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.

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. FY2018 Consolidated Financial Results
   FY2019 Forecasts

II. Initiatives for Sustainable Growth

III. Capital Allocation
## FY2018 FINANCIAL RESULTS (CORE BASIS)

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY17</th>
<th>FY18</th>
<th>Change</th>
<th>FY18 FCST*</th>
<th>Achievement</th>
<th>CER growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>1,300.3</td>
<td>1,306.3</td>
<td>+0.5%</td>
<td>1,300.0</td>
<td>100.5%</td>
<td>+0.8%</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>294.2</td>
<td>292.0</td>
<td>-0.7%</td>
<td>292.0</td>
<td>22.4%</td>
<td></td>
</tr>
<tr>
<td>% of revenue</td>
<td>22.6%</td>
<td>22.4%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SG&amp;A expenses</td>
<td>478.3</td>
<td>490.3</td>
<td>+2.5%</td>
<td>490.3</td>
<td>37.5%</td>
<td></td>
</tr>
<tr>
<td>% of revenue</td>
<td>36.8%</td>
<td>37.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>220.8</td>
<td>208.7</td>
<td>-5.5%</td>
<td>216.0</td>
<td>96.6%</td>
<td></td>
</tr>
<tr>
<td>% of revenue</td>
<td>17.0%</td>
<td>16.0%</td>
<td></td>
<td>16.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amortisation of intangible assets</td>
<td>35.8</td>
<td>35.2</td>
<td>-1.7%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share of profit (loss) of investments accounted for using equity method</td>
<td>-2.4</td>
<td>-1.6</td>
<td>-</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Core operating profit</td>
<td>268.7</td>
<td>278.5</td>
<td>+3.7%</td>
<td>270.0</td>
<td>103.2%</td>
<td>+3.8%</td>
</tr>
<tr>
<td>Core profit</td>
<td>204.3</td>
<td>249.3</td>
<td>+22.0%</td>
<td>221.0</td>
<td>112.8%</td>
<td></td>
</tr>
<tr>
<td>Core EPS (yen)</td>
<td>100.64</td>
<td>129.07</td>
<td>+28.2%</td>
<td>114.11</td>
<td>113.1%</td>
<td></td>
</tr>
</tbody>
</table>

*Announced in Oct. 2018
CER: Constant Exchange Rate
REVENUE ANALYSIS (YEAR ON YEAR)

Sales increase in XTANDI, mirabegron and new products sales

- Decrease in long-listed drugs (incl. Micardis) and Tarceva
- -4.6 billion yen

FY17: 1,300.3 billion yen
FY18: 1,306.3 billion yen

OAB: Overactive bladder
OAB products: Vesicare + mirabegron (Betanis/Myrbetriq/BETMIGA)
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY)
NHI price revision in Japan: -17.6 bil.yen
**CORE OP ANALYSIS (YEAR ON YEAR)**

*Increased core OP by 4% through steady growth of main products*

<table>
<thead>
<tr>
<th></th>
<th>FY17</th>
<th>FY18</th>
<th>(billion yen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross profit*</td>
<td></td>
<td></td>
<td>268.7</td>
</tr>
<tr>
<td>R&amp;D expenses*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SG&amp;A expenses*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fx impacts</td>
<td></td>
<td>-0.3</td>
<td></td>
</tr>
</tbody>
</table>

- Increase in XTANDI US co-promotion fee
- Launch costs for new products
- Increase investments to key late-stage pipeline and new area / modality
- Decrease due to wind-down of Agensys research operations, etc.

*Excluding Fx impacts*
### FY2018 FINANCIAL RESULTS (FULL BASIS)

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY17</th>
<th>FY18</th>
<th>Change</th>
<th>FY18 FCST*</th>
<th>Achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core operating profit</td>
<td>268.7</td>
<td>278.5</td>
<td>+3.7%</td>
<td>270.0</td>
<td>103.2%</td>
</tr>
<tr>
<td>Other income</td>
<td>11.9</td>
<td>14.2</td>
<td>+19.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other expense</td>
<td>67.3</td>
<td>48.8</td>
<td>-27.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Operating profit</strong></td>
<td>213.3</td>
<td>243.9</td>
<td>+14.4%</td>
<td>234.0</td>
<td>104.2%</td>
</tr>
<tr>
<td>Profit before tax</td>
<td>218.1</td>
<td>249.0</td>
<td>+14.1%</td>
<td>236.0</td>
<td>105.5%</td>
</tr>
<tr>
<td>Profit</td>
<td>164.7</td>
<td>222.3</td>
<td>+35.0%</td>
<td>195.0</td>
<td>114.0%</td>
</tr>
<tr>
<td>EPS (yen)</td>
<td>81.11</td>
<td>115.05</td>
<td>+41.8%</td>
<td>100.69</td>
<td>114.3%</td>
</tr>
</tbody>
</table>

**Other expense in FY2018**
- Expenses related to business restructuring: 23.1**
- Litigation costs: 12.3

**Including restructuring costs and impairment losses of Nishine plant**

*Announced in Oct. 2018
## FY2019 FORECASTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY18 ACT</th>
<th>FY19 FCST</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>1,306.3</td>
<td>1,224.0</td>
<td>-6.3%</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>208.7</td>
<td>211.0</td>
<td>+1.1%</td>
</tr>
<tr>
<td>% of revenue</td>
<td>16.0%</td>
<td>17.2%</td>
<td>+1.2ppt</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>278.5</td>
<td>240.0</td>
<td>-13.8%</td>
</tr>
<tr>
<td>Core profit</td>
<td>249.3</td>
<td>194.0</td>
<td>-22.2%</td>
</tr>
<tr>
<td>Core EPS (yen)</td>
<td>129.07</td>
<td>102.87</td>
<td>-20.3%</td>
</tr>
<tr>
<td>Operating profit</td>
<td>243.9</td>
<td>229.0</td>
<td>-6.1%</td>
</tr>
<tr>
<td>Profit</td>
<td>222.3</td>
<td>182.0</td>
<td>-18.1%</td>
</tr>
<tr>
<td>EPS (yen)</td>
<td>115.05</td>
<td>96.51</td>
<td>-16.1%</td>
</tr>
</tbody>
</table>
FY2019 FORECASTS: REVENUE

Revenue to decrease due to LOE of major products.
Main products continue to grow and new products contribute throughout the year

<table>
<thead>
<tr>
<th>FY18</th>
<th>1,306.3 (billion yen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTANDI</td>
<td></td>
</tr>
<tr>
<td>mirabegron</td>
<td></td>
</tr>
<tr>
<td>XOSPATA</td>
<td></td>
</tr>
<tr>
<td>New products in Japan</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
<tr>
<td>Fx impacts</td>
<td></td>
</tr>
<tr>
<td>FY19 FCST</td>
<td>1,224.0</td>
</tr>
</tbody>
</table>

LOE: Loss of exclusivity
mirabegron (Betanis/Myrbetriq/BETMIGA)
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

*Termination of sale and distribution for Symbicort and KM bio products
FY2019 FORECASTS: CORE OP

Securing investments to maximize product VALUE while reviewing cost structure

(billion yen)

<table>
<thead>
<tr>
<th>FY18</th>
<th>Gross profit</th>
<th>278.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>SG&amp;A expenses</td>
<td>- Decrease in amortisation of Tarceva intangible assets</td>
<td></td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>- Investment in Focus Area and six key late-stage projects</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>- Other SG&amp;A expenses: Increase in launch costs for new products absorbed by reviewing cost structure</td>
<td></td>
</tr>
<tr>
<td>FY19 FCST</td>
<td>- Increase in XTANDI US co-promotion fee with sales expansion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- LOE impact of Vesicare and Tarceva</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Transfer of sale and distribution in Japan</td>
<td></td>
</tr>
</tbody>
</table>

LOE: Loss of exclusivity
## PROGRESS TOWARDS THE STRATEGIC PLAN 2018 GUIDANCE

<table>
<thead>
<tr>
<th>Indicators</th>
<th>FY17 ACT</th>
<th>FY18 ACT</th>
<th>FY19 FCST</th>
<th>FY20 Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>1,300.3</td>
<td>1,306.3</td>
<td>1,224.0</td>
<td>FY2017 level</td>
</tr>
<tr>
<td>R&amp;D investment</td>
<td>220.8</td>
<td>208.7</td>
<td>211.0</td>
<td>More than 200.0 billion yen</td>
</tr>
<tr>
<td>Core OP</td>
<td>268.7</td>
<td>278.5</td>
<td>240.0</td>
<td>Core OP margin 20%</td>
</tr>
<tr>
<td>Core EPS</td>
<td>100.64 yen</td>
<td>129.07 yen</td>
<td>102.87 yen</td>
<td>Exceed FY2017</td>
</tr>
</tbody>
</table>
AGENDA

I  FY2018 Consolidated Financial Results
   FY2019 Forecasts

II  Initiatives for Sustainable Growth

III Capital Allocation
REVIEW OF FY2018

*Initiatives aiming at 3 Strategic Goals advancing as planned*

**Strategic Goal 1**
Maximizing Product VALUE and Operational Excellence

**Maximizing Product VALUE**
- Steady top line growth in XTANDI and OAB products as planned
- Launches of XOSPATA in Japan and US
- Continued launches of new products in Japan

- 6 post-POC projects: Achieved important milestones as planned

**Operational Excellence**
- Restructuring of operations in Europe/Japan*
  Succession of Nishine plant
  *Applicant for early retirement program: Approx. 700 employees

**Strategic Goal 2**
Evolving How We Create VALUE -With Focus Area Approach-

- Progress of early stage pipeline in identified Primary Focus
- Acquiring external innovation aligned with our strategy
  - Acquisitions: Quethera Potenza
  - Collaborations: Juventas Gene Therapy Research Institution

**Strategic Goal 3**
Developing Rx+™programs

- Build connections and networks with technology and knowledge from various fields
  - Established US basis for Rx+™ business
  - Collaboration with venture capitals
- Progress on multiple Rx+™ programs

*Applicant for early retirement program: Approx. 700 employees*
Maximizing Product VALUE and Operational Excellence
MAIN GROWTH DRIVERS: XTANDI AND MIRABEGRON

**XTANDI**

- FY2018: XTANDI revenue increased in all regions due to penetration in earlier stage of prostate cancer
- FY2019: Enhance market access and further penetration of urologists in the M0 CRPC indication
  FY2019 forecast: 364.2 billion yen
- Regulatory decision to be expected in FY2019
  (Filed in Mar 2018)

**mirabegron**

- FY2018: Double digit growth in each region by expanding share in approved markets
- FY2019: Continue to expand OAB market through ongoing disease awareness activities globally
  FY2019 forecast: 160.6 billion yen
- Launched in China in May 2018. Enhance efforts to improve drug adherence, consultation and diagnosis rate

M0 CPRC: Non-metastatic castration-resistant prostate cancer

mirabegron (Betanis/Myrbetriq/BETMIGA)
NEW PRODUCT: XOSPATA
FIRST FLT3 INHIBITOR FOR R/R AML WITH FLT3 MUTATION

*Launched in Japan and US as new treatment option for AML*

- Patients with AML with activating FLT3 mutations have short survival and high relapse rates. No standard of care established for R/R AML with FLT3 mutation.

- The NCCN guidelines included XOSPATA within days of FDA approval. Secured patient access through broad payer coverage.

- Many doctors experienced remarkably effective responses in target patients identified by companion diagnostics and the reaction from the prescribers is favorable. High rates of XOSPATA awareness post launch.

- Now initiating launch preparations in Europe.

- Educate around importance of FLT3 mutation testing and promote XOSPATA’s characteristics for highly specialized hematologists/oncologists.

**FY18 ACT**

**FY19 FCST**

15.1 (+12.6)

(billion yen)

* Total of JP, US

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FLT3: FML-like tyrosine kinase 3, R/R AML: Relapsed or refractory acute myeloid leukemia, NCCN: National Comprehensive Cancer Network
NEW PRODUCTS IN JAPAN

Sales increase due to launch of new products and additional indications

Strategic plan 2018 Guidance: Exceed 100.0 billion yen in early 2020’s

- **Repatha (evolocumab)** injection 10mg/ml: Launch in May 2018
- **Suglat** Additional indication Dec. 2018
- **Linzess (linaclotide) capsules**: Additional indication Aug. 2018
- **SUJANU**: Launched in Nov. 2018
- **Dafclir**: Launched in Sep. 2018
- **BLINCYTO**: Launched in May 2018
- **EVENITY (romosozumab) injection**: Launched in Mar. 2019
- **Smyraf**: Approved in Mar. 2019

FY17 ACT: 14.7 (billion yen)
FY18 ACT: 26.2 (billion yen)
FY19 FCST: Approx. 45.0 (billion yen)
NEW COMMERCIAL STRUCTURE AS OF APRIL 2019

New sales and marketing structure aims to maximize product VALUE on a global basis

- **Reorganization from the 4 unit commercial structure to 5 unit structure**
  - In addition to US as single division, independence of China where further market expansion to be expected
  - Bring regions and countries with similar payer systems and business practices into one division

<table>
<thead>
<tr>
<th>Past</th>
<th>From April 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>Japan</td>
</tr>
<tr>
<td>Americas</td>
<td>United States</td>
</tr>
<tr>
<td>EMEA</td>
<td>Greater China*</td>
</tr>
<tr>
<td>Asia/Oceania</td>
<td>Established Market*</td>
</tr>
<tr>
<td></td>
<td>International*</td>
</tr>
</tbody>
</table>

- **Enhancing strategic planning and execution capabilities for priority products by expanding global marketing functions**
  - Brand General Managers (BGM) for six key late-stage projects build/promote consistent, effective and efficient product strategies on a global basis
  - Enhance collaboration with medical and development functions through leadership of BGM to more accurately reflect market needs to product profiles
  - Reinforce market access functions to secure drug access in each country

*Greater China: China, Hong Kong, Taiwan
*Established Market: Europe, Canada, Australia
*International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea
ENHANCEMENT OF INITIATIVES IN CHINA (1)

Expecting further market expansion by promoting innovation in addition to economic growth

External environment and business opportunities

- Continued market growth from rising income levels due to economic growth and aging society
- Potential for accelerated approval of innovative drugs through deregulation
- Improving patient accessibility by increasing access opportunity to the National Health Insurance Reimbursed Drug List (NRDL)
- Changing healthcare environment such as the rise of digital health thanks to rapid evolution of ICT

ICT: Information and communication technology
Enhancement of initiatives in China (2)

Invest sufficient resources to accelerate development of innovative medicines in top-tier market

- Enhancing development and regulatory functions
  - Establishing drug development capabilities similar to other top-tier market like Japan, US and Europe
  - Enhancing capabilities in medical affairs, regulatory affairs and other functions
  - Allocating sufficient resources to multiple key late-stage projects

### Late-stage projects

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>enzalutamide (XTANDI)</td>
<td>M1 CRPC</td>
<td>Filed in Mar. 2018; Regulatory decision to be expected in FY2019</td>
</tr>
<tr>
<td>gilteritinib (XOSPATA)</td>
<td>R/R AML</td>
<td>P3 study ongoing</td>
</tr>
<tr>
<td>enfourtumab vedotin</td>
<td></td>
<td>Metastatic urothelial cancer Development plan under discussion</td>
</tr>
<tr>
<td>zolbetuximab</td>
<td></td>
<td>Gastric and GEJ adenocarcinoma Plan to join in P3 studies in FY2019</td>
</tr>
<tr>
<td>fezolinetant</td>
<td>MR-VMS</td>
<td>Plan to initiate P3 studies in FY2019</td>
</tr>
<tr>
<td>peficitinib</td>
<td></td>
<td>Rheumatoid arthritis P3 study ongoing</td>
</tr>
</tbody>
</table>

**Abbreviations**

- M1: Metastatic
- CRPC: Castration resistant prostate cancer
- AML: Acute myeloid leukemia
- GEJ: Gastroesophageal junction
- MR-VMS: Menopause-related vasomotor symptom
Enhancement of commercial functions to support continuous launch of new products into growth market

- Enhancement of Government affairs function
- Enhancement of Marketing function
  - Market expansion through disease awareness activities
  - Access enhancement by digital marketing, etc
- Deployment of Oncology Sales Force

FY2018

- Existing growth products (Prograf / Harnal, etc)

FY2019

- New products in FY2018 (BETMIGA, Feburic)
- XTANDI (Filed in Mar. 2018)

FY2020 beyond

- Post-POC projects
PURSUE OPERATIONAL EXCELLENCE

Progress as planned against profit improvement plan of over 30.0 billion yen announced in Strategic plan 2018

- Prioritize advertising and sales promotion expenses
- Prioritize R&D expenses
- Strengthen global procurement
- Review costs not contributing to competitiveness

Contributing to mid- to long-term cost structure reform in FY2020 onward along with implemented initiatives

- Wind-down of Agensys research operations
- Reorganization of R&D and sales & marketing functions in EMEA
- Restructuring of domestic group company/ early retirement program in Japan
- Business transfers (Nishine Plant, etc.)
CONTINUED PROGRESS ON 6 POST-POC PROJECTS SINCE APR 2018

Development advancing as intended in Strategic Plan 2018

<table>
<thead>
<tr>
<th>Indication</th>
<th>P1</th>
<th>P2</th>
<th>P3</th>
<th>Filed</th>
<th>Approved</th>
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<tbody>
<tr>
<td>enzalutamide</td>
<td>M0 CRPC</td>
<td></td>
<td></td>
<td></td>
<td>US, EU</td>
</tr>
<tr>
<td></td>
<td>M1 HSPC</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>M0 HSPC</td>
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<tr>
<td>gilteritinib</td>
<td>Relapsed or refractory AML</td>
<td></td>
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<td></td>
<td>US, JP</td>
</tr>
<tr>
<td></td>
<td>Newly diagnosed AML*1</td>
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<tr>
<td></td>
<td>Newly diagnosed AML*2</td>
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<tr>
<td></td>
<td>AML (Post- HSCT maintenance)</td>
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<td></td>
<td>AML (Post-chemo maintenance)</td>
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</tr>
<tr>
<td>enfortumab vedotin</td>
<td>mUC, 3rd line</td>
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<tr>
<td></td>
<td>mUC, 2nd line</td>
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</tr>
<tr>
<td></td>
<td>mUC, 1st line</td>
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</tr>
<tr>
<td>zolbetuximab</td>
<td>Gastric and GEJ carcinoma</td>
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<tr>
<td></td>
<td>Pancreatic adenocarcinoma</td>
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<tr>
<td>roxadustat</td>
<td>Japan, CKD on dialysis</td>
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<td>Japan, CKD not on dialysis</td>
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<td>EU, CKD</td>
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<td>CIA</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>fezolinetant</td>
<td>MR-VMS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


*1: intensive chemo eligible
*2: intensive chemo ineligible
FY2018 ACHIEVEMENTS AND STATUS UPDATE
(Underline: Updates since Q3/FY2018 Announcement)

**enzalutamide**

M0 CRPC
- **US**: Approved in July 2018
- **EU**: Approved in Oct 2018

M1 HSPC
- **ARCHES study**: Results obtained
- Filing planned by mid-2019 in US/EU/Japan

**gilteritinib**

FLT3 mut+ R/R AML
- **ADIMARAL study**: Results obtained
- **Japan**: Launched in Dec 2018. Plan to include OS data in label in 3Q/2019
- **US**: Launched in Dec 2018. Submitted sNDA to include OS data in the label in Feb 2019
- **EU**: MAA submitted in Feb 2019

**enfortumab vedotin**

mUC with prior CPI treatment
- **Cohort 1 in Phase 2 study** (platinum-pretreated): TLR obtained
- **BLA submission planned in US in 2019

**zolbetuximab**

Gastric and GEJ adenocarcinoma
- **SPOTLIGHT study**: FPI in Oct 2018
- **GLOW study**: FPI in Jan 2019

Pancreatic cancer
- Phase 2 to start in 2Q/2019

**roxadustat**

Anemia associated with CKD
- **EU**: Results obtained from 6 studies. MAA planned in 2H/2019
- **JP**: Data readout in 2 studies. Filed for patients on dialysis in Sep 2018. For non-dialysis, TLR of the remaining study expected in 2019

Chemotherapy induced anemia
- **Phase 2 to start in 2019

**fezolinetant**

MR-VMS
- **Phase 2b study**: Results obtained
- **Phase 3 study**: Under preparation

---

ENZALUTAMIDE:
RESULTS OF PHASE 3 ARCHES IN M1 HSPC

Enzalutamide significantly improved rPFS
Filing for M1 HSPC in US/EU/Japan planned by mid-2019

- The preliminary safety analysis appears consistent with the safety profile of XTANDI in previous clinical trials in CRPC

Andrew J. Armstrong et al., ASCO-GU 2019
GILTERITINIB:
RESULTS OF PHASE 3 ADMIRAL RESULTS IN R/R AML

Gilertitinib significantly improved survival compared with salvage chemotherapy
US sNDA to include OS and MAA in EU submitted in Feb 2019

- Compared with salvage chemotherapy, gilteritinib was generally associated with lower toxicity
during the first 30 days of treatment, which facilitated outpatient administration of the drug

Alexander E. Perl et al., American Association for Cancer Research 2019
sNDA: Supplemental new drug application, OS, overall survival, MAA: Marketing authorization application, CI: Confidence interval, HR: Hazard ratio
Plan to start 2 head-to-head studies in newly diagnosed patients

- In a Phase 1 study in combination with high intensity chemotherapy, gilteritinib showed a CRc rate of ≥90% in patients with FLT3 mutations **

- Two collaborative studies to be initiated in 3Q/2019
  - Phase 3 study by HOVON primarily in EU
  - Phase 2 study by PrECOG in US

- Head-to-head comparator studies vs midostaurin, in combination with high intensity chemotherapy

** K. Pratz et al., ASH 2018
FLT3 mut+: Fms-like tyrosine kinase 3 mutation positive, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, ASH: American Society of Hematology
ENFORTUMAB VEDOTIN

Obtained positive results from Cohort 1 of Phase 2 study.
BLA submission in US planned later this year

### Characteristics

- First and only ADC targeting Nectin-4, which is highly expressed in bladder cancer and has limited expression on normal tissue
- Breakthrough Therapy designation for CPI-pretreated mUC patients granted by FDA

### Status update

**EV-201 study**

- Single-arm, pivotal phase 2 study
- Cohort 1 enrolled 128 patients previously treated with a PD-1 or PD-L1 inhibitor and a platinum-containing chemotherapy

**Top line results**

- 44% ORR (primary endpoint)
- Duration of response was consistent with previous phase 1 study
- The most common treatment-related AEs included fatigue, alopecia, decreased appetite, rash and peripheral neuropathy
- Data to be presented at ASCO in June

### Next step

- Intend to submit a BLA to the FDA later this year
- Confirmatory phase 3 study ongoing

### Unmet medical needs in urothelial cancer

- Approximately 56,000 cases of newly diagnosed or recurrent metastatic bladder cancer annually (US, EU5, JP) *1
- 5-year survival rate of 4% for metastatic bladder cancer*2
- Approx. 80% of patients do not respond to PD-1/PD-L1 therapy, requiring further treatment options

---

ROXADUSTAT

Readout of all Phase-3 studies ongoing, MAA planned in 2H/2019

Initiated development for additional indication

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Status update</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Novel mechanism of action</td>
<td>• Obtained TLRs of 6 Phase 3 studies to support EU filing and reimbursement</td>
</tr>
<tr>
<td>• Orally administered</td>
<td>• Pooled safety analysis planned in 1H/2019</td>
</tr>
<tr>
<td>• Reduces the need for IV iron</td>
<td>• MAA submission planned in 2H/2019</td>
</tr>
<tr>
<td>• Comparable efficacy to current treatment (i.e. ESAs)</td>
<td></td>
</tr>
<tr>
<td>• Erythropoietin levels within or near the physiological range, potentially</td>
<td></td>
</tr>
<tr>
<td>avoiding the concerns from the existing therapy</td>
<td></td>
</tr>
<tr>
<td>• Efficacy in patients with inflammation who have reduced response to existing</td>
<td></td>
</tr>
<tr>
<td>therapy</td>
<td></td>
</tr>
</tbody>
</table>

Maximizing VALUE in chemotherapy-induced anemia (CIA)

Unmet medical needs

• Up to 50% of patients with cancer develop CIA over the course of chemotherapy *1
• 25%-40% of patients are non-responders to existing ESAs *2

Next step

• Phase 2 study in non-myeloid malignancies with anemia due to chemotherapy to start in 2019 (Study sponsor: FibroGen)

---


MAA: Marketing authorization application, IV: Intravenous, ESA: Erythropoietin-stimulating agent, TLR: Topline result
FEZOLINETANT: EFFICACY IN PHASE 2B

Statistically significant improvement across all four co-primary endpoints in most cohorts; comparable efficacy and treatment effect size for BID and QD

Frequency of moderate and severe VMS per 24 hours with fezolinetant BID/QD

*P<0.05 for all pairwise comparisons of fezolinetant vs placebo at weeks 4 and 12, with no adjustments for multiplicity
Fezolinetant was generally well tolerated; Phase 3 preparation ongoing

<table>
<thead>
<tr>
<th>Safety</th>
<th>Status update</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Overall TEAE rates were similar across cohorts; TEAEs were mostly mild or moderate.</td>
<td>• End of Phase 2 Meeting is being held with FDA; incorporating their feedback into the planned Phase 3 program</td>
</tr>
<tr>
<td>• There were no treatment-related serious TEAEs or deaths</td>
<td>• Plan to also consult with other regulatory authorities</td>
</tr>
<tr>
<td>• 9 patients (less than 3%) treated with higher doses had transient increases in the liver enzymes ALT and AST; No cases of bilirubin greater than two times the upper limit of normal; Patients returned to baseline levels after discontinuation of dosing</td>
<td><strong>Next step</strong></td>
</tr>
<tr>
<td></td>
<td>• Plan to initiate Phase 3 in 2H/2019</td>
</tr>
<tr>
<td></td>
<td>• Plan to conduct multiple Phase 3 studies including long term safety studies in Western and Asian populations</td>
</tr>
</tbody>
</table>

TEAE: Treatment emergent adverse event, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, FDA: Food and Drug Administration
# EXPECTED KEY EVENTS IN FY2019

*Continued progress on important milestones for 6 post-POC projects*

<table>
<thead>
<tr>
<th>Regulatory decisions</th>
<th>enzalutamide</th>
<th>M1 CRPC (China)</th>
</tr>
</thead>
<tbody>
<tr>
<td>gilteritinib</td>
<td></td>
<td>Relapsed/refractory AML (EU)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Label update to include OS data (US)</td>
</tr>
<tr>
<td>roxadustat</td>
<td></td>
<td>Anemia associated with CKD, dialysis (Japan)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory submissions*</th>
<th>enzalutamide</th>
<th>M1 HSPC (US/EU/Japan)</th>
</tr>
</thead>
<tbody>
<tr>
<td>enfortumab vedotin</td>
<td></td>
<td>mUC, CPI-pretreated/platinum-pretreated (US)</td>
</tr>
<tr>
<td>roxadustat</td>
<td></td>
<td>Anemia associated with CKD, dialysis/non-dialysis (EU)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data readouts</th>
<th>roxadustat</th>
<th>Pooled safety analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>P3 study in Japanese CKD patients, non-dialysis (1517-CL-0310)</td>
</tr>
</tbody>
</table>

*:Subject to study outcome, internal assessment, decision and regulatory consultation, as appropriate Please refer to R&D pipeline list for details including target disease.

Evolving How We Create VALUE -With Focus Area Approach-
FOCUS AREA APPROACH

Focusing on the areas to turn innovative science to VALUE for patients

Focus Area approach

- Exploring multiple sets of combinations of Biology, Modality/Technology and Disease

  Biology
  Pathophysiology Characterized

  Modality/Technology
  Versatile Technology

  Disease
  Disease with high UMN

- Primary Focus is selected from Focus Areas based on;
  - Scientific evidence
  - Identified lead program
  - Potential follow-on programs

Our efforts in current and potential Primary Focus

Primary Focus

- Prioritize investment in 4 Primary Focus

  Regeneration & blindness
  Immuno-oncology

  ASIM biology
  Mitochondria biology

Potential future Primary Focus

- Explore the components and connections of Biology, Modality/Technology and Disease further and identify a lead program
- Exploring Genetic regulation and other areas

ASIM: Antigen-specific immuno-modulation
### ACQUIRING AND PARTNERING EXTERNAL CAPABILITIES

*I incorporate game changing technology and cutting-edge science*

<table>
<thead>
<tr>
<th>Primary Focus</th>
<th>Companies/Institutions</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regeneration &amp; blindness</td>
<td>Ocata Therapeutics Universal Cells Quethera * Clino Co. Harvard Medical School</td>
<td></td>
</tr>
<tr>
<td>Immuno-oncology</td>
<td>Potenza Therapeutics * Tottori University</td>
<td></td>
</tr>
<tr>
<td>ASIM biology</td>
<td>Immunomic Therapeutics Affinivax</td>
<td></td>
</tr>
<tr>
<td>Mitochondria biology</td>
<td>Mitobridge</td>
<td></td>
</tr>
<tr>
<td>Potential future Primary Focus</td>
<td><em>Gene Therapy Research Institution</em> <em>Juventas Therapeutics</em></td>
<td></td>
</tr>
</tbody>
</table>

*Note) This chart includes M&As, license agreements and research collaborations related to Primary Focus
* Agreements executed or updated in FY2018
ASIM: Antigen-specific immuno-modulation, M&A: Merger and acquisition
Established research and manufacturing platform for cell therapy

1. PSC (iPSC/ESC) Cell bank
2. Desired cells
3. Drug substance
4. Logistics
5. Patients

Post-Ocata Acquisition
- PSC sourcing: Established
- UDC: Established
- Gene-editing: Underway
- Differentiation: Underway
- Standardization: Underway

Post-UCells Acquisition
- PSC sourcing: Underway
- UDC: Underway
- Gene-editing: Not Established / To be considered
- Differentiation: Not Established / To be considered
- Standardization: Not Established / To be considered

Current AIRM
- PSC sourcing: Established
- UDC: Established
- Gene-editing: Underway
- Differentiation: Underway
- Standardization: Underway

PSC: Pluripotent stem cell, iPSC: Induced pluripotent stem cell, ESC: Embryonic stem cell, UDC: Universal donor cell, QA: Quality assurance, RA: Regulatory affairs, IMT: Immunosuppressant, AIRM: Astellas Institute for Regenerative Medicine
Building a portfolio of cell therapy, gene therapy and other approaches to address blindness

Strategy

• Provide therapy to regain lost sight or prevent blindness by cell therapy and gene therapy in intractable ophthalmic diseases
• Leverage UDC technology to enrich cell therapy pipeline, including non-ocular indications, and build cell therapy platform throughout value chain

Clinical program

**ASP7317**

Dry age-related macular degeneration
Recruitment for Phase 1b/2 ongoing

ASP7317 overview

Previous cell line (MA09-hRPE)

• 38 patients were successfully transplanted with hESC-derived RPE cells.
• The cells were well tolerated at all doses up to 4 years post–transplantation.
• Initial gains in vision followed by gradual loss in patients with late stage AMD

Established new cell line (ASP7317)

• Compliant to latest FDA guideline
• Developed a new cell line and an improved formulation with an extended shelf life
• Phase 1b/2 (dose-escalation and POC) study is ongoing; first patient treated in US.
IMMUNO-ONCOLOGY

Building a portfolio of novel immuno-oncology programs

Strategy

- Harnessing the immune system to treat intractable cancers

Clinical program

Projects from Potenza
- Started collaboration in 2015
- Acquired the company in Dec 2018
3 projects are in Phase 1 stage
- ASP8374/PTZ-201
- ASP1948/PTZ-329
- ASP1951/PTZ-522

ASP9801 (oncolytic virus)
- Entered into Phase 1 stage

3 clinical projects targeting patients non-responsive to existing therapies

- Release break
  - Anti-TIGIT antibody (Immune checkpoint inhibitor)
    - ASP8374/PTZ-201
  - GITR agonistic antibody (T cell priming & costimulation)
    - ASP1951/PTZ-522
  - Anti-NRP1 antibody (Treg function inhibitor)
    - ASP1948/PTZ-329

Enhance T cell response
ASIM BIOLOGY AND MITOCHONDIRA BIOLOGY

Exploring potential of multiple clinical programs

ASIM biology

- Exploring LAMP-Vax platform as a potential approach to develop immune tolerance in allergic individuals
- Explore new platform which can prevent serious infectious diseases

Clinical program

LAMP-Vax vaccine
- ASP0892 for peanut allergy
  Phase 1 ongoing
- ASP2390 for house dust mite allergy
  Preparing clinical trial

MAPS vaccine
- ASP3772 for pneumococcal disease
  Phase 1 ongoing

Mitochondria biology

- Develop mitochondria biology-based therapies to address various diseases related to mitochondrial dysfunction

Clinical program

ASP1128/MA-0217
- Acute kidney injury
  Entered into Phase 2 stage

ASP0367/MA-0211
- Duchenne muscular dystrophy
  Phase 1 ongoing

ASIM: Antigen-specific immuno-modulation, MAPS: Multiple antigen presenting system
Developing Rx+™ Programs
**Rx+™ PROGRAM: ACHIEVEMENTS IN FY2018**

- Established US basis for Rx+™ business
- Collaborations with venture capitals
- Progress on multiple programs

<table>
<thead>
<tr>
<th></th>
<th>Progress in FY18</th>
<th>Expected key events in FY19</th>
</tr>
</thead>
</table>
| **Exercise therapy**     | • Exercise support application: Executed an agreement with BANDAI NAMCO Entertainment Inc.  
                           | • Exercise therapy: Clinical research ongoing                             | • Exercise support application: Plan to conduct a clinical research |
|                          |                                                                                 |                                                                 |
| **Image-guided precision surgery** | • ASP5354; first compound as the image-guided precision surgery to identify ureter: Started Phase 1 study | • ASP5354: Plan to initiate POC study  
                           |                                                                                 | • Second compound enabling identification of cancer for surgically removal: Plan to initiate Phase 1 study |
| **Theranostics* with radioisotope-labeled antibodies** |                                                                                 | • PET imaging material: Plan to initiate clinical trial          |
AGENDA

I  FY2018 Consolidated Financial Results
    FY2019 Forecasts

II  Initiatives for Sustainable Growth

III  Capital Allocation
**CAPITAL ALLOCATION**

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

---

### Business investment

### Shareholder return

- **Aiming for steady dividend increase during FY2018-FY2020**
- **Flexible share buybacks**

<table>
<thead>
<tr>
<th></th>
<th>FY2017 ACT</th>
<th>FY2018 ACT</th>
<th>FY2019 FCST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividend</td>
<td>36 yen</td>
<td>38 yen (planned)</td>
<td>40 yen (forecast)</td>
</tr>
<tr>
<td>Share buybacks</td>
<td>130.0 billion yen</td>
<td>160.0 billion yen</td>
<td>Flexible share buybacks</td>
</tr>
<tr>
<td>Total return ratio</td>
<td>123%</td>
<td>105%</td>
<td>-</td>
</tr>
</tbody>
</table>
## FY2018 ACT: REVENUE BY REGION

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY17 ACT</th>
<th>FY18 ACT</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>421.2</td>
<td>396.6</td>
<td>-5.8%</td>
</tr>
<tr>
<td>Americas</td>
<td>433.3</td>
<td>461.5</td>
<td>+6.5%</td>
</tr>
<tr>
<td>EMEA</td>
<td>343.8</td>
<td>340.3</td>
<td>-1.0%</td>
</tr>
<tr>
<td>Asia/Oceania</td>
<td>102.0</td>
<td>107.9</td>
<td>+5.8%</td>
</tr>
</tbody>
</table>
## FY2018: SALES OF MAIN PRODUCTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY17 ACT</th>
<th>FY18 ACT</th>
<th>Change</th>
<th>CER growth</th>
<th>FY18 FCST*</th>
<th>Achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTANDI</td>
<td>294.3</td>
<td>333.1</td>
<td>+13.2%</td>
<td>+13.6%</td>
<td>325.9</td>
<td>102.2%</td>
</tr>
<tr>
<td>XOSPATA</td>
<td>-</td>
<td>2.5</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>OAB products</td>
<td>228.1</td>
<td>242.2</td>
<td>+6.2%</td>
<td>+6.5%</td>
<td>245.7</td>
<td>98.6%</td>
</tr>
<tr>
<td>Vesicare</td>
<td>102.3</td>
<td>95.0</td>
<td>-7.2%</td>
<td>-6.8%</td>
<td>96.1</td>
<td>98.8%</td>
</tr>
<tr>
<td>Mirabegron</td>
<td>125.7</td>
<td>147.2</td>
<td>+17.0%</td>
<td>+17.2%</td>
<td>149.6</td>
<td>98.4%</td>
</tr>
<tr>
<td>Prograf</td>
<td>198.5</td>
<td>195.7</td>
<td>-1.4%</td>
<td>-0.7%</td>
<td>196.0</td>
<td>99.8%</td>
</tr>
</tbody>
</table>

Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL
OAB products: Vesicare + mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)

*Announced in Oct. 2018
## FY2019 FCST: REVENUE BY REGION

<table>
<thead>
<tr>
<th>Region</th>
<th>FY18 ACT</th>
<th>FY19 FCST</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>369.5</td>
<td>316.8</td>
<td>-14.3%</td>
</tr>
<tr>
<td>United States</td>
<td>421.6</td>
<td>404.7</td>
<td>-4.0%</td>
</tr>
<tr>
<td>Established Market</td>
<td>300.0</td>
<td>286.8</td>
<td>-4.4%</td>
</tr>
<tr>
<td>Greater China</td>
<td>62.4</td>
<td>70.9</td>
<td>+13.6%</td>
</tr>
<tr>
<td>International</td>
<td>122.7</td>
<td>124.4</td>
<td>+1.4%</td>
</tr>
</tbody>
</table>

Greater China: China, Hong Kong, Taiwan  
Established Market: Europe, Canada, Australia  
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea
FY2019 FCST: XTANDI SALES BY REGION

Sales by region

Japan (billion yen)
- FY17
- FY18: +24%
- FY19: +10%

US (million USD)
- FY17
- FY18: +14%
- FY19: +10%

Established Market (million euro)
- FY17
- FY18: +8%
- FY19: +11%

International (billion yen)
- FY17
- FY18: +30%
- FY19: +24%

Greater China (billion yen)
- FY17
- FY18: +42%
- FY19: +42%

Greater China: China, Hong Kong, Taiwan
Established Market: Europe, Canada, Australia
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea
FY2019 FCST: MIRABEGRON SALES BY REGION

Sales by region

Japan (billion yen)
- FY17: +11%
- FY18: +4%
- FY19 FCST: +4%

US (million USD)
- FY17: +17%
- FY18: +10%
- FY19 FCST: +23%

Established Market (million euro)
- FY17: +20%
- FY18: +11%
- FY19 FCST: +11%

International (billion yen)
- FY17: +36%
- FY18: +23%
- FY19 FCST: +23%

Greater China (billion yen)
- FY17: +62%
- FY18: +93%
- FY19 FCST: +93%

Greater China: China, Hong Kong, Taiwan
Established Market: Europe, Canada, Australia
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea
## FX RATE (ACTUAL)

### Average rate for the period

<table>
<thead>
<tr>
<th>Currency</th>
<th>FY17</th>
<th>FY18</th>
<th>change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>111 yen</td>
<td>111 yen</td>
<td>+0 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>130 yen</td>
<td>128 yen</td>
<td>-1 yen</td>
</tr>
</tbody>
</table>

### Change in closing rate from PY end

<table>
<thead>
<tr>
<th>Currency</th>
<th>FY17</th>
<th>FY18</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>-6 yen</td>
<td>+5 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>+11 yen</td>
<td>-6 yen</td>
</tr>
</tbody>
</table>

Fx impact on elimination of unrealized gain: COGs ratio -0.1 ppt
## FY2019 FCST: FX RATE & FX SENSITIVITY

### Average rate for the period

<table>
<thead>
<tr>
<th>Currency</th>
<th>FY18</th>
<th>FY19 FCST</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>111 yen</td>
<td>110 yen</td>
<td>-1 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>128 yen</td>
<td>125 yen</td>
<td>-3 yen</td>
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</tbody>
</table>

### Change in closing rate from PY end

<table>
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<th>Currency</th>
<th>FY18</th>
<th>FY19 FCST</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>+5 yen</td>
<td>-1 yen</td>
<td></td>
</tr>
<tr>
<td>EUR</td>
<td>-6 yen</td>
<td>+0 yen</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Currency</th>
<th>Average rate 1 yen higher than assumption</th>
<th>Year-end rate 1 yen higher than assumption</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Revenue</td>
<td>Core OP</td>
</tr>
<tr>
<td>USD</td>
<td>Approx. -5.2 bil yen</td>
<td>Approx. -1.1 bil yen</td>
</tr>
<tr>
<td>EUR</td>
<td>Approx. -2.6 bil yen</td>
<td>Approx. -1.0 bil yen</td>
</tr>
</tbody>
</table>
### BALANCE SHEET/CASH FLOW HIGHLIGHTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY17 end</th>
<th>FY18 end</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total assets</strong></td>
<td>1,858.2</td>
<td>1,897.6</td>
</tr>
<tr>
<td><strong>Cash and cash equivalents</strong></td>
<td>331.7</td>
<td>311.1</td>
</tr>
<tr>
<td><strong>Total equity attributable to owners of the parent</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equity ratio (%)</td>
<td>68.3%</td>
<td>66.3%</td>
</tr>
<tr>
<td><strong>Cash flows from operating activities</strong></td>
<td>312.6</td>
<td>258.6</td>
</tr>
<tr>
<td><strong>Cash flows from investing activities</strong></td>
<td>-121.8</td>
<td>-41.8</td>
</tr>
<tr>
<td><strong>Free cash flows</strong></td>
<td>190.8</td>
<td>216.9</td>
</tr>
<tr>
<td><strong>Cash flows from financing activities</strong></td>
<td>-203.4</td>
<td>-233.7</td>
</tr>
<tr>
<td>Acquisition of treasury shares</td>
<td>1,268.3</td>
<td>1,258.4</td>
</tr>
<tr>
<td><strong>Dividends paid</strong></td>
<td>-130.7</td>
<td>-160.4</td>
</tr>
<tr>
<td><strong>Acquisition of treasury shares</strong></td>
<td>-71.6</td>
<td>-72.1</td>
</tr>
</tbody>
</table>
Details of shareholder returns

- **Dividends per Share** (left axis)
- **Profit for the year** (right axis)

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Dividends (yen)</th>
<th>Acquisition of Own Share (yen)</th>
<th>Total Return Ratio (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY05</td>
<td>39.3</td>
<td>46.2</td>
<td>82</td>
</tr>
<tr>
<td>FY06</td>
<td>42.3</td>
<td>219.9</td>
<td>200</td>
</tr>
<tr>
<td>FY07</td>
<td>55.2</td>
<td>81.8</td>
<td>77</td>
</tr>
<tr>
<td>FY08</td>
<td>56.9</td>
<td>123.4</td>
<td>106</td>
</tr>
<tr>
<td>FY09</td>
<td>58.2</td>
<td>27.0</td>
<td>70</td>
</tr>
<tr>
<td>FY10</td>
<td>57.7</td>
<td>-18.4</td>
<td>85</td>
</tr>
<tr>
<td>FY11</td>
<td>57.7</td>
<td>-</td>
<td>74</td>
</tr>
<tr>
<td>FY12</td>
<td>59.4</td>
<td>49.4</td>
<td>118</td>
</tr>
<tr>
<td>FY13</td>
<td>60.6</td>
<td>30.0</td>
<td>100</td>
</tr>
<tr>
<td>FY14</td>
<td>66.0</td>
<td>58.2</td>
<td>92</td>
</tr>
<tr>
<td>FY15</td>
<td>68.5</td>
<td>119.3</td>
<td>97</td>
</tr>
<tr>
<td>FY16</td>
<td>71.3</td>
<td>91.4</td>
<td>74</td>
</tr>
<tr>
<td>FY17</td>
<td>72.1</td>
<td>130.0</td>
<td>123</td>
</tr>
<tr>
<td>FY18</td>
<td>72.4</td>
<td>160.0</td>
<td>105</td>
</tr>
<tr>
<td>FY19 (Forecast)</td>
<td>75.6</td>
<td>38.0</td>
<td>40.0</td>
</tr>
</tbody>
</table>

*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 year 2005.*

**From fiscal year 2013, figures are in accordance with International Financial Reporting Standards (IFRS).**
## Filing Opportunities Announced in Strategic Plan

- **Approved**: ✓ ✓ ✓
- **Filed**: ✓ ✓
- **Data obtained, filing under preparation**: ✓

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Product</th>
<th>Indication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY2018 (including filed pipeline)</td>
<td>enzalutamide</td>
<td>M0 CRPC</td>
<td>✓ ✓ ✓</td>
</tr>
<tr>
<td></td>
<td>gilteritinib</td>
<td>R/R AML JP/US EU</td>
<td>✓ ✓ ✓</td>
</tr>
<tr>
<td></td>
<td>roxadustat</td>
<td>Anemia associated with CKD Dialysis (JP)</td>
<td>✓ ✓</td>
</tr>
<tr>
<td>FY2019-2020</td>
<td>enzalutamide</td>
<td>M1 HSPC</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>enfentumab vedotin</td>
<td>Metastatic urothelial cancer</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>roxadustat</td>
<td>Anemia associated with CKD Non-dialysis (JP)</td>
<td>✓ ✓</td>
</tr>
<tr>
<td></td>
<td>roxadustat</td>
<td>Anemia associated with CKD Dialysis/Non-dialysis (EU)</td>
<td>✓</td>
</tr>
<tr>
<td>FY2021 or beyond</td>
<td>enzalutamide</td>
<td>M0 HSPC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>zolbetuximab</td>
<td>Gastric and gastroesophageal junction adenocarcinoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>gilteritinib</td>
<td>AML (Post-HSCT maintenance)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>gilteritinib</td>
<td>AML (Post-chemo maintenance)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>gilteritinib</td>
<td>AML (1st line low intensity induction chemo)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>gilteritinib</td>
<td>AML (1st line high intensity induction chemo)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>fezolinetant</td>
<td>MR-VMS</td>
<td></td>
</tr>
</tbody>
</table>

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

**Filing timing in the first country/region within US/EU/JP. If the project is regional specific (i.e. development right only in JP/Asia), the region is specified in the column.*

# ROBUST PIPELINE OF ASTELLAS

### Phase 1
- ASP1235/AGS62P1
- ASP8374/PTZ-201
- ASP1948/PTZ-329
- ASP1951/PTZ-522
- ASP9801
- ASP0892
- ASP0367/MA-0211
- MucoRice-CTB
- ASP3772

### Phase 2
- zolbetuximab (Pancreatic adenocarcinoma)
- AGS-16C3F (Renal cell carcinoma)
- ASP1650 (Testicular cancer)
- bleselumab (rFSGS)
- reldesemtiv (SMA, ALS)
- ASP7317 (Dry AMD etc.)
- ASP6294 (BPS/IC)
- ASP8302 (Underactive bladder)
- ASP1128/MA-0217 (AKI)
- roxadustat (CIA)
- fezolinetant (MR-VMS)
- ASP0819 (Fibromyalgia)
- ASP4345 (CIAS)
- isavuconazole (Pediatric, US)

### Phase 3
- enzalutamide (M0 HSPC, M1 HSPC)
- gilteritinib (R/R AML: China, Other AML)
- enfortumab vedotin (Urothelial cancer)
- zolbetuximab (Gastric and gastroesophageal junction adenocarcinoma)
- peficitinib (Rheumatoid arthritis, China)
- mirabegron (Pediatric OAB & NDO)

### Filed
- enzalutamide (M1 CRPC, China)
- gilteritinib (R/R AML, EU)
- solifenacin* (Pediatric NDO, US)
- roxadustat (Anemia associated with CKD in dialysis, JP)
- evolocumab (Statin intolerant hypercholesterolemia, JP)
- fidaxomicin (Clostridium difficile infection in pediatric patients, EU)

*Received Complete Response Letter from FDA in Aug 2017.

Outline of the projects are shown. Please refer to R&D pipeline list for details including target disease.

- Oncology
- Immunology, Muscle disease, Ophthalmology
- Urology, Nephrology
- Others

PROGRESS IN OVERALL PIPELINE
Phase 1 entry to filing, since Q3/FY2018 financial results announcement in Jan 2019

**Phase 1 Entry**

- **ASP9801**
  - Cancer

**Phase 2 Entry**

- roxadustat
  - Chemotherapy-induced anemia

**Phase 3 Entry**

- **gilteritinib**
  - Relapsed or Refractory acute myeloid leukemia: EU

**Filing**

- **fidaxomicin**
  - *Clostridium difficile* infection in pediatric patients: EU

---

**Discontinuation**

**ASP5094**: Rheumatoid arthritis (Phase 2)

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.

IND: Investigational new drug
ENZALUTAMIDE

Underline indicates the changes from the previous announcement on Jan 31, 2019.

<table>
<thead>
<tr>
<th>Study</th>
<th>Phase</th>
<th>Condition</th>
<th>Comparator</th>
<th>Enrollment Status</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: ARCHES</td>
<td>M1 HSPC</td>
<td>vs. placebo, combination with ADT, n=1,150</td>
<td></td>
<td>Data presented at ASCO-GU, Filing planned in US/EU/Japan by mid-2019</td>
<td></td>
</tr>
<tr>
<td>P3: EMBARK</td>
<td>M0 HSPC</td>
<td>vs. placebo, combination with ADT, n=1,068</td>
<td></td>
<td>Enrollment completed</td>
<td></td>
</tr>
</tbody>
</table>
GILTERITINIB

FLT3 mut+ AML patients

Relapsed or refractory

P3: ADMIRAL
Monotherapy vs salvage chemo (2:1), n=371
MAA submitted in Feb 2019
Label update to include OS data
US: sNDA submitted Feb 2019 (RTOR pilot program)
JP: Planned in 3Q/2019

Newly diagnosed (intensive chemo eligible)

P3: HOVON
Combo with high intensity chemo
gilteritinib vs midostaurin (1:1)
n=768
FPI planned in: 3Q2019 (Sponsor: HOVON)

P2: PrECOG
n=179
FPI planned in: 3Q2019 (Sponsor: PrECOG, LLC.)

Newly diagnosed (intensive chemo ineligible)

P3: LACEWING
Combo with azacitidine vs azacitidine alone
(2:1), n=323
First Patient in: Nov 2016

Post-HSCT maintenance

P3: MORPHO
Monotherapy vs placebo (1:1), n=346
First Patient In: Jul 2017
Collaborating with BMT-CTN

Post-chemo maintenance

P3: GOSSAMER
Monotherapy vs placebo (2:1), n=354
First Patient In: Apr 2017

Underline indicates the changes from the previous announcement on Jan 31, 2019.
**ENFORTUMAB VEDOTIN**

**Treatment Landscape** *Overall treatment flow is similar among regions even though the standard of care and approved drugs varies.*

1st line

- **cisplatin eligible**
  - Gem-Cis

- **cisplatin ineligible**
  - CPI*
  - Gem-Carlo
  - EV-103

2nd line

- CPI
- Gem-Carlo
- Single agent chemo

3rd line

- EV-201 (Cohort 1)
  - Single agent chemo
  - Clinical trial
  - Palliative care

- EV-301

* Patients with high PD-1 expression

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>N</th>
<th>Enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: EV-301</td>
<td>Pts with prior CPI treatment (platinum-pretreated)</td>
<td>n=550</td>
<td>First Patient In: Jul 2018</td>
</tr>
</tbody>
</table>
| P2: EV-201 | Pts with prior CPI treatment  
        Cohort 1: Platinum-pretreated  
        Cohort 2: Platinum naïve/cisplatin ineligible | n=200 | First Patient In: Oct 2017  
        Cohort 1: TLR obtained  
        Cohort 2: Recruiting |
| P1b: EV-103 | Combination with CPI and/or platinum | n=159 | First Patient In: Nov 2017                                                |
| P1: EV-101 | Part A: mUC pts  
        Part B: mUC pts with renal insufficiency  
        metastatic NSCLC, metastatic ovarian cancer  
        Part C: mUC pts with prior CPI treatment | n= 215 | Renal insufficiency cohort: Recruiting  
        Other cohorts: Completed enrollment  
        Matured data presented at ASCO-GU |

Underline indicates the changes from the previous announcement on Jan 31, 2019.

**ZOLBETUXIMAB**

**Target: Claudin 18.2**

- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- Broadly expressed in various cancer types
  - ~70-90% biliary duct, pancreatic, gastric and mucinous ovarian cancer *1
  - ~10% ovarian cancer and NSCLC *1

**Gastric and gastroesophageal junction (GEJ) adenocarcinoma**

- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin 18.2 expression
- Fourth leading cause of cancer death worldwide.
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20% *2, *3
- Median OS for Stage IV gastric cancer is 10-15 months *4, *5

<table>
<thead>
<tr>
<th>Gastric and GEJ adenocarcinoma</th>
<th>P3: SPOTLIGHT</th>
<th>Combination with mFOLFOX6</th>
<th>vs. placebo, n=550</th>
<th>First Patient In: Oct 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: GLOW</td>
<td>Combination with CAPOX</td>
<td>vs. placebo, n=500</td>
<td>First Patient In: Jan 2019</td>
<td></td>
</tr>
<tr>
<td>P2: ILUSTRO</td>
<td>Monotherapy, Combination with mFOLFOX6</td>
<td>n=102</td>
<td>First Patient In: Sep 2018</td>
<td></td>
</tr>
</tbody>
</table>

| Pancreatic adenocarcinoma       | P2            | Combination with nab-paclitaxel and gemcitabine | vs. placebo, n=141 | Study initiation planned in 2Q/2019 |

Underline indicates the changes from the previous announcement on Jan 31, 2019.


NSCLC: Non-small cell lung cancer, OS: Overall survival, CAPOX: Capecitabine and oxaliplatin, mFOLFOX6: 5-FU, leucovorin and oxaliplatin
FEZOLINETANT: EFFICACY IN PHASE 2B

Mean severity of moderate and severe VMS per 24 hours with fezolinetant QD

**Week 4:** P<0.05 for all pairwise comparisons of fezolinetant doses vs placebo, without adjustments for multiplicity.

**Week 12:** P<0.05 for fezolinetant 60 mg QD vs placebo, based on pairwise comparisons without adjustment for multiplicity.

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ENDO 2019
VMS: Vasomotor symptom, QD: Once daily, BID: Twice daily, ENDO: Endocrine Society’s Annual Meeting
ON THE FOREFRONT OF HEALTHCARE CHANGE