Q3/FY2018 FINANCIAL RESULTS
ENDED DECEMBER 31, 2018

Chikashi Takeda
Chief Financial Officer
Astellas Pharma Inc.
January 31, 2019
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  Q3/FY2018 Consolidated Financial Results

II  Pipeline

III  Initiatives for Sustainable Growth
## Q3/FY2018 FINANCIAL RESULTS (CORE BASIS)

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q3/FY17</th>
<th>Q3FY18</th>
<th>Change</th>
<th>FY18 FCST*</th>
<th>Progress</th>
<th>CER growth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net sales</strong></td>
<td>999.4</td>
<td>1,005.0</td>
<td>+0.6%</td>
<td>1,300.0</td>
<td>77.3%</td>
<td>+0.6%</td>
</tr>
<tr>
<td><strong>Cost of sales</strong></td>
<td>238.9</td>
<td>227.7</td>
<td>-4.7%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>23.9%</td>
<td>22.7%</td>
<td>-</td>
<td>227.7</td>
<td>22.7%</td>
<td></td>
</tr>
<tr>
<td><strong>SG&amp;A expenses</strong></td>
<td>350.0</td>
<td>355.8</td>
<td>+1.6%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>35.0%</td>
<td>35.4%</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>R&amp;D expenses</strong></td>
<td>161.6</td>
<td>150.0</td>
<td>-7.2%</td>
<td>216.0</td>
<td>69.4%</td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>16.2%</td>
<td>14.9%</td>
<td>-</td>
<td>150.0</td>
<td>14.9%</td>
<td></td>
</tr>
<tr>
<td>Amortisation of intangible assets</td>
<td>27.0</td>
<td>26.5</td>
<td>-1.9%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share of profits/losses of associates and JVs</td>
<td>-1.4</td>
<td>-1.1</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Core operating profit</strong></td>
<td>220.5</td>
<td>244.0</td>
<td>+10.7%</td>
<td>270.0</td>
<td>90.4%</td>
<td>+7.4%</td>
</tr>
<tr>
<td><strong>Core profit for the period</strong></td>
<td>167.9</td>
<td>217.9</td>
<td>+29.8%</td>
<td>221.0</td>
<td>98.6%</td>
<td></td>
</tr>
<tr>
<td><strong>Core EPS (yen)</strong></td>
<td>82.22</td>
<td>112.20</td>
<td>+36.5%</td>
<td>114.11</td>
<td>98.3%</td>
<td></td>
</tr>
</tbody>
</table>

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

Growth of XTANDI and mirabegron contributed to increase in net sales

Q3/FY17

<table>
<thead>
<tr>
<th>Category</th>
<th>Q3/FY17</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTANDI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OAB products</td>
<td>999.4</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>-0.3</td>
<td></td>
</tr>
<tr>
<td>Fx impacts</td>
<td>-0.3</td>
<td></td>
</tr>
<tr>
<td>Q3/FY18</td>
<td>1,005.0</td>
<td></td>
</tr>
</tbody>
</table>

OAB: Overactive bladder
OAB products: Vesicare + mirabegron (Betanis/Myrbetriq/BETMIGA)

Impact of NHI price revision in Japan: -13.9 bil. yen
Increased core OP by 11% through combination of increased sales of main products and optimal resource allocation

Q3/FY17: 220.5 billion yen

- Gross profit*
- SG&A expenses*
- R&D expenses*
- Others*
- Fx impacts

Q3/FY18: 244.0 billion yen

*Excluding Fx impacts

- Increase in XTANDI US co-promotion fee
- Efficient spending and optimal resource allocation
- Increase in key late-stage pipeline and new area / modality investments
- Decrease due to wind-down of Agensys research operations, etc.
- +7.1
## Q3/FY2018 FINANCIAL RESULTS (FULL BASIS)

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q3/FY17</th>
<th>Q3/FY18</th>
<th>Change</th>
<th>FY18 FCST*</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core operating profit</td>
<td>220.5</td>
<td>244.0</td>
<td>+10.7%</td>
<td>270.0</td>
<td>90.4%</td>
</tr>
<tr>
<td>Other income</td>
<td>10.4</td>
<td>13.1</td>
<td>+25.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other expense</td>
<td>51.2</td>
<td>47.8</td>
<td>-6.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating profit</td>
<td>179.8</td>
<td>209.4</td>
<td>+16.5%</td>
<td>234.0</td>
<td>89.5%</td>
</tr>
<tr>
<td>Profit before tax</td>
<td>184.6</td>
<td>212.8</td>
<td>+15.3%</td>
<td>236.0</td>
<td>90.2%</td>
</tr>
<tr>
<td>Profit for the period</td>
<td>142.6</td>
<td>191.5</td>
<td>+34.3%</td>
<td>195.0</td>
<td>98.2%</td>
</tr>
<tr>
<td>EPS (yen)</td>
<td>69.84</td>
<td>98.63</td>
<td>+41.2%</td>
<td>100.69</td>
<td>98.0%</td>
</tr>
</tbody>
</table>

*Announced in Oct. 2018
SALES OF MAIN PRODUCTS

Main growth products contributing to increased net sales

| (billion yen)                        | Q3/FY17 | Q3/FY18 | Change  | CER growth | | | FY18 FCST* | Progress |
|-------------------------------------|---------|---------|---------|------------| | |-----------|----------|
| XTANDI                              | 219.9   | 253.4   | +15.2%  | +15.3%     | | | 325.9     | 77.7%    |
| OAB products in Urology             | 171.6   | 184.3   | +7.4%   | +7.5%      | | | 245.7     | 75.0%    |
| Vesicare                            | 78.5    | 74.4    | -5.2%   | -5.2%      | | | 96.1      | 77.4%    |
| Mirabegron                          | 93.1    | 109.9   | +18.0%  | +18.3%     | | | 149.6     | 73.5%    |
| Prograf                             | 150.2   | 150.0   | -0.1%   | -0.2%      | | | 196.0     | 76.5%    |

*Announced in Oct. 2018

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

CER: Constant Exchange Rate
XTANDI sales increased in all regions due to penetration in earlier stage of prostate cancer

Sales by region

- **Japan** (billion yen): 20.0 (Q3/FY17) → 25.1 (Q3/FY18) (+25.3%)
  - **Americas** (million USD): 1,045 (Q3/FY17) → 1,227 (Q3/FY18) (+17.4%)
- **EMEA** (million euro): 615 (Q3/FY17) → 672 (Q3/FY18) (+9.3%)
- **Asia/Oceania** (billion yen): 4.0 (Q3/FY17) → 4.8 (Q3/FY18) (+18.4%)

CER: Constant Exchange Rate
**OAB FRANCHISE IN UROLOGY**

*Mirabegron growth driving OAB franchise sales. Educating on novel mechanism of action with balance of efficacy and safety*

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**Quarterly sales (Global)**

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Vesicare</th>
<th>Mirabegron</th>
<th>OAB products total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2/FY11</td>
<td></td>
<td></td>
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<tr>
<td>Q3/FY11</td>
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<tr>
<td>Q4/FY11</td>
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<td>Q1/FY12</td>
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<td>Q2/FY12</td>
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<td>Q3/FY12</td>
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<td>Q4/FY12</td>
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<td>Q1/FY13</td>
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<td>Q2/FY13</td>
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<td>Q3/FY13</td>
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<td>Q4/FY13</td>
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<td>Q1/FY14</td>
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<td>Q2/FY14</td>
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<td>Q3/FY14</td>
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<td>Q4/FY14</td>
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<td>Q1/FY15</td>
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<td>Q2/FY15</td>
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<td>Q3/FY15</td>
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<td>Q4/FY15</td>
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<td>Q1/FY16</td>
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<td>Q2/FY16</td>
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<tr>
<td>Q2/FY18</td>
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</tr>
<tr>
<td>Q3/FY18</td>
<td></td>
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</tr>
</tbody>
</table>

- **Vesicare**
- **Mirabegron**
- **OAB products total**

**Notes:**
- Mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
- OAB: Overactive bladder
AGENDA

I  Q3/FY2018 Consolidated Financial Results

II Pipeline

III Initiatives for Sustainable Growth
FOUR APPROVALS OBTAINED SINCE LAST EARNINGS

Continue to deliver VALUE for patients

<table>
<thead>
<tr>
<th>New molecular entity</th>
<th>gilteritinib</th>
<th>ipragliflozin</th>
<th>romosozumab</th>
<th>degarelix</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nov 2018 (US)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapsed or refractory (R/R) FLT3 mut+ AML</td>
<td>First FLT3 inhibitor for R/R AML</td>
<td>First SGLT2 inhibitor for type 1 diabetes, which has limited treatment options (insulin and α-GI)</td>
<td>First approval of romosozumab in the world, with a new mechanism of action</td>
<td>Prostate cancer (12-week formulation)</td>
</tr>
<tr>
<td><strong>Dec 2018 (JP)</strong></td>
<td></td>
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<tr>
<td>Type I diabetes</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Jan 2019 (JP)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoporosis in patients at high risk of fracture</td>
<td>First approval of romosozumab in the world, with a new mechanism of action</td>
<td>Reduce the treatment burden for prostate cancer patients</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please refer the label/package insert for detailed indication.

FLT3 mut+: FMS-like tyrosine kinase 3 mutation positive, AML: Acute myeloid leukemia, α-GI: α-glucosidase inhibitor, SGLT-2: Sodium-glucose co-transporter 2
GILTERITINIB: APPROVED AS FIRST FLT3 INHIBITOR FOR R/R AML

Achieved important milestone in accordance with Strategic Plan 2018

- Approved in US in Nov 2018, launched in Japan and US in Dec 2018, for FLT3 mut+ R/R AML
- First FLT3 inhibitor for this patient segment
- Utilized regulatory expedited pathways including Sakigake designation in Japan and Priority Review and Fast track in US.
- Patients with AML with activating FLT3 mutations have short survival and high relapse rates and are less likely to respond to chemotherapy. No standard of care established for R/R AML with FLT3 mutation.
- Gilteritinib inhibits both FLT3-ITD and FLT3-TKD, two well characterized mutations in AML, which are associated with poor prognosis.
- Phase 3 ADMIRAL study met OS endpoint and full data to be presented at a future scientific meeting
- Deliver value for patients through highly specialized hematologists/oncologists

1: Yanada M et al., Leukemia. 2005;19:1345-9
FLT3: FML-like tyrosine kinase 3, R/R AML: Relapsed or refractory acute myeloid leukemia, ITD: Internal tandem duplication, TKD: Tyrosine kinase domain, OS: Overall survival
ROMOSOZUMAB: JAPAN APPROVAL FIRST IN THE WORLD

Aiming at paradigm shift in osteoporosis treatment

• Approved in Japan in Jan. 2019 for osteoporosis in patients at high risk of fracture
• Prior fracture is one of the major risk factors for further fractures in osteoporosis patients. Especially the risk of secondary fracture is high within a year after fracture, requiring early treatment effect.
• Romosozumab has dual effects of increasing bone formation and decreasing bone resorption. It reduces the risk of fracture by increasing bone density rapidly and maintaining and improving the micro structure of bone and strengthening it.
• Reduces the risk of fracture by administration of 12 months
• Administered once a month for 12 months, expected to improve adherence to treatment

P1NP: N-terminal propeptide of type I procollagen, sCTX: serum C-telopeptide cross-link of type 1 collagen, RANKL: Receptor activator of NF-κB ligand, PTH: Parathyroid hormone
UPDATES IN 6 POST-POC PROJECTS
Since Q2/FY2018 financial results announcement in Oct 2018

Steady progress and successful achievements of late-stage projects

**enzalutamide**

**M1 HSPC**
- **ARCHES study**: Met primary endpoint (rPFS)
- Filing planned by mid-2019 in US/EU/Japan

**gilteritinib**

**FLT3 mut+ R/R AML**
- **ADIMRAL study**: Met primary endpoint (OS) for final analysis
- **US**: Approved in Nov. 2018
- **EU**: MAA planned in 1Q/2019
- Plan to include OS data in label (US sNDA in 1Q/2019, JP in 3Q/2019)

**enfortumab vedotin**

**mUC with prior CPI treatment**
- TLR of Phase 2 study Cohort 1 (platinum-pretreated) planned in 1Q/2019
- If TLR is positive, BLA submission planned in US in 2019

**zolbetuximab**

**Gastric and GEJ adenocarcinoma**
- GLOW study (combination with CAPOX): FPI achieved

**roxadustat**

**Anemia associated with CKD**
- **EU**: TLRs obtained from 6 P3 studies required for MAA and reimbursement. MAA planned in mid-2019
- **JP**: Filed for patients on dialysis in Sep. 2018. For non-dialysis, TLR of remaining study expected in 2019

**fezolinetant**

**MR-VMS**
- Phase 2b study met all four co-primary endpoints in most cohorts.
- Phase 2b study results to be presented at ENDO2019

---

M1 HSPC: Metastatic hormone-sensitive prostate cancer, rPFS: Radiographic progression free survival, OS: Overall survival, MAA: Marketing authorization application, sNDA: Supplemental new drug application, mUC: metastatic urothelial cancer, CPI: Check point inhibitor, TLR: Tope line result, BLA: Biologics License Application, GEJ: Gastroesophageal junction, FPI: First patient in, CKD: Chronic kidney disease, MR-VMS: Menopause-related vasomotor symptom, ENDO: Endocrine Society
**ARCHES study in M1 HSPC met its primary endpoint.**

Filing for M1 HSPC in US/EU/Japan planned by mid-2019

### M1 HSPC

**Disease background**
- Approximately 38,000 men in the US develop M1 HSPC every year.\(^1\)\(^2\)
- Currently, androgen deprivation therapy is commonly used as first line treatment.

**Unmet medical needs**
- Men with prostate cancer who have developed distant metastases have a worse prognosis, requiring improved treatment.
- M1 HSPC is a heterogeneous disease; limited data on how to treat M1 HSPC patients with low-volume or recurrent disease.

### ARCHES study

- **Randomize**
  - ADT + enzalutamide
  - ADT + placebo

**Primary endpoint: rPFS**
- The study met its primary endpoint, significantly improving rPFS.
- The preliminary safety analysis appears consistent with the safety profile of XTANDI in previous clinical trials in CRPC.
- Data to be presented at ASCO-GU


M1 HSPC: Metastatic hormone-sensitive prostate cancer, rPFS: Radiographic progression-free survival, CRPC: Castration-resistant prostate cancer

ASCO-GU: American Society of Clinical Oncology, Genitourinary Cancers Symposium
**FEZOLINETANT**

*Phase 2b study met all four co-primary endpoints in most cohorts. Full results to be presented at ENDO2019 in March 2019*

### Study Design

- Post menopausal woman suffering from at least 50 moderate to severe VMS per week
- Screening: 4 weeks
- Randomized: n=352

#### Treatment duration: 12 weeks

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
<th>n=44/cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>fezolinetant QD</td>
<td>3 dose cohorts</td>
<td></td>
</tr>
<tr>
<td>fezolinetant BID</td>
<td>4 dose cohorts</td>
<td></td>
</tr>
</tbody>
</table>

### Co-primary endpoints:

- Mean change from baseline in the number of hot flashes (moderate and severe)*
- Mean change from baseline in the severity of hot flashes (moderate and severe)*
  *: At Week 4 and Week 12

### Top Line Results

#### Efficacy

- All four co-primary endpoints demonstrated statistically significant improvement in most cohorts.
- Efficacy in hot flash frequency and severity and treatment effect size of BID and QD were similar.

#### Safety

- No death or treatment-related SAEs were reported.
- Overall TEAE rates were similar across cohorts and mostly mild or moderate.
- Asymptomatic liver enzyme elevations were observed in a small number of patients in the higher dosing cohorts.

### Next step:

Preparing regulatory consultation for Phase 3 program including dose selection

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VMS: Vasomotor symptoms, QD: once daily, BID: twice daily, PoC: Proof of concept, SAE: Serious adverse event, TEAE: Treatment emergent adverse event, ENDO: Endocrine Society
ROXADUSTAT

Potential first-in-class oral treatment for anemia associated with CKD

Target profile

- Novel mechanism of action
- Potential new treatment option that is orally administered
- Potential new treatment option that may reduce the treatment burden for patients
- Comparable efficacy to the current treatment (i.e. ESAs)
- Minimize the use of IV iron
- Erythropoietin levels within or near the physiological range, potentially avoiding the concerns from the existing therapy
- Efficacy in the patients who cannot be well controlled with the current treatment (i.e. patients with inflammation)

CKD: Chronic kidney disease, HIF: Hypoxia-inducible factor, PH: Prolyl hydroxylase, Hb: Hemoglobin, EPO: erythropoietin, ESAs: Erythropoiesis-stimulating agents, IV: intravenous
ROXADUSTAT

TLRs of all 6 Phase 3 studies supporting EU filing were obtained. MAA submission in EU planned in mid-2019

Phase 3 program supporting EU filing and reimbursement

<table>
<thead>
<tr>
<th>Dialysis</th>
<th>Non-dialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIMALAYAS</strong></td>
<td><strong>DOLOMITES</strong>*</td>
</tr>
<tr>
<td>Incident dialysis, vs epoetin alfa, n=1,043</td>
<td>vs darbepoetin alfa, n=616</td>
</tr>
<tr>
<td><strong>SIERRAS</strong></td>
<td><strong>ALPS</strong>:</td>
</tr>
<tr>
<td>Stable dialysis, vs epoetin alfa, n=741</td>
<td>vs placebo, n=594</td>
</tr>
<tr>
<td><strong>PYRENEES</strong></td>
<td><strong>ANDES</strong>:</td>
</tr>
<tr>
<td>Stable dialysis, vs epoetin alfa or darbepoetin alfa, n=836</td>
<td>vs placebo, n=922</td>
</tr>
</tbody>
</table>

*Interim analysis

TLRs of all 6 Phase 3 studies obtained

- All studies met their primary endpoints.
- Roxadustat was well tolerated. Preliminary safety analysis showed that the overall safety profile is consistent with the previous clinical studies.

Pooled safety analysis: Planned in 1H/2019

MAA submission planned in mid-2019

TLR: Top line results, MAA: Marketing authorization application
**MAXIMIZE VALUE OF KEY LATE STAGE PROJECTS**

*Initiated development of additional indication for zolbetuximab to expand the value for patients*

**Target disease: pancreatic adenocarcinoma**

- Pancreatic cancer is the 7th most common cause of cancer death globally.¹
- The 5-year survival rate remains as low as 8% in US and 4% worldwide.¹
- 50% to 70% of pancreatic cancer patients show significant expression of CLDN18.2.²,³,⁴

**Phase 2a study**

- Patient segment: metastatic pancreatic adenocarcinoma with CLDN18.2 positive
- Combination with Nab-Paclitaxel and Gemcitabine as first line treatment
- Study initiation planned in 2Q/2019

---

PROGRESS IN OVERALL PIPELINE
P1 entry to filing, since Q2/FY2018 financial results announcement in Oct 2018

Steady progression of pipeline

P1 Entry | P2 Entry | P3 Entry | Filing
---|---|---|---
ASP3772<br>Prevention of pneumococcal disease | zolbetuximab<br>Pancreatic adenocarcinoma | ASP1128/MA-0217<br>Acute kidney injury | 

Discontinuation of a part of indication etc.

reldesemtiv: Chronic obstructive pulmonary disease (P2)<br>ASP4070/JRC2-LAMP-vax: Pollinosis caused by Japanese red cedar (P2)<br>ASP7713: Underactive bladder (P1)<br>ASP1807/CC8464: Neuropathic pain (P1)

*Please refer the label/package insert for detailed indication.

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.
# Expected Key Events Within A Year

**Important milestones from POC study through registration**

<table>
<thead>
<tr>
<th>Data readouts</th>
<th>Phase 2 (POC) study reldesemtiv (CK-2127107)</th>
<th>ALS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phase 2 study enfortumab vedotin</td>
<td>mUC, Cohort 1 (CPI-pretreated/platinum-pretreated)</td>
</tr>
</tbody>
</table>

| Filings*               | roxadustat                                    | Anemia associated with CKD, dialysis/non-dialysis (EU) |
|                        | gilteritinib                                   | R/R FLT3 mut+ AML (EU) |
|                        | enfortumab vedotin                             | mUC, CPI-pretreated/platinum-pretreated |
|                        | enzalutamide                                   | M1 HSPC |

| Regulatory decisions   | peficitinib                                    | Rheumatoid arthritis (Japan) |
|                        | roxadustat                                     | Anemia associated with CKD, dialysis (Japan) |
|                        | evolocumab                                     | Statin-intolerant hypercholesterolemia (Japan) |

| Presentations at scientific meetings | enzalutamide                                    | ASCO-GU (ARCHES) |
|                                      | gilteritinib                                    | Upcoming meeting (ADMIRAL OS) |
|                                      | enfortumab vedotin                              | ASCO-GU (P1) |
|                                      | fezolinetant                                    | ENDO 2019 (P2b) |

Please refer to pipeline list for details including target disease.

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

AGENDA

I  Q3/FY2018 Consolidated Financial Results

II  Pipeline

III  Initiatives for Sustainable Growth
FOCUS AREA APPROACH: ACQUISITION OF POTENZA

Expand our oncology portfolio

Strategy

• Introduced novel immuno-oncology programs in clinical stage
  ➢ 3 programs entered into Phase1
  ➢ Targeting patient population who are non-responsive to existing immuno-oncology therapies
  ➢ Provides platform for immuno-oncology combinations with existing pipeline products

Mechanism of Immunomodulation

- 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
**Management priorities for resource allocation in FY2018**

### IN

- **Capex in new modality / technology**
  - New centers in Japan (Toyama and Tsukuba)
  - Enhancement of AIRM production facility in US

- **Focus Area investments**
  - Gene therapy:
    - Acquisition of Quethera
    - Alliance with Gene Therapy Research Institution
    - Alliance with Juventas
  - Novel immuno-oncology therapy:
    - Acquisition of Potenza

### OUT

- **Review of organization / structure**
  - Optimization of organization / structure in EMEA
  - Restructuring of operations in Japan

- **Review of production structure**
  - Succeeding pharmaceutical manufacturing business of Nishine Plant

*Underline indicates the initiatives during Q3/FY2018*
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

Dividends in FY2018 (Forecast): 38 yen (2 yen increase)

Acquisition of own shares (Actual) in FY2018: 100 billion yen (55 million shares)
## Q3/FY2018: SALES BY REGION

<table>
<thead>
<tr>
<th>Region</th>
<th>Q3/FY17 (billion yen)</th>
<th>Q3/FY18 (billion yen)</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>337.3</td>
<td>312.7</td>
<td>-7.3%</td>
</tr>
<tr>
<td>Americas</td>
<td>326.8</td>
<td>352.0</td>
<td>+7.7%</td>
</tr>
<tr>
<td>EMEA</td>
<td>260.0</td>
<td>261.8</td>
<td>+0.7%</td>
</tr>
<tr>
<td>Asia/Oceania</td>
<td>75.3</td>
<td>78.5</td>
<td>+4.3%</td>
</tr>
</tbody>
</table>
FX RATE (ACTUAL)

Average rate for the period

<table>
<thead>
<tr>
<th>Currency</th>
<th>Q3/FY17</th>
<th>Q3/FY18</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>112 yen</td>
<td>111 yen</td>
<td>-1 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>129 yen</td>
<td>129 yen</td>
<td>+1 yen</td>
</tr>
</tbody>
</table>

Change in closing rate from PY end

<table>
<thead>
<tr>
<th>Currency</th>
<th>Q3/FY17</th>
<th>Q3/FY18</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>+1 yen</td>
<td>+5 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>+15 yen</td>
<td>-4 yen</td>
</tr>
</tbody>
</table>

Fx impact on elimination of unrealized gain: COGs ratio -0.6 ppt
**FY2018 FCST: FX RATE & FX SENSITIVITY**

Forecast rates from October 2018 onwards: 110 USD/yen, 130 EUR/yen

Estimated Fx sensitivity (October 2018 and onward) 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>Net sales</td>
<td>Core OP</td>
</tr>
<tr>
<td>USD</td>
<td>Approx. -2.6 bil yen</td>
<td>Approx. -0.6 bil yen</td>
</tr>
<tr>
<td>EUR</td>
<td>Approx. -1.3 bil yen</td>
<td>Approx. -0.6 bil yen</td>
</tr>
</tbody>
</table>

*Sensitivity to fluctuation of Fx rates used for consolidation of overseas affiliates’ results compared to forecasted rates from October 2018 and onwards*
# BALANCE SHEET/CASH FLOW HIGHLIGHTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY17 end</th>
<th>Dec. 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total assets</td>
<td>1,858.2</td>
<td>1,928.3</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>331.7</td>
<td>331.3</td>
</tr>
<tr>
<td>Total net assets</td>
<td>1,268.3</td>
<td>1,292.2</td>
</tr>
<tr>
<td>Equity ratio (%)</td>
<td>68.3%</td>
<td>67.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q3/FY17</th>
<th>Q3/FY18</th>
<th>FY17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flows from operating activities</td>
<td>215.3</td>
<td>203.7</td>
<td>312.6</td>
</tr>
<tr>
<td>Cash flows from investing activities</td>
<td>(93.8)</td>
<td>(28.5)</td>
<td>(121.8)</td>
</tr>
<tr>
<td>Free cash flows</td>
<td>121.5</td>
<td>175.2</td>
<td>190.8</td>
</tr>
<tr>
<td>Cash flows from financing activities</td>
<td>(143.1)</td>
<td>(173.3)</td>
<td>(203.4)</td>
</tr>
<tr>
<td>Acquisition of treasury shares</td>
<td>(70.7)</td>
<td>(100.4)</td>
<td>(130.7)</td>
</tr>
<tr>
<td>Dividends paid</td>
<td>(71.6)</td>
<td>(72.1)</td>
<td>(71.6)</td>
</tr>
</tbody>
</table>
**DETAILS OF SHAREHOLDER RETURNS**

*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).*
ROBUST PIPELINE OF ASTELLAS

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

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

Phase 2
- zolbetuximab (IMAB362) (Pancreatic adenocarcinoma)
- AGS-16C3F (Renal cell carcinoma)
- ASP1650 (Testicular cancer)
- bleselumab (ASKP1240) (rFSGS)
- ASP5094 (Rheumatoid arthritis)
- rledesemtiv (CK-2127107) (SMA, ALS)
- ASP7317 (Dry AMD etc.)
- ASP6294 (BPS/IC)
- ASP8302 (Underactive bladder)
- ASP1128/MA-0217 (AKI)
- fezolinetant (ESN364) (MR-VMS)
- ASP0819 (Fibromyalgia)
- ASP4345 (CIAS)
- isavuconazole (Pediatric, US)

Phase 3
- enzalutamide (M0 HSPC:US/EU/Asia, M1 HSPC:US/EU/JP/Asia)
- gilteritinib (ASP2215) (R/R AML: EU/Asia, Other AML: US/EU/JP/Asia)
- enfortumab vedotin (ASG-22ME) (Urothelial cancer: US/EU/JP/Asia)
- zolbetuximab (Gaustic and gastroesophageal junction adenocarcinoma, US/EU/JP/Asia)
- mirabegron (Pediatric NDO, EU)
- roxadustat (Anemia associated with CKD in dialysis, JP)
- evolocumab (Statin intolerant hypercholesterolemia, JP)

Filed
- peficitinib (ASP015K) (Rheumatoid arthritis, JP)
- solifenacin* (Pediatric NDO, US)
- roxadustat (Anemia associated with CKD in dialysis, JP)
- evolocumab (Statin intolerant hypercholesterolemia, JP)

*Received Complete Response Letter from FDA in Aug 2017.

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

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

<table>
<thead>
<tr>
<th>Filed/Expected filing</th>
<th>FY2018</th>
<th>FY2019-FY2020</th>
<th>FY2021 -</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>gilteritinib</strong></td>
<td></td>
<td><strong>enzalutamide</strong></td>
<td></td>
</tr>
<tr>
<td>(Relapsed or Refractory AML: EU)</td>
<td></td>
<td>(M1 HSPC)</td>
<td><strong>enzalutamide</strong></td>
</tr>
<tr>
<td><strong>roxadustat</strong></td>
<td></td>
<td><strong>enfortumab vedotin</strong></td>
<td></td>
</tr>
<tr>
<td>(Anemia associated with CKD Dialysis: JP)</td>
<td></td>
<td>(Metastatic urothelial cancer)</td>
<td><strong>gilteritinib</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>roxadustat</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Anemia associated with CKD Non-dialysis: JP Dialysis/Non-dialysis: EU)</td>
<td><strong>zolbetuximab</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(Gastric and gastroesophageal junction adenocarcinoma)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>fezolinetant</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(MR-VMS)</td>
</tr>
</tbody>
</table>

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

Please refer to pipeline list for details including target disease.

ENZALUTAMIDE

Underline indicates the changes from the previous announcement on Oct 31, 2018.

<table>
<thead>
<tr>
<th>Study</th>
<th>Stage</th>
<th>Description</th>
<th>Enrollment Status</th>
<th>Additional Information</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>TLR obtained in Dec/2018 Data to be presented at ASCO-GU Filing planned in US/EU/Japan by mid-2019</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>
</tr>
</tbody>
</table>

Definitive Therapy
- Initial Diagnosis
  - Active Surveillance
    - Surgery
    - Radiation
  - Salvage

Hormone or Castration Sensitive
- ARCHES
  - M1 HSPC newly-diagnosed
  - M1 HSPC recurrent
- EMBARK
  - M0 HSPC

Castration-Resistant
- PROSPER
  - M0 CRPC
- PREVAIL
  - M1 CRPC (1st line)
- AFFIRM
  - M1 CRPC (lines 2+)
GILTERITINIB

Phase 1 study

High-intensity induction chemo

Chemo consolidation

Transplant

Maintenance

GOSSAMER

Maintenance

MORPHO

Salvage therapy

ADMIRAL

Launched (US, JP)
Filing planned in 1Q/2019 (EU)

P3: ADMIRAL
Relapsed or refractory
Monotherapy vs salvage chemo (2:1), n=371
Full OS data obtained
Label update to include OS data
US: sNDA planned in 1Q/2019
JP: Planned in 3Q/2019

P3: LACEWING
1st line intensive chemo ineligible
Combo with azacitidine vs azacitidine alone (2:1), n=323
First Patient In: Nov 2016

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

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

Underline: indicates the changes from the previous announcement on Oct 31, 2018.
**ENFORTUMAB VEDOTIN**

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

<table>
<thead>
<tr>
<th>1&lt;sup&gt;st&lt;/sup&gt; line</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; line</th>
<th>3&lt;sup&gt;rd&lt;/sup&gt; line</th>
</tr>
</thead>
</table>
| **cisplatin eligible** | • CPI  
• Gem-Carbo | **EV-201 (Cohort 1)**  
**EV-301** |
| **cisplatin ineligible** | • CPI  
• Gem-Carbo  
**EV-103** | • Single agent chemo  
• Clinical trial  
• Palliative care  
**EV-201 (Cohort 2)** |

**P3: EV-301**  
Pts with prior CPI treatment (platinum-pretreated)  
n=550  
First Patient In: Jul 2018

**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 expected in 1Q/2019  
Cohort 2: Recruiting

**P1b: EV-103**  
Combination with CPI  
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  
First Patient In: Jun 2014  
Matured data to be presented at ASCO-GU

Underline indicates the changes from the previous announcement on Oct 31, 2018, Pts: Patients, CPI: Checkpoint inhibitor, TLR: Top line results, mUC: metastatic urothelial cancer, NSCLC: Non-small cell lung carcinoma, Gem-Cis: gemcitabine and cisplatin, Gem-Carbo: gemcitabine and carboplatin, ASCO-GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium
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
  - ~10% ovarian cancer and NSCLC

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%.
- Median OS for Stage IV gastric cancer is 10-15 months.

<table>
<thead>
<tr>
<th>GEJ adenocarcinoma</th>
<th>P3: SPOTLIGHT</th>
<th>Combination with mFOLFOX6 vs. placebo, n=550</th>
<th>First Patient In: Oct 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: GLOW</td>
<td>Combination with CAPOX vs. placebo, n=500</td>
<td>First Patient In: Jan 2018</td>
<td></td>
</tr>
<tr>
<td>P2: ILUSTRO</td>
<td>Monotherapy, Combination with mFOLFOX6 n= 102</td>
<td>First Patient In: Sep 2018</td>
<td></td>
</tr>
<tr>
<td>Pancreatic adenocarcinoma</td>
<td>P2</td>
<td>Combination with nab-paclitaxel and gemcitabine n=141</td>
<td>Study initiation planned in 2Q/2019</td>
</tr>
</tbody>
</table>

Underline indicates the changes from the previous announcement on Oct. 31, 2018.
NSCLC: Non-small cell lung cancer
ON THE FOREFRONT OF HEALTHCARE CHANGE