# FY2016 FINANCIAL RESULTS
## ENDED MARCH 31, 2017




**Yoshihiko Hatanaka**
**President and CEO**
**Astellas Pharma Inc.**
**April 27, 2017**

# CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION



In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

# AGENDA



I Full Year FY2016 Highlights

II FY2016 Financial Results and FY2017 Forecasts

III Initiatives to Build Resilience for Sustainable Growth

IV Profit Distribution Policy

# FULL YEAR FY2016 HIGHLIGHTS



*Achieved performance forecasts and steadily progressed strategic initiatives*

## Financial Update

Y-on-Y increase in earnings, in spite of decrease in sales due to Fx impact

- Net sales: -4.4%
- Core operating profit: +2.7%
- Core net profit: +7.3%

Increase in sales and profit excluding impacts from Fx and dermatology business transfer

- Net sales: +2%
- Core operating profit: +9%

ROE: 17.3%

## Strategic Initiatives

Maximize the Product Value

- Sales expansion of XTANDI
- Maximizing OAB franchise
- Launches in Japan (Repatha and LINZESS)

Create Innovation

- Enhance oncology franchise and expand Astellas' pipeline
  - Acquisition of Ganymed Pharmaceuticals
  - Acquisition of Ogeda SA*
- Achieved many milestones in development

Pursue Operational Excellence

- Optimize resource allocation
  - Transfer of US manufacturing subsidiary
  - Transfer of 16 long-listed products in Japan

Create Social Value

- Initiatives for Access to Health

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ROE: Return on equity attributable to owners of the parent
OAB: Overactive bladder

*Transaction announced; completion pending

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# FY2016 FINANCIAL RESULTS (CORE BASIS)



*Core OP and net profit increased, while net sales decreased due to Fx impacts*

| (billion yen) | FY15 | FY16 | Change | FY16 FCST* | Achieve-ment | Excl impacts from Fx and business transfer |
|---|---|---|---|---|---|---|
| **Net sales** | **1,372.7** | **1,311.7** | **-4.4%** | **1,300.0** | **100.9%** | +2% |
| Cost of sales | 335.6 | 320.5 | -4.5% | | | |
| % of sales | 24.4% | 24.4% | -0.0ppt | | | |
| SG&A expenses | 500.4 | 470.8 | -5.9% | | | |
| % of sales | 36.5% | 35.9% | -0.6ppt | | | |
| R&D expenses | 225.7 | 208.1 | -7.8% | 216.0 | 96.4% | |
| % of sales | 16.4% | 15.9 | -0.6ppt | 16.6% | | |
| Amortisation of intangible | 42.4 | 35.8 | -15.5% | | | |
| Share of associates/JVs losses | -1.2 | -1.9 | - | | | |
| **Core operating profit** | **267.5** | **274.6** | **+2.7%** | **274.0** | **100.2%** | +9% |
| **Core profit for the year** | **198.8** | **213.3** | **+7.3%** | **202.0** | **105.6%** | |
| **Core EPS (yen)** | **92.12** | **101.15** | **+9.8%** | **95.60** | **105.8%** | |

| | | |
|---|---|---|
| USD: Average for the year | FY15:120yen | FY16: 108yen (-12yen) /FY16FCST:103yen |
| Change from PY end | FY15: -7yen | FY16: -0yen |
| EUR: Average for the year | FY15: 133yen | FY16: 119yen (-14yen) /FY16FCST:117yen |
| Change from PY end | FY15: -3yen | FY16: -8yen |

| **Fx impacts** | | |
|---|---|---|
| | Net Sales: | -94.7 |
| | Core OP: | -36.3 |

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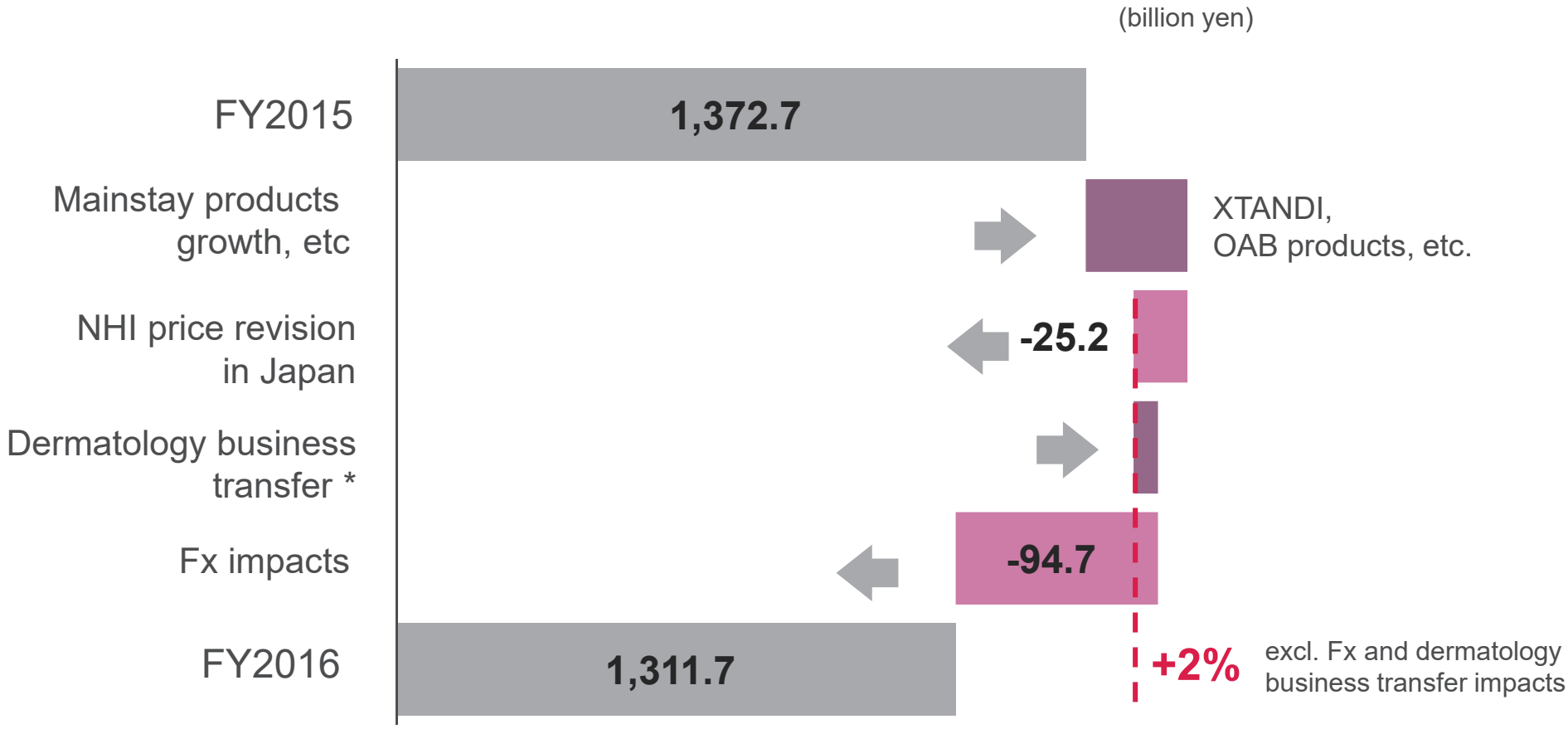
*Revised in Oct.2016

# FY2016 SALES ANALYSIS VS PY



*2% growth excl. impacts from Fx and dermatology business transfer*



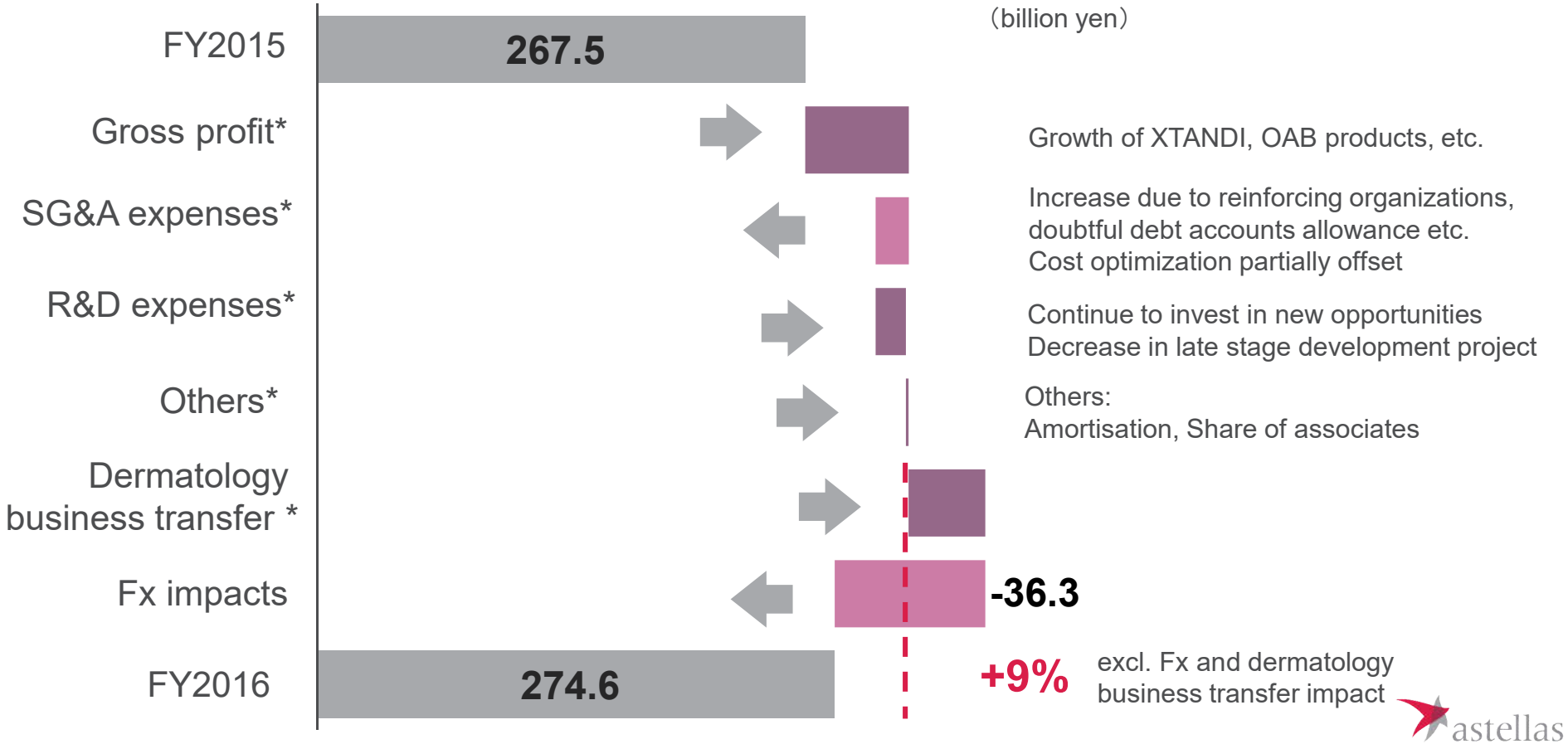

*Dermatology business transfer: Amortisation of deferred revenue – PY sales of transferred products

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

# FY2016 CORE OP ANALYSIS VS PY



*9% growth excl. impacts from Fx and dermatology business transfer*




*Fx impacts excluded from each item

Dermatology business transfer: Amortisation of deferred revenue – PY profit from transferred products

# FY2016 FINANCIAL RESULTS (FULL BASIS)



*Increase in operating profit and profit for the year*

| (billion yen) | FY2015 | FY2016 | Change | FU2016 FCST* | Achieve-ment |
|---|---|---|---|---|---|
| **Core operating profit** | **267.5** | **274.6** | **+2.7%** | **274.0** | **100.2%** |
| Other income | 1.7 | 9.6 | +467.9% | | |
| Other expenses | 20.2 | 23.3 | +15.7% | | |
| **Operating profit** | **249.0** | **260.8** | **+4.8%** | **267.0** | **97.7%** |
| Financial income | 14.4 | 22.9 | +59.0% | | |
| Financial loss | 1.6 | 2.0 | +21.5% | | |
| Profit before tax | 261.8 | 281.8 | +7.6% | 268.0 | 105.1% |
| **Profit for the year** | **193.7** | **218.7** | **+12.9%** | **198.0** | **110.5%** |
| **EPS (yen)** | **89.75** | **103.69** | **+15.5%** | **93.71** | **110.6%** |

FY2016 Other income: Fx gain (6.9 bil.yen)
FY2016 Other expenses: Loss on sale and disposal of PP&E (7.9 bil.yen),
Impairment loss of other intangible assets (10.2 bil.yen), etc.
FY2016 Financial income: Gain on sale of financial assets (21.3 bil.yen)

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*Revised in Oct. 2016

# SALES IN THREE KEY AREAS



*Each franchise showed solid performance on a CER basis*

| (billion yen) | FY15 | FY16 | Change | CER growth |
|---|---|---|---|---|
| **Oncology** | **320.3** | **307.7** | **-4%** | **+6%** |
| XTANDI | 252.1 | 252.1 | +0% | +10% |
| **OAB in Urology** | **217.4** | **214.9** | **-1%** | **+7%** |
| Vesicare | 135.6 | 116.1 | -14% | -7% |
| Betanis/Myrbetriq/BETMIGA | 81.7 | 98.8 | +21% | +31% |
| **Transplantation** | **203.6** | **186.2** | **-9%** | **-0%** |

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

CER: Constant exchange rate

# OTHER KEY GROWTH DRIVERS



*Focus on growing/new local products in addition to global products*

**Japan**

Suglat®

Symbicort

CELECOX

cimzia (certolizumab pegol)

Sales of 4 products:
104.0 bil.yen (+6.3 bil.yen)

Repatha (evolocumab) injection 140 mg/mL

Launched in
Apr. 2016

Linzess (linaclotide) capsules

Launched in
Mar. 2017

**Americas**

Lexiscan (regadenoson) injection

CRESEMBA (isavuconazonium sulfate) 372 mg for injection · 186 mg capsules

Sales of 2 products:
$713M (+$57M)

# FY2017 FORECASTS：SUMMARY



- ✓ **Net sales**
  - ➢ XTANDI & OAB franchise to continue growth on a global basis. Prograf to show steady progress.
  - ➢ Micardis-family to decrease due to patent expiry
  - ➢ Negative impact on sales of dermatology business transfer and long-listed drug business transfer
- ✓ **Continue to invest in R&D and business development to create innovation for future growth**
  - ➢ R&D expenses ratio to sales 17%
- ✓ **Pursue operational excellence through optimal resource allocation and continuously enhancing organization structure**
- ✓ **Lower Fx impact is anticipated: USD 110 yen, Euro 120 yen**
- ✓ **Dividends per share：forecasted 2 yen increase to 36 yen**

# FY2017 FORECASTS



*OP to grow adjusting business transfers and Fx, while net sales and OP to decrease*

| (billion yen) | FY2016 ACT | FY2017 FCST | Change |
|---|---|---|---|
| **Net sales** | **1,311.7** | **1,279.0** | **-2.5%** |
| R&D expenses | 208.1 | 218.0 | +4.7% |
| as % of sales | 15.9% | 17.0% | +1.1ppt |
| **Core operating profit** | **274.6** | **254.0** | **-7.5%** |
| **Core profit for the year** | **213.3** | **195.0** | **-8.6%** |
| **Core EPS (yen)** | **101.15** | **94.43** | **-6.6%** |
| **Operating profit** | **260.8** | **254.0** | **-2.6%** |
| **Profit for the year** | **218.7** | **198.0** | **-9.5%** |
| **EPS (yen)** | **103.69** | **95.88** | **-7.5%** |

| Exchange rate | FY2016 ACT | FY2017 FCST | Change |
|---|---|---|---|
| USD: Average for the year | 108yen | 110yen | +2yen |
| EUR: Average for the year | 119yen | 120yen | +1yen |
| USD: Change from PY end | -0yen | -2yen | |
| EUR: Change from PY end | -8yen | +0yen | |

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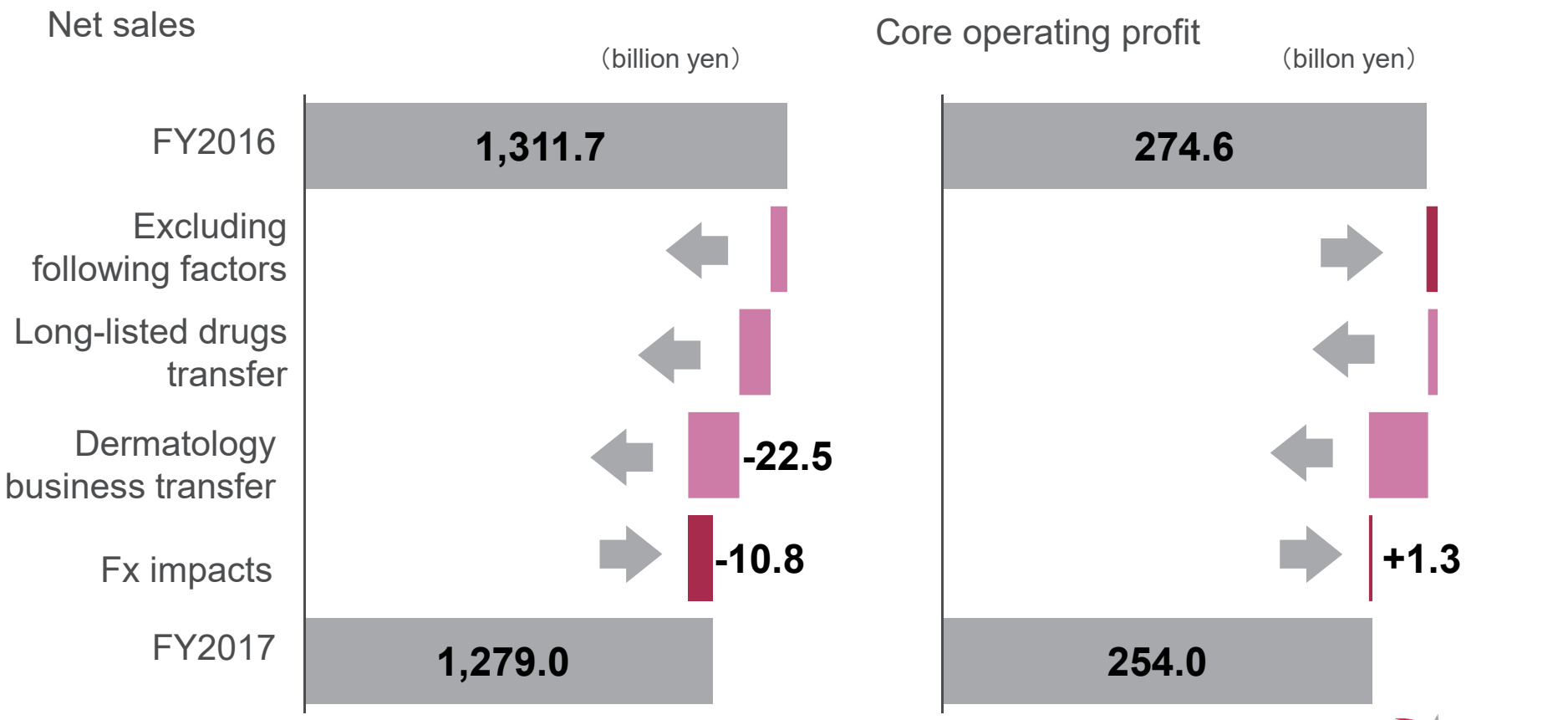
# FY2017 FCST：NET SALES/OPERATING PROFIT



*OP to grow adjusting business transfer and Fx*




Long-listed drugs transfer: Amortisation of deferred revenue for this year - PY sales (profit) of transferred products

Dermatology business transfer: Amortisation of deferred revenue for this year - PY amortisation of deferred revenue

# FY2017 FCST: SALES IN 3 KEY AREAS



*Continued growth of Oncology and OAB franchise*

| (billion yen) | FY16 | FY17 | Change | CER growth |
|---|---|---|---|---|
| **Oncology** | **307.7** | - * | — | - |
| XTANDI | 252.1 | 277.7 | +10% | +9% |
| **OAB in Urology** | **214.9** | **237.4** | **+10%** | **+9%** |
| Vesicare | 116.1 | 114.6 | -1% | -2% |
| Betanis/Myrbetriq/BETMIGA | 98.8 | 122.8 | +24% | +23% |
| **Transplantation** | **186.2** | **186.7** | **+0%** | **+0%** |

*Not disclosed due to agreement with some partners

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



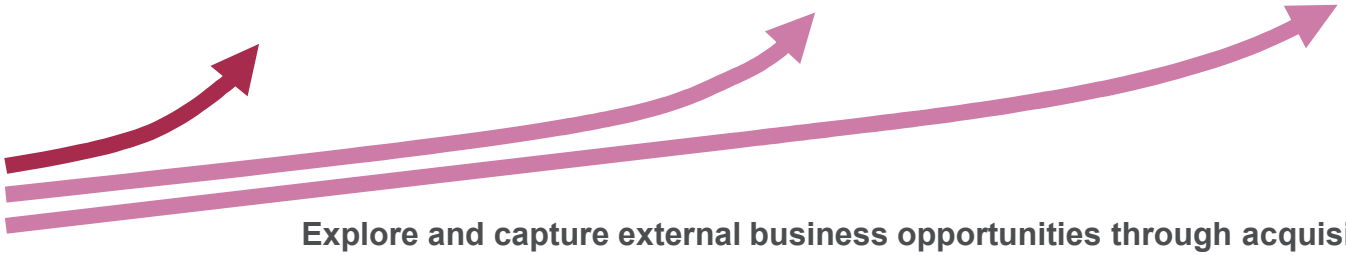
*New products will drive mid-term growth;*
*Sustainable growth will be reinforced by continuous selective investment in innovation and strengthening of the business foundation*

**Maximizing the Product Value**

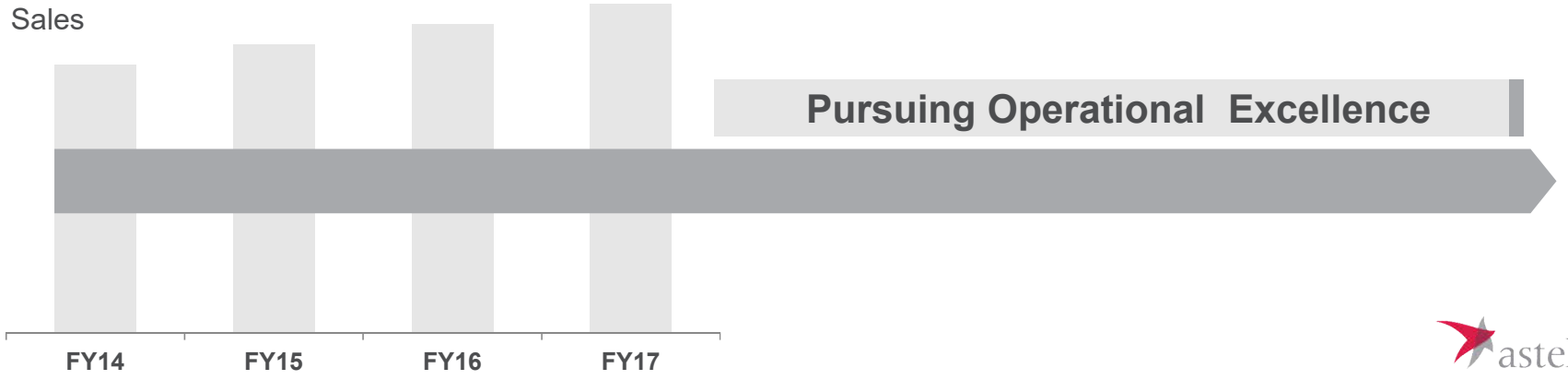
**Creating Innovation**

**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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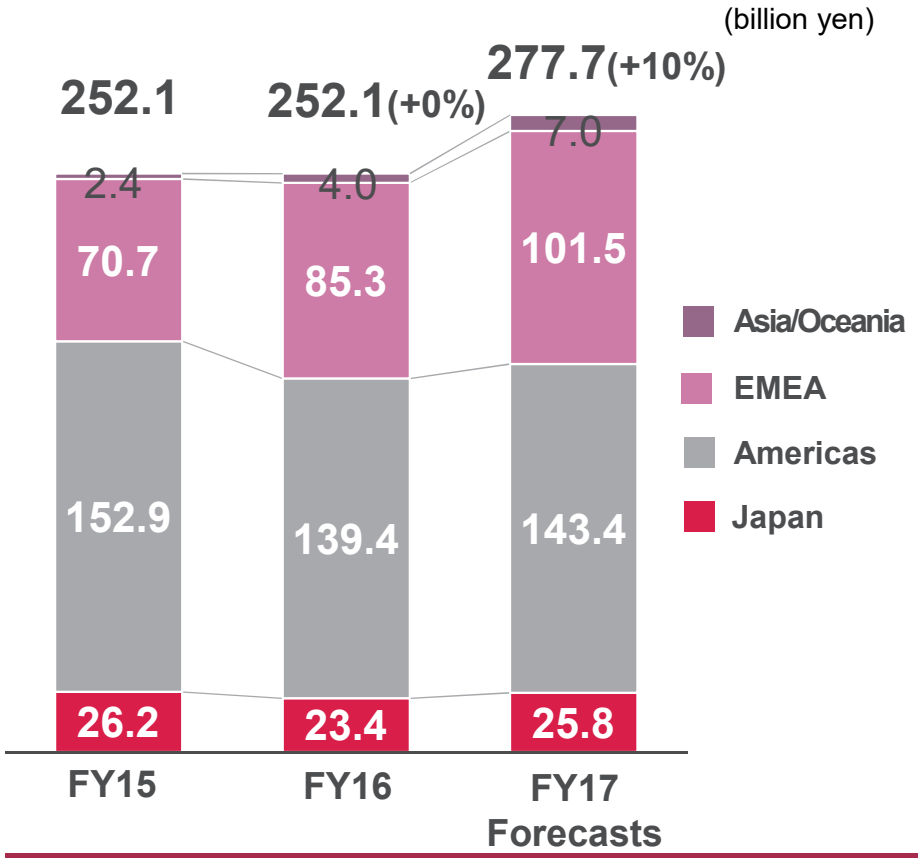
# XTANDI



*Pursue further penetration in chemo-naive mCRPC*

**Sales by region**



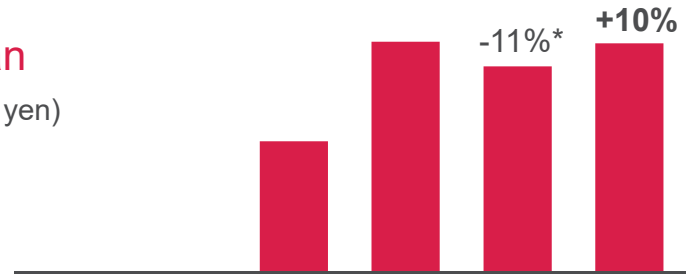

- Further penetration in earlier treatment within the current indications
  - ➢ Solid evidence obtained in clinical trials
  - ➢ Cooperation with Pfizer in the US
- Expansion to new markets
  - ➢ Launched in >70 countries
  - ➢ NDA filed in China for chemo-naive indication in Mar. 2017

mCRPC: Metastatic castration-resistant prostate cancer

*Growth in ex-US market such as EMEA drives profit growth*

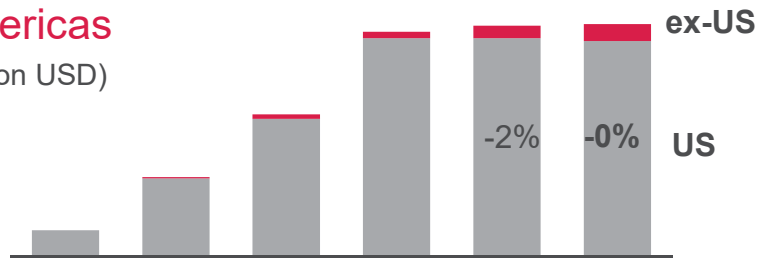
## Sales since launch by region

Japan
(billion yen)

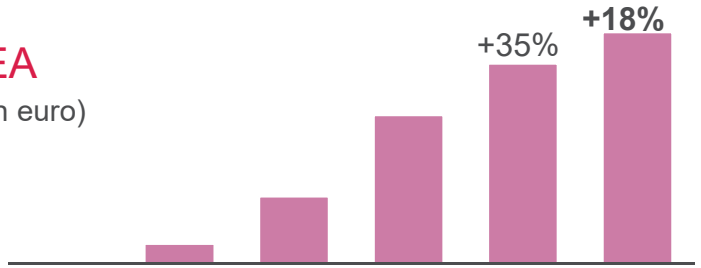



*+19% excl. NHI drug price cut impacts

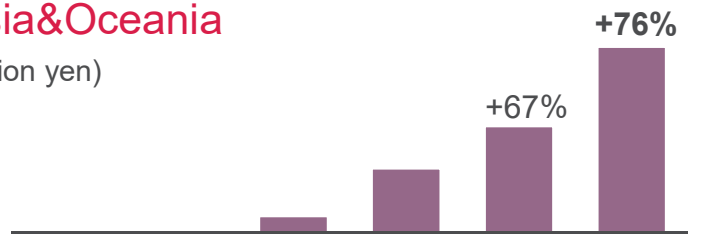
Americas
(million USD)




EMEA
(million euro)




Asia&Oceania
(billion yen)




## Sales composition by region (FY2017 Forecasts on JPY basis)

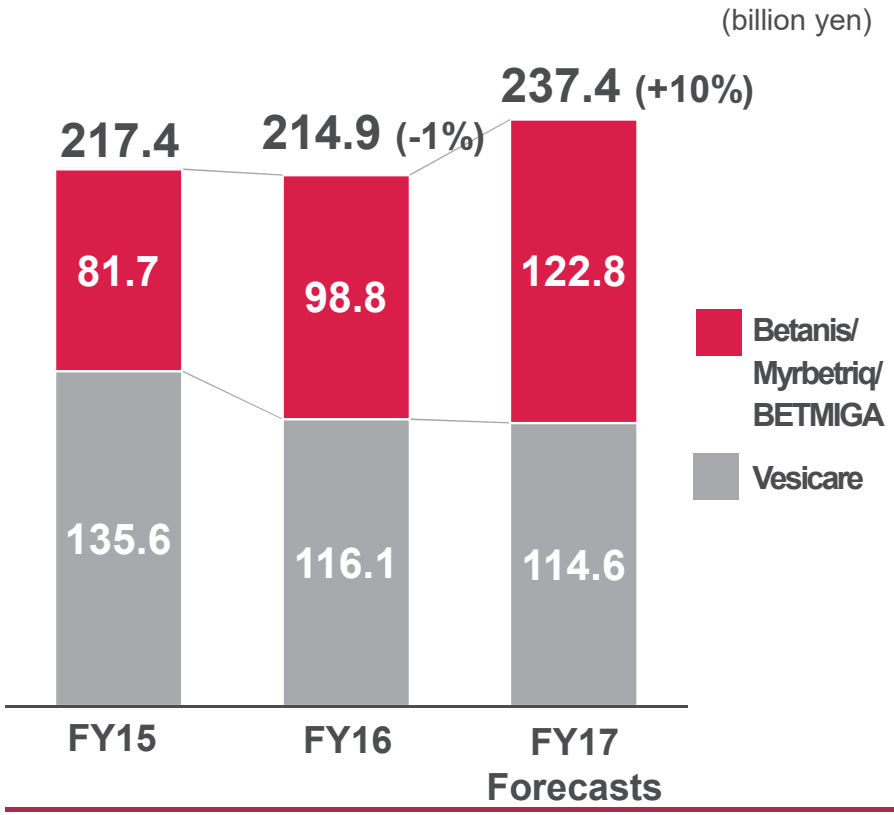
**US : ex-US = 48% : 52%**

# OAB FRANCHISE IN UROLOGY

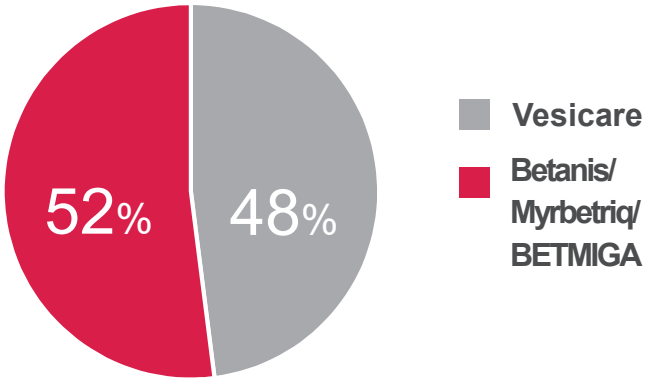


*Betanis/Myrbetriq/BETMIGA growth enhances OAB Franchise*

## Sales by products




## Sales composition ratio by product




### Year on Year sales growth（FY16 vs FY17)

**Japan**: +10%
**Americas**: +10% (USD basis)
**EMEA**: +5% (EUR basis)
**Asia/Oceania**: +26% (CER basis)

# LAUNCH OF LINZESS



*Provides a new therapeutic option for patients suffering from IBS-C*

## Launch of LINZESS

### Indication

Irritable bowel syndrome with predominant constipation (IBS-C)

### Launched on

March 22, 2017




## IBS-C and LINZESS

### IBS-C

-2.9% of adults are estimated to suffer from IBS-C in Japan*

-First treatment approved for the indication of IBS-C in Japan

### LINZESS

-LINZESS locally binds to the guanylate cyclase-C (GC-C) receptor expressed on the intestinal epithelium.

-Activation of the GC-C receptor results in improved visceral hypersensitivity, increased intestinal fluid secretion and accelerated intestinal transit.

Ironwood

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*Kubo *et al., Neurogastroenterol Motil.* 2011;23:249-54

# CREATE INNOVATION

## PIPELINE

# STEADY PROGRESS IN DEVELOPMENT
## SUMMARY OF CHANGES FROM JANUARY 2017 TO APRIL 2017



*Three new P2 entries since January 2017*




**ASP7713**
Underactive bladder

**enfortumab vedotin**
Urothelial cancer (JP)

**ASP6294**
Bladder pain syndrome/
Interstitial cystitis

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

**CK-2127107**
Amyotrophic lateral sclerosis

**solifenacin**

Filed in Feb. 2017 in US,
Filed in Apr. 2017 in EU
Neurogenic detrusor overactivity
in pediatric patients

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Note: Phase transition is defined by company decision.

# ROBUST PIPELINE OF ASTELLAS



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

## Phase 1

- ASG-15ME
- ASP5878
- AGS67E
- ASP4132
- AGS62P1
- ASP6282
- ASP7398
- ASP8302
- ASP7713
- ASP5094
- ASP4345
- ASP7266
- ASP0892
- ASP1807/CC8464

## Phase 2

- enzalutamide (BC, 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)
- ASP3662 (Agitation associated with AD)
- ASP4070 (Pollinosis caused by Japanese red cedar)
- ASP1707 (Rheumatoid arthritis etc.)
- CK-2127107 (SMA, COPD, ALS)
- 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)
- naquotinib (ASP8273) (NSCLC, US/EU/JP/Asia)
- solifenacin/mirabegron (Concomitant use, US/EU/Asia)
- mirabegron (Pediatric NDO, EU)
- roxadustat (ASP1517/FG-4592) (Anemia associated with CKD, EU/JP)
- ASP0113/VCL-CB01 (CMV-HCT, US/EU/JP)
- peficitinib (ASP015K) (Rheumatoid arthritis, JP/Asia)
- fidaxomicin (Infectious enteritis: JP, pediatric: EU)
- ipragliflozin/sitagliptin (Fixed dose combination, JP)
- ipragliflozin (Type 1 diabetes, JP)
- linaclotide (Chronic constipation, JP)

## Filed

- enzalutamide (Tablet, EU/JP)
- solifenacin (Pediatric NDO, US/EU)
- quetiapine (BP-D, JP)
- romosozumab (AMG 785) (Osteoporosis, 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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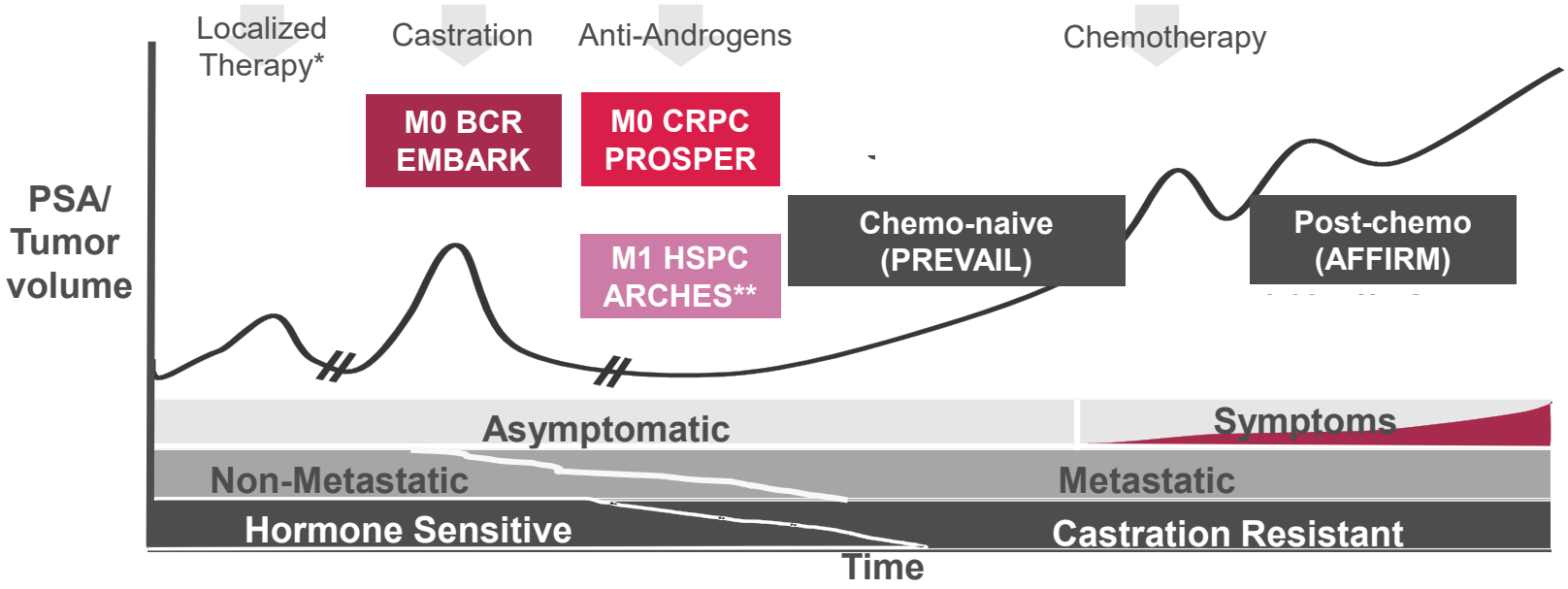
BC: Breast cancer, HCC: Hepatocellular carcinoma, BPS/IC: Bladder pain syndrome/Interstitial cystitis, rFSGS: Recurrence of focal segmental glomerulosclerosis, AD: Alzheimer's disease, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, ALS: Amyotrophic lateral sclerosis, RPE: 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, TNBC: Triple-negative breast cancer, AML: Acute myeloid leukemia, NSCLC: Non-small cell lung cancer, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, CMV: Cytomegalovirus, HCT: Hematopoietic cell transplant, BP-D: Bipolar disorder depressive episodes,

# ENZALUTAMIDE: MAXIMIZE THE VALUE FOR PROSTATE CANCER PATIENTS



*Steady progress in three P3 studies*




| | | | | |
|---|---|---|---|---|
| | PROSPER study P3 | M0 CRPC Non-metastatic CRPC | Placebo-controlled, combination with ADT, n=1,500 | First Patient In: Nov. 2013 |
| | 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

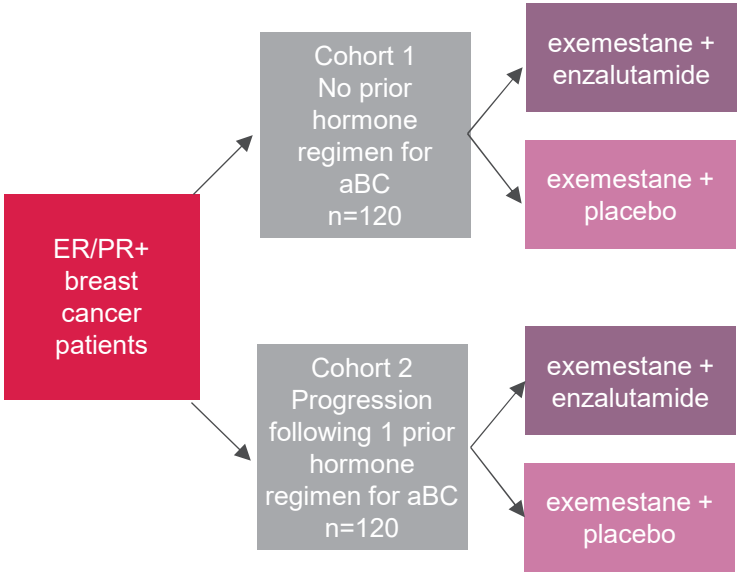
PSA: Prostate-specific antigen

# ENZALUTAMIDE: TOP LINE RESULTS IN P2 STUDY FOR ER/PR+ BREAST CANCER PATIENTS



*Further assessment ongoing to determine next steps*

## Study design




Co-primary endpoints
1) PFS in ITT in each cohort
2) PFS in Biomarker+ population in each cohort

## Top line results

### Efficacy

- The study did not meet its primary endpoint in the ITT population for either cohort.
- The study met its primary endpoint in the Biomarker+ cohort 1 group.
- There was a positive trend in Biomarker+ cohort 2.

### Safety

- No unexpected safety findings were observed.

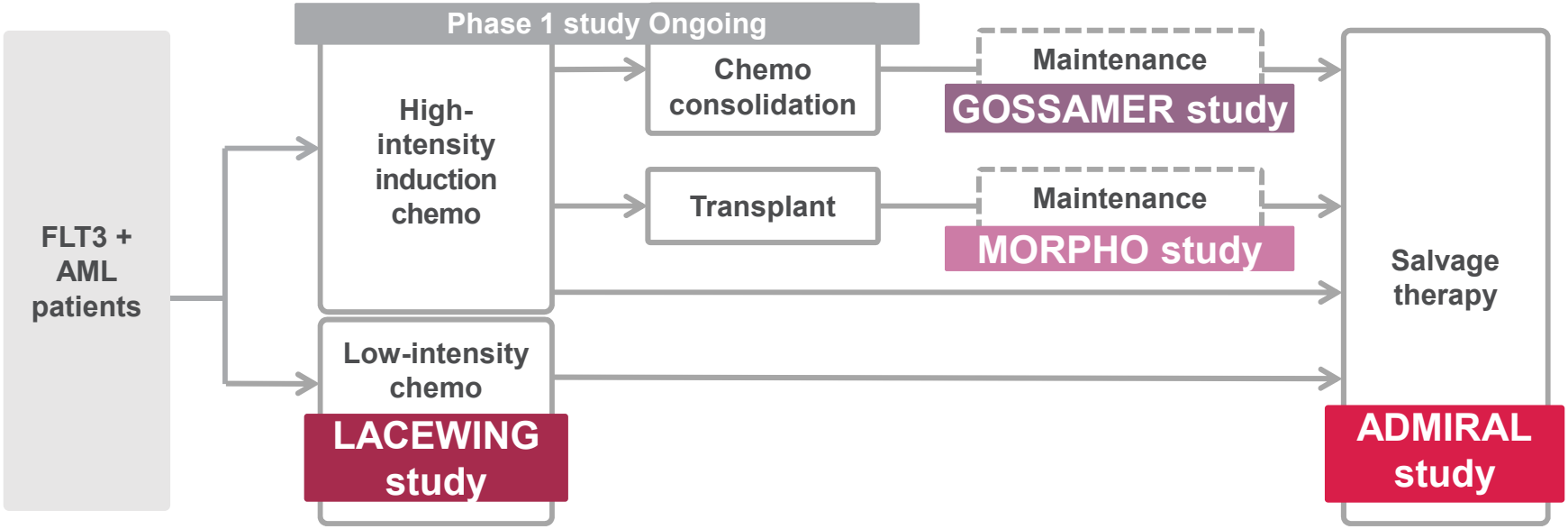
### Plan

- Conducting further assessment to discuss next steps.
- Detail results to be presented at future scientific meetings.

ER/PR+: Estrogen/progesterone positive, aBC: Advanced breast cancer, ITT: Intent to treat

# GILTERITINIB: TREATMENT LANDSCAPE IN AML

*Clinical program evaluating potential across treatment paradigm*




| | | | |
|---|---|---|---|
| **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 |
| **MORPHO study P3** | **HSCT maintenance** FLT3-ITD positive | Double-blind, randomized, monotherapy vs placebo (1:1), n=346 | Under preparation Collaborating with BMT-CTN |
| **GOSSAMER study P3** | **Post-chemo maintenance** FLT3-ITD positive | Double-blind, randomized, monotherapy vs placebo (2:1), n=354 | First Patient In: Apr. 2017 |

AML: Acute myeloid leukemia, HSCT: Hematopoietic Stem Cell Transplant, BMT-CTN: Blood and Marrow Transplant – Clinical Trial Network

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



*4 studies completed enrollment, with data expected from 3 of them (ALPS, 2 Japanese studies) within a year*

| | 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** |
| | PYRENEES: astellas<br>Stable dialysis,<br>vs epoetin alfa or darbepoetin<br>**Enrollment completed** | FIBROGEN<br>ANDES, vs placebo |
| **Japan** astellas | HD: Conversion, vs darbepoetin | Conversion, vs darbepoetin |
| | HD: Conversion, long-term<br>**Enrollment completed** | |
| | HD: Correction | Correction |
| | PD<br>**Enrollment completed** | |

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HD: Hemodialysis, PD: Peritoneal dialysis
Note: Company logo in the table shows the sponsor of studies.

# ADVANCEMENT IN NEW THERAPEUTIC AREAS/MODALITIES

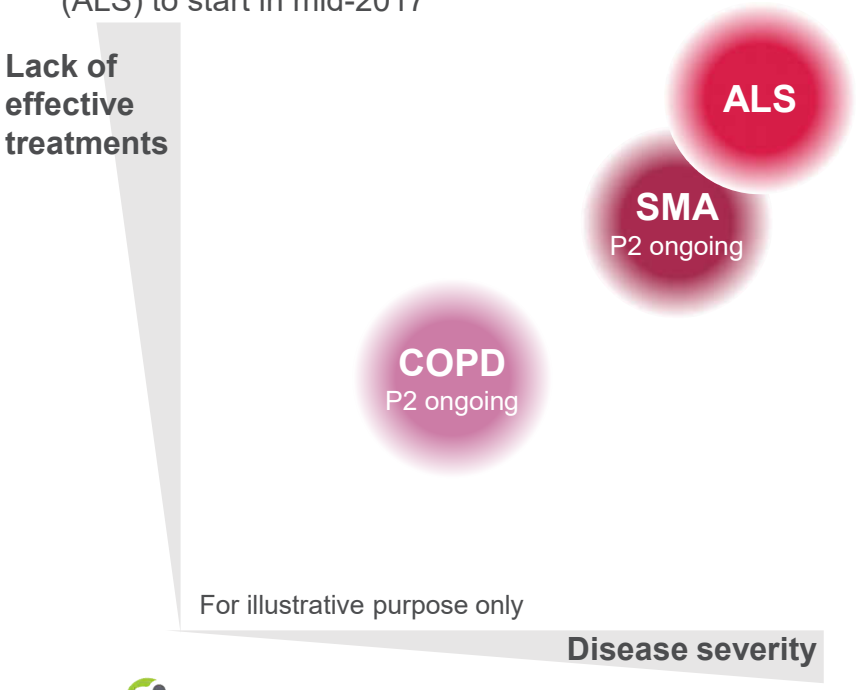


*Making progress in muscle diseases and next-generation vaccines platform*

## Muscle Diseases

CK-2127107

New Phase 2 study in amyotrophic lateral sclerosis (ALS) to start in mid-2017



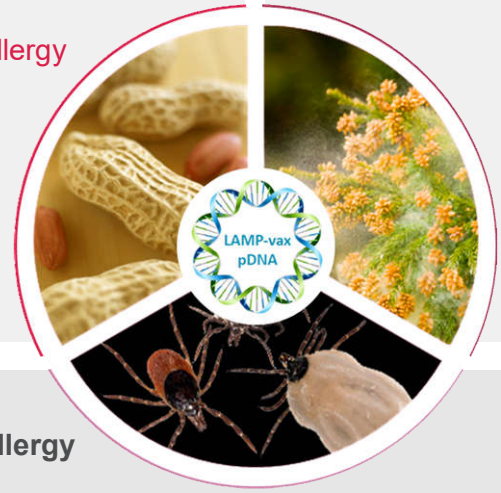

## Next Generation Vaccines

Versatile LAMP-vax platform

New Phase 2 study for ASP4070 to start in 2Q/2017

**Food allergy**
ASP0892
for peanut allergy
FDA granted FAST-Track Designation
P1 ongoing

**Seasonal pollen allergy**
ASP4070
for pollinosis caused by Japanese red cedar
P2




**Perennial allergy**
Pre-clinical
e.g. house dust mite, cat, etc.

Cytokinetics

IMMUNOMIC Therapeutics, Inc.

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SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease

# POTENTIAL GROWTH DRIVERS



*Future growth driven by compounds that already have achieved POC*

## Current growth drivers

- Xtandi (enzalutamide)
- OAB franchise
  - VESIcare (solifenacin succinate) 5 mg, 10 mg tablets
  - Myrbetriq (mirabegron)
- Repatha (evolocumab) injection 140 mg/mL
- Suglat®

## 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**
- **naquotinib** (ASP8273)
- **IMAB362**
- **roxadustat**
- **ASP0113**
- **peficitinib**
- **fezolinetant***

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

*Transaction of Ogeda announced; completion pending

POC: Proof of Concept

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

# EXPECTED KEY PIPELINE EVENTS WITHIN A YEAR



*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

**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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RA: Rheumatoid arthritis, BP-D: Depressive symptoms associated with bipolar disorder, NDO: Neurogenic detrusor overactivity

# CREATE INNOVATION

NEW INITIATIVE

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# ACQUISITION OF Ogeda SA



*Acquisition expands Astellas' late stage clinical pipeline with fezolinetant*

## Transaction Summary

### Acquisition

100% Equity in Ogeda

### Up-front payment

EUR 500 million

### Earn-outs

Up to EUR 300 million in further contingent payments based on progress in the development of fezolinetant, Ogeda's most advanced clinical program

### Closing

2Q/2017

*Subject to expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of the United States and other customary closing conditions

## Overview of Ogeda

### General information

Privately owned clinical-stage drug discovery company that invents and develops small molecule drug candidates targeting GPCRs

Based in Gosselies, Belgium

Founded in 1994

Number of employees: 41

### Most advanced program fezolinetant

-Currently being investigated in menopause-related vasomotor symptoms (MR-VMS) or hot flashes
-Tachykinin NK3 receptor antagonist

ogeda

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GPCRs: G-protein coupled receptors

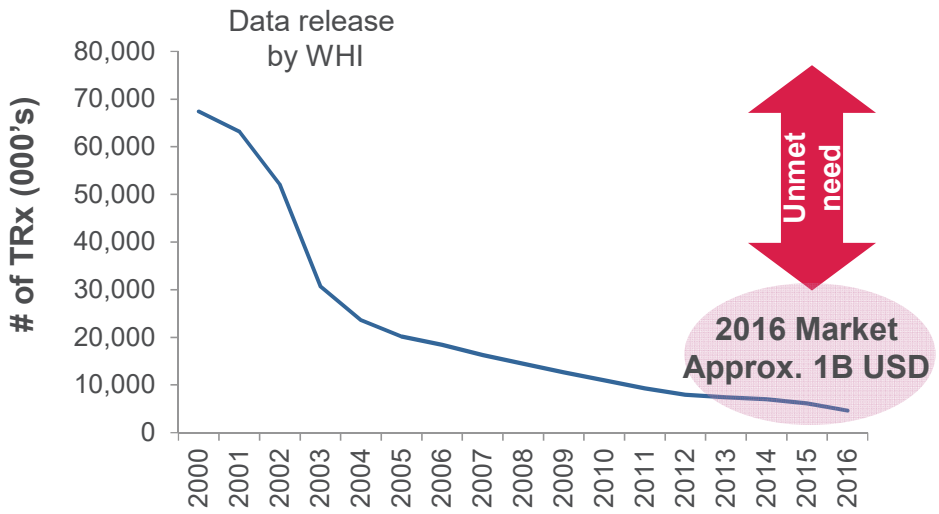
Transaction announced; completion pending

# STRATEGIC FIT FOR ASTELLAS

*Astellas has category leading experience in successful development and commercialization in urology*

## Unmet Medical Needs

### US Annual Branded TRx Trends for MR-VMS

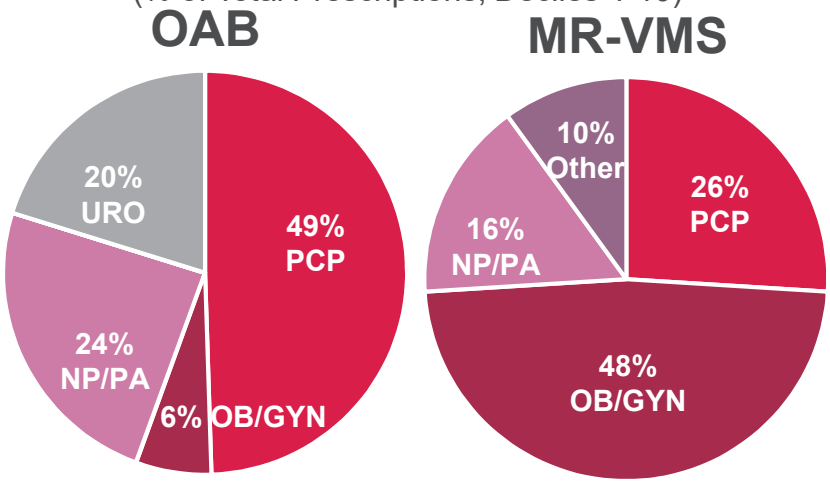



- Following the release of WHI data, HT is no longer the mainstay treatment for MR-VMS because of personal preference or contraindications.
- Surveys report that 50% to 80% of midlife women prefer nonhormonal therapies for VMS.
- These data indicate the need for additional treatment options.

## Synergy with OAB Franchise

### Treating Physicians in 2016

(% of Total Prescriptions, Deciles 4-10)




- In the US, almost 400 sales representatives are currently dedicated to reaching more than 50,000 PCP and OB/GYN providers annually for our current OAB franchise.
- 10 marketing professional are assigned to our OAB franchise. OAB is a condition that affects women beginning around age 40.Astellas has 13 years of commercial experience in OAB.

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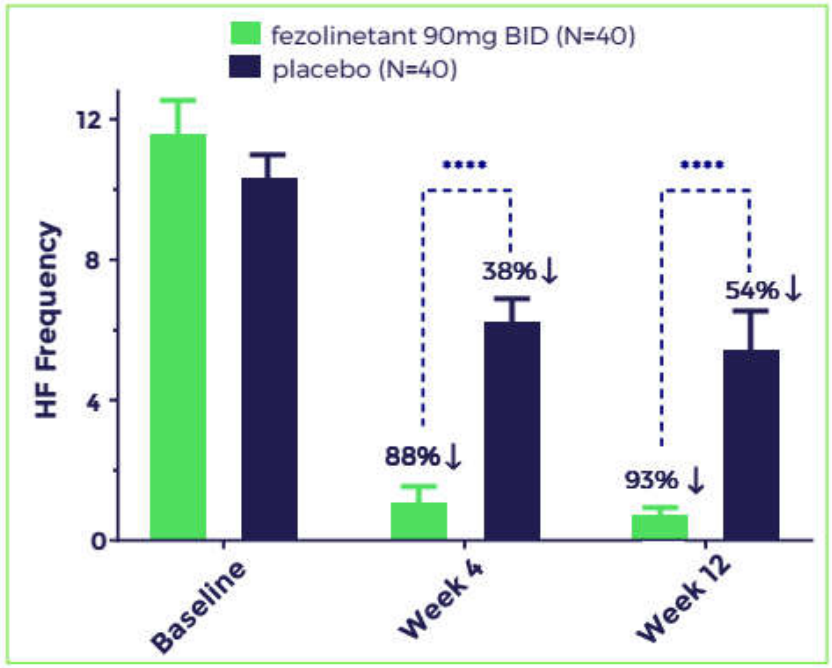
Data Source: IMS NPA (2000-2016), IMS NSP (2000-2016). (3 HTs and SSRI) Data source: IMS Open Claims Dec 2015-Dec 2016; * Based on deciles 4-10
NAMS 2015 Position Statement. Transaction announced; completion pending
WHI: Women's Health Initiative, PCP: Primary care physician, OB/GYN: Obstetrician/Gynecologist, NP/PA: Nurse practitioners/Physician assistants

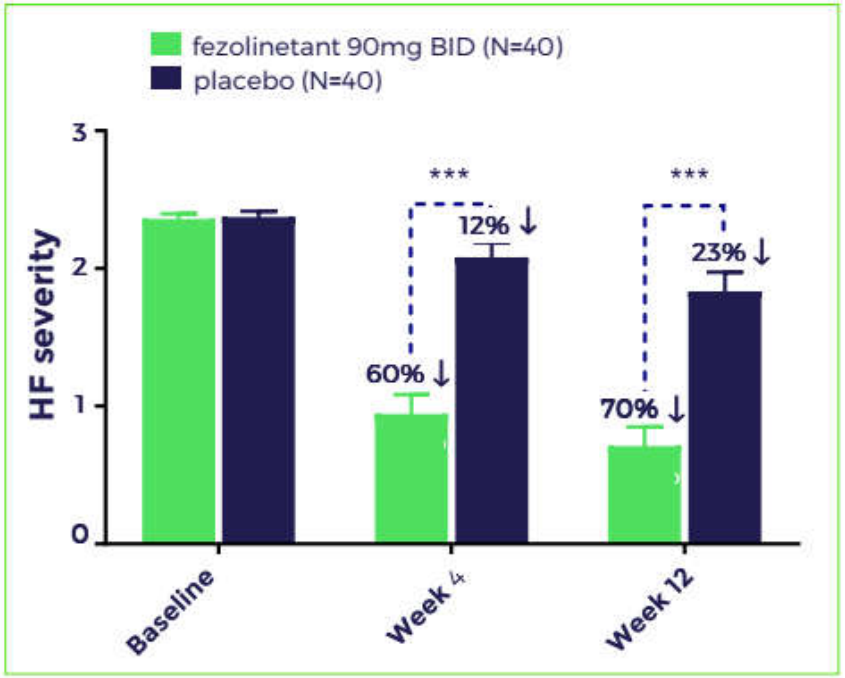
# PHASE 2A RESULTS OF FEZOLINETANT

*Phase 2a study in early postmenopausal women with moderate to severe hot flashes met its primary endpoint*

Effect on frequency of moderate + severe HF




Effect on HF severity




## Safety

No severe adverse events were reported in either treatment group. The mild-to-moderate adverse events (such as headache and nasopharyngitis) were reported in 67% of fezolinetant group and 80% in placebo group.

# PURSUE OPERATIONAL EXCELLENCE

# TRANSFER OF LONG-LISTED PRODUCTS



*Reallocate internal resources to activities that drive our competitive advantage*

## Products

-16 products including Gaster, Nasea, Cefamezin and Cefzon

-Gross sales in FY2015: 29.0 billion yen
(including bulk and royalties)

## Transaction Summary

### Transferred to

LTL Pharma Co., Ltd.

### Schedule

March 28, 2017: Agreement

April 28, 2017: Closing (planned)

From April 29, 2017:
Transition of products
To be completed by April 2020

### Price

20.1 billion yen

# STRENGTHENING MANAGEMENT STRUCTURE



*Further enhance global management structure*

## Executive Committee

Added General Counsel as a standing member from Apr. 1, 2017



From left:
CAO&CECO: Fumiaki Sakurai, CFO: Chikashi Takeda,
CEO: Yoshihiko Hatanaka, General Counsel: Linda Friedman,
CSTO&CCO: Kenji Yasukawa, Ph.D., CMO: Sef Kurstjens, M.D., Ph.D.

## Global Function

Enhancement of Compliance (Since Apr. 1, 2016)
-Divided the Legal and Compliance functions structurally in all regions. Established a new global function to integrate and manage the regional Ethics & Compliance functions in Japan, Americas, EMEA and Asia/Oceania regions.

Enhancement of Legal (Since Apr. 1, 2017)
-Established a new global function, Legal, to manage the regional legal functions. Directly report to CEO.

Enhancement of Intellectual Property (Since Apr. 1, 2017)
-Established a new global function, Intellectual Property, to manage the regional intellectual property functions. Directly report to CEO.

Restructuring of Pharmaceutical Technology (Since Apr. 1, 2017)
-Restructured Technology into a new functional structure to strengthen its global operations and management of contract manufacturing organization, and to enhance the administrative structure, Technology. Renamed as Pharmaceutical Technology.

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CAO&CECO: Chief Administrative Officer & Chief Ethics & Compliance Officer, CSTO&CCO: Chief Strategy Officer & Chief Commercial Officer,
CMO: Chief Medical Officer

# CREATE SOCIAL VALUE



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

## Initiatives for Access to Health

### Chagas' disease

- New collaborative research agreement
- Research to discover new drugs using technology obtained through the existing collaborative research

AIST
NATIONAL INSTITUTE OF ADVANCED INDUSTRIAL SCIENCE AND TECHNOLOGY (AIST)

### Cholera and enterotoxigenic *E Coli*

- Collaborative development agreement for rice-based oral vaccine

The Institute of Medical Science
The University of Tokyo

### Participation in Access Accelerated

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

ACCESS ACCELERATED
*Moving NCD Care Forward*

### Support of Action on Fistula

- In 3 years through 2017, the program had treated more than 2,300 patients with surgery

Action on Fistula

## Prevention of doping

### Agreement with the World Anti-Doping Agency (WADA)

- To partner on the prevention of misuse and abuse of medicines for doping in sports
- Astellas identify solely developed compounds with the potential for doping abuse and share relevant information to aid WADA to develop detection methods
- Cooperate to minimize the risk of misuse of compounds with doping potential during clinical trials

WORLD ANTI-DOPING AGENCY
play true

astellas

# AGENDA



I Full Year FY2016 Highlights

II FY2016 Financial Results and FY2017 Forecasts

III Initiatives to Build Resilience for Sustainable Growth

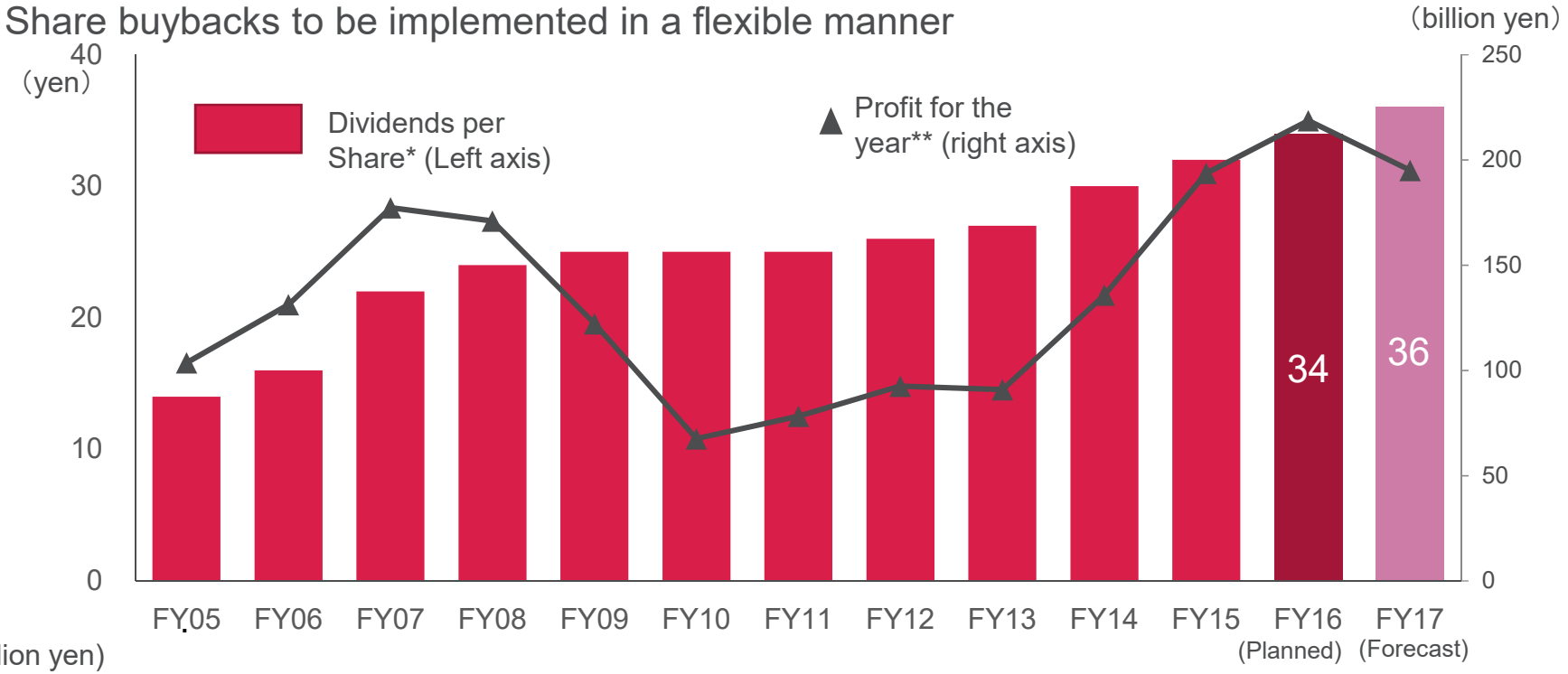
IV Profit Distribution Policy

# Profit Distribution Policy



*Working to boost shareholder returns through sustained growth in enterprise value*

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



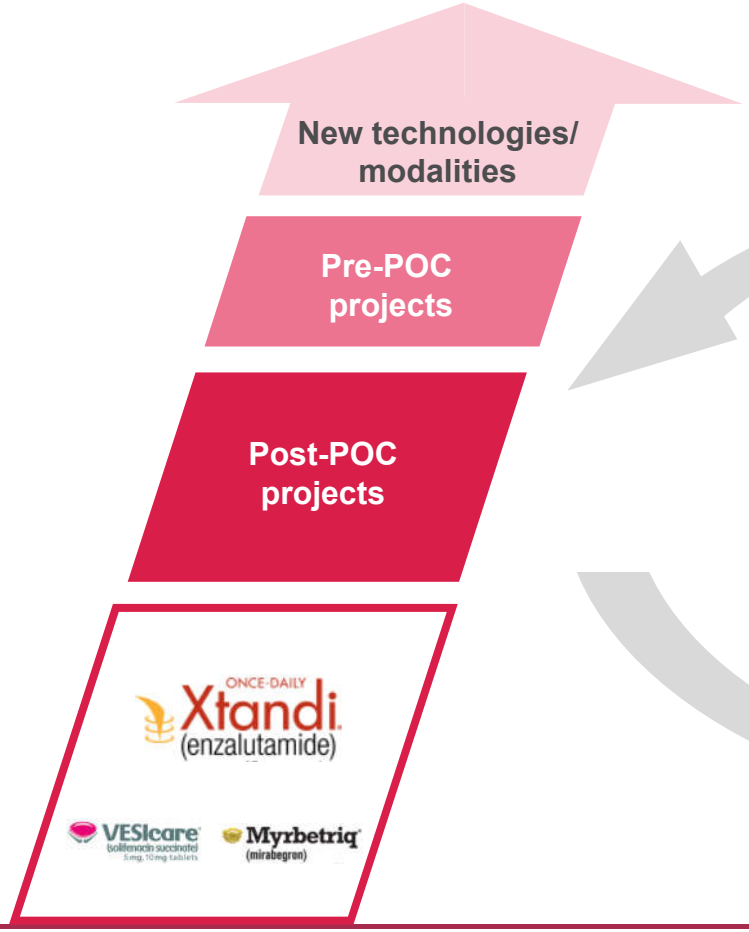

| (billion yen) | FY05 | FY06 | FY07 | FY08 | FY09 | FY10 | FY11 | FY12 | FY13 | FY14 | FY15 | FY16 (Planned) | FY17 (Forecast) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total dividends | 39.3 | 42.3 | 55.2 | 56.9 | 58.2 | 57.7 | 57.7 | 59.4 | 60.6 | 66.0 | 68.5 | 71.3 | 74.4 |
| 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,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 2011.
**From fiscal 2012 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

# FY2016 ACT : SALES BY REGION



| | FY2015 | FY2016 | Changes |
|---|---|---|---|
| **Japan (billion yen)** | **497.2** | **480.8** | -3.3% |
| of sales in Japanese market | 483.0 | 452.7 | -6.3% |
| **Americas (million USD)** | **3,788** | **3,805** | +0.5% |
| **EMEA (million EUR)** | **2,484** | **2,785** | +12.1% |
| **Asia/Oceania (billion yen)** | **91.1** | **87.7** | -3.8% |

# FY2017 FCST：SALES BY REGION



| | FY2016 | FY2017 | Changes |
|---|---|---|---|
| **Japan (billion yen)** | **480.8** | **426.9** | -11.2% |
| of sales in Japanese market | 452.7 | 391.0 | -13.6% |
| **Americas (million USD)** | **3,805** | **3,915** | +2.9% |
| **EMEA (million EUR)** | **2,785** | **2,661** | -4.4% |
| **Asia/Oceania (billion yen)** | **87.7** | **102.1** | +16.4% |

# 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) | FY15 end | FY16 end |
|---|---|---|
| Total assets | 1,799.3 | 1,820.9 |
| Cash and cash equivalents | 360.0 | 340.9 |
| Total net assets | 1,259.2 | 1,271.8 |
| Equity ratio(%) | 70.0% | 69.8% |

| (billion yen) | FY2015 | FY2016 |
|---|---|---|
| Cash flows from operating business | 313.7 | 235.6 |
| Cash flows from investing activities | -147.1 | -73.4 |
| Free cash flows | 166.7 | 162.2 |
| Cash flows from financial activities | -193.5 | -166.2 |
| Acquisition of treasury shares | -120.1 | -92.2 |
| Dividends paid | -69.6 | -70.1 |

# PROFIT DISTRIBUTION POLICY



| | FY2015 | FY2016 | FY2017 (forecast) |
|---|---|---|---|
| Core EPS | 92.12 | 101.15 | 94.43 |
| Divided per share | 32 | 34 (planned) | 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 (planned) |

# ON THE FOREFRONT OF HEALTHCARE CHANGE

