# 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 |

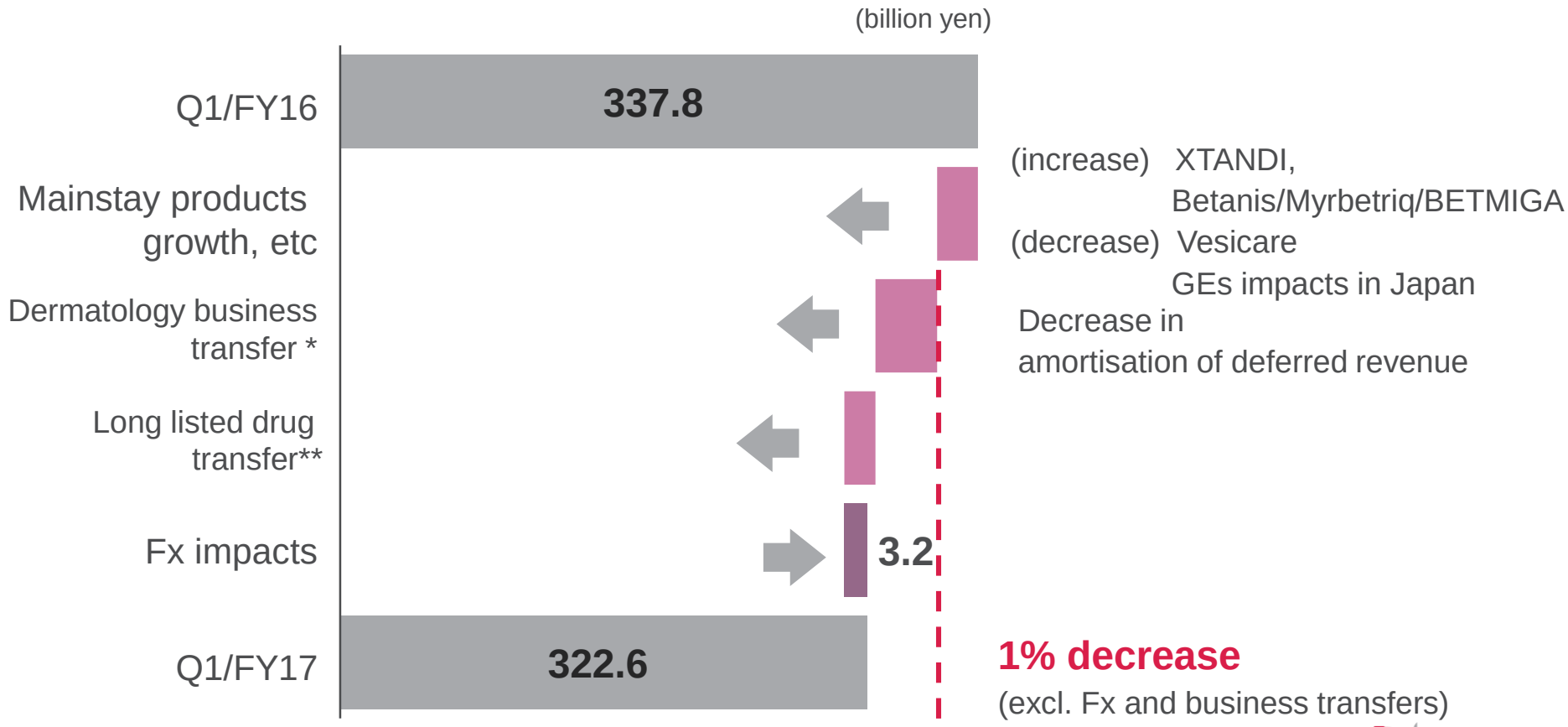
| **Fx impacts** | | |
|---|---|---|
| | Net Sales: | +3.2 |
| | Core OP: | -11.5 |

*Announced in April 2017

# SALES ANALYSIS (YEAR ON YEAR)



## Slight decrease excluding impacts of Fx and business transfers



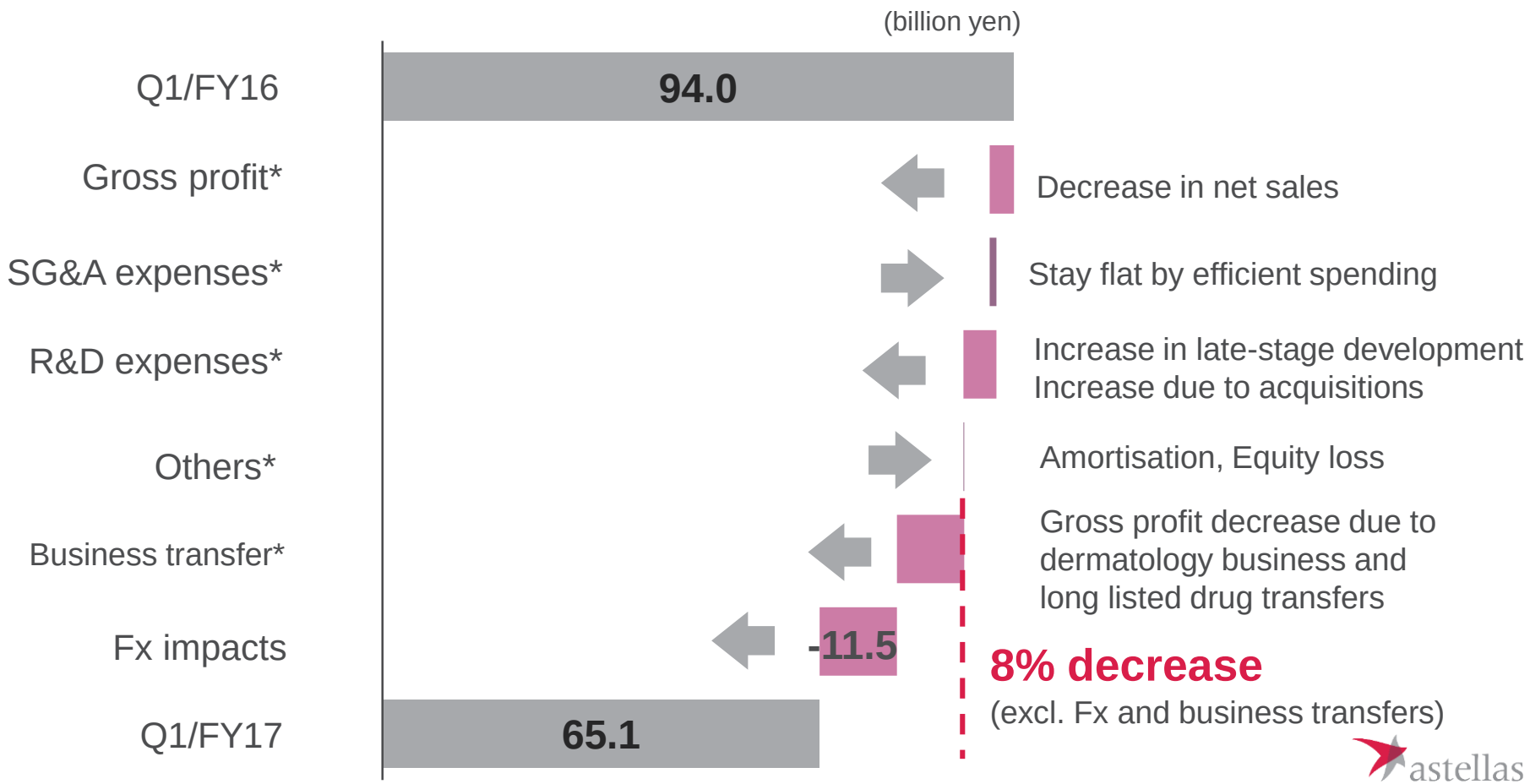

*Dermatology business transfer: Decrease in amortisation of deferred revenue

**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

*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%** |

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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)



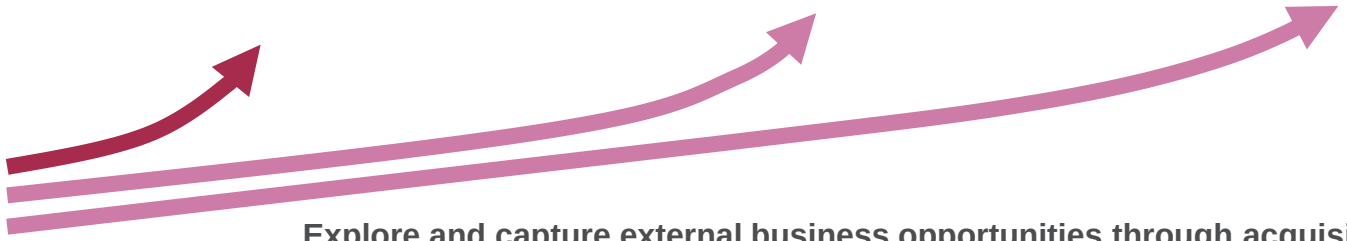
*New products will drive mid-term growth;*
*Sustainable growth will be reinforced by continuous selective investment in innovation and strengthening of the business foundation*

**Maximizing the Product Value**

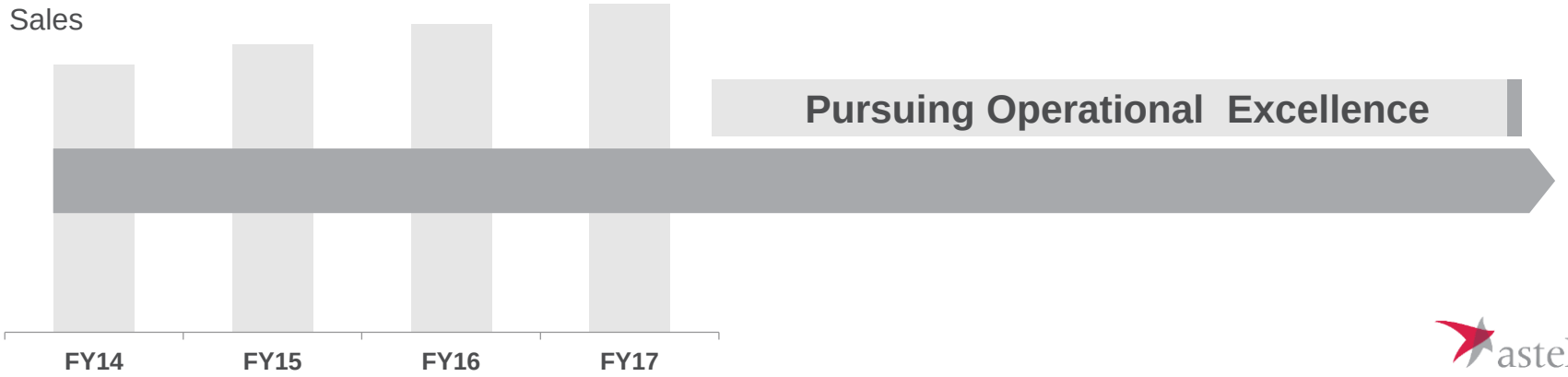
**Creating Innovation**

**Enhancing Capabilities to Deliver Innovative Medicines**

**Advancing into New Opportunities**



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

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# MAXIMIZE THE PRODUCT VALUE

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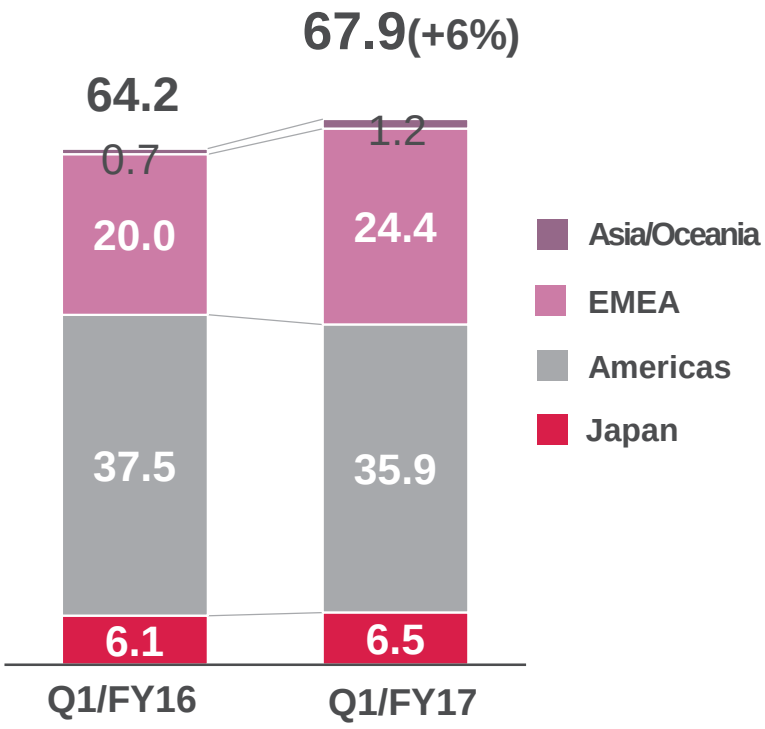
# XTANDI



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

### Sales by region

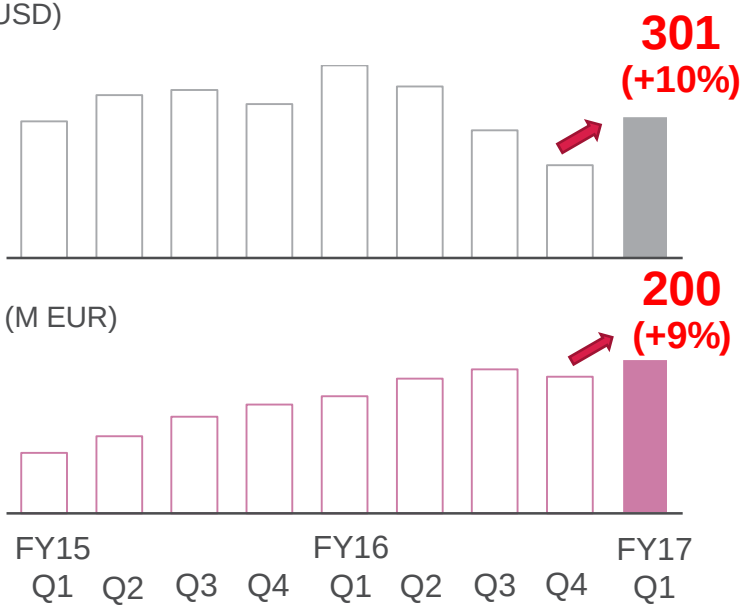
(billion yen)




### Quarterly sales (local currency)

US (M USD)

EMEA (M EUR)




- 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).

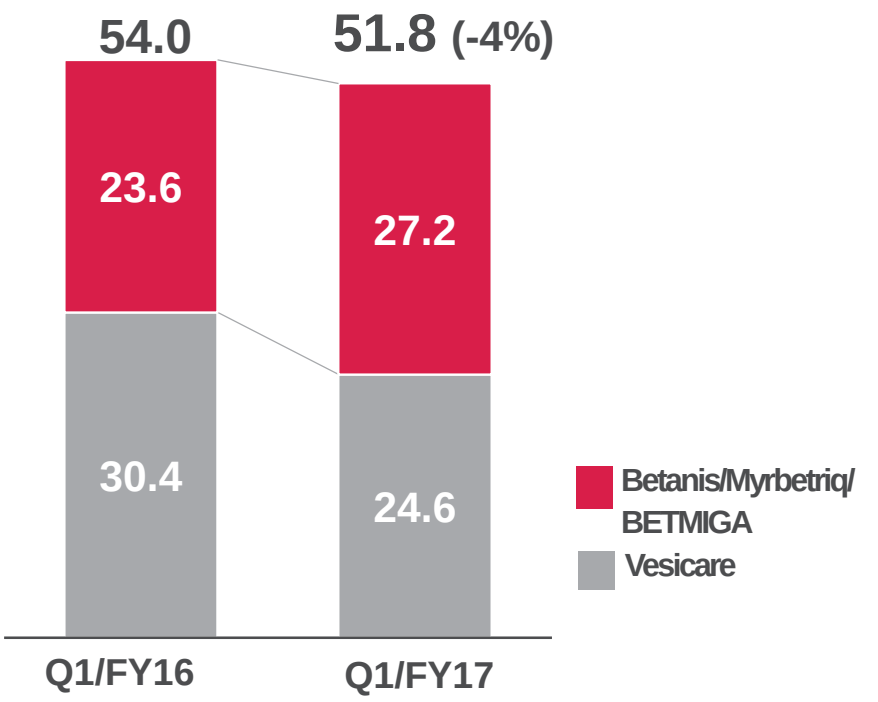
# OAB FRANCHISE IN UROLOGY



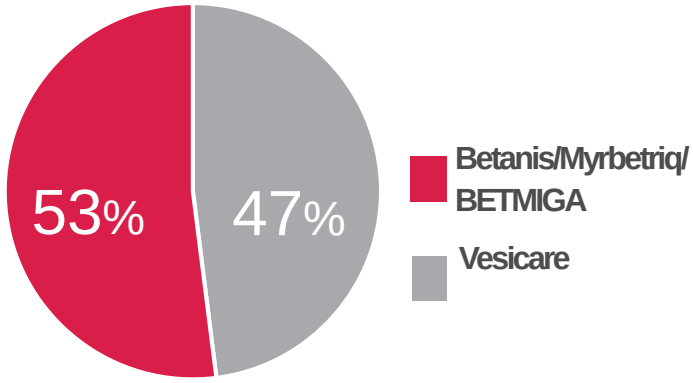
## Betanis/Myrbetriq/BETMIGA showed steady sales

### 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

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# 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.

*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*


**ASP6981**
Cognitive impairment associated with schizophrenia

**MA-0211**
Duchenne muscular dystrophy

**ASP5094**
Rheumatoid arthritis

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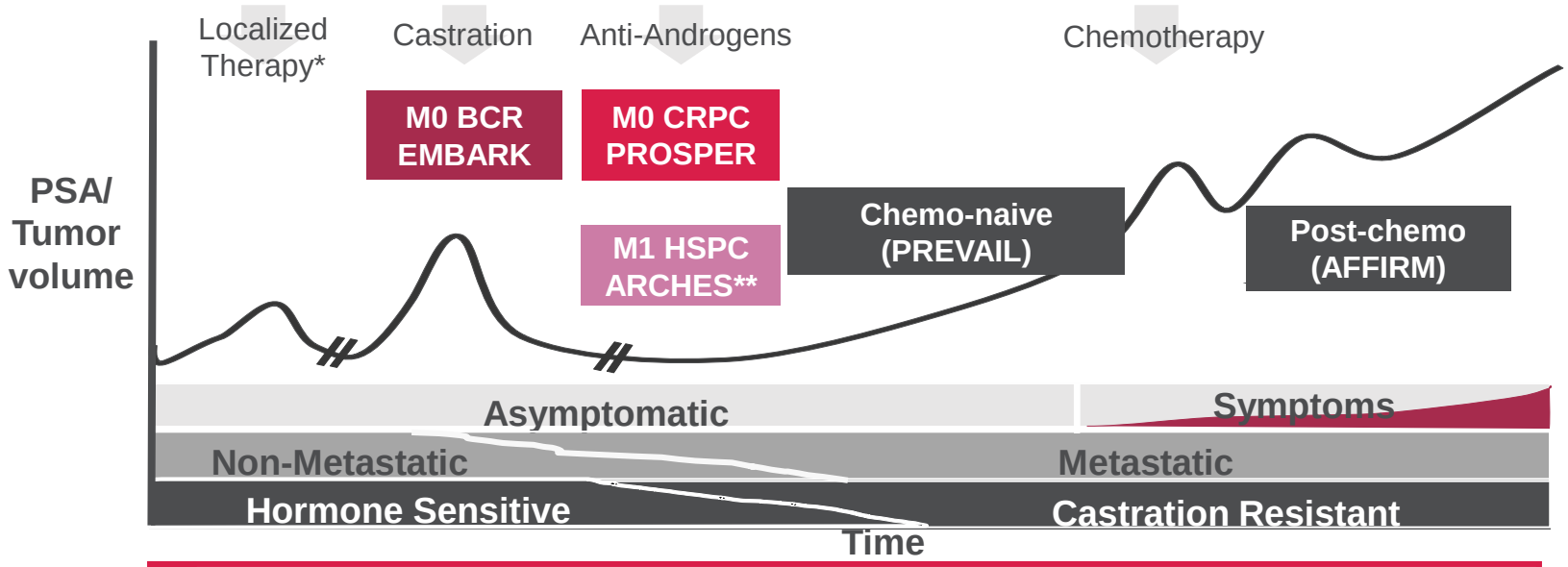
Note: Phase transition is defined by company decision.
ER/PR: Estrogen/progesterone, IDMC: Independent data monitoring committee

# ENZALUTAMIDE: MAXIMIZE THE VALUE FOR PROSTATE CANCER PATIENTS



*Data readout of PROSPER study is planned in 2017.*

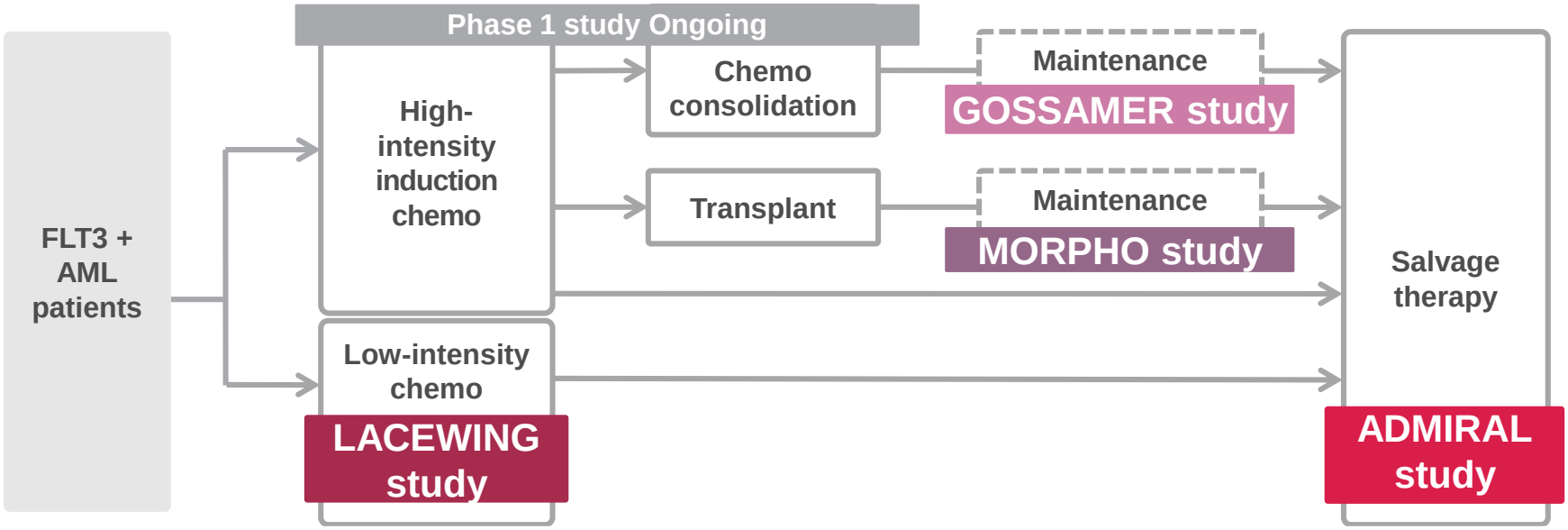



| | | | | |
|---|---|---|---|---|
| | PROSPER study P3 | M0 CRPC Non-metastatic CRPC | Placebo-controlled, combination with ADT, n=1,440 | Enrollment completed Jun 2017 |
| | EMBARK study P3 | M0 BCR Non-metastatic prostate cancer, biochemical recurrence | To compare with ADT and combination, n=1,860 | 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 |

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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

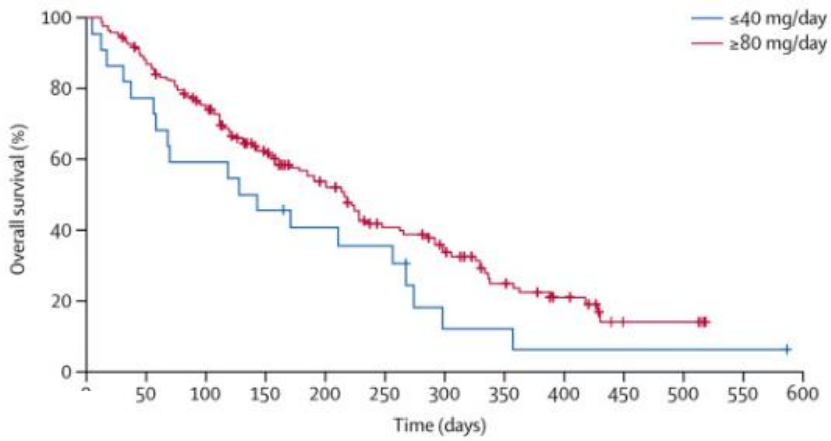


*The Lancet Oncology publishes anti-leukemic activity and safety data from Phase 1/2 CHRYSALIS study*

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

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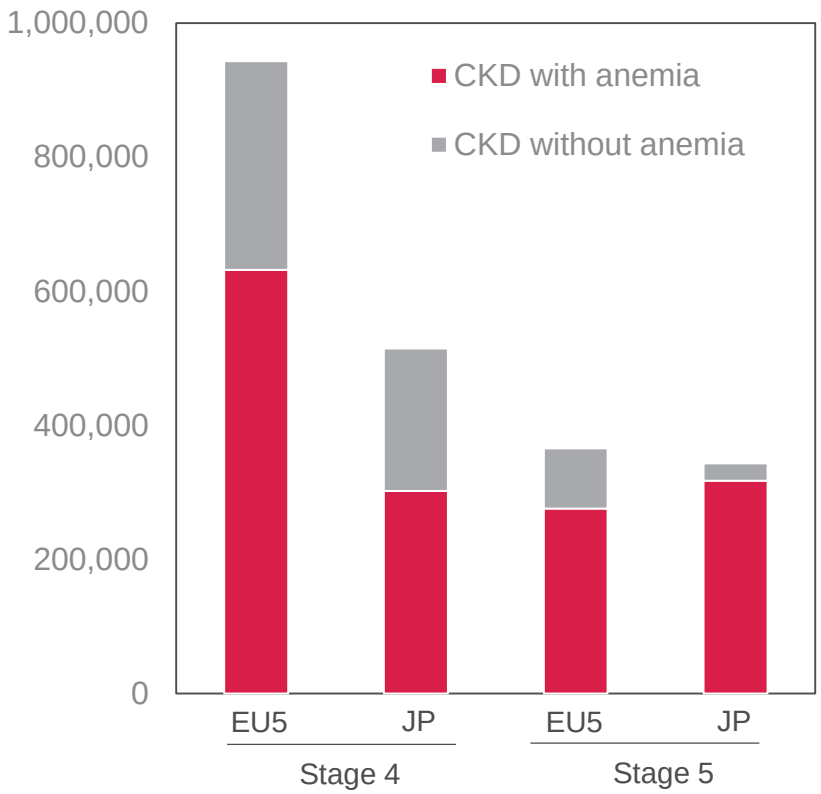
Note: Company logo in the table shows the sponsor of studies
HD: Hemodialysis, PD: Peritoneal dialysis, ESA: Erythropoietin stimulation agents

# 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

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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

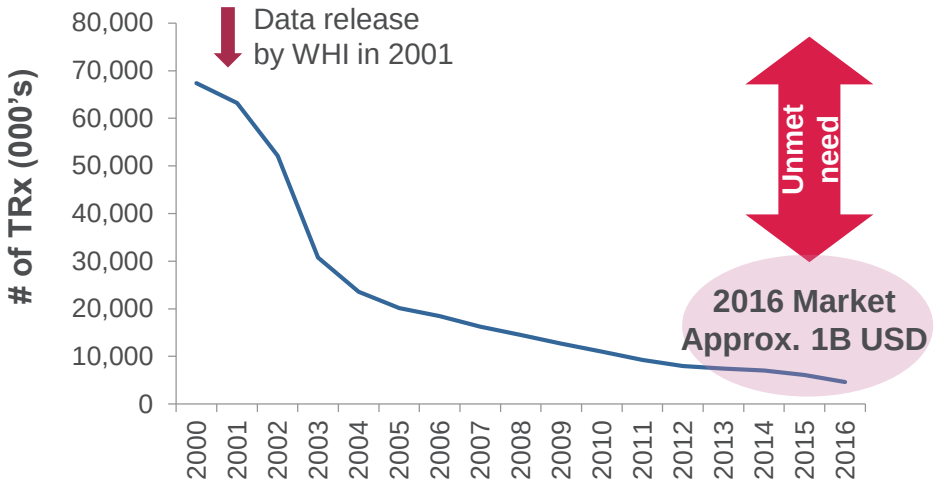
*A safe non-hormonal drug has been awaited by patients with VMS*

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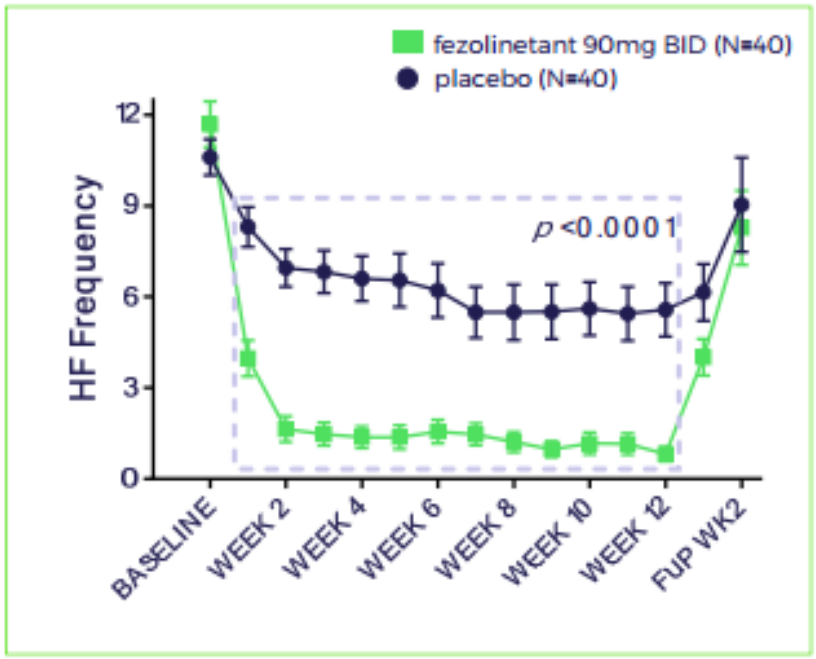
*1: Up to Date (Literature review current through: June 2017), *2:Data Source: IMS NPA (2000-2016), IMS NSP (2000-2016). (3 HTs and SSRI) NAMS 2015 Position Statement., *3: JAMA 2013 Oct 2; 210(13): 1353-1368, MR-VMS: Menopause related vasomotor symptoms, HRT: Hormone replacement therapy, TRx: Total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

# FEZOLINETANT: POC STUDY IN MR-VMS



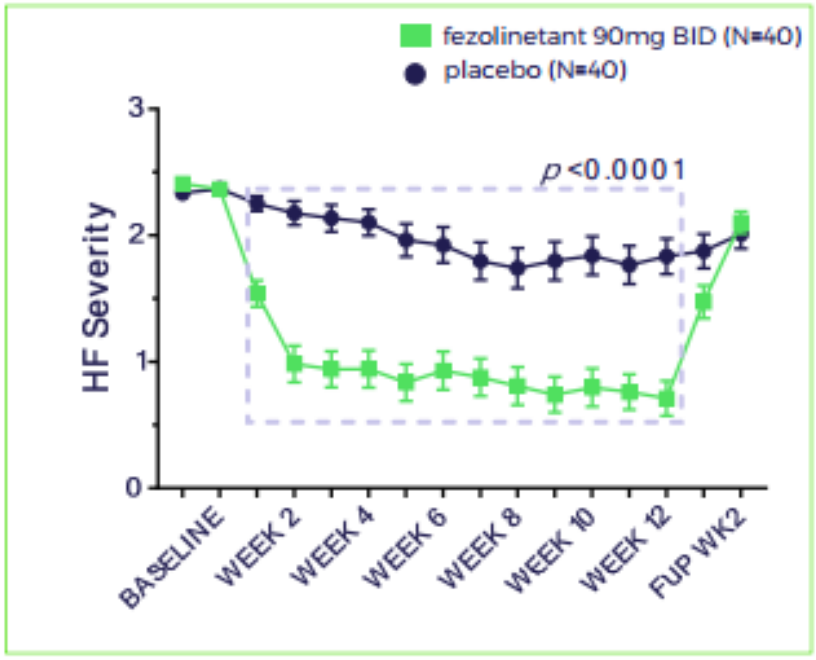
*Robust data in terms of improvement in the frequency and extent of hot flashes*

## 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

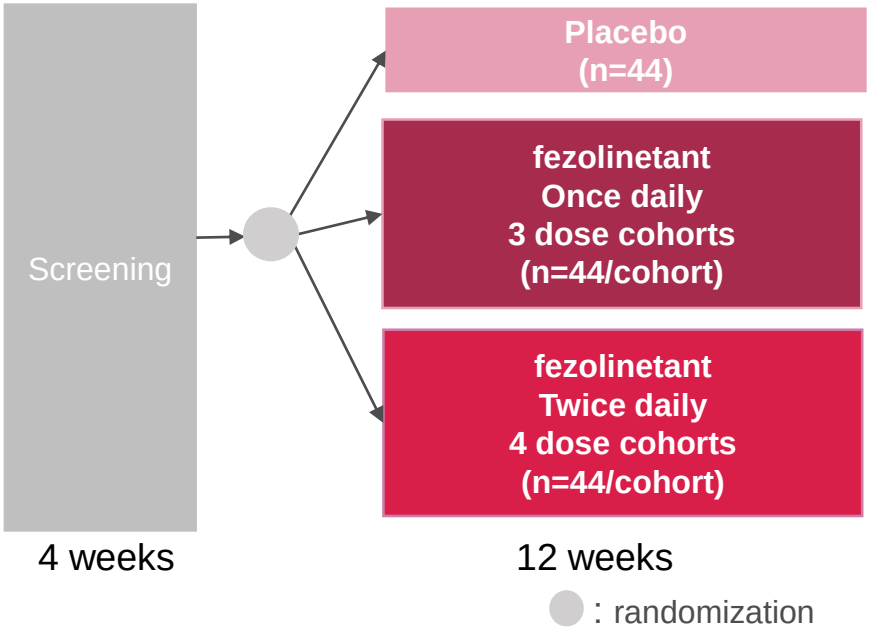


*First Patient is expected soon*

## 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) ONCE-DAILY
- OAB franchise
  - VESIcare (solifenacin succinate) 5 mg, 10mg tablets
  - 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

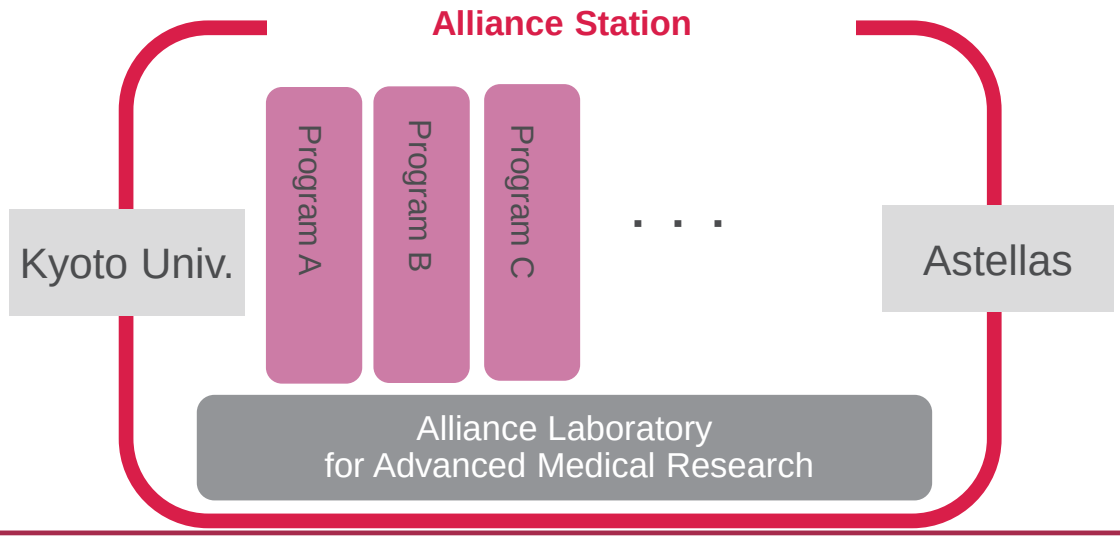
## NEW INITIATIVES

# 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*

東京大学
医科学研究所
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

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

Action on Fistula

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# AGENDA



I Q1/FY2017 Financial Results

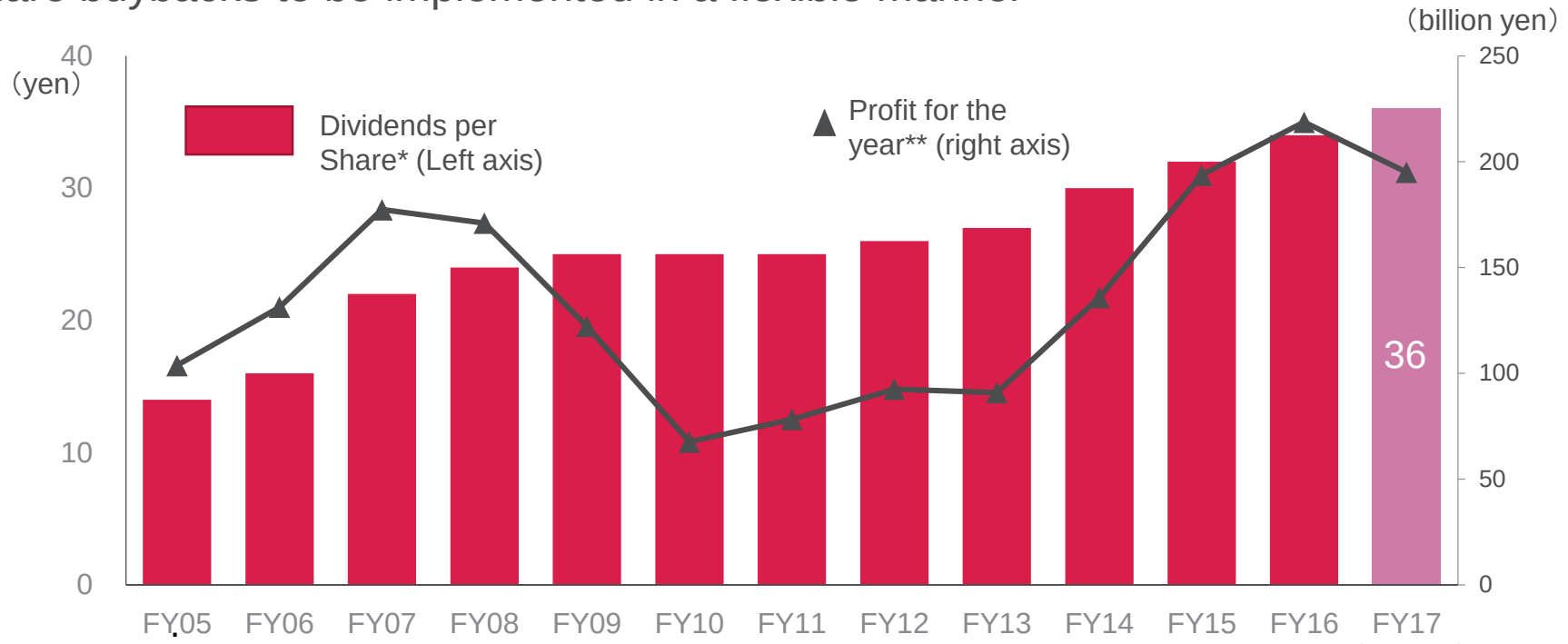
II Initiatives to Build Resilience for Sustainable Growth

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



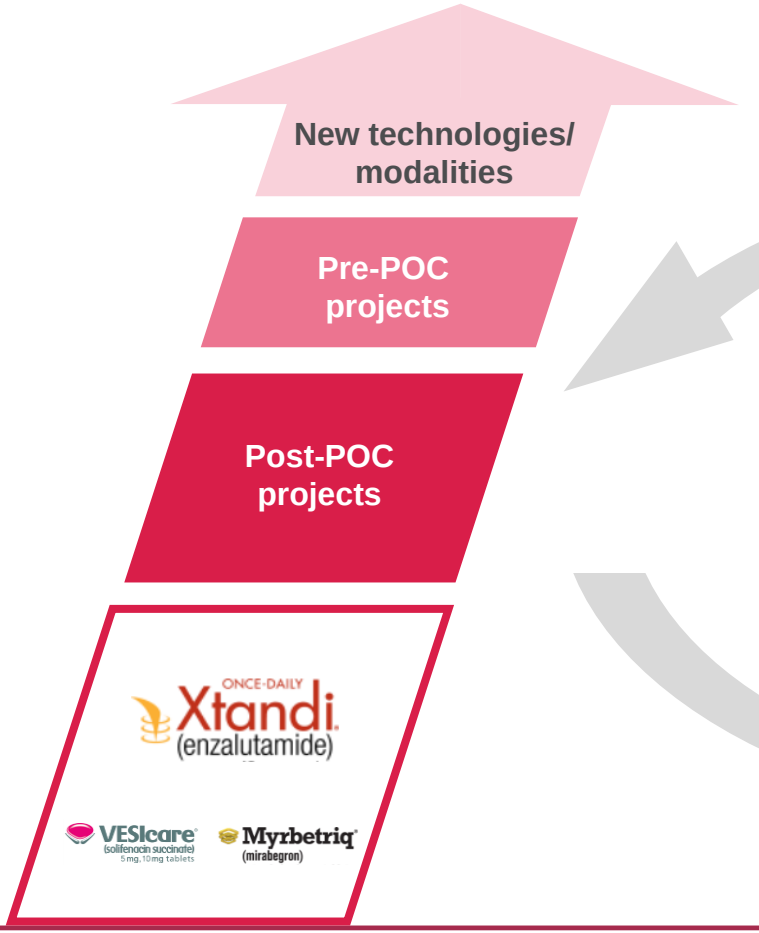

| (billion yen) | FY05 | FY06 | FY07 | FY08 | FY09 | FY10 | FY11 | FY12 | FY13 | FY14 | FY15 | FY16 | FY17 (Forecast) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total dividends | 39.3 | 42.3 | 55.2 | 56.9 | 58.2 | 57.7 | 57.7 | 59.4 | 60.6 | 66.0 | 68.5 | 71.3 | 74.4 |
| Acquisition 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*





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<br>119.3 billion yen | 60 million shares<br>91.4 billion yen | - |
| Treasury stock cancellation | 38 million shares | 68 million shares | 85 million shares |

# ON THE FOREFRONT OF HEALTHCARE CHANGE