DP, *et al*., ASCO2017 ASCO: American Society of Clinical Oncology, CR: Complete response, PR: Partial response, SD: Stable disease, ORR: Overall response rate (ORR=CR+PR), DCR: Disease control rate (DCR=CR+PR+SD), mUC: Metastatic urothelial cancer, CPI: Checkpoint inhibitor, UTI: Urinary tract infection, AE: Adverse event

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

Planned data readouts from 3 studies (1 global, 2 Japanese studies) in FY2017.

	Dialysis	Non-dialysis
Global	**HIMALAYAS:** FibroGen Incident dialysis, vs epoetin alfa	**DOLOMITES**, vs darbepoetin astellas
	SIERRAS: FibroGen Stable dialysis, vs epoetin alfa	**ALPS**, vs placebo astellas **Enrollment completed** Data readout planned in 1Q/2018
	PYRENEES: astellas Stable dialysis, vs epoetin alfa or darbepoetin **Enrollment completed**	**ANDES**, vs placebo FibroGen
Japan astellas	**HD:** Conversion, vs darbepoetin	Conversion, vs darbepoetin
	HD: Conversion, long-term **Enrollment completed** Data readout planned in 1Q/2018	
	HD: Correction (ESA-naïve) **Enrollment completed** Data readout planned in 1H/2018	Correction
	PD: **Enrollment completed** Data readout planned in 4Q/2017	

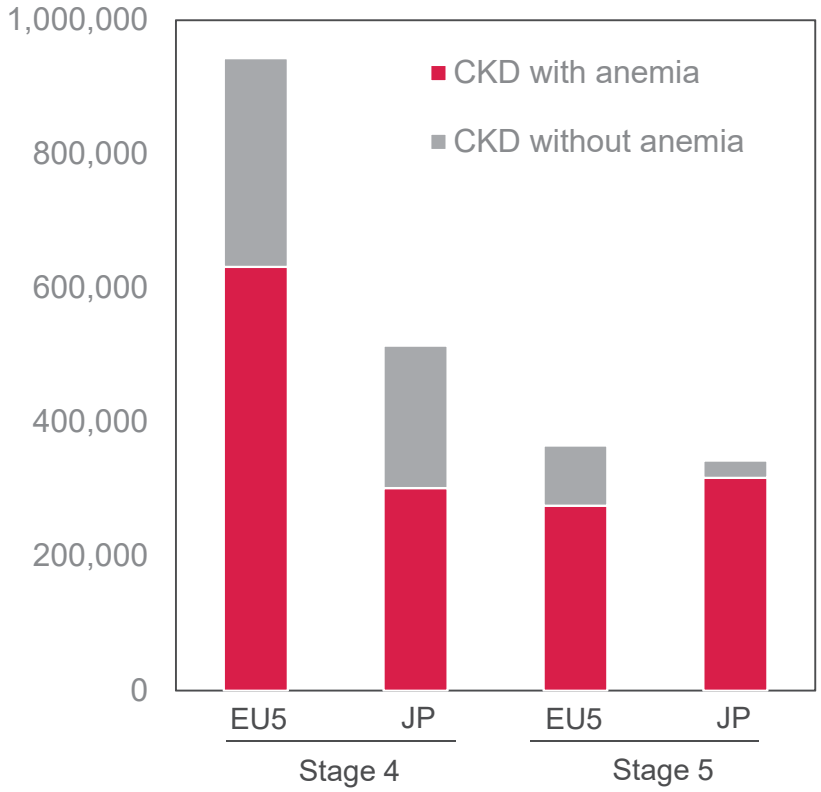
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Note: Company logo in the table shows the sponsor of studies
HD: Hemodialysis, PD: Peritoneal dialysis, ESA: Erythropoietin stimulation agents

ROXADUSTAT: TREATMENT LANDSCAPE OF CKD WITH ANEMIA

Potential to become a new treatment option for CKD patients with anemia

Patient numbers*



Characteristics

- Orally administrated
- Small molecule agent
- New mechanism of action that is different from current SOC of anemia treatment in CKD patients
- Transient elevation of endogenous EPO within physiologic range
- Potential for increased iron availability for red blood cell production
- Potentially no need for IV iron

FIBROGEN

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*Patient number in 2015. PatientBase, a Service of Decision Resources Group ©2015 DR/Decision Resources LLC
CKD: Chronic kidney disease, SOC: Standard of Care, EPO: Erythropoietin, IV: Intravenous injection

FEZOLINETANT: HIGH UNMET MEDICAL NEEDS IN VMS

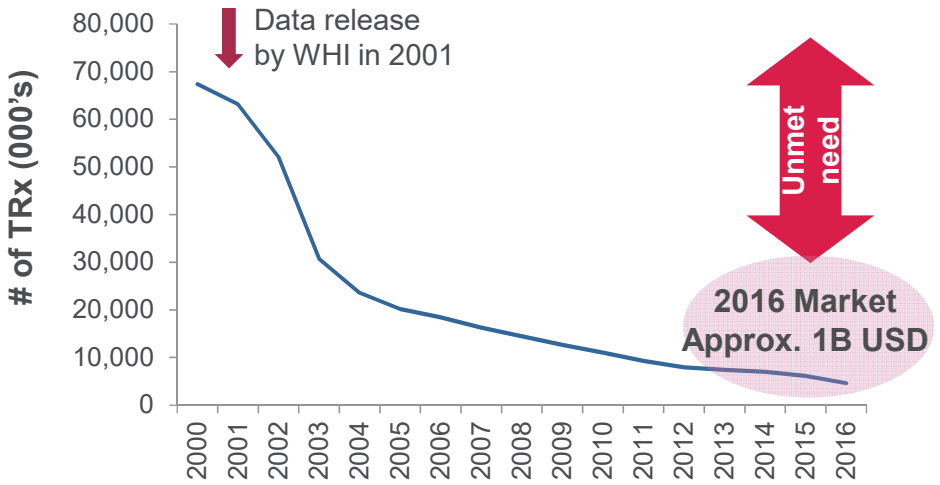
A safe non-hormonal drug has been awaited by patients with VMS

Disease Background

- MR-VMS patients are women generally in mid-40's to mid-60's.
- VMS found in up to 80%*1 of menopausal women, prevalence depends on region.
- Average VMS episodes may last from 30 sec to 5 min in menopausal women.
- VMS also occurs in patients receiving cancer treatment (TR-VMS), with episode from 40 sec to 45 min.
- Severity range from slight discomfort to complete debilitation.

Unmet Medical Needs

US Annual Branded TRx Trends for MR-VMS*2



Women's Health Initiative (WHI) Study*3

- NIH supported clinical study to investigate the risk and benefic of HRT in post-menopausal women.
- The data contraindicating chronic treatment with HRT due to safety concerns including cancer and cardiovascular risks of HRT.

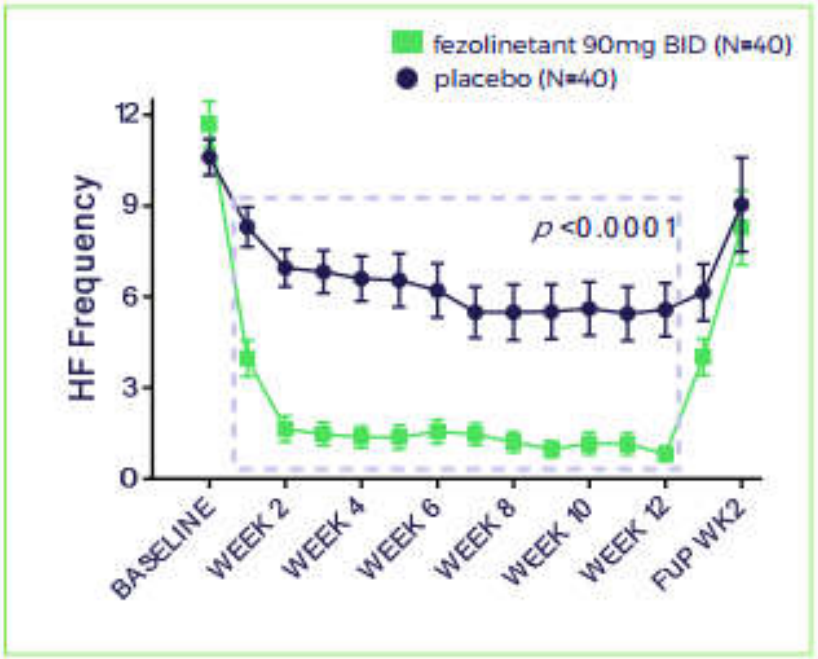
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*1: Up to Date (Literature review current through: June 2017), *2:Data Source: IMS NPA (2000-2016), IMS NSP (2000-2016). (3 HTs and SSRI) NAMS 2015 Position Statement., *3: JAMA 2013 Oct 2; 210(13): 1353-1368, MR-VMS: Menopause related vasomotor symptoms, HRT: Hormone replacement therapy, TRx: Total prescription

FEZOLINETANT: POC STUDY IN MR-VMS

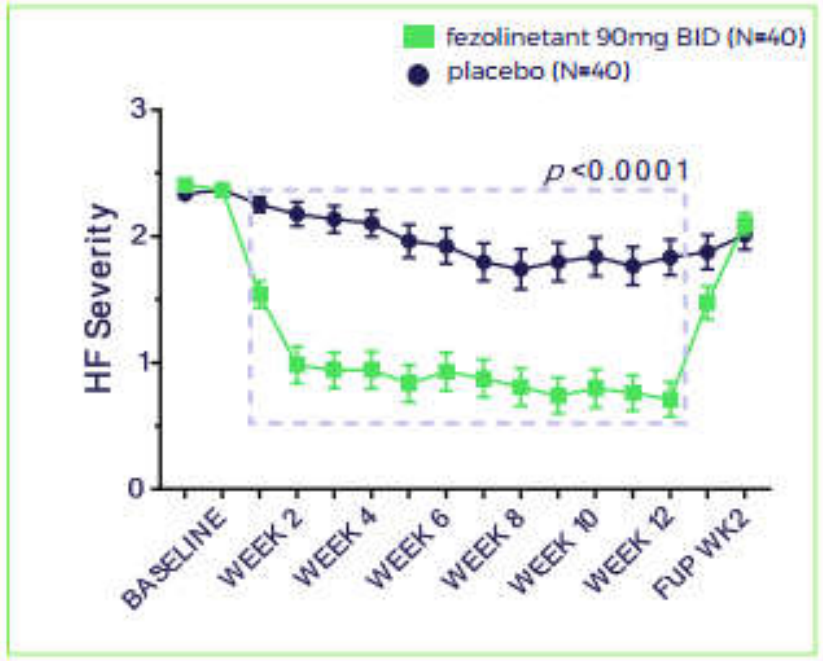
Robust data in terms of improvement in the frequency and extent of hot flashes

Average Daily Hot Flash Frequency*



At Week 4: 14/40 patients have ZERO hot flash in fezolinetant group (vs 2/40 in placebo group)

Score of average severity of Hot Flash*



1 - Mild: sensation of heat without sweating
2 - Moderate: heat with sweating, but able to continue activity
3 - Severe: heat with sweating, causing cessation of activity

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Herman Depypere *et al*., ENDO2017, ENDO: The Eendocrine Society, MR-VMS: Menopause-related vasomotor symptoms, HF: hot flash
*The study has been conducted under FDA's guideline (Guidance for Industry, Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms - Recommendations for Clinical Evaluation

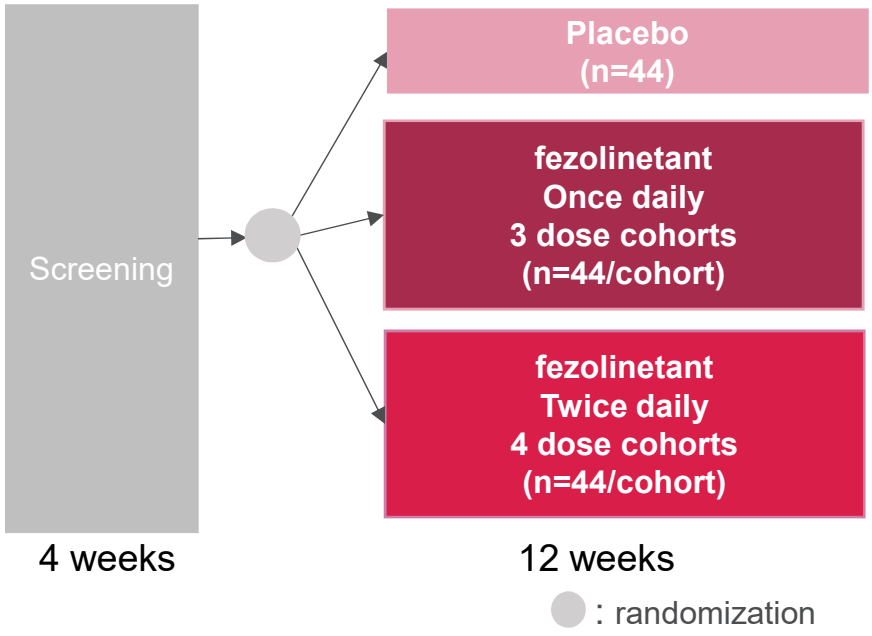
FEZOLINETANT: PHASE 2B STUDY INITIATION IN MR-VMS

First Patient is expected soon

Target patient

- Post menopausal women suffering from moderate to severe vasomotor symptoms at least 50 per week (n=352)

Study Design



Co-primary endpoints

- Change from baseline in the mean number of hot flashes (mild, moderate and severe) per day
  - to Week 4
  - to Week 12
- Change from baseline in the mean severity of hot flashes (mild, moderate and severe) per day
  - to Week 4
  - to Week 12

Plan

- Study completion in Aug 2018*.

*: from ClinicalTrial.gov (Study number: NCT03192176)

PHASE 2 PROGRAMS: HIGHLIGHTS

Steady progress and near-term plans of Phase 2 programs

IMAB362

- Regulatory meetings in US/EU/JP planned in 2017 to consult the overall development plan for Phase 3 study design in gastroesophageal adenocarcinoma.

ASP4070

- POC study in patients with pollinosis caused by Japanese red cedar was initiated in Japan.
- FPI achieved in July 2017
- TLR is planned in 1Q/2018

Note: Phase 1 study for peanuts allergy is being conducted with ASP0892, DNA vaccine utilizing LAMP-vax technology like ASP4070.

CK-2127107

- Top Line Result of Phase 2 study in SMA patients is planned in 1Q/2018.
- FDA granted orphan drug designation to CK-2127107 in patients with SMA
- Phase 2 study for COPD is on-going.
- Phase 2 study in ALS patients is planned to start in 3Q 2017.

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POC: Proof of Concept, FPI: First patient in, TLR: Top line results, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, ALS: Amyotrophic lateral sclerosis

EXPECTED KEY PIPELINE EVENTS IN FY2017

Important milestones from POC through registration

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

Data Readouts

Phase 2 (POC) study

enzalutamide
Breast Cancer (HER2+)

ASP4070 (JRC2-LAMP-vax)
Pollinosis caused by Japanese red cedar

ASP1707
Rheumatoid Arthritis (MTX-IR)

CK-2127107
Spinal Muscular Atrophy

ASP7962
Osteoarthritis

Phase 3 study

enzalutamide
M0 CRPC (PROSPER)

roxadustat
Non-dialysis pts (ALPS)
Hemodialysis: Conversion, long-term (Japan)
Peritoneal dialysis (Japan)

ASP0113
Hematopoietic Cell Transplantation

peficitinib
RA pts with MTX-IR
RA pts with DMARD-IR

Filing*

solifenacin/mirabegron
Concomitant use of solifenacin and mirabegron (US)

linaclotide
Chronic constipation (Japan)

evolocumab
Cardiovascular outcome study (Japan)

ipragliflozin/sitagliptin
Fixed dose combination (Japan)

Regulatory Decisions

enzalutamide
Tablet (EU)
Tablet (Japan)

romosozumab
Osteoporosis (Japan)

quetiapine
BP-D (Japan)

solifenacin
Pediatric NDO (US)
Pediatric NDO (EU)

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

POTENTIAL GROWTH DRIVERS

Future growth driven by compounds that already have achieved POC

Current growth drivers

- Xtandi (enzalutamide)
- OAB franchise
  - VESIcare (solifenacin succinate)
  - Myrbetriq (mirabegron)
- Repatha (evolocumab) injection 140 mg/mL
- Suglat®
- Linzess (linaclotide) capsules

Near term growth drivers
(Filed/Filing expected in FY2017)

- **solifenacin/ mirabegron** (Combination therapy)
- **evolocumab** (Cardiovascular outcome study)
- **linaclotide** (Chronic constipation)
- **romosozumab** (Filed in Dec 2016)

Mid-term growth drivers
(FY2018-)

- **gilteritinib**
- **enzalutamide** (label expansion)
- **enfortumab vedotin**
- **IMAB362**
- **roxadustat**
- **ASP0113**
- **peficitinib**
- **fezolinetant**

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

POC; Proof of Concept

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

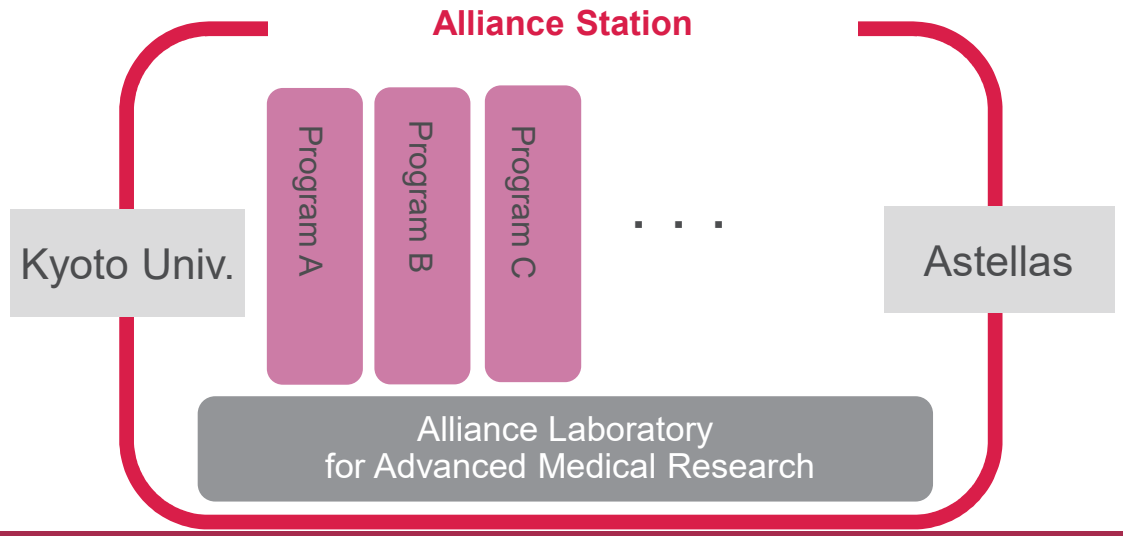
CREATE INNOVATION

NEW INITIATIVES

INITIATIVES TO CREATE INNOVATION

Alliance Station in Kyoto University with aim of realizing advanced medical treatment

- New open innovation scheme evolving 10-year collaborative research since 2007
- Establish Alliance Laboratory for Advanced Medical Research in Graduate School of Medicine Kyoto University
- Discover innovative drug seeds to address unmet medical need and invent new technologies to predict clinical validation
- Prompt and flexible joint research projects



PURSUE OPERATIONAL EXCELLENCE

OPTIMAL RESOURCE ALLOCATION: WIND-DOWN AGENSYS RESEARCH OPERATIONS

Optimize resource allocation to further refine oncology strategy

- Continuous evaluation of oncology strategy:
  Reduce focus on Antibody-Drug Conjugate (ADC) research
  Expand investment in the research in new technologies and modalities
- Continue certain clinical trials and collaborations on ADC programs such as enfortumab vedotin
- To complete the wind-down within FY2017
- Financial impacts: Under review

CREATE SOCIAL VALUE

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

Expand scope of collaborative research for rice-based oral vaccine MucoRice technology

- To viral gastroenteritis diarrhea in addition to original scope; cholera and enterotoxigenic *Escherichia coli*

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THE INSTITUTE OF MEDICAL SCIENCE
THE UNIVERSITY OF TOKYO

Global Health Innovative Technology Fund (GHIT Fund): Second phase

- 5 years commitment (2018-2022) to leverage Japanese expertise and capability for life-saving health innovations

Action on Fistula: Second phase

Action on Fistula

- Continue to build capacity in Kenya to deliver treatment by providing surgeries to an additional 2,000 women with fistula by 2020

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AGENDA

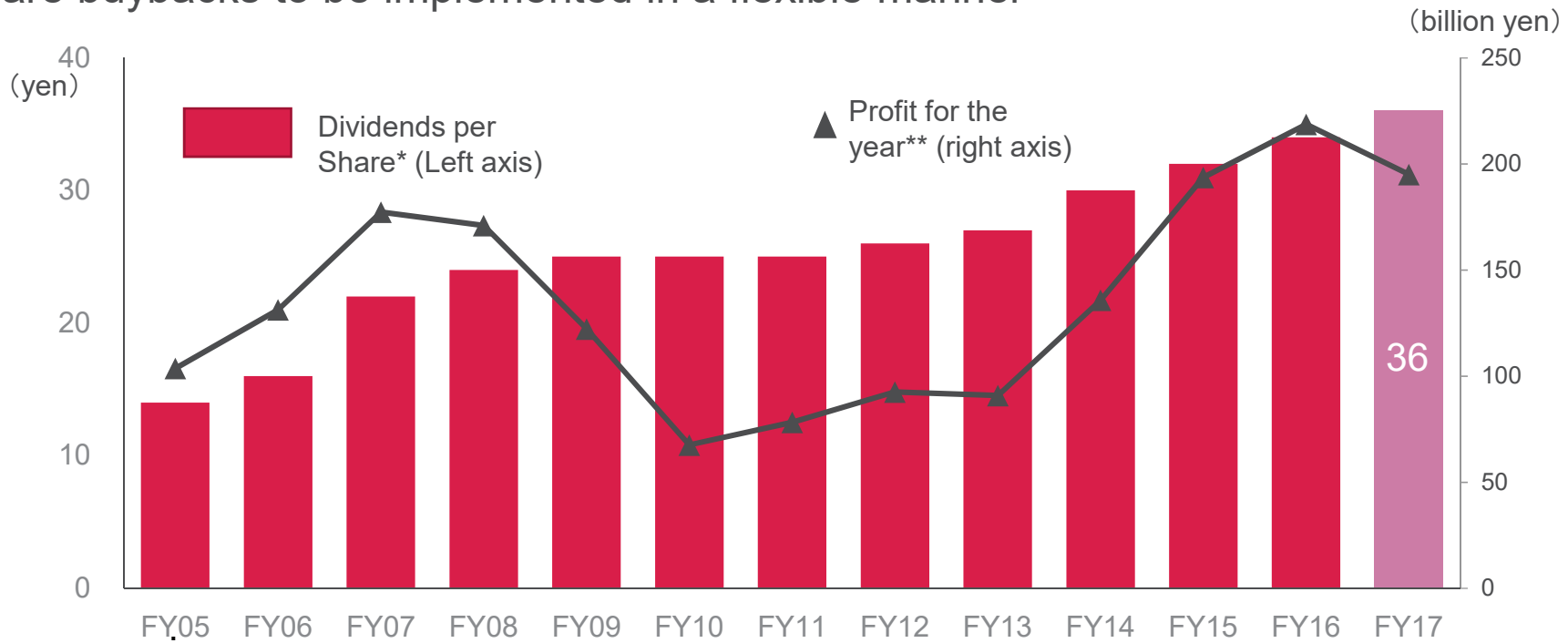
I Q1/FY2017 Financial Results

II Initiatives to Build Resilience for Sustainable Growth

III Profit Distribution Policy

Profit Distribution Policy

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

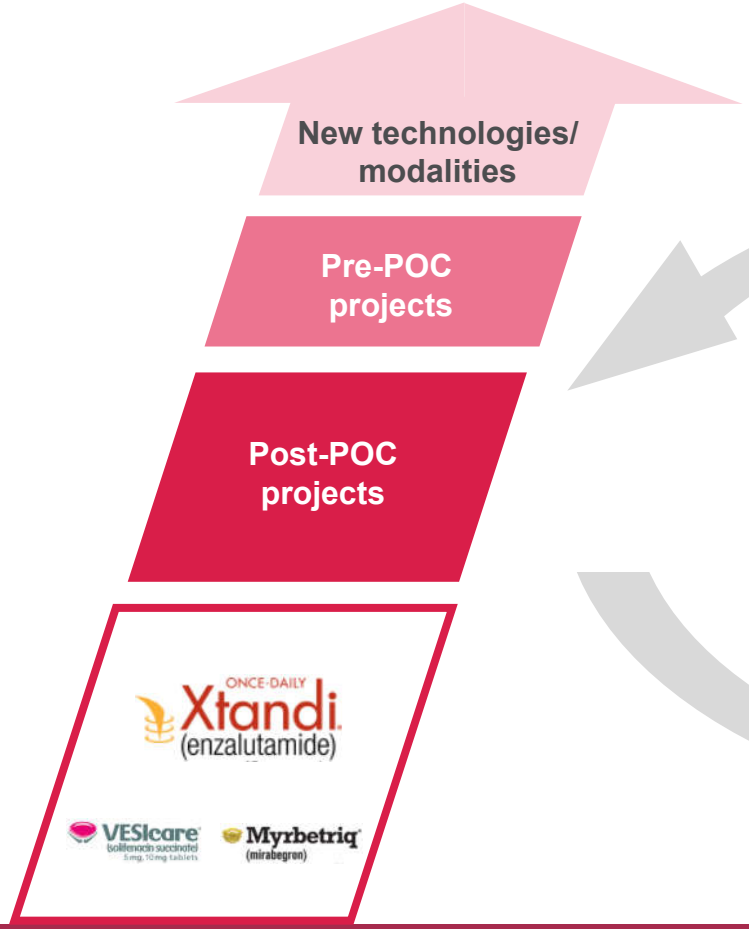


(billion yen)	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17 (Forecast)
Total dividends	39.3	42.3	55.2	56.9	58.2	57.7	57.7	59.4	60.6	66.0	68.5	71.3	74.4
Acquisition of own share	46.2	219.9	81.8	123.4	27.0	-	-	49.4	30.0	58.2	119.3	91.4	
Total return ratio(%)	82	200	77	106	70	85	74	118	100	92	97	74	

*The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014, Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal 2005.
**From fiscal 2013 are in accordance with International Financial Reporting Standards (IFRS).

REALIZE SUSTAINABLE GROWTH

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



* OCATA THERAPEUTICS, GANYMED Pharmaceuticals AG, ogeda

Strategic resource allocation

-Transfer of dermatology business
-Transfer of US manufacturing subsidiary
-Transfer of 16 long-listed products in Japan

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POC: Proof of concept

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

APPENDIX

Q1/FY2017: SALES BY REGION

	Q1/FY16	Q1/FY17	Change
Japan (billion yen)	**124.2**	**114.2**	-8.1%
of sales in Japanese market	114.8	106.1	-7.5%
Americas (million USD)	**995**	**914**	-8.1%
EMEA (million EUR)	**699**	**683**	-2.4%
Asia/Oceania (billion yen)	**20.7**	**23.4**	+13.2%

FY2017 FCST：FX SENSITIVITY

Estimated Fx sensitivity of FY2017 forecasts by 1 yen appreciation

Currency	Average rate 1 yen higher than expected assumption		Year-end rate 1 yen higher than expected assumption
	Net sales	Core OP	Core OP
USD	Approx. -4.9 bil yen	Approx. -1.2 bil yen	Approx. +0.5 bil yen
EUR	Approx. -2.7 bil yen	Approx. -1.1 bil yen	Approx. +0.3 bil yen

Forecast rates in FY2017:
USD：110yen
EUR：120yen

BALANCE SHEET/CASH FLOW HIGHLIGHTS

(billion yen)	FY16 end	Jun. 2017
Total assets	1,820.9	1,901.2
Cash and cash equivalents	340.9	314.4
Total net assets	1,271.8	1,319.7
Equity ratio (%)	69.8%	69.4%

(billion yen)	Q1/FY16	Q1/FY17	FY16
Cash flows from operating business	18.2	59.5	235.6
Cash flows from investing activities	(6.6)	(56.0)	(73.4)
Free cash flows	11.6	3.5	162.2
Cash flows from financial activities	(35.2)	(36.2)	(166.2)
Acquisition of treasury shares	(0.8)	(0.7)	(92.2)
Dividends paid	(34.0)	(35.1)	(70.1)

PROFIT DISTRIBUTION

	FY2015	FY2016	FY2017 (forecast)
Core EPS	92.12	101.15	94.43
Divided per share	32	34	36 (forecast)
ROE	15.0%	17.3%	-
DOE	5.4%	5.6%	-
Share buyback	68 million shares 119.3 billion yen	60 million shares 91.4 billion yen	-
Treasury stock cancellation	38 million shares	68 million shares	85 million shares

ON THE FOREFRONT OF HEALTHCARE CHANGE

