# FY2017 FINANCIAL RESULTS
ENDED MARCH 31, 2018


**Kenji Yasukawa, Ph.D**
**President and CEO**
**Astellas Pharma Inc.**
**April 26, 2018**

# 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 Pharma. 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.

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# AGENDA



I Review of Strategic Plan 2015-2017

II FY2017 Financial Results and FY2018 Forecasts

III Initiatives to Build Resilience for Sustainable Growth

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# REVIEW OF STRATEGIC PLAN 2015-2017 (FINANCIAL)



*Achieved profit targets despite net sales behind assumptions*

## Financial overview

- **Net sales (CAGR*) : +1.4%**
- **Core OP (CAGR*) : +7.5%**
  - R&D investment: 16-17% of net sales / improvement of cost structure
- **Core EPS (CAGR*) : +13.2%**
  - Achieved EPS CAGR exceeding CAGR of Core OP along with enhancement of capital efficiency
- **ROE (Full basis) : 15.1% (average for three years, FY2015 – FY2017)**
- **Shareholder return:** Dividend per share increased by 2 yen per year (planned for FY17)
  Average total return ratio for three years including share buybacks was 98.4%

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*CAGR for 3 years starting from FY2014 results

# REVIEW OF STRATEGIC PLAN 2015-2017 (STRATEGIC INITIATIVES)



*Steady progress in 3 strategic initiatives*

## Maximizing the Product Value

- Maximized sales of XTANDI in the current indications and steadily progressed development in earlier stages of prostate cancer
- Shifted resources from Vesicare to Betanis/ Myrbetriq/ Betmiga
  Advancing development for pediatric indication and combination therapy of solifenacin and mirabegron
- Launched Repatha and Linzess in Japan

*GEs impacts in Japan exceeded our expectations*

*Further pressure on prices in EU and the US*

## Creating Innovation

- Steadily progressed late-stage pipeline including gilteritinib, enfortumab vedotin and roxadustat
- Expanded pipeline through acquisition of Ganymed and Ogeda
- Unique development programs with various modality and biology into clinical study

## Pursuing Operational Excellence

- Transferred US manufacturing subsidiary
- Transferred dermatology business and 16 long-listed Japanese products
- Enhanced global management structure
- Pursued strategic outsourcing
- Wind-down of Agensys research operations
- Optimized EMEA organizational structure

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# FY2017 FINANCIAL RESULTS (CORE BASIS)



| (billion yen) | FY16 | FY17 | Change | FY17 FCST* | Achieve-ment | Excl impacts from Fx and business transfer |
|---|---|---|---|---|---|---|
| **Net sales** | **1,311.7** | **1,300.3** | **-0.9%** | **1,297.0** | **100.3%** | -1.2% |
| Cost of sales | 320.5 | 294.2 | -8.2% | | | |
| % of sales | 24.4% | 22.6% | | | | |
| SG&A expenses | 470.8 | 478.3 | +1.6% | | | |
| % of sales | 35.9% | 36.8% | | | | |
| R&D expenses | 208.1 | 220.8 | +6.1% | 218.0 | 101.3% | |
| % of sales | 15.9% | 17.0% | | 16.8% | | |
| Amortisation of intangible | 35.8 | 35.8 | +0.0% | | | |
| Share of associates/JVs losses | - 1.9 | - 2.4 | - | | | |
| **Core operating profit** | **274.6** | **268.7** | **-2.1%** | **258.0** | **104.1%** | +4.6% |
| **Core profit for the period** | **213.3** | **204.3** | **-4.2%** | **201.0** | **101.7%** | |
| **Core EPS (yen)** | **101.15** | **100.64** | **-0.5%** | **98.43** | **102.2%** | |

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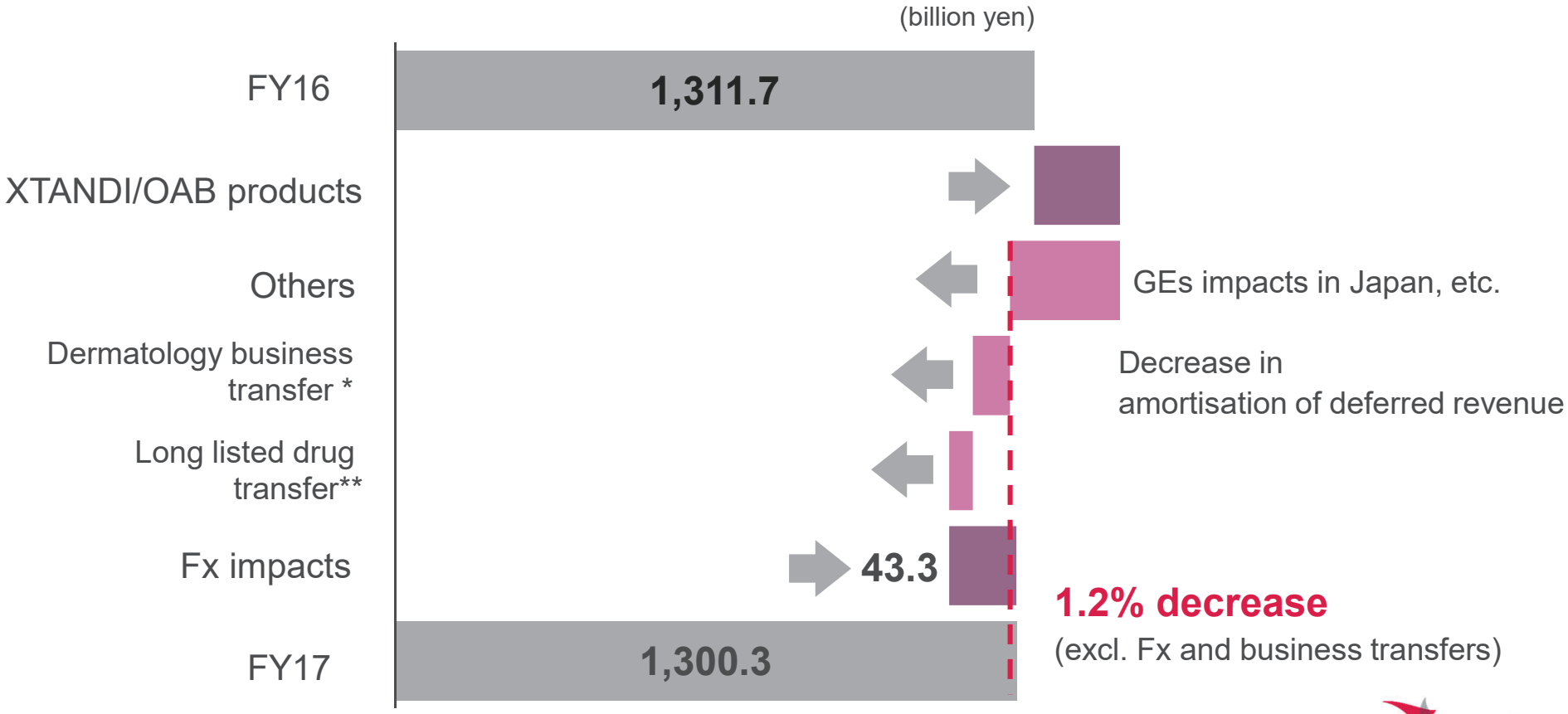
* Revised in Oct. 2017

# SALES ANALYSIS (YEAR ON YEAR)



*Growth drivers in good shape despite slight decrease in net sales due to mainly GEs impacts in Japan*




*Dermatology business transfer: Decrease in amortisation of deferred revenue

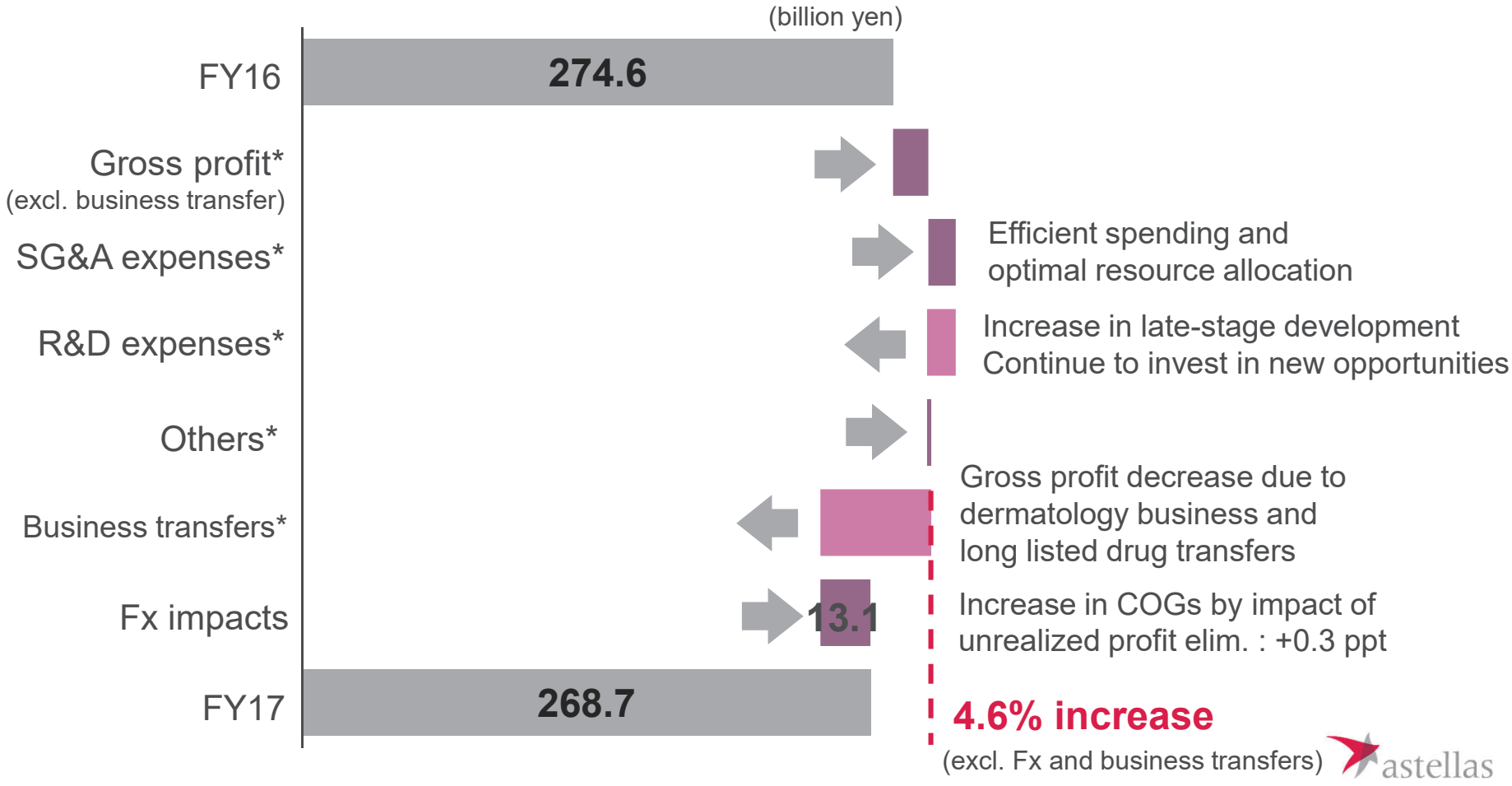
**Long listed drug transfer: Amortisation of deferred revenue in FY17 – Sales of transferred products in FY16

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

# CORE OP ANALYSIS (YEAR ON YEAR)



*Increased operating profit excluding impacts of Fx and business transfers, while increased development costs for late-stage projects, etc.*




*Fx impacts excluded from each item

# FY2017 FINANCIAL RESULTS (FULL BASIS)



*Booked other expenses for business restructuring and impairment loss*

| (billion yen) | FY16 | FY17 | Change | FY17FCST* | Achieve-ment |
|---|---|---|---|---|---|
| **Core operating profit** | **274.6** | **268.7** | **-2.1%** | **258.0** | **104.1%** |
| Other income | 9.6 | 11.9 | +23.7% | | |
| Other expenses | 23.3 | 67.3 | +188.7% | | |
| **Operating profit** | **260.8** | **213.3** | **-18.2%** | **222.0** | **96.1%** |
| Financial income | 22.9 | 6.6 | -71.0% | | |
| Financial loss | 2.0 | 1.8 | -9.8% | | |
| Profit before tax | 281.8 | 218.1 | -22.6% | 228.0 | 95.7% |
| **Profit for the period** | **218.7** | **164.7** | **-24.7%** | **180.0** | **91.5%** |
| **EPS (yen)** | **103.69** | **81.11** | **-21.8%** | **88.15** | **92.0%** |

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* Revised in Oct. 2017

# SALES IN KEY AREAS



*XTANDI and OAB franchise increase globally*

| (billion yen) | FY16 | FY17 | Change | CER growth | FY17 FCST* | Achieve-ment |
|---|---|---|---|---|---|---|
| **XTANDI** | **252.1** | **294.3** | **+16.8%** | **+11.7%** | **291.3** | **101.0%** |
| **OAB in Urology** | **214.9** | **228.1** | **+6.1%** | **+2.7%** | **232.3** | **98.2%** |
| Vesicare | 116.1 | 102.3 | -11.9% | -15.2% | 106.2 | 96.3% |
| Betanis/Myrbetriq/BETMIGA | 98.8 | 125.7 | +27.2% | +23.7% | 126.1 | 99.7% |
| **Transplantation** | **186.2** | **198.5** | **+6.6%** | **+1.5%** | **194.8** | **101.9%** |

Transplantation: Prograf, Advagraf/Graceptor/ASTAGRAF XL

CER : Constant Exchange Rate

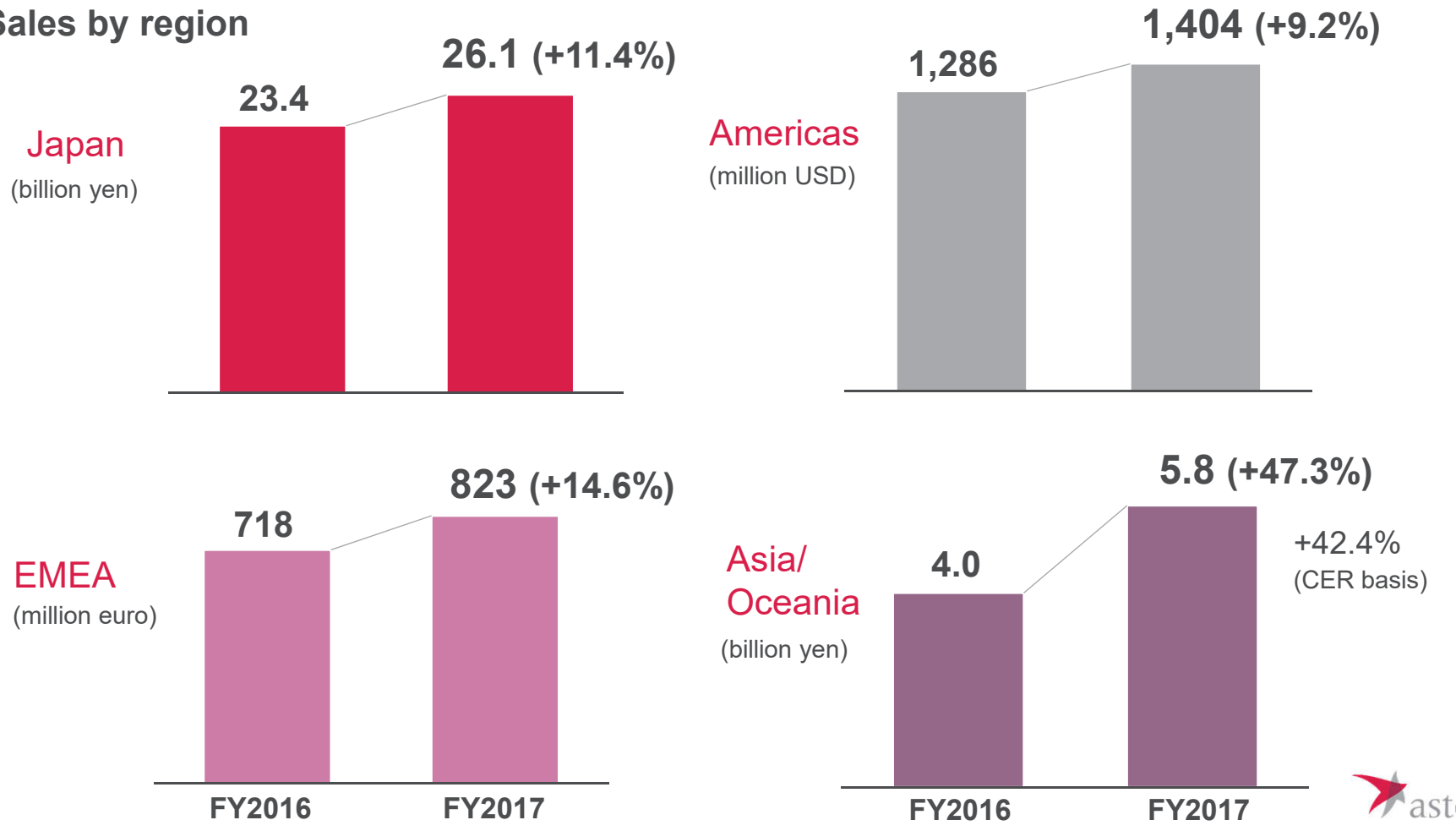
* Revised in Oct. 2017

# XTANDI



*Steadily increasing XTANDI sales in all regions*

**Sales by region**

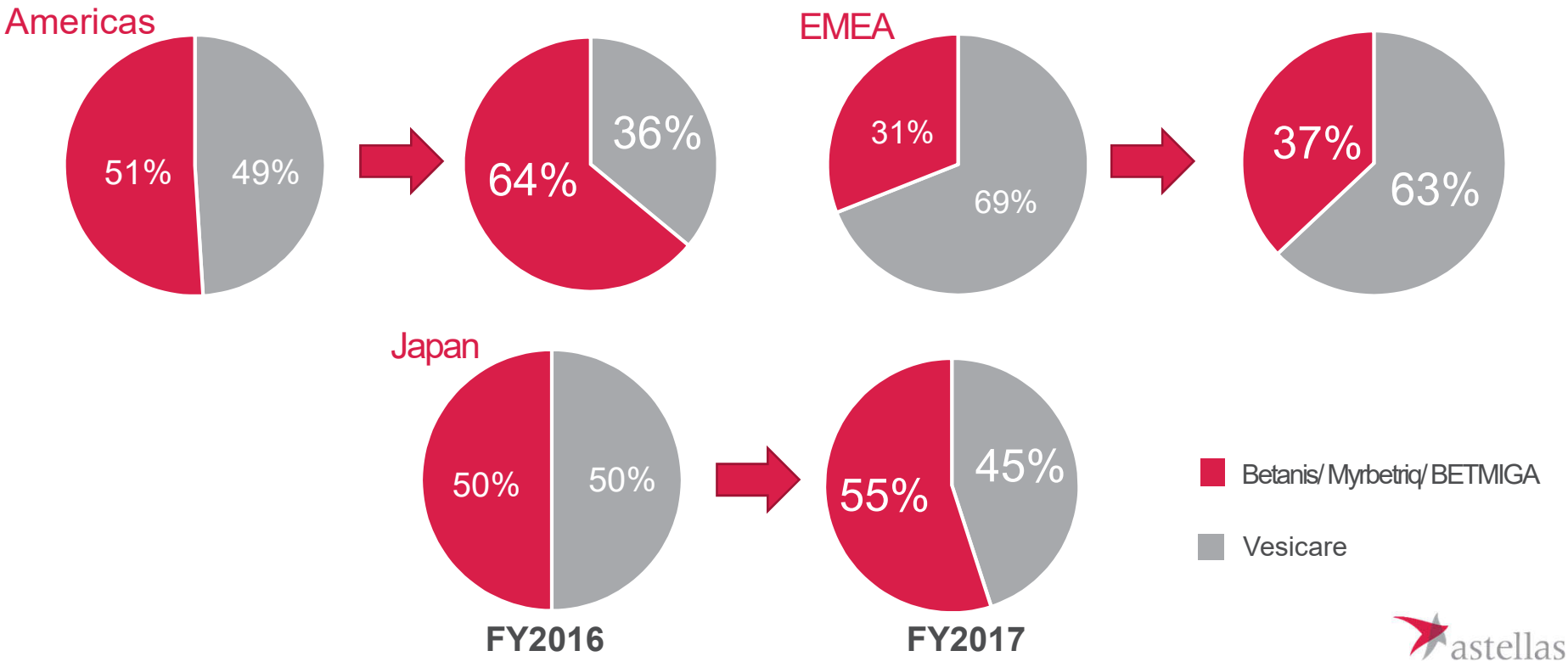


# OAB FRANCHISE IN UROLOGY



*Proportion of Betanis/Myrbetriq/BETMIGA sales steadily expanding by shifting resources from Vesicare*

**Sales composition ratio by product**
**(FY2016 vs FY2017:local currency basis)**



# FY2018 FORECASTS：SUMMARY



- **Net sales**
  - XTANDI & OAB franchise to continue growth on a global basis. Prograf to show steady progress
  - Decrease in sales in Japan due to NHI price revision and GEs impacts
  - Negative impacts on sales due to decrease in deferred revenue of dermatology business transfer and long-listed drug business transfer
- **Continue to invest in R&D and business development for future growth**
  - R&D expenses:  214.0 bil.yen (Ratio to sales 16.7%)
- **Pursue operational excellence through zero-based budgeting and continuous enhancement of organization structure**
- **Fx impact on Core OP to be minimal while negative impact on net sales is anticipated : USD 105 yen, Euro 130 yen**
- **Dividends per share：Forecasted 2 yen increase to 38 yen**

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# FY2018 FORECASTS



*Core basis: Profit for the year and EPS to increase, while operating profit to decrease*

| (billion yen) | FY2017 ACT | FY2018 FCST | Change |
|---|---|---|---|
| **Net sales** | **1,300.3** | **1,278.0** | **-1.7%** |
| R&D expenses | 220.8 | 214.0 | -3.1% |
| as % of sales | 17.0% | 16.7% | -0.3ppt |
| **Core operating profit** | **268.7** | **262.0** | **-2.5%** |
| **Core profit for the year** | **204.3** | **210.0** | **+2.8%** |
| **Core EPS (yen)** | **100.64** | **106.27** | **+5.6%** |
| **Operating profit** | **213.3** | **265.0** | **+24.3%** |
| **Profit for the year** | **164.7** | **213.0** | **+29.3%** |
| **EPS (yen)** | **81.11** | **107.79** | **+32.9%** |

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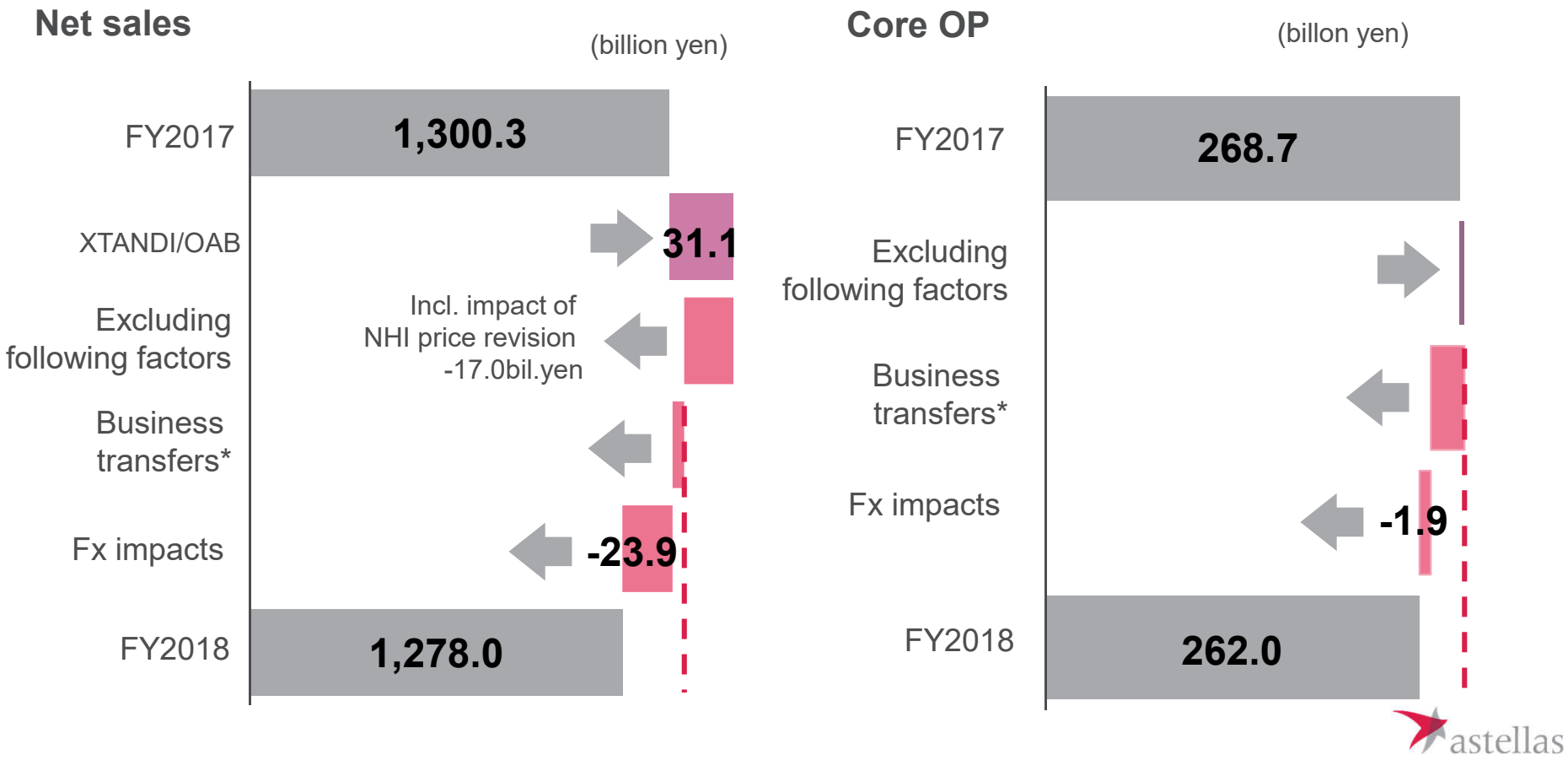
# FY2018 FCST: NET SALES/CORE OP



*Flat net sales and Core OP adjusted for business transfer and Fx impacts despite NHI price revision*



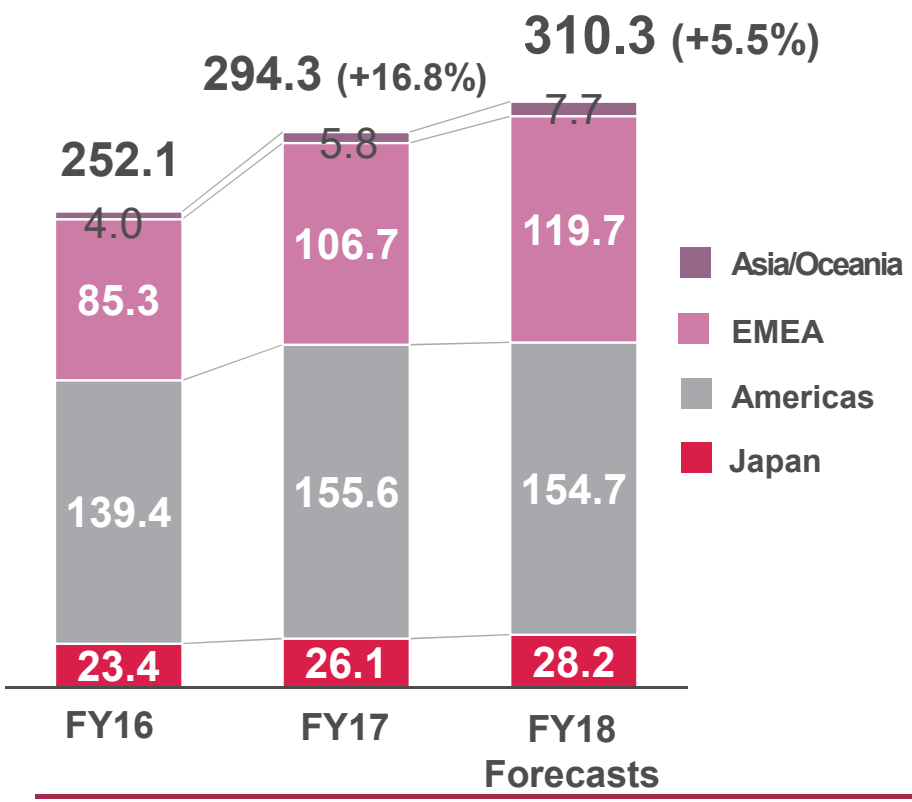

*Dermatology business and long-listed drugs transfer: Amortisation of deferred revenue for this year - PY amortisation of deferred revenue

# FY2018 FCST: XTANDI



*XTANDI sales to increase in all regions on a local currency basis*

**Sales by region** (billion yen)




- Further penetration in earlier treatment within the current indications
  - Utilize solid evidence obtained in clinical trials and our strong presence in the urology field
  - Cooperation with Pfizer in the US
- Further maximize the value of XTANDI through expanded indication

**Year on Year sales growth (FY17 vs FY18)**

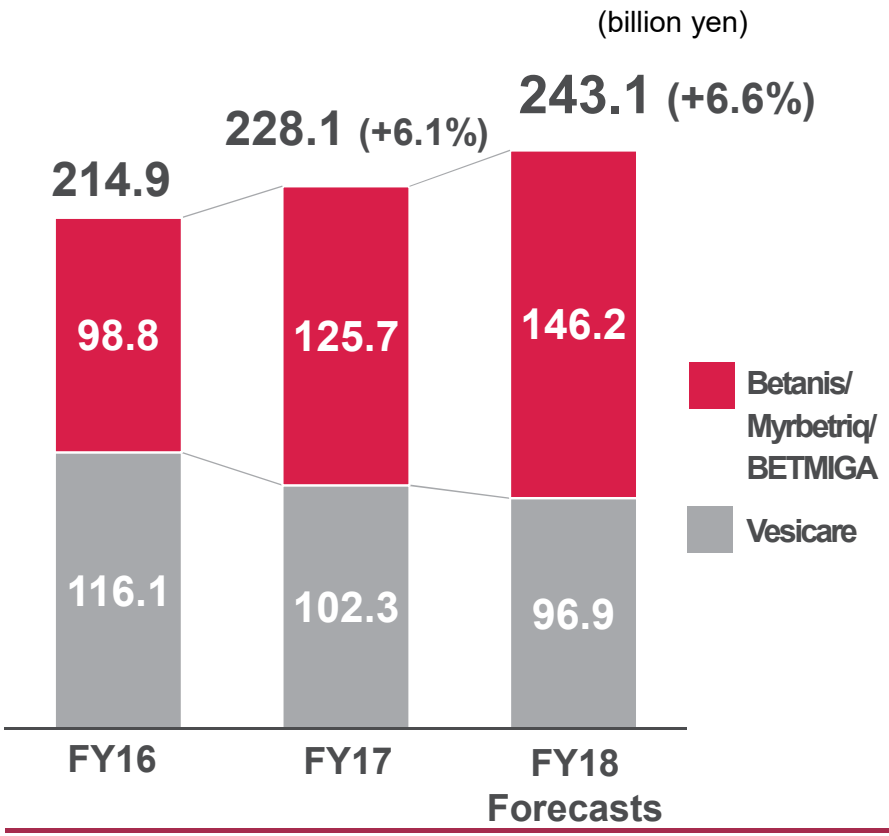
**Japan**: +8%
**Americas**: +5% (USD basis)
**EMEA**: +12% (EUR basis)
**Asia/Oceania**: +34% (CER basis)

# FY2018 FCST: OAB FRANCHISE IN UROLOGY

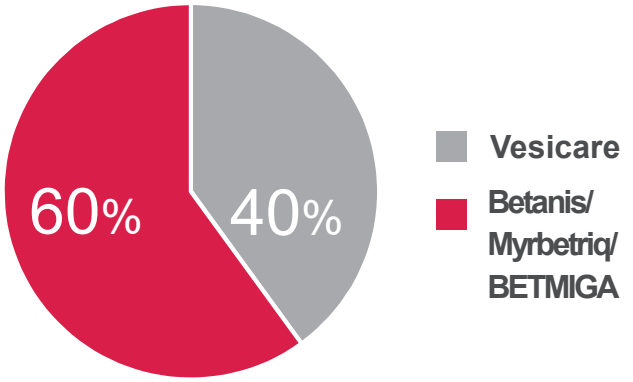


*Betanis/Myrbetriq/BETMIGA growth enhances OAB Franchise*

**Sales by products**




**Sales composition ratio by product (FY18 FCST: yen basis)**




**Year on Year sales growth (FY17 vs FY18)**

**Japan**: +3%
**Americas**: +15% (USD basis)
**EMEA**: +3% (EUR basis)
**Asia/Oceania**: +18% (CER basis)

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# INITIATIVES TO BUILD RESILIENCE FOR SUSTAINABLE GROWTH

## PIPELINE

# ROBUST PIPELINE OF ASTELLAS



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

## Phase 1

- AGS67E
- AGS62P1
- ASP8374/PTZ-201
- ASP7713
- MA-0217
- ASP0892
- ASP1807/CC8464
- ASP6981
- MA-0211

## Phase 2

- enfortumab vedotin (ASG-22ME) (Urothelial cancer)
- AGS-16C3F (Renal cell carcinoma)
- YM311/FG-2216 (Renal anemia)
- ASP8232 (Diabetic kidney disease)
- ASP6294 (BPS/IC)
- ASP8302 (Underactive bladder)
- bleselumab (ASKP1240) (rFSGS)
- peficitinib (ASP015K) (Rheumatoid arthritis, US/EU)
- ASP8062 (Fibromyalgia)
- ASP0819 (Fibromyalgia)
- ASP4070 (Pollinosis caused by Japanese red cedar)
- ASP5094 (Rheumatoid arthritis)
- ASP4345 (CIAS)
- fezolinetant (ESN364) (MR-VMS)
- reldesemtiv(CK-2127107) (SMA, COPD, ALS)
- ASP7317 (Dry AMD etc.)

## Phase 3

- enzalutamide (M0 BCR:US/EU/Asia, M1 HSPC:US/EU/JP/Asia,)
- gilteritinib (ASP2215) (AML, US/EU/JP/Asia)
- zolbetuximab(IMAB362) (Gastric and gastroesophageal junction adenocarcinoma, US/EU/JP/Asia)
- mirabegron (Pediatric NDO, EU)
- roxadustat (ASP1517/FG-4592) (Anemia associated with CKD, EU/JP)
- peficitinib (ASP015K) (Rheumatoid arthritis, JP/Asia)
- fidaxomicin (Pediatric, EU)

## Filed

- enzalutamide (M0 CRPC: US/EU)
- gilteritinib (R/R AML: US/JP)
- blinatumomab (AMG 103) (Acute lymphoblastic leukemia, JP)
- degarelix (3-month, JP)
- solifenacin (Pediatric NDO, US)
- solifenacin/mirabegron (Concomitant use, US)
- tacrolimus (granule for pediatric, US)
- romosozumab (AMG 785) (Osteoporosis, JP)
- ipragliflozin (Type 1 diabetes, JP)
- fidaxomicin (Infectious enteritis, JP)
- linaclotide (Chronic constipation, 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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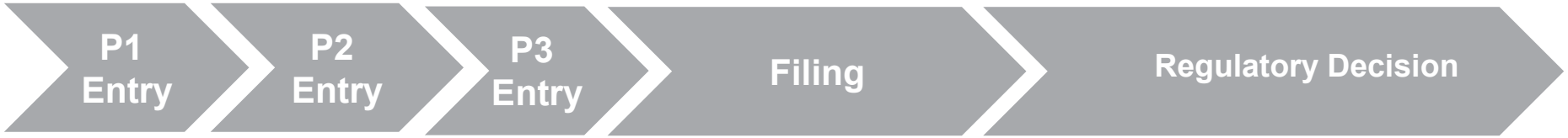
BPS/IC: Bladder pain syndrome/Interstitial cystitis, rFSGS: Recurrence of focal segmental glomerulosclerosis, CIAS: Cognitive impairment associated with schizophrenia, MR-VMS: Menopause-related vasomotor symptoms, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, ALS: Amyotrophic lateral sclerosis, AMD: Age-related macular degeneration, M0 BCR: Non-metastatic biochemical recurrence, M1 HSPC: Metastatic hormone sensitive prostate cancer, M0 CRPC: Non-metastatic castration-resistant prostate cancer, AML: Acute myeloid leukemia, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, R/R: Relapsed and refractory

# STEADY PROGRESS IN DEVELOPMENT
## SUMMARY OF PROGRAM PROGRESS FROM JAN 2018 TO APR 2018



*Steady progression of pipeline*




**gilteritinib**
**Mar 2018 (JP)**
**Mar 2018 (US)**
Relapsed or refractory AML

**solifenacin**
**Approved in Feb 2018 (EU)**
NDO in pediatric

**ipragliflozin/ sitagliptin**
**Approved in Mar 2018 (JP)**
Fixed dose for Type 2 diabetes

**enzalutamide**
**Approved in Feb 2018 (JP)**
Tablets for CRPC

**Discontinuation (in a part of indications) etc.**

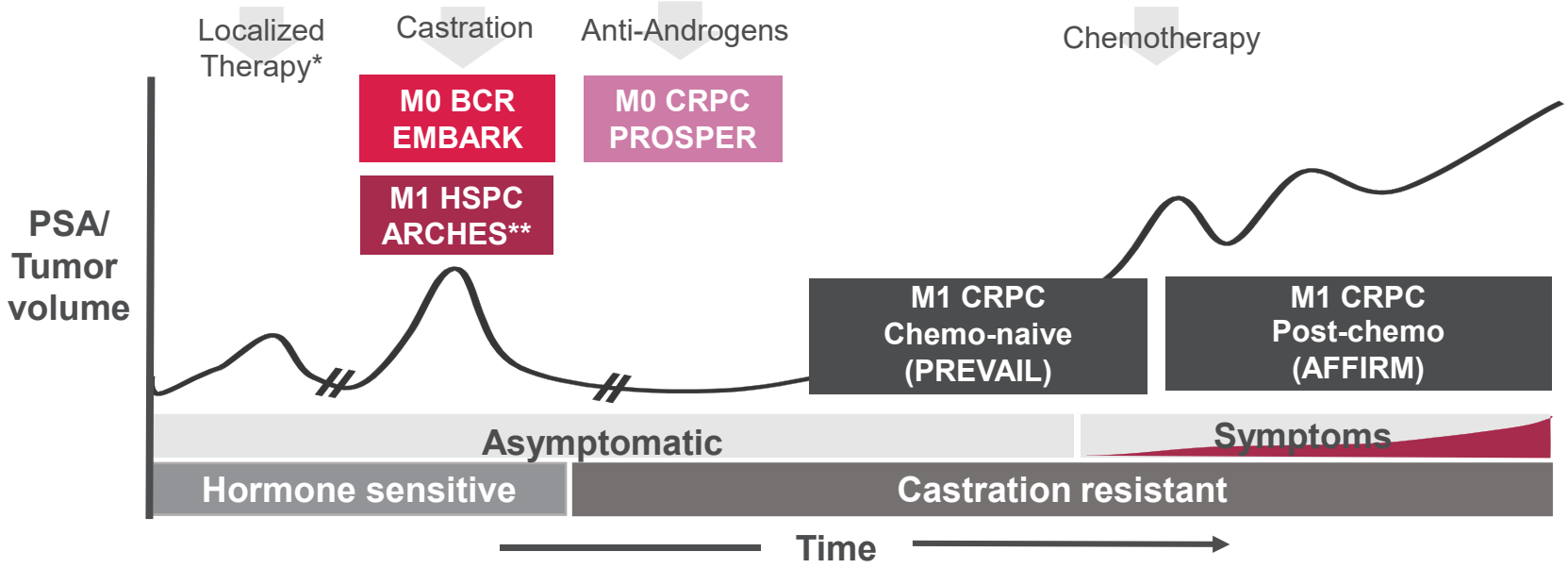
**ASP0113:** Cytomegalovirus reactivation in hematopoietic cell transplant recipients (P3)
**ASP1707:** Rheumatoid arthritis, Endometriosis (P2)

Note: Phase 1 entry is defined as confirmation of IND open. Phase transition is defined by approval of company decision body for entering to next clinical phase. Filing is defined as submission of application to health authorities. Discontinuation is defined by the decision of company decision body.

# ENZALUTAMIDE: MAXIMIZE THE VALUE FOR PROSTATE CANCER PATIENTS



*Acceptance of application from FDA/EMA were received. PDUFA date is Jul 2018.*




| | | | |
|---|---|---|---|
| **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 | Enrollment completed |
| **PROSPER study** P3 | M0 CRPC Non-metastatic CRPC | Placebo-controlled, combination with ADT, n=1,440 | Accepted for review (US/EU) |

P. Mulders *et al. EAU2012,* modified by Astellas * Radiotherapy, prostatectomy, ** Metastatic at the time of diagnosis

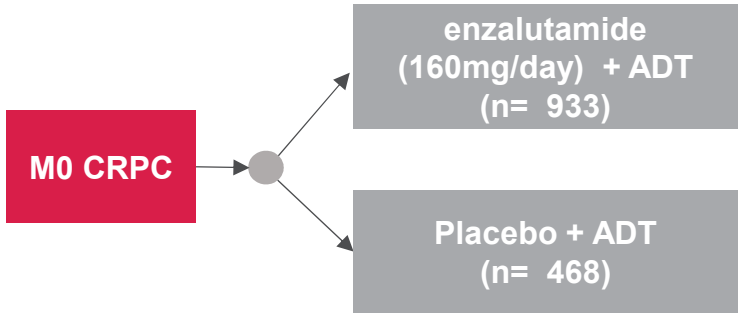
PSA: Prostate-specific antigen, PDUFA: the prescription drug user fee act

# ENZALUTAMIDE: PROSPER STUDY RESULTS



*Enzalutamide decreased the risk of metastasis or death by 71% and delayed median metastasis-free survival by approximately 3 years in M0 CRPC patients.*

## Study design:




**Primary endpoints:**

- Metastasis Free Survival (MFS)

**Secondary endpoints:**

- Safety
- Overall Survival (OS)
- Time to PSA progression
- Time to use of new antineoplastic therapy
- PSA response
- Quality of Life

## Conclusion:

- In men with M0 CRPC with rapid PSA doubling time (median 3.7 months), enzalutamide resulted in a clinically meaningful and statistically significant **71% reduction** in the relative risk of developing M1 CRPC or death.
- Enzalutamide showed consistent improvement across the secondary endpoints compared to placebo.
- Median OS was not reached in either group in the interim analysis, though a trend toward benefit was observed.(HR = 0.80 [95% CI: 0.58-1.09]; p = 0.1519)
- Therapy was well tolerated; adverse events were generally **consistent with those reported in prior clinical trials** in men with metastatic CRPC.

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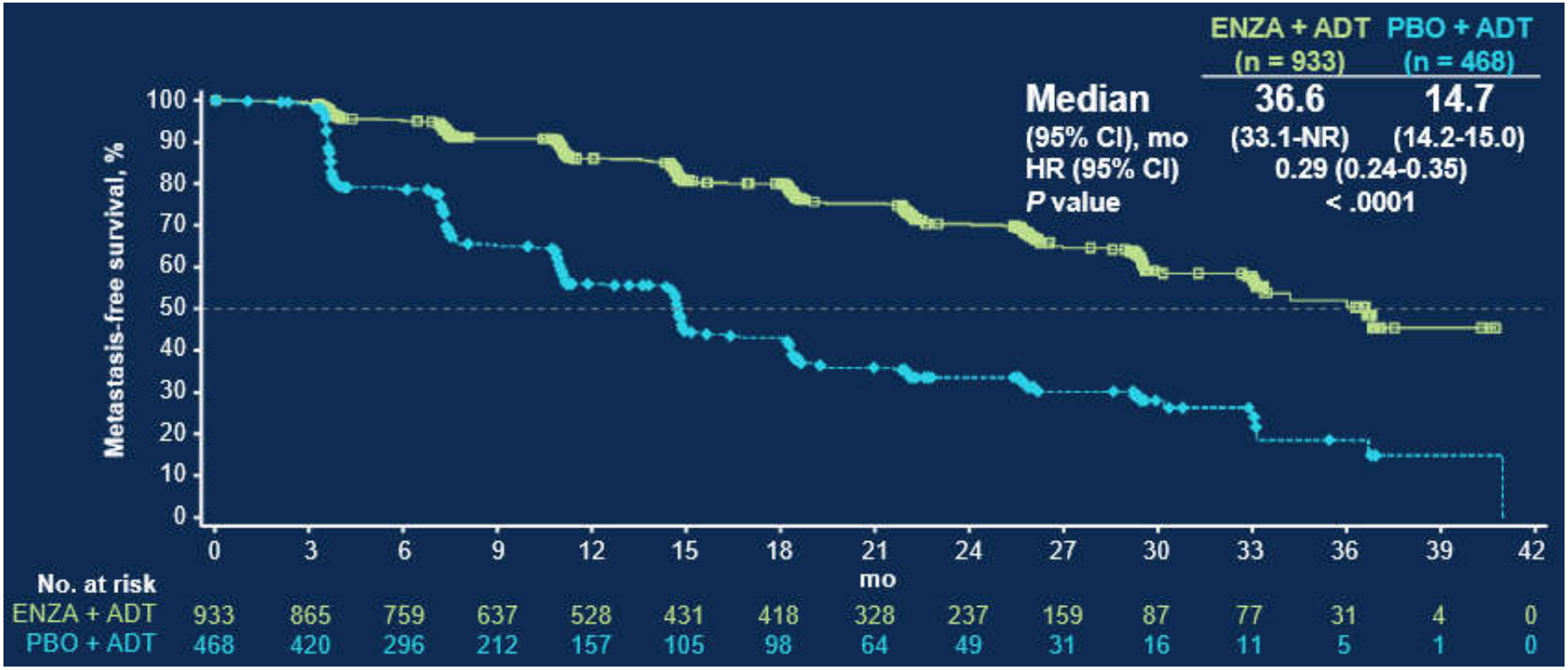
ADT: Androgen deprivation therapy, PSA: Prostate-specific antigen, HR: hazard ration, CI: Confidence interval

# ENZALUTAMIDE: PROSPER STUDY RESULTS



*Median MFS was approximately 3 years with enzalutamide compared to 14.7 months for placebo (71% reduction in relative risk of radiographic progression or death)*

## Primary endpoint: Metastatic Free Survival (MFS)*




***MFS:** a measure of the amount of time that passes until a cancer can be radiographically detected as having metastasized, or until death, within 112 days of treatment discontinuation.

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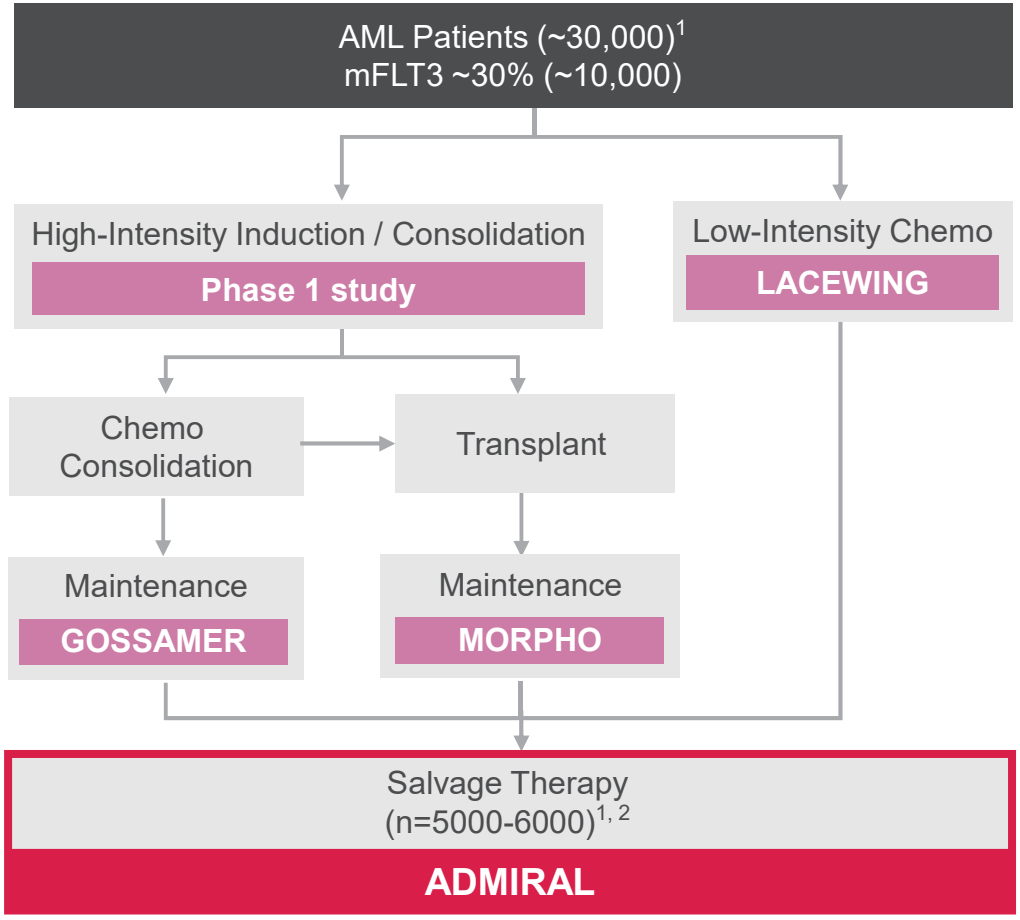
ENZA: enzalutamide, PBO: placebo, CI: confidence interval, NR: not reached, HR: hazard ratio, mo: month

*Maha Hussain, et. al.,* ASCO Genitourinary Cancer symposium 2018

# GILTERITINIB: RELAPSED AND REFRACTORY(R/R) AML



*Application for market authorization for R/R AML was submitted to PMDA in Mar 2018 under SAKIGAKE designation. NDA submission in US followed in Mar 2018*




## ADMIRAL study

- Enrollment completed
- Submission was made based on interim analysis of CR/CRh rate
- Study is being continued to obtain the final data analysis including OS co-primary endpoint.

## Japan:

- Filed in Mar 2018 for R/R AML in Japan ahead of global submission under Sakigake designation.

## US:

- NDA submitted in Mar 2018 for R/R AML. Fast track designation was granted by FDA.

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1: Annual incidence in U.S., EU5, JP, KantarHealth CancerMPact 2016, 2: 2016 ClearView Market Research, 2016 ZS Market Research
CR: complete remission, CRh: CR with partial hematological recovery

# ENFORTUMAB VEDOTIN: METASTATIC UROTHELIAL CANCER



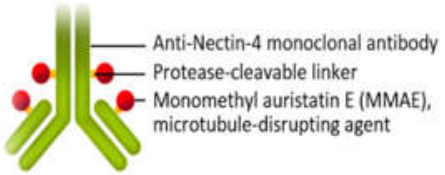
*FDA granted "Breakthrough therapy designation" for locally advanced or metastatic urothelial cancer (mUC) with prior checkpoint inhibitor (CPI) treatment*

## Target: Nectin-4

- Targeting Nectin-4 which is a type I transmembrane protein that belongs to the Nectin family of adhesion molecules.
- Highly expressed in bladder cancer with more moderate expression in breast, pancreatic, lung and ovarian cancer tissue microarrays (TMA)

## Antibody Drug Conjugate (ADC)

- enfortumab vedotin is utilizing ADC technology*.




## Locally advanced and metastatic urothelial cancer

| | | | | |
|---|---|---|---|---|
| | **P3: EV-301 study** | Pts with prior CPI treatment | Open-label, randomized, n=550 | First Patient in: 2H/2018 |
| | **P2: EV-201 study** | Pts with prior CPI treatment | Open-label, single arm, n=120 | First Patient in: Oct 2017 |
| | **P1b: EV-103 study** | Combination with CPI | Open-label, single arm, n=85 | First Patient In: Nov 2017 |
| | **P1: EV-101 study** | mUC pts (Part A)<br>Pts with renal insufficiency (Part B)<br>Pts with prior CPI treatment (Part C) | Open-label, dose-escalation/expansion, n=185 | First Patient In: Jun 2014 |

## Exploration in other solid tumor

| | | | | |
|---|---|---|---|---|
| | **P1: EV-101 study** | metastatic NSCLC (Part B)<br>metastatic ovarian cancer (Part B) | Open-label, dose-expansion, n= 30 | First Patient in: Jun 2014 |

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*: ADC technology is license-in from Seattle Genetics, Inc.

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



*Steady progress of Phase 3 program in dialysis and non-dialysis patients*

| | Dialysis | Non-dialysis |
|---|---|---|
| **Global** | **HIMALAYAS:** (FibroGen)<br>Incident dialysis, vs epoetin alfa | **DOLOMITES**, vs darbepoetin (Astellas)<br>**Enrollment completed**<br>**Data readout planned in 4Q/2018** |
| | **SIERRAS:** (FibroGen)<br>Stable dialysis, vs epoetin alfa | **ALPS**, vs placebo (Astellas)<br>**Study completed**<br>**Data readout in 2018** |
| | **PYRENEES:** (Astellas)<br>Stable dialysis, vs epoetin alfa or darbepoetin<br>**Enrollment completed**<br>**Data readout planned in 3Q/2018** | **ANDES**, vs placebo (FibroGen)<br>**Enrollment completed**<br>**Data readout planned in 4Q/2018** |
| **Japan** (Astellas) | **HD:** Conversion, vs darbepoetin<br>**Study completed**<br>**Data readout planned in 2Q/2018** | Conversion, vs darbepoetin |
| | **HD:** Conversion, long-term<br>**Study completed (TLR obtained in Feb 2018)** | |
| | **HD:** Correction (ESA-naïve)<br>**Study completed (TLR obtained in Feb 2018)** | Correction<br>**Enrollment completed**<br>**Data readout planned in 4Q/2018** |
| | **PD:**<br>**Study completed (TLR obtained in Oct 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: JAPANESE STUDIES IN DIALYSIS PATIENTS



*Positive results obtained from 2 Phase 3 studies in Japanese dialysis patients*

## Hemodialysis: Correction (ESA-naive)

- **Study design:** multi-center, open-label, randomized, non-comparator study
- **Enrolled patients:** 75
- **Dose:** 50 mg or 70 mg for initial dose[1]
- **Treatment :** 3 times/week, up to 24 weeks
- **Key outcome measure:**

  Hemoglobin (Hb) response rate[2] from baseline to End of Treatment (EOT)

**Results:**

- Hb response rate from baseline to EOT was 86.5% in starting 50 mg group and 89.2% in starting 70 mg group.
- roxadustat was well tolerated and in line with the safety data available to date.

## Hemodialysis: ESA-conversion, long-term

- **Study design:** multi-center, open-label, non-comparator study
- **Enrolled patients:** 164
- **Dose:** 70 mg or 100 mg for initial dose[3]
- **Treatment :** 3 times/week, up to 52 weeks
- **Key outcome measure:**

  Maintenance rate of target Hb level[4] for Week 18-24 and for Week 46-52.

**Results:**

- Hb maintenance rate was 79.1% for Week 18-24 and 71.2% for Week 46-52.
- roxadustat was well tolerated. The long-term treatment with roxadustat was consistent with the previously known safety profile.

FIBROGEN

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1: Dose adjustment was allowed between 20 to 300 mg. 2: Proportion of subjects who achieve Hb response (Hb ≥ 10.0 g/dL and a Hb increase from baseline by ≥ 1.0 g/dL).
3: Subjects were assigned to 70 mg or 100 mg initial dose based on the average weekly dose of previous ESA. Dose adjustment was allowed between 20-300 mg.
4: Proportion of subjects who achieve the target Hemoglobin (Hb) level (10.0 g/dL to 12.0 g/dL) based on the average Hb level which was measured every two weeks.

# PHASE 2 PROGRAMS: RECENT UPDATES



*Making progress and near-term plan for Phase 2 programs*

## ASP4070

**Pollinosis caused by Japanese red cedar**

- TLR (preliminary) of POC study obtained
- Study didn't meet the primary endpoint
- Final data readout expected in 2H/2018

IMMUNOMIC Therapeutics, Inc.

## ASP0819

**Fibromyalgia**

- POC study: Patient enrollment completed
- TLR planned in 2Q/2018

## ASP8062

**Fibromyalgia**

- POC study: Patient enrollment completed
- TLR planned in 2Q/2018

## reldesemtiv (CK-2127107)

**< Cytokinetics-sponsored study >**

Cytokinetics

**SMA**

- Phase 2 study: enrollment completed
- TLR planned in 2Q/2018

**ALS**

- Phase 2 study: Recruiting patients
- TLR planned in 4Q/2018

**< Astellas-sponsored study >**

astellas

**COPD**

- Phase 2 study: Recruiting patients
- TLR planned in 4Q/2018

**Note:** P1b (proof of mechanism) study in elderly subjects with limited mobility is also on-going

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# EXPECTED KEY PIPELINE EVENTS IN FY2018



*Important milestones from POC through registration*

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

## Data Readouts

### Phase 2 (POC) study

**ASP0819**
Fibromyalgia

**ASP8062**
Fibromyalgia

**reldesemtiv (CK-2127107)**
SMA
COPD
ALS

**ASP5094**
Rheumatoid arthritis

### Phase 2b study

**fezolinetant**
MR-VMS

### Phase 3 study

**gilteritinib**
R/R AML (ADMIRAL study)**

**roxadustat**

EU: Non-dialysis pts
- ALPS study
- DOLOMITE study
- ANDES study

EU: Dialysis pts
- HIMALAYA study
- SIERRA study
- PYRENEES study

JP: Dialysis pts
- Conversion in HD pts

JP: Non-dialysis pts
- Correction study (ESA-naive)

## Filing*

**peficitinib**
Rheumatoid arthritis (Japan)

## Regulatory Decisions

**enzalutamide**
M0 CRPC (US, EU)

**gilteritinib**
Relapsed and refractory AML (US, Japan)

**solifenacin/mirabegron**
concomitant use in OAB (US)

**blinatumomab**
ALL (Japan)

**degarelix**
Prostate cancer, 3M (Japan)

**romosozumab**
Osteoporosis (Japan)

**linaclotide**
Chronic constipation (Japan)

**ipragliflozin**
Type 1 diabetes (Japan)

**fidaxomicin**
Infectious enteritis (Japan)

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**: event-driven study, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, ALS: Amyotrophic lateral sclerosis, MR-VMS: Menopause-related vasomotor symptoms, R/R: Relapsed and refractory, AML: Acute myeloid leukemia, HD: hemodialysis, M0 CRPC: Non-metastatic castration-resistant prostate cancer, OAB: overactive bladder, ALL: Acute lymphoblastic leukemia

# POTENTIAL GROWTH DRIVERS



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

**Growth drivers/ new products**

- Xtandi (enzalutamide)
- Myrbetriq (mirabegron)
- CRESEMBA (isavuconazonium sulfate) 372 mg for injection・186 mg capsules
- cimzia (certolizumab pegol)
- Suglat®
- Repatha (evolocumab) injection 140 mg/mL
- Linzess (linaclotide) capsules

**Near term growth drivers**
(Filed or Filing expected in FY2018)

- **enzalutamide** (M0 CRPC)
- **gilteritinib** (Relapsed and Refractory AML)
- **solifenacin/mirabegron** (Combination therapy)
- **roxadustat** (JP: Dialysis)
- **peficitinib**
- **linaclotide** (Chronic constipation)
- **romosozumab**

**Mid-term growth drivers**
(FY2019- )

- **enzalutamide** (label expansion)
- **gilteritinib** (Other AML patient segments)
- **enfortumab vedotin**
- **zolbetuximab (IMAB362)**
- **roxadustat** (EU: Dialysis/Non-dialysis) (JP: Non-dialysis)
- **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

# INITIATIVES TO BUILD RESILIENCE FOR SUSTAINABLE GROWTH

## STRATEGIC INITIATIVES

# MODALITY:
# ACQUISITION OF UNIVERSAL CELLS



*Reinforce focus on cell therapy by acquiring Universal Donor Cell technology*

- Strength of Universal Donor Cell technology
  - Technology to create stem cell therapies that overcome immune rejection
  - Universal Donor Cell technology can be administered to any recipient without the need for Human Leukocyte Antigen (HLA) matching
  - Expands research potential to wide range of differentiated cells

→ Universal Donor Cell technology is essential for expansion to systemic diseases such as autoimmune diseases and blood diseases

Further strengthens R&D focus in cell therapy by combining capability of AIRM* with Universal Donor Cell technology

Universal Cells

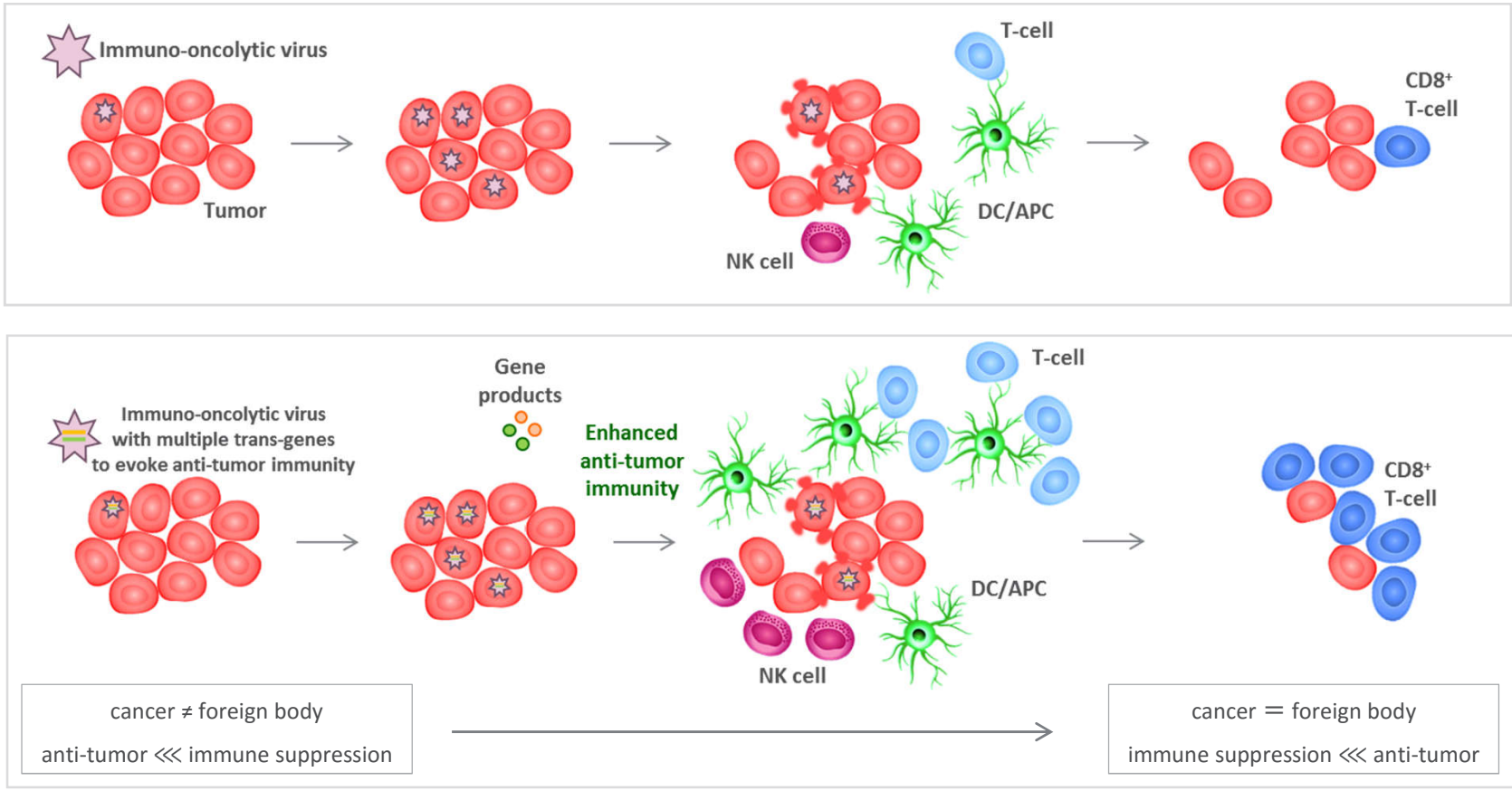
astellas

*Astellas Institute for Regenerative Medicine

# MODALITY:
# LICENSE AGREEMENT WITH TOTTORI UNIVERSITY



*Immuno-oncolytic virus with multiple trans-genes to evoke anti-tumor immunity*




鳥取大学 Tottori University

astellas

NK cell: Natural Killer cell, DC: Dendritic Cell, APC: Antigen Presenting Cell

# INITIATIVES TO BUILD RESILIENCE FOR SUSTAINABLE GROWTH

## PURSUE OPERATIONAL EXCELLENCE

# OPTIMIZATION OF ORGANIZATION / STRUCTURE IN EMEA



*Evolve operating model with changes in external environment*

- R&D activities in Netherlands consolidated in Japan and the U.S.
- Further improving efficiency of finance function in EMEA through outsourcing and reorganization
- Enhancing sales & marketing efficiency and strategy quality in EMEA through the optimization of sales & marketing organization / structure

# Information meeting on Strategic Plan
# May 22, 2018

2:00 pm – 3:30 pm (JST)

# APPENDIX

# FY2017: SALES BY REGION



| | FY16 | FY17 | Change |
|---|---|---|---|
| **Japan (billion yen)** | **480.8** | **421.2** | -12.4% |
| of sales in Japanese market | 452.7 | 383.4 | -15.3% |
| **Americas (million USD)** | **3,805** | **3,909** | +2.7% |
| **EMEA (million EUR)** | **2,785** | **2,651** | -4.8% |
| **Asia/Oceania (billion yen)** | **87.7** | **102.0** | +16.3% |

# FY2018 FCST: SALES BY REGION



| | FY17 | FY18 FCST | Change |
|---|---|---|---|
| **Japan (billion yen)** | **421.2** | **396.8** | -5.8% |
| of sales in Japanese market | 383.4 | 365.3 | -4.7% |
| **Americas (million USD)** | **3,909** | **4,042** | +3.4% |
| **EMEA (million EUR)** | **2,651** | **2,645** | -0.2% |
| **Asia/Oceania (billion yen)** | **102.0** | **112.9** | +10.7% |

# FY2018 FCST: SALES IN KEY AREAS



| (billion yen) | FY17 | FY18 FCST | Change | CER growth |
|---|---|---|---|---|
| **XTANDI** | **294.3** | **310.3** | **+5.5%** | **+8.4%** |
| **OAB in Urology** | **228.1** | **243.1** | **+6.6%** | **+9.6%** |
| Vesicare | 102.3 | 96.9 | -5.2% | -3.2% |
| Betanis/Myrbetriq/BETMIGA | 125.7 | 146.2 | +16.3% | +20.1% |
| **Transplantation** | **198.5** | **190.7** | **-3.9%** | **-3.3%** |

Transplantation: Prograf, Advagraf/Graceptor/ASTAGRAF XL

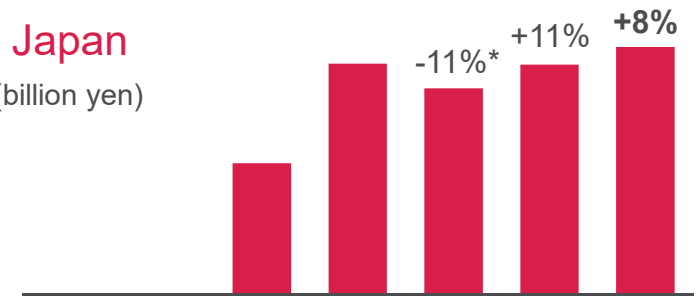
CER：Constant Exchange Rate

# FY2018 SALES FCST: XTANDI



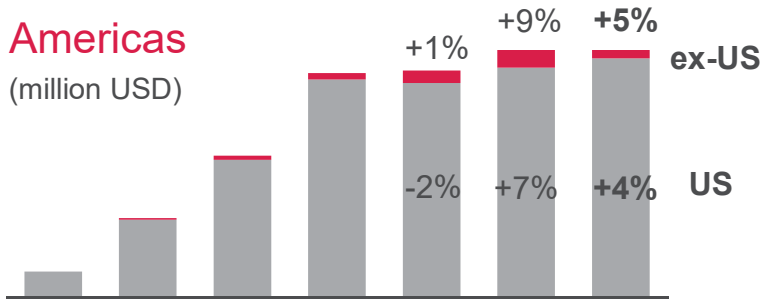
## Sales since launch by region

### Japan
(billion yen)

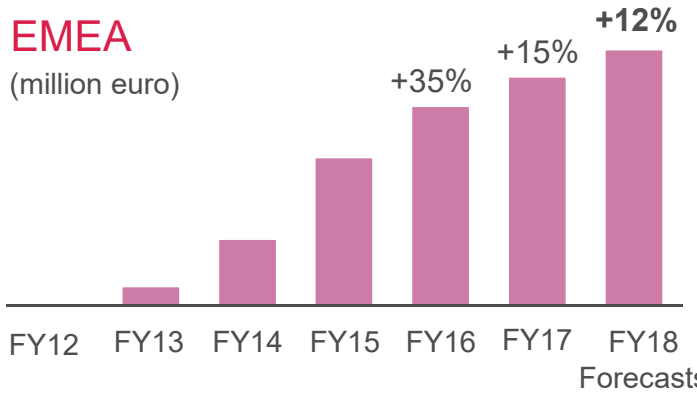



*+19% excl. NHI drug price cut impacts

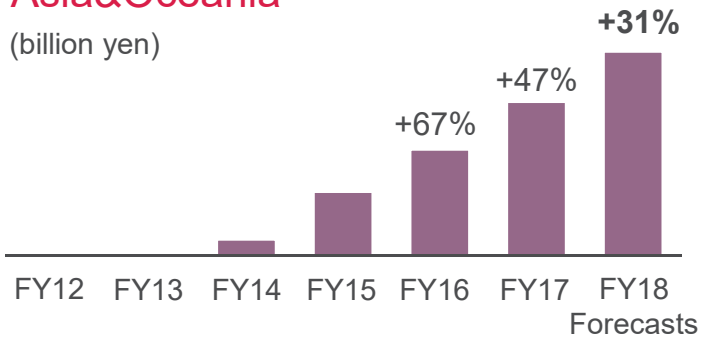
### Americas
(million USD)




### EMEA
(million euro)




### Asia&Oceania
(billion yen)



# FX RATE (ACTUAL)



**Average rate for the period** (yen)

| Currency | FY16 | FY17 | Change |
|---|---|---|---|
| USD | 108 | 111 | +2 |
| EUR | 119 | 130 | +11 |

**Change in closing rate from PY end**

| Currency | FY16 | FY17 |
|---|---|---|
| USD | -0 | -6 |
| EUR | -8 | +11 |

Exchange rate change +: Yen Weakening, - : Yen Strengthening

# FY2018 FCST：FX RATE & FX SENSITIVITY



(yen)

**Average rate for the period**

| Currency | FY17 | FY18 FCST | Change |
|---|---|---|---|
| USD | 111 | 105 | -6 |
| EUR | 130 | 130 | +0 |

**Change in closing rate from PY end**

| Currency | FY17 | FY18 FCST |
|---|---|---|
| USD | -6 | -1 |
| EUR | +11 | -1 |

**Estimated Fx sensitivity of FY2018 forecasts by 1 yen appreciation**

| Currency | Average rate 1 yen higher than assumption | | Year-end rate 1 yen higher than assumption |
|---|---|---|---|
| | Net sales | Core OP | Core OP |
| USD | Approx. -5.1 bil yen | Approx. -1.2 bil yen | Approx. +0.6 bil yen |
| EUR | Approx. -2.6 bil yen | Approx. -1.1 bil yen | Approx. +0.3 bil yen |

# BALANCE SHEET/CASH FLOW HIGHLIGHTS



| (billion yen) | FY2016 end | FY2017 end |
|---|---|---|
| Total assets | 1,814.1 | 1,858.2 |
| Cash and cash equivalents | 340.9 | 331.7 |
| Total net assets | 1,271.8 | 1,268.3 |
| Equity ratio (%) | 70.1% | 68.3% |

| (billion yen) | FY16 | FY17 |
|---|---|---|
| Cash flows from operating activities | 235.6 | 312.6 |
| Cash flows from investing activities | (73.4) | (121.8) |
| Free cash flows | 162.2 | 190.8 |
| Cash flows from financing activities | (166.2) | (203.4) |
| Acquisition of treasury shares | (92.2) | (130.7) |
| Dividends paid | (70.1) | (71.6) |

# PROFIT DISTRIBUTION



| | FY2016 | FY2017 | FY2018 (Forecast) |
|---|---|---|---|
| EPS (yen) | 103.69 | 81.11 | 107.79 |
| Divided per share (yen) | 34 | 36 (planned) | 38 (forecast) |
| ROE | 17.3% | 13.0% | - |
| DOE | 5.6% | 5.7% | - |
| Share buyback | 60 million shares<br>91.4 billion yen | 88 million shares<br>129.9 billion yen | - |
| Treasury stock cancellation | 68 million shares | 85 million shares | 89 million shares (planned) |

# ON THE FOREFRONT OF HEALTHCARE CHANGE