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 Q2/FY2020 Consolidated Financial Results and FY2020 Revised Forecasts

II Initiatives for Sustainable Growth
# Q2/FY2020 FINANCIAL RESULTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q2/FY19</th>
<th>Q2/FY20</th>
<th>Change</th>
<th>Change (%)</th>
<th>CER growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>650.5</td>
<td>615.5</td>
<td>-35.0</td>
<td>-5.4%</td>
<td>-4.6%</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>138.9</td>
<td>119.5</td>
<td>-19.3</td>
<td>-13.9%</td>
<td></td>
</tr>
<tr>
<td>% of revenue</td>
<td>21.3%</td>
<td>19.4%</td>
<td>-1.9 ppt</td>
<td>-1.9 ppt</td>
<td>-13.9%</td>
</tr>
<tr>
<td>SG&amp;A expenses</td>
<td>226.1</td>
<td>242.1</td>
<td>+16.1</td>
<td>+7.1%</td>
<td></td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>105.0</td>
<td>111.7</td>
<td>+6.7</td>
<td>+6.4%</td>
<td></td>
</tr>
<tr>
<td>Amortisation of intangible assets</td>
<td>11.2</td>
<td>11.5</td>
<td>+0.3</td>
<td>+3.1%</td>
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</tr>
<tr>
<td><strong>Core operating profit</strong></td>
<td>168.0</td>
<td>130.3</td>
<td>-37.7</td>
<td>-22.4%</td>
<td>-18.5%</td>
</tr>
</tbody>
</table>

<Full basis>

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<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Other income</td>
<td>7.2</td>
<td>4.3</td>
<td>-3.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other expense</td>
<td>13.0</td>
<td>47.7</td>
<td>+34.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Operating profit</strong></td>
<td>162.2</td>
<td>86.9</td>
<td>-75.3</td>
<td>-46.4%</td>
<td></td>
</tr>
<tr>
<td>Profit before tax</td>
<td>161.6</td>
<td>89.1</td>
<td>-72.5</td>
<td>-44.9%</td>
<td></td>
</tr>
<tr>
<td><strong>Profit</strong></td>
<td>128.5</td>
<td>72.8</td>
<td>-55.7</td>
<td>-43.3%</td>
<td></td>
</tr>
</tbody>
</table>
Q2/FY2020 FINANCIAL RESULTS: REVENUE

Main products and new products continue to grow strongly

<table>
<thead>
<tr>
<th>Q2/FY2020 actual (billion yen)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>XTANDI</strong></td>
<td>225.5 +30.5</td>
</tr>
<tr>
<td><strong>XOSPATA</strong></td>
<td>11.0 +5.2</td>
</tr>
<tr>
<td><strong>PADCEV</strong></td>
<td>6.0 +6.0</td>
</tr>
<tr>
<td>mirabegron</td>
<td>80.0 +1.2</td>
</tr>
<tr>
<td>New products in Japan</td>
<td>34.9 +7.1</td>
</tr>
</tbody>
</table>

Growth of main products and new products: **+50.1 billion yen**

Consolidated revenue for Q2/FY2020: -35.0 billion yen, YoY
- Sales decreases from termination of sales and distribution in Japan and loss of exclusivity
- Lexiscan, Geninax, etc. negatively impacted by COVID-19

PADCEV: Co-promotion revenue from Seagen
mirabegron (Betanis/Myrbetriq/BETMIGA)
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)
Q2/FY2020 FINANCIAL RESULTS: PROGRESS AGAINST FORECAST

- Core basis Q2/FY2020 financial results are in line with full-year forecast revised in August 2020

<table>
<thead>
<tr>
<th></th>
<th>Q2/FY20</th>
<th>FY20 FCST</th>
<th>Progress against FCST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>615.5 bil. yen</td>
<td>1,256.5 bil. yen</td>
<td>49.0%</td>
</tr>
<tr>
<td>Core OP</td>
<td>130.3 bil. yen</td>
<td>251.0 bil. yen</td>
<td>51.9%</td>
</tr>
</tbody>
</table>

- Steady growth of main products such as XTANDI, XOSPATA and PADCEV
- Sales decreases from termination of sales and distribution in Japan and LOE
- Moderate impact of COVID-19 compared to Q1/FY2020, as expected

Full basis: Booked impairment losses, not included into full-year forecast

- Impairment losses on intangible asset due to termination of development for ASP8374 (30.5 billion yen)

LOE: Loss of exclusivity
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL
FY2020 REVISED FORECAST

- No changes have been made to Core basis FY2020 forecast

<table>
<thead>
<tr>
<th></th>
<th>Q2/FY20 Actual</th>
<th>Forecast (Revised in Aug.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>615.5</td>
<td>1,256.5</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>111.7</td>
<td>233.5</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>130.3</td>
<td>251.0</td>
</tr>
<tr>
<td>Core profit</td>
<td>106.2</td>
<td>200.5</td>
</tr>
</tbody>
</table>

Forecast: No changes

- Downward revision of Full basis profit due to impairment losses on intangible asset

<table>
<thead>
<tr>
<th></th>
<th>Q2/FY20 Actual</th>
<th>Forecast (Revised in Aug.)</th>
<th>Revised Forecast</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating profit</td>
<td>86.9</td>
<td>246.5</td>
<td>210.5</td>
<td>-36.0</td>
</tr>
<tr>
<td>Profit</td>
<td>72.8</td>
<td>197.5</td>
<td>169.5</td>
<td>-28.0</td>
</tr>
</tbody>
</table>
AGENDA

I  Q2/FY2020 Consolidated Financial Results and FY2020 Revised Forecasts

II  Initiatives for Sustainable Growth
<table>
<thead>
<tr>
<th>Project</th>
<th>Area</th>
<th>Status Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>enzalutamide</strong></td>
<td>M0 CRPC</td>
<td>Approved in US in Oct 2020 and filed in EU in Jun 2020 for label update to include the OS data</td>
</tr>
<tr>
<td></td>
<td>M1 CSPC</td>
<td>Filed in EU in Jul 2019</td>
</tr>
<tr>
<td></td>
<td>M0 CSPC</td>
<td>Phase 3 study ongoing</td>
</tr>
<tr>
<td><strong>gilteritinib</strong></td>
<td>R/R AML</td>
<td>China: Filed in Mar 2020</td>
</tr>
<tr>
<td></td>
<td>Earlier-stage AML</td>
<td>Phase 3 studies ongoing</td>
</tr>
<tr>
<td><strong>zolbetuximab</strong></td>
<td>Gastric &amp; GEJ adenocarcinoma</td>
<td>Phase 3 studies ongoing</td>
</tr>
<tr>
<td></td>
<td>Pancreatic adenocarcinoma</td>
<td>Phase 2 study ongoing</td>
</tr>
<tr>
<td><strong>fezolinetant</strong></td>
<td>MR-VMS</td>
<td>US &amp; EU: LSLV for 12w DB period achieved in Phase 3 SKYLIGHT 2 study and enrollment completed in SKYLIGHT 1 study. Patient screening closed in long-term SKYLIGHT 4 study. Asia: Phase 3 studies ongoing</td>
</tr>
<tr>
<td><strong>enfortumab vedotin</strong></td>
<td>mUC</td>
<td>Previously treated: Met the primary endpoint (OS) in Phase 3 EV-301 study in patients, platinum and PD-1/L1 inhibitor pretreated. Obtained positive results (ORR) in Phase 2 EV-201 study Cohort 2 in patients, PD-1/L1 inhibitor pretreated, platinum-naïve and cis-ineligible</td>
</tr>
<tr>
<td></td>
<td>Previously untreated (first line; combo with pembrolizumab): Phase 3 study ongoing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>China: Currently under preparation to join global studies in mUC. IND filed for China bridging study</td>
<td></td>
</tr>
<tr>
<td><strong>AT132 (resamirigene bilparvovec)</strong></td>
<td>XLMTM</td>
<td>Clinical study for registration put on clinical hold by FDA, due to serious adverse events</td>
</tr>
</tbody>
</table>
ENFORTUMAB VEDOTIN (EV) (1/5): OVERALL mUC PROGRAM

**NMIBC**
- Stages 0a-1
  - Ta: Noninvasive papillary carcinoma
  - Tis: Carcinoma in situ
  - T1: Tumor invades lamina propria

**MIBC**
- Stages 2 and 3
  - T2: Tumor invades muscle
  - T3: Tumor invades perivesical fat
  - T4a: Tumor invades contiguous organs (prostate, uterus, vagina)

**mUC**
- Stage 4
  - T4b: Tumor invades pelvic wall, abdominal wall
  - N1-3: Any lymph node involvement
  - M1: Distant metastases

**Clinical studies for EV**
- **mUC patient treatment**
  - Previously untreated (first line)
    - P3: EV-302
      - Platinum-eligible
      - EV + Pembrolizumab vs. Chemo
    - P1b/2: EV-103
      - (Dose escalation cohort and Cohort A)
      - Cis-ineligible; EV + Pembrolizumab (Cohort K)
      - Cis-ineligible
      - EV mono vs. EV + Pembrolizumab

- **PD-1/L1 inhibitor pretreated**
  - P2: EV-201 (Cohort 2)
    - PD-1/L1 inhibitor pretreated, platinum-naïve and cis-ineligible
    - EV mono
  - P2: EV-201 (Cohort 1)
    - Platinum and PD-1/L1 inhibitor pretreated; EV mono

- **Platinum and PD-1/L1 inhibitor pretreated**
  - P3: EV-301
    - Platinum and PD-1/L1 inhibitor pretreated
    - EV mono vs. Chemo
  - P2: EV-203
    - (Bridging study in China)
    - Platinum and PD-1/L1 inhibitor pretreated; EV mono

Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020
NMIBC: Non-muscle invasive bladder cancer, MIBC: Muscle invasive bladder cancer, mUC: Metastatic urothelial cancer, Cis: Cisplatin, mono: Monotherapy, Pembrolizumab, Chemo: Chemotherapy, AA: Accelerated Approval, ORR: Objective response rate, OS: Overall survival
Global development

- Phase 3 EV-301 study in mUC, platinum and PD-1/L1 inhibitor pretreated:
  - Met the primary endpoint of OS (HR=0.70; p=0.001) and the secondary endpoint of PFS (HR=0.61; p<0.00001), compared to chemotherapy, based on the planned interim analysis
  => US-sBLA submission planned to convert from Accelerated Approval to Regular Approval, and global registration such as EU and Japan also planned

- Phase 2 EV-201 study Cohort 2 in mUC, PD-1/L1 inhibitor pretreated, platinum-naïve and cis-ineligible: Obtained positive topline results, ORR 52%
  => US-sBLA submission planned to expand the indication in the US

Development in China

- Previously treated - EV monotherapy:
  - IND filed to conduct China bridging study (Phase 2 EV-203 study) in mUC, platinum and PD-1/L1 inhibitor pretreated, to bridge the global Phase 3 EV-301 and Phase 2 EV-201 study data for China registration

- Previously untreated (first line) - EV + pembrolizumab combo:
  - To add sites in China in the ongoing global Phase 3 EV-302 study
ENFORTUMAB VEDOTIN (EV) (3/5): MIBC TREATMENT OVERVIEW

**NMIBC**
- Stages 0a-1
  - Ta: Noninvasive papillary carcinoma
  - Tis: Carcinoma in situ
  - T1: Tumor invades lamina propia

**MIBC**
- Stages 2 and 3
  - T2: Tumor invades muscle
  - T3: Tumor invades perivesical fat
  - T4a: Tumor invades contiguous organs (prostate, uterus, vagina)

**mUC**
- Stage 4
  - T4b: Tumor invades pelvic wall, abdominal wall
  - N1-3: Any lymph node involvement
  - M1: Distant metastases

**Unmet medical needs**
- Despite RC + PLND, approximately 40% die from metastatic disease within 3 years of diagnosis.
- Treatment options are limited to cisplatin-based regimens. Patients who are cis-ineligible currently have no available systemic therapies.

**MIBC treatment** *(Approved drugs and SoC varies by region)*
- Radical cystectomy (RC) plus pelvic lymph node dissection (PLND) is the established SoC
- In cis-eligible, "neoadjuvant chemo" has emerged as the preferred modality of delivering systemic therapy to nonmetastatic MIBC patients planning RC

---

1: Stein JP, et al., 2001

NMIBC: Non-muscle invasive bladder cancer, MIBC: Muscle invasive bladder cancer, mUC: Metastatic urothelial cancer, Cis: Cisplatin, Chemo: Chemotherapy, SoC: Standard of care, Pembro: Pembrolizumab
ENFORTUMAB VEDOTIN (EV) (4/5): MIBC DEVELOPMENT PROGRAM

To expand the potential of EV and Pembro combo to MIBC, where high unmet medical needs still exist

Rationales of EV + Pembro use for MIBC

- EV + Pembro has shown promise as a platinum free option in the EV-103 study results for first line mUC
- The combo may have potential to enhance anti-tumor activity by evoking adaptive immunity, supported by the non-clinical data

Pivotal studies in MIBC

1) Phase 3 study in **cis-ineligible** MIBC (KEYNOTE-905):
   Perioperative EV + Pembro vs. Cystectomy alone

   - **Arm A**: Pembro [3 cycles]
   - **Arm B**: Direct to cystectomy (SoC)
   - **Arm C**: EV+Pembro [3 cycles]

   - **Cystectomy**
   - **pCR**: Pembro [14 cycles]
   - **Observation (SoC)**: EV+Pembro [6 cycles]
   - **Pembro [8 cycles]**

   - **Endpoints:**
     - Primary (dual): EFS and pCR
     - Key secondary: OS

   - n=836, randomized 1:1:1
   - Arm C added to the ongoing Merck’s KEYNOTE-905 study

2) Phase 3 study in **cis-eligible** MIBC: Under preparation (in collaboration with Seagen and Merck)

MIBC: Muscle invasive bladder cancer, Pembro: Pembrolizumab, mUC: Metastatic urothelial cancer, Cis: Cisplatin, Gem: Gemcitabine, SoC: Standard of care, EFS: Event-free survival, pCR: Pathologic complete response, OS: Overall survival
**ENFORTUMAB VEDOTIN (EV) (5/5): UPDATED POTENTIAL SALES SIZE**

*Significant upward revision*

*Potential peak sales in mUC and MIBC to be 300.0 - 400.0 billion yen*

<table>
<thead>
<tr>
<th>Potential sales size (at peak, billion yen)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>300 - 400</td>
<td>✔</td>
</tr>
<tr>
<td>200 - 300</td>
<td></td>
</tr>
<tr>
<td>100 - 200</td>
<td></td>
</tr>
<tr>
<td>50 - 100</td>
<td></td>
</tr>
</tbody>
</table>

Note) Peak sales are expected in-market sales all of which are not booked as revenue by Astellas

---

**mUC**: Metastatic urothelial cancer, **MIBC**: Muscle-invasive bladder cancer
FDA has granted Fast Track designation for the development of ASP0367 as a treatment for primary mitochondrial myopathies

**Primary mitochondrial myopathies (PMM)**

- A complex mitochondrial disease in which genetic mutations primarily impair the function of mitochondria, resulting in reduced muscle function, reduced endurance to exercise (i.e. exercise intolerance), increased fatigue, and muscle atrophy
- In addition, present serious and life-threatening health conditions due to multiple organ involvement
- The prevalence of mitochondrial disease is estimated at 1 in 8,000 for adults w/ clinical manifestation, and 1 in 4,300 for adults with or without clinical manifestations
- No approved treatment for PMM, a disease with high unmet medical need

**ASP0367/MA-0211 characteristics**

- Selective PPARδ modulator, discovered by Mitobridge
- Activates a gene expression program to produce proteins essential for mitochondrial activity
  - Increase use of fatty acids as fuel to make ATP/energy
  - Produce new mitochondria
- <Nonclinical> ASP0367 increased the expression of PPARδ target genes and enhanced mitochondrial function in fibroblasts collected from patients with PMM
- <Clinical> ASP0367 showed dose-dependent increased expression of PPARδ target genes, along with safety and well-tolerated data, in Phase 1 study in healthy adults

**ASP0367 development status**

- Under preparation of Phase 2/3 study to start in 1Q 2021
- Also being developed as a treatment for DMD (under preparation of Phase 1b study)

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1: Gorman GS, et al., 2015

FDA: Food and Drug Administration, PPARδ: Peroxisome proliferator-activated receptor delta, ATP: Adenosine triphosphate, DMD: Duchenne muscular dystrophy
PROGRESS IN FOCUS AREA APPROACH (2/3): ASP7317 FOR DRY AMD

A Phase 1b/2 study amendment aimed to optimize the overall development program has been submitted for FDA’s review

- Significant enrollment delay has occurred, due to:
  - More difficulty in enrollment of patients with severe vision impairment than originally expected, because of high screen failure rates in the limited number of such patients
  - COVID-19 impact, where screening and enrollment is still halted, given possible serious and potentially life-threatening complications of COVID-19 while on immunosuppression in the post-operative period

- The protocol amendment is targeted to enhance the overall development program:
  - Allow enrollment of patients with moderate vision impairment which would expand the eligible patient pool and allow for inclusion of this group in the PoC
  - Change the adjunct immunosuppressive therapy (tacrolimus and MMF) to a tacrolimus-only regimen, with a shorter duration to reduce the risks associated with immunosuppression in this elderly population
  - Decouple the PoC portion of the study to enable greater flexibility in the overall program execution, such as allowing the Phase 1b results to inform the PoC design, including selection of a primary endpoint that may reduce the required PoC sample size

The ASP7317 clinical development plan will be updated once Phase 1b/2 study amendment is finalized based on FDA feedback
PROGRESS IN FOCUS AREA APPROACH (3/3): UPDATED PRIMARY FOCUS (PF)

Completed Primary Focus “ASIM Biology” and shift to next-generation research

- LAMP-vax, the key ASIM platform, has reached a stage of clinical validation, after completion of discovery research
  - ASP0892 for peanut allergy: Phase 1
  - ASP2390 for house dust mite-induced allergic rhinitis: Phase 1
- Exploration of next-generation immune modulation technologies led to identification of platforms with mechanisms and modalities distinct from ASIM. To deliver innovative therapeutics by utilizing endogenous homeostatic mechanism, in-house research (cell therapy) and research collaboration (Pandion Therapeutics) have been started

“ASIM Biology” completed its role as a PF to generate projects. The next generation research has been designated as a PF Candidate “Immune Homeostasis*”
  - Continue the clinical studies for the ongoing 2 projects, ASP0892 and ASP2390
  - Total number of PFs is 4 for now

* PF Candidate - “Multi-immune Regulation” was renamed to “Immune Homeostasis” to reflect its research concept

ASIM: Antigen-specific immuno-modulation, R&D: Research and development
### KEY EVENTS EXPECTED IN FY2020

| Regulatory decision | enzalutamide | M1 CSPC (EU)  
| | | M0 CRPC (China)  
| | | M0 CRPC, label update to include the OS data (EU)  
| roxadustat | Anemia associated with chronic kidney disease, non-dialysis (JP)  
| Regulatory submissions * | enfortumab vedotin | mUC, platinum and PD-1/L1 inhibitor pretreated (US†, EU, JP)  
| | | mUC, PD-1/L1 inhibitor pretreated, cis-ineligible (US‡)  

Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020

* Subject to study outcome, internal assessment, decision and regulatory consultation, as appropriate
† Supplemental BLA submission to convert Accelerated Approval to Regular Approval
‡ Supplemental BLA submission to expand the indication

Please refer to R&D pipeline list for details including target disease

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, OS: Overall survival, Cis: Cisplatin, BLA: Biologics License Application
Steadily progress to establish a solid ground for business acceleration

**New style fitness service (Fit-eNce):**
- From Sep 1\(^{st}\), 2020, the service was offered through fitness clubs in Kanagawa Prefecture

**Smartphone exercise support application:**
- Implementing medical and health research

**Digital therapeutics:**
- BlueStar: Under development

**Image-guided precision surgery:**
- ASP5354: Phase II study ongoing
  (FSFT of Phase 2 study achieved in Oct 2020)
  FDA granted Fast Track Designation

**Ultra-small implantable medical devices:**
- Entered into a Merger Agreement pursuant to acquire Iota Biosciences, Inc.
FSFT of Phase 2 study achieved in October 2020

FDA granted Fast Track Designation based on nonclinical data for the development of a new imaging agent, ASP5354

Iatrogenic Ureteral Injury (IUI)

- IUI is widely recognized as a devastating complication of modern surgery. The seriousness of the IUI condition is evidenced by the findings from over 2-million U.S. surgical procedures, where IUIs were independently associated with higher mortality, morbidity, longer length of hospital stays and increased healthcare cost.

- The International Urological Guidelines state “the best method to prevent iatrogenic ureteric injury is intraoperative identification of both ureters.”

- Current strategies to identify the ureters (e.g., placement of a ureter stent) carry risks for patients, including serious short-and long-term complications such as septic state, chronic renal failure, loss of renal function, etc.

- There is a high unmet medical need for a novel agent such as ASP5354

ASP5354

- An imaging agent that is in development and has the potential to improve surgeon’s ability in visualizing the ureter(s) in patients undergoing abdominopelvic surgery leading to minimizing the risk for IUI.

- Nonclinical and clinical data to date indicates ASP5354 has been well tolerated with no serious safety issues.

- The nonclinical (porcine model) and preliminary human findings are consistent with clear visualization in both species.

FDA: Food and Drug Administration, FSFT: First Subject First Treatment

1: Halabi WJ et al., Dis Colon Rectum. 2014; 57:179-86
2: Chahin et al., 2002; Redan & McCarus, 2009; Fanning et al., 2011; Boyanet al, 2017; Nakada & Patel, 2019; Preminger, 2020.
Entered into a Merger Agreement pursuant to acquire Iota Biosciences, Inc.

- Acquire cutting-edge technologies applicable to multiple spheres, which Rx+ identified as focus business areas that embodies Rx+ World / Rx+ Values
- Secure commercialization rights of and accelerate advancement of multiple projects including those under the R&D Agreement since Aug 2019 and further expand the scope of applications
- Acquire innovative technology for ultra-small implantable medical devices and world-class talent
- Iota powered by Astellas is to be Center of Excellence of Astellas’ bioelectronics

PROGRESS IN Rx+ PROGRAM (1/2):
ULTRA-SMALL IMPLANTABLE MEDICAL DEVICES

Uses ultrasound as a tool for power supply and wireless communication

- Prevent disease onset and slow progression by using personal data
- Expand options for people with limited access to current therapeutics
- Support active living by enhancing physical and sensory function

Accurate local bio-sensing e.g. O₂ level, pH, Pressure, Temperature

Local organ stimulation by electricity e.g. Nerves, Muscle
Dec 10th, 2020: R&D meeting
- Progress of Focus Area approach -

May 2021: New Corporate Strategic Plan
APPENDIX
Q2/FY2020 FINANCIAL RESULTS: COST ITEMS

Core basis: Year-on-Year comparison

- **Cost of sales**
  - % of revenue
  - 1.9 ppt decrease
  - Decrease mainly due to changes in product mix
  - (FX impact on elimination of unrealized gain: Increase in COGs ratio (+1.0 ppt))

- **SG&A expenses**
  - 7.1% increase
  - XTANDI US co-promotion fee increased significantly due to sales expansion
  - Decrease due to one-off reversal of loss allowance in Q2/FY19 (8.2 bil. yen)
  - 1.9% decrease, excluding the above

- **R&D expenses**
  - 6.4% increase
  - In addition to investment increase in development costs for late-stage projects, Audentes' R&D expenses increased
### Q2/FY2020: REVENUE BY REGION

<table>
<thead>
<tr>
<th>Region</th>
<th>Q2/FY19 (billion yen)</th>
<th>Q2/FY20 (billion yen)</th>
<th>Change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>183.3</td>
<td>144.2</td>
<td>-21.3%</td>
</tr>
<tr>
<td>United States</td>
<td>216.7</td>
<td>236.7</td>
<td>+9.2%</td>
</tr>
<tr>
<td>Established Markets</td>
<td>146.7</td>
<td>138.9</td>
<td>-5.4%</td>
</tr>
<tr>
<td>Greater China</td>
<td>29.4</td>
<td>29.6</td>
<td>+0.5%</td>
</tr>
<tr>
<td>International</td>
<td>63.4</td>
<td>56.7</td>
<td>-10.5%</td>
</tr>
</tbody>
</table>

*Established Markets: Europe, Canada, Australia
Greater China: China, Hong Kong, Taiwan
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.*
<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q2/FY19</th>
<th>Q2/FY20</th>
<th>Change</th>
<th>CER growth</th>
<th>FY20 FCST *</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTANDI</td>
<td>195.0</td>
<td>225.5</td>
<td>+15.6%</td>
<td>+16.8%</td>
<td>464.6</td>
</tr>
<tr>
<td>XOSPATA</td>
<td>5.7</td>
<td>11.0</td>
<td>+91.9%</td>
<td>+94.0%</td>
<td>23.1</td>
</tr>
<tr>
<td>PADCEV</td>
<td>-</td>
<td>6.0</td>
<td>-</td>
<td>-</td>
<td>13.0</td>
</tr>
<tr>
<td>OAB products</td>
<td>103.8</td>
<td>96.1</td>
<td>-7.4%</td>
<td>-6.5%</td>
<td>197.9</td>
</tr>
<tr>
<td>mirabegron</td>
<td>78.8</td>
<td>80.0</td>
<td>+1.5%</td>
<td>+2.6%</td>
<td>167.9</td>
</tr>
<tr>
<td>Vesicare</td>
<td>25.1</td>
<td>16.2</td>
<td>-35.4%</td>
<td>-35.1%</td>
<td>30.0</td>
</tr>
<tr>
<td>Prograf</td>
<td>96.2</td>
<td>89.6</td>
<td>-6.9%</td>
<td>-6.1%</td>
<td>182.0</td>
</tr>
</tbody>
</table>

PADCEV: Co-promotion revenue from Seagen
OAB (overactive bladder) products: Vesicare + mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL

* Announced in Aug 2020
## FY2020 REVISED FORECAST

<table>
<thead>
<tr>
<th></th>
<th>FY20 Forecast (Revised in August)</th>
<th>FY20 Revised forecast</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td>1,256.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>R&amp;D expenses</strong></td>
<td>233.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Core operating profit</strong></td>
<td>251.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Core profit</strong></td>
<td>200.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**<Full basis>**

<table>
<thead>
<tr>
<th></th>
<th>Operating profit</th>
<th>Profit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating profit</strong></td>
<td>246.5</td>
<td>210.5</td>
</tr>
<tr>
<td><strong>Profit</strong></td>
<td>197.5</td>
<td>169.5</td>
</tr>
</tbody>
</table>

No changes
## Q2/FY2020 ACTUAL: FX RATE

### Average rate for the period

<table>
<thead>
<tr>
<th>Currency</th>
<th>Q2/FY19</th>
<th>Q2/FY20</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>109 yen</td>
<td>107 yen</td>
<td>-2 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>121 yen</td>
<td>121 yen</td>
<td>-0 yen</td>
</tr>
</tbody>
</table>

### Change in closing rate from previous fiscal year end

<table>
<thead>
<tr>
<th>Currency</th>
<th>Q2/FY19</th>
<th>Q2/FY20</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>-3 yen</td>
<td>-3 yen</td>
<td>0 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>-7 yen</td>
<td>+5 yen</td>
<td>0 yen</td>
</tr>
</tbody>
</table>

### <Impact of exchange rate on financial results>
- 5.3 billion yen decrease in revenue, 6.5 billion yen decrease in core OP
- FX impact on elimination of unrealized gain: COGs ratio +1.0 ppt
**FY2020 FCST: FX RATE & FX SENSITIVITY**

<table>
<thead>
<tr>
<th>Exchange rate (yen) Average for the period</th>
<th>FY20 FCST</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>109 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>120 yen</td>
</tr>
</tbody>
</table>

Forecast rates from Q2/FY2020 onwards: 110 USD/yen, 120 EUR/yen

*Estimated FX sensitivity (Q2 and onward) of FY2020 revised 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. -4.3 bil. yen</td>
<td>Approx. -0.8 bil. yen</td>
</tr>
<tr>
<td>EUR</td>
<td>Approx. -2.0 bil. yen</td>
<td>Approx. -0.8 bil. yen</td>
</tr>
</tbody>
</table>

* Sensitivity to fluctuation of FX rates used for consolidation of overseas affiliates’ results compared to forecasted rates from Q2/FY2020 and onwards
### BALANCE SHEET & CASH FLOW HIGHLIGHTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY19 end</th>
<th>Sep 30, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total assets</td>
<td>2,315.2</td>
<td>2,237.0</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>318.4</td>
<td>286.7</td>
</tr>
<tr>
<td>Total equity attributable to owners of the parent</td>
<td>1,289.2</td>
<td>1,329.6</td>
</tr>
<tr>
<td>Equity ratio (%)</td>
<td>55.7%</td>
<td>59.4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q2/FY19</th>
<th>Q2/FY20</th>
<th>FY19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flows from operating activities</td>
<td>101.7</td>
<td>115.0</td>
<td>222.0</td>
</tr>
<tr>
<td>Cash flows from investing activities</td>
<td>-46.6</td>
<td>-38.3</td>
<td>-389.8</td>
</tr>
<tr>
<td>Free cash flows</td>
<td>55.1</td>
<td>76.7</td>
<td>-167.8</td>
</tr>
<tr>
<td>Cash flows from financing activities</td>
<td>-46.0</td>
<td>-109.7</td>
<td>181.1</td>
</tr>
<tr>
<td>Bonds and short-term borrowings</td>
<td>-</td>
<td>-142.0</td>
<td>326.0</td>
</tr>
<tr>
<td>Proceeds from long-term borrowings</td>
<td>-</td>
<td>80.0</td>
<td>-</td>
</tr>
<tr>
<td>Dividends paid</td>
<td>-35.8</td>
<td>-37.2</td>
<td>-73.5</td>
</tr>
</tbody>
</table>
**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**
**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 Apr 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 FY2005. From FY2013, figures are in accordance with International Financial Reporting Standards (IFRS).*

<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>-</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>-</td>
<td>118</td>
</tr>
<tr>
<td>FY13</td>
<td>60.6</td>
<td>49.4</td>
<td>100</td>
</tr>
<tr>
<td>FY14</td>
<td>66.0</td>
<td>30.0</td>
<td>92</td>
</tr>
<tr>
<td>FY15</td>
<td>68.5</td>
<td>58.2</td>
<td>97</td>
</tr>
<tr>
<td>FY16</td>
<td>71.3</td>
<td>119.3</td>
<td>74</td>
</tr>
<tr>
<td>FY17</td>
<td>72.1</td>
<td>91.4</td>
<td>123</td>
</tr>
<tr>
<td>FY18</td>
<td>72.4</td>
<td>130.0</td>
<td>105</td>
</tr>
<tr>
<td>FY19</td>
<td>75.0</td>
<td>160.0</td>
<td>64</td>
</tr>
<tr>
<td>FY20 (FCST)</td>
<td>78.0</td>
<td>50.0</td>
<td></td>
</tr>
</tbody>
</table>
FILING OPPORTUNITIES ANNOUNCED IN STRATEGIC PLAN 2018

As of Oct 2020
✓✓✓: Approved
✓✓: Filed
✓: Data obtained, filing under preparation

<table>
<thead>
<tr>
<th>Therapeutic area</th>
<th>FY2018</th>
<th>FY2019-2020</th>
<th>FY2021 or beyond</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>enzalutamide</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M0 CRPC</td>
<td>✓✓✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>gilteritinib</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R/R AML</td>
<td>✓✓✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>roxadustat</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia associated with CKD, Dialysis (JP)</td>
<td>✓✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**enfortumab vedotin**
Metastatic urothelial cancer, Platinum and PD-1/L1 inhibitor pretreated (US) ✓✓✓

**roxadustat**
Anemia associated with CKD, Non-dialysis (JP) ✓✓
Anemia associated with CKD, Dialysis/Non-dialysis (EU) ✓✓

**fezolinetant**
MR-VMS

**Note:** Subject to internal assessment, decision and regulatory consultation, as appropriate. Filing (submission) timing in the first country/region within US/EU/JP.

### ROBUST PIPELINE OF ASTELLAS

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Filed</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASP1948/PTZ-329</td>
<td>zolbetuximab (Pancreatic adenocarcinoma)</td>
<td>enzalutamide (M0 CSPC, M1 CSPC: China)</td>
<td>enzalutamide (M1 CSPC: EU)</td>
</tr>
<tr>
<td>ASP1951/PTZ-522</td>
<td>enfortumab vedotin (Other solid tumors)</td>
<td>gilteritinib (Earlier-stage AML, Pediatric use)</td>
<td>enzalutamide (M0 CRPC: China)</td>
</tr>
<tr>
<td>ASP9801</td>
<td>ASP7317 (Dry AMD, etc.)</td>
<td>enfortumab vedotin (mUC, MIBC)</td>
<td>gilteritinib (R/R AML: China)</td>
</tr>
<tr>
<td>ASP7517</td>
<td>ASP1128/MA-0217 (AKI)</td>
<td>zolbetuximab (Gastric and GEJ adenocarcinoma)</td>
<td>roxadustat (Anemia associated with CKD, non-dialysis: JP)</td>
</tr>
<tr>
<td>ASP0892</td>
<td>ASP3772 (Pneumococcal disease)</td>
<td>peficitinib (Rheumatoid arthritis: China)</td>
<td>roxadustat (Anemia associated with CKD: EU)</td>
</tr>
<tr>
<td>ASP0367/MA-0211</td>
<td>FX-322 (Sensorineural hearing loss)</td>
<td>mirabegron (Pediatric use: EU)</td>
<td>mirabegron (Pediatric NDO: US)</td>
</tr>
<tr>
<td>ASP2390</td>
<td>resamirigene bilparvovec/AT132 (XLMTM)</td>
<td>fezolinetant (MR-VMS)</td>
<td></td>
</tr>
<tr>
<td>ASP0598</td>
<td>ASP0367/MA-0211 (PMM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AT845</td>
<td>bleselumab (rFSGS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASP8062</td>
<td>roxadustat (CIA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASP1617</td>
<td>isavuconazole (Pediatric use: US)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Oncology** | **Projects with Focus Area approach (excluding Immuno-oncology projects)** | **Others**

Please refer to R&D pipeline list for details including target disease.

# PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since Q1/FY2020 Financial Results Announcement in Aug 2020

<table>
<thead>
<tr>
<th>Phase 1 Entry</th>
<th>Phase 2 Entry</th>
<th>Phase 3 Entry</th>
<th>Filing</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASP0367</strong></td>
<td><strong>enfortumab vedotin</strong></td>
<td><strong>mirabegron</strong></td>
<td>enzalutamide Tablet (new formulation): US</td>
<td></td>
</tr>
<tr>
<td>Primary mitochondrial myopathies</td>
<td>Muscle-invasive bladder cancer</td>
<td>Neurogenic detrusor in pediatric patients: US</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Discontinuation**

- ASP1650: Testicular cancer (Phase 2)
- ASP8302: Underactive bladder (Phase 2)
- ASP1235/AGS62P1: Acute myeloid leukemia (Phase 1)
- ASP8374/PTZ-201: Cancer (Phase 1)

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: ANDROGEN RECEPTOR INHIBITOR (1/2)

US/EU/JP

Initial Diagnosis
.relu
.active
.surveillance

Definitive Therapy
- Surgery
- Radiation
- Salvage

Castration-Sensitive

ARCHES
- M1 CSPC newly-diagnosed
- M1 CSPC recurrent

EMBARK
- M0 CSPC

Castration-Resistant

PREVAIL
- M1 CRPC (1st line)

AFFIRM
- M1 CRPC (2nd line+)

P3: ARCHES M1 CSPC Combo with ADT, vs. placebo n=1,150 Approved in US in Dec 2019 and in JP in May 2020 Filed in EU in Jul 2019

P3: EMBARK M0 CSPC Combo with ADT, vs. placebo n=1,068 Enrollment completed

China
- M1 CRPC: Approved in Nov 2019 and launched in Mar 2020
- M0 CRPC: Filed in Oct 2019, based on global Phase 3 PROSPER study data
- M1 CSPC: FSFT of Phase 3 China-ARCHES study in Sep 2019

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy, FSFT: First subject first treatment
ENZALUTAMIDE (2/2): PHASE 3 STUDY DATA BY DISEASE STAGE

Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

<table>
<thead>
<tr>
<th>Disease stage</th>
<th>Early stage</th>
<th>Late stage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Castration-sensitive (CSPC)</td>
<td>Castration-resistant (CRPC)</td>
</tr>
<tr>
<td></td>
<td>M0</td>
<td>M1</td>
</tr>
<tr>
<td>Phase 3 study</td>
<td>EMBARK</td>
<td>ARCHES</td>
</tr>
<tr>
<td>Control</td>
<td>Placebo</td>
<td>Placebo</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>MFS (Ongoing)</td>
<td>✓ rPFS HR 0.39</td>
</tr>
<tr>
<td>OS</td>
<td>(Ongoing)</td>
<td>(Not reached)</td>
</tr>
<tr>
<td>DoT</td>
<td>(Ongoing)</td>
<td>(Not reached)</td>
</tr>
</tbody>
</table>

✓: Data obtained, *: Prespecified interim analysis
### GILTERITINIB: FLT3 INHIBITOR

**FLT3 mut+ AML**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Study</th>
<th>Description</th>
<th>Enrollment</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relapsed or refractory</td>
<td>P3: ADMIRAL</td>
<td>Monotherapy vs salvage chemo (2:1)</td>
<td>n=371</td>
<td>Launched in US, JP, and EU, Filed in China in Mar 2020 (Priority Review granted)</td>
</tr>
<tr>
<td>Newly diagnosed (intensive chemo eligible)</td>
<td>P3: PASHA (HOVON)</td>
<td>Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)</td>
<td>n=768</td>
<td>FSFT: Dec 2019 (Sponsor: HOVON)</td>
</tr>
<tr>
<td></td>
<td>P2: PrE0905 (PrECOG)</td>
<td>Combo with azacitidine vs. azacitidine alone (2:1)</td>
<td>n=179</td>
<td>FSFT: Dec 2019 (Sponsor: PrECOG, LLC.)</td>
</tr>
<tr>
<td>Newly diagnosed (intensive chemo ineligible)</td>
<td>P3: LACEWING</td>
<td>Monotherapy vs. placebo (1:1)</td>
<td>n=250</td>
<td>FSFT: Nov 2016</td>
</tr>
<tr>
<td>Post-HSCT maintenance</td>
<td>P3: MORPHO</td>
<td>Monotherapy vs. placebo (1:1)</td>
<td>n=346</td>
<td>Enrollment completed Collaborating with BMT-CTN</td>
</tr>
<tr>
<td>Post-chemo maintenance</td>
<td>P2: GOSSAMER</td>
<td>Monotherapy vs. placebo (2:1)</td>
<td>n=98</td>
<td>Enrollment completed</td>
</tr>
</tbody>
</table>

**PASHA (HOVON)**

- **PrE0905 (PrECOG)**
  - **High-intensity induction chemo**
  - **Chemo consolidation**
  - **Transplant**
  - **Maintenance**
    - **GOSSAMER**
    - **MORPHO**

**ADMIRAL**

- **Salvage therapy**
  - Launched

---

Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020

FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, FSFT: First subject first treatment, HSCT: Hematopoietic stem cell transplant, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands, BMT-CTN: Blood and Marrow Transplant - Clinical Trial Network
ENFORTEUMAB VEDOTIN (EV) : NECTIN-4 TARGETED ADC (1/3)

For urothelial cancer

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Patient Population</th>
<th>Results/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P3: EV-301</strong></td>
<td>mUC, Platinum and PD-1/L1 inhibitor pretreated; EV monotherapy vs. Chemotherapy</td>
<td>n=608</td>
<td>Met the primary endpoint (OS) in Sep 2020, based on the planned interim analysis</td>
</tr>
<tr>
<td><strong>P3: EV-302</strong></td>
<td>mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemotherapy</td>
<td>n=760</td>
<td>FSFT: Apr 2020, Removed Arm C “EV+Pembro +Platinum”, due to the strength of EV+Pembro combo data in EV-103 study and the evolving first line mUC landscape</td>
</tr>
<tr>
<td><strong>P3: EV-303 /KEYNOTE-905</strong></td>
<td>MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone</td>
<td>n=836</td>
<td>Pembro + EV arm added in Jul 2020</td>
</tr>
<tr>
<td><strong>P3</strong></td>
<td>MIBC, Cis-eligible</td>
<td></td>
<td>Currently under preparation (in collaboration with Seagen and Merck)</td>
</tr>
<tr>
<td><strong>P2: EV-201</strong></td>
<td>mUC, PD-1/L1 inhibitor pretreated; EV monotherapy Cohort 1: Platinum pretreated Cohort 2: Platinum naive and cis-ineligible</td>
<td>n=219</td>
<td>Cohort 1: Approved (under the Accelerated Approval program) and launched in US in Dec 2019 Cohort 2: Obtained positive ORR in Oct 2020</td>
</tr>
<tr>
<td><strong>P2: EV-203</strong></td>
<td>&lt;Bridging study in China&gt; mUC, Platinum and PD-1/L1 inhibitor pretreated; EV monotherapy</td>
<td>n≈40</td>
<td>Currently under preparation (IND filed)</td>
</tr>
</tbody>
</table>

For other solid tumors

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Patient Population</th>
<th>Results/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P2: EV-202</strong></td>
<td>HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric, gastroesophageal junction or esophageal cancer</td>
<td>n=240</td>
<td>FSFT: Mar 2020</td>
</tr>
</tbody>
</table>

**Underlined:** Updates since Q1/FY2020 financial results announcement in Aug 2020

## ENFORTUMAB VEDOTIN (EV) (2/3): PHASE 1b/2 EV-103 STUDY DESIGN

<table>
<thead>
<tr>
<th>Dose Escalation Cohort</th>
<th>Dose Expansion Cohorts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Locally advanced or metastatic urothelial cancer</strong></td>
<td><strong>Recommended EV dose</strong></td>
</tr>
<tr>
<td>EV + Pembro Cis-ineligible 1L or 2L</td>
<td><strong>Cohort A</strong> EV + Pembro Cis-ineligible 1L</td>
</tr>
<tr>
<td></td>
<td><strong>Cohort D</strong> EV + Cis, 1L</td>
</tr>
<tr>
<td></td>
<td><strong>Cohort E</strong> EV + Carbo, 1L</td>
</tr>
<tr>
<td></td>
<td><strong>Cohort G</strong> EV + Cis/Carbo + Pembro 1L</td>
</tr>
<tr>
<td></td>
<td><strong>Optional Cohort B</strong> EV + Pembro, 2L</td>
</tr>
<tr>
<td></td>
<td><strong>Optional Cohort F</strong> EV + gemcitabine 1L or 2L</td>
</tr>
<tr>
<td><strong>Muscle-invasive bladder cancer</strong></td>
<td><strong>Results from cis-ineligible and 1L in these cohorts presented at ESMO 2019 and ASCO GU 2020</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Cohort K</strong> EV mono vs. EV+Pembro (1:1, n=150 in total) Cis-ineligible, 1L</td>
</tr>
<tr>
<td></td>
<td><strong>Cohort H</strong> EV mono Cis-ineligible</td>
</tr>
<tr>
<td></td>
<td><strong>Cohort J</strong> EV + Pembro Cis-ineligible</td>
</tr>
</tbody>
</table>

Data from Cohort K, along with other data from the EV-103 study evaluating EV combined with pembrolizumab as first-line therapy for cisplatin-ineligible patients, could potentially support registration under Accelerated Approval regulations in US.

Pembro: pembrolizumab, 1L: First line, 2L: Second line, Cis: Cisplatin, Carbo: Carboplatin, mono: Monotherapy, RC: Radical cystectomy, ESMO: European Society for Medical Oncology, ASCO GU: Genitourinary Cancers Symposium of the American Society of Clinical Oncology.
ENFORTUMAB VEDOTIN (3/3):
NUMBER OF UC PATIENTS

<table>
<thead>
<tr>
<th>Urothelial cancer (Annual)</th>
<th>All stages (Incidence)</th>
<th>MIBC</th>
<th>mUC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Post-cystectomy</td>
<td>Total (Incident + Newly recurrent)</td>
</tr>
<tr>
<td>US</td>
<td>79,000</td>
<td>20,000</td>
<td>19,000</td>
</tr>
<tr>
<td>EU5</td>
<td>118,000</td>
<td>32,000</td>
<td>29,000</td>
</tr>
<tr>
<td>JP</td>
<td>39,000</td>
<td>10,000</td>
<td>8,000</td>
</tr>
<tr>
<td>China</td>
<td>101,000</td>
<td>24,000</td>
<td>29,000</td>
</tr>
</tbody>
</table>

Number of drug treated patients expected to rise after new drug launch

Kantar Health incident and newly recurrent patients
mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer

* 2L+: Platinum and/or PD-1/L1 inhibitor pretreated
ZOLBETUXIMAB:  
ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

**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% of gastric tumors; ~30% of these meet the eligibility criteria for the ongoing Phase 3 studies
  - ~60% of primary pancreatic adenocarcinomas; approx. 20% of these meet the eligibility criteria for the ongoing Phase 2 study

**Gastric and gastroesophageal junction (GEJ) adenocarcinoma**
- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin 18.2 expression
- Gastric cancer is the third leading cause of cancer death worldwide
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20%
- Median overall survival for Stage IV gastric cancer is 10-15 months

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Comparator</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: SPOTLIGHT</td>
<td>First line, combo with mFOLFOX6, vs. placebo</td>
<td>n=550</td>
<td>FSFT: Oct 2018</td>
</tr>
<tr>
<td>P3: GLOW</td>
<td>First line, combo with CAPOX, vs. placebo</td>
<td>n=500</td>
<td>FSFT: Jan 2019</td>
</tr>
<tr>
<td>P2: ILUSTRO</td>
<td>Cohort 1: Third or later line, zolbetuximab monotherapy Cohort 2: First line, combo with mFOLFOX6 Cohort 3: Third or later line, combo with pembrolizumab</td>
<td>n=112</td>
<td>FSFT: Sep 2018</td>
</tr>
<tr>
<td>Pancreatic adenocarcinoma</td>
<td>P2</td>
<td>Combo with nab-paclitaxel and gemcitabine, vs. placebo</td>
<td>n=141</td>
</tr>
</tbody>
</table>

mFOLFOX6: 5-FU, leucovorin and oxaliplatin, CAPOX: Capecitabine and oxaliplatin, FSFT: First subject first treatment
FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

VMS has a significant negative impact on quality of life

- Physical symptoms include hot flashes and sweating/night sweats, which can impact sleep.
- Physical symptoms lead to emotional impact including embarrassment, irritability, anxiety, and sadness.
- Symptoms have a negative impact on multiple aspects of everyday life

Women’s Health Initiative (WHI) Study

- Initial data analyses showed an association between chronic HRT use and increased risk of cardiovascular disease and cancer.
- Since WHI’s findings, no replacement for HRT with similar efficacy and no significant safety concern, resulting in huge unmet medical needs.

US and EU

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>n</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: SKYLIGHT 1</td>
<td>Moderate to severe MR-VMS; The first 12 weeks: DBT, 30 mg vs. 45 mg vs. placebo (1:1:1)</td>
<td>527</td>
<td>Enrollment completed</td>
</tr>
<tr>
<td>P3: SKYLIGHT 2</td>
<td>The last 40 weeks: non-controlled, 30 mg or 45 mg</td>
<td>501</td>
<td>LSLV for 12w DB period achieved</td>
</tr>
<tr>
<td>P3: SKYLIGHT 4</td>
<td>MR-VMS; 52 weeks: DBT, 30 mg vs. 45 mg vs. placebo (1:1:1)</td>
<td>1740</td>
<td>Patient screening closed</td>
</tr>
</tbody>
</table>

Asia (except for Japan)

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>n</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: MOONLIGHT 1</td>
<td>Moderate to severe MR-VMS; The first 12 weeks: DBT, 30 mg vs. placebo (1:1)</td>
<td>300</td>
<td>FSFT: Apr 2020</td>
</tr>
<tr>
<td>P3: MOONLIGHT 3</td>
<td>The last 12 weeks: non-controlled, 30 mg</td>
<td>150</td>
<td>FSFT: Aug 2020</td>
</tr>
</tbody>
</table>

JP: Independent development plan under preparation

Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020


AT132 (RESAMIRIGENE BILPARVOVEC): rAAV8-Des-hMTM1

Characteristics of AT132

- Lead program in the gene therapy pipeline of Audentes Therapeutics, acquired by Astellas in Jan 2020
- Designed to deliver a functional copy of human MTM1 gene by AAV8 to transfec and express myotubularin in skeletal muscle cells
- Regulatory designations granted:
  - <US> RMAT, Rare Pediatric Disease, Fast Track, and Orphan Drug designations
  - <EU> PRIME and Orphan Drug designations

X-linked myotubular myopathy (XLMTM)

- Rare neuromuscular disease with X-linked, loss of function mutations in MTM1 gene
  - Approximately 1 in 40,000 to 50,000 newborn males
  - Estimated 50% mortality by 18 months
- > 80% require ventilator support
- Motor milestones substantially delayed
- No treatment available; supportive care only

ASPIRO (clinical study for registration in XLMTM patients)

vs. Delayed-treatment control
Part 1: Dose escalation
  - Cohort 1: $1 \times 10^{14}$ vg/kg
  - Cohort 2: $3 \times 10^{14}$ vg/kg
Part 2: Pivotal expansion ($3 \times 10^{14}$ vg/kg)

n=26 Study on clinical hold due to serious adverse events

(r)AAV: (recombinant) Adeno-associated virus, Des: Desmin promoter, hMTM1: Human myotubularin gene,
RMAT: Regenerative Medicine Advanced Therapy, PRIME: PR!ority Medicines, vg/kg: Vector genomes per kilogram
ON THE FOREFRONT OF HEALTHCARE CHANGE