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. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.
AGENDA

I Q1/FY2022 Consolidated Financial Results

II Initiatives for Sustainable Growth
## Q1/FY2022 Financial Results: FX Impact and One-Time Factors (Full Basis)

Affected the significant FX impact incl. elimination of unrealized profit due to the sharp depreciation of yen in Q1. Financial results were on track when excluding FX impact and one-time factors.

<table>
<thead>
<tr>
<th>(Billion yen)</th>
<th>Q1/FY21</th>
<th>Q1/FY22</th>
<th>1. FX Impact</th>
<th>Q1/FY22 (excl. 1)</th>
<th>2. One-Time Factors</th>
<th>Q1/FY22 (excl. 1 &amp; 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>326.1</td>
<td>381.8</td>
<td>+35.5</td>
<td>346.3</td>
<td></td>
<td>346.3</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>62.2</td>
<td>88.9</td>
<td>+18.5*</td>
<td>70.4</td>
<td>20.3%</td>
<td>68.6</td>
</tr>
<tr>
<td>% of revenue</td>
<td>19.1%</td>
<td>23.3%</td>
<td></td>
<td>23.3%</td>
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<td>19.8%</td>
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<tr>
<td>SG&amp;A expenses</td>
<td>137.1</td>
<td>153.4</td>
<td>+16.7</td>
<td>136.7</td>
<td></td>
<td>136.7</td>
</tr>
<tr>
<td>US XTANDI co-pro fee</td>
<td>34.5</td>
<td>43.1</td>
<td>+6.7</td>
<td>36.4</td>
<td></td>
<td>36.4</td>
</tr>
<tr>
<td>SG&amp;A excl. the above</td>
<td>102.6</td>
<td>110.3</td>
<td>+10.0</td>
<td>100.3</td>
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<td>100.3</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>58.3</td>
<td>74.0</td>
<td>+7.5</td>
<td>66.5</td>
<td>One-time expenses (+13.1)</td>
<td>53.4</td>
</tr>
<tr>
<td>Amort./Equity</td>
<td>5.7</td>
<td>10.4</td>
<td>+0.2</td>
<td>10.2</td>
<td></td>
<td>10.2</td>
</tr>
<tr>
<td>Gain on divestiture of intangible assets</td>
<td>-</td>
<td>0.2</td>
<td></td>
<td>-</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Core OP</strong></td>
<td>62.8</td>
<td>55.3</td>
<td>-7.4</td>
<td><strong>62.7</strong></td>
<td></td>
<td><strong>77.6</strong></td>
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<tr>
<td>Other income</td>
<td>0.4</td>
<td>16.3</td>
<td>+14.1</td>
<td>2.2</td>
<td></td>
<td>2.2</td>
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<tr>
<td>Other expenses</td>
<td>27.1</td>
<td>38.4</td>
<td>-</td>
<td>38.4</td>
<td>fezolinetant: Increased fair value of contingent consideration (+13.6)</td>
<td>24.8</td>
</tr>
<tr>
<td><strong>Full OP</strong></td>
<td>36.1</td>
<td>33.1</td>
<td>+6.7</td>
<td><strong>26.5</strong></td>
<td></td>
<td><strong>55.0</strong></td>
</tr>
</tbody>
</table>

No changes have been made to Full-year FCST as there are no items that are beyond expectations. Expect to have a positive FX impact for the full year.

*Incl. FX impact on elimination of unrealized profit (+12.3)
Amort./Equity: Amortisation of intangible assets/Share of profit (loss) of investments accounted for using equity method
Q1/FY2022 FINANCIAL RESULTS: OVERVIEW

Revenue increased 17% YoY and was on track when excluding FX impact

- Sales of XTANDI and Strategic products increased 26% YoY
- Cost of sales ratio increased YoY due to significant FX impact
- SG&A expenses were on track and decreased YoY when excluding FX impact
- R&D expenses were on track

Operating profit

- Core OP decreased YoY, same level as previous year when excluding FX impact, progress on track
- Full basis decreased YoY
  - Booked net foreign exchange gains as Other income (14.1 billion yen)
  - Booked impairment losses on intangible assets:
    - Termination of research and development for AT702, AT751, AT753 (22.0 billion yen)
  - Booked fair value remeasurements on contingent consideration for fezolinetant US NDA submission as Other expenses (13.6 billion yen)
## Q1/FY2022 FINANCIAL RESULTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q1/FY21</th>
<th>Q1/FY22</th>
<th>Change</th>
<th>Change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td>326.1</td>
<td>381.8</td>
<td>+55.6</td>
<td>+17.1%</td>
</tr>
<tr>
<td><strong>Cost of sales</strong></td>
<td>62.2</td>
<td>88.9</td>
<td>+26.6</td>
<td></td>
</tr>
<tr>
<td>% of revenue</td>
<td>19.1%</td>
<td>23.3%</td>
<td>+4.2 ppt</td>
<td>+42.8%</td>
</tr>
<tr>
<td><strong>SG&amp;A expenses</strong></td>
<td>137.1</td>
<td>153.4</td>
<td>+16.3</td>
<td>+11.9%</td>
</tr>
<tr>
<td>US XTANDI co-pro fee</td>
<td>34.5</td>
<td>43.1</td>
<td>+8.6</td>
<td>+25.1%</td>
</tr>
<tr>
<td>SG&amp;A excl. the above</td>
<td>102.6</td>
<td>110.3</td>
<td>+7.6</td>
<td>+7.4%</td>
</tr>
<tr>
<td><strong>R&amp;D expenses</strong></td>
<td>58.3</td>
<td>74.0</td>
<td>+15.7</td>
<td>+26.9%</td>
</tr>
<tr>
<td>Amortisation of intangible assets</td>
<td>6.0</td>
<td>10.7</td>
<td>+4.8</td>
<td>+80.2%</td>
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<tr>
<td>Gain on divestiture of intangible assets</td>
<td>-</td>
<td>0.2</td>
<td>+0.2</td>
<td></td>
</tr>
<tr>
<td><strong>Core operating profit</strong></td>
<td>62.8</td>
<td>55.3</td>
<td>-7.5</td>
<td>-12.0%</td>
</tr>
</tbody>
</table>

### <Full basis>

<table>
<thead>
<tr>
<th></th>
<th>Q1/FY21</th>
<th>Q1/FY22</th>
<th>Change</th>
<th>Change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Other income</strong></td>
<td>0.4</td>
<td>16.3</td>
<td>+15.9</td>
<td>-</td>
</tr>
<tr>
<td><strong>Other expenses</strong></td>
<td>27.1</td>
<td>38.4</td>
<td>+11.3</td>
<td>+41.7%</td>
</tr>
<tr>
<td><strong>Operating profit</strong></td>
<td>36.1</td>
<td>33.1</td>
<td>-2.9</td>
<td>-8.2%</td>
</tr>
<tr>
<td><strong>Profit before tax</strong></td>
<td>35.8</td>
<td>31.7</td>
<td>-4.2</td>
<td>-11.6%</td>
</tr>
<tr>
<td><strong>Profit</strong></td>
<td>30.7</td>
<td>24.8</td>
<td>-5.9</td>
<td>-19.1%</td>
</tr>
</tbody>
</table>

### FY22 Initial FCST: 1,443.0 billion yen, Progress: 26.5%

### FX impact

- +35.5 bil. yen
- +18.5 bil. yen*
- +16.7 bil. yen
- +10.0 bil. yen
- +7.5 bil. yen
- -7.4 bil. yen

### Additional Notes

- Incl. FX impact on elimination of unrealized profit (+12.3 bil. yen)

- Net foreign exchange gains: 14.1 bil. yen
- Impairment losses on intangible assets (AT702, AT751, AT753): 22.0 bil. yen
- Fezolinetant increased fair value of contingent consideration: 13.6 bil. yen
# Q1/FY2022 FINANCIAL RESULTS: XTANDI AND STRATEGIC PRODUCTS

Sales of XTANDI and Strategic products increased 26% YoY

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q1/FY2022 Act</th>
<th>YoY</th>
<th>FY2022 Initial FCST</th>
<th>Progress</th>
</tr>
</thead>
</table>
| **Xtandi** (enzalutamide) | 162.4         | +29.5 (+22%) | 642.5            | ✓ Global sales are in line with expectations  
✓ Signs of sales recovery in US from Q4 slowdown |
| **PADCEV** (enfortumab vedotin-ejfv) | 10.6          | +6.4 (+152%) | 36.5             | ✓ Global sales are above expectations  
• New patients starts far exceeded expectations in Japan  
• Clinical trial orders booked ahead of schedule in US  
✓ Possibility of exceeding initial full-year forecast |
| **XOSPATA** (gilteritinib) | 10.5          | +2.2 (+26%)  | 46.2             | ✓ Global sales are almost in line with expectations  
✓ US performed below expectations due to inventory burn |
| **Evrenzo** (roxadustat)   | 0.7           | +0.1 (+19%)  | 9.9              | ✓ Sales in Japan and Europe are below expectations  
✓ Expect reimbursement to start in European countries in 2H/FY2022 |

Strategic products: PADCEV, XOSPATA, EVRENZO

PADCEV (US): Co-promotion revenue from Seagen
Q1/FY2022 FINANCIAL RESULTS: BUSINESS UPDATE FOR XTANDI AND PADCEV

Global sales grew as expected, mainly from M1 CSPC contribution

<US> Performed below expectations, but showed signs of sales recovery
- Impact from generic competitor pressure continued, no significant expansion
- Signs of PAP rate settling, still slightly higher level than expected
- New patient starts are in upward trend, expect positive impact

<ex-US> Performed above expectations, especially contribution from Europe
- In Europe, M1 CSPC showed strong growth, and countries with reimbursement increased, contributing to demand increase
- Positive price impact, higher price than assumed was agreed upon (Germany)

Sales grew in all regions, global sales growth exceeding expectations

<US> Performed as expected, even excluding revenue from clinical trial orders
- Strong growth from cis-ineligible mUC 2L therapy

<JP> Market penetration far exceeding expectations since launched in Nov 2021
- Highly evaluated by physicians, new patient starts and market share higher than expected

<Europe> Approved in Apr 2022, currently launched in 8 countries, strong initial uptake
- Expect further increase in launch countries and reimbursement start
Q1/FY2022 FINANCIAL RESULTS: COST ITEMS

Cost of sales ratio increased YoY due to significant FX impact
SG&A expenses were on track and decreased YoY when excluding FX impact
R&D expenses were on track

Core basis: Main items for YoY and progress against FCST

Cost of sales
% of revenue
YoY: +4.2 ppt
- FX impact on elimination of unrealized profit: +3.2 ppt (+12.3 bil. yen)
- XTANDI royalty payment adjustment for prior year: +0.5 ppt (+1.8 bil. yen)

SG&A expenses (excl. XTANDI US co-pro fee)
YoY: +7.4%
Progress against FCST: 27%
- SG&A excl. FX impact: -2.4 bil. yen (YoY -2.3%)
- Global optimization of personnel aligned with transformation of product portfolio (Approx. -3.0 bil. yen)
- Reduction of mature products-related costs (Approx. -2.0 bil. yen)
- Investment for new product launch readiness (Approx. +2.0 bil. yen)

R&D expenses
YoY: +26.9%
Progress against FCST: 29%
- FX impact (+7.5 bil. yen)
- Increase in one-time expenses that already factored into full-year FCST (+13.1 bil. yen)
AGENDA

I  Q1/FY2022 Consolidated Financial Results

II  Initiatives for Sustainable Growth
## XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2022

<table>
<thead>
<tr>
<th></th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>enzalutamide / XTANDI</td>
<td></td>
<td></td>
<td>EMBARK TLR&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Filing (M0 CSPC; US)</td>
</tr>
<tr>
<td>enfortumab vedotin / PADCEV</td>
<td></td>
<td></td>
<td></td>
<td>China ARCHES TLR&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>zolbetuximab</td>
<td></td>
<td></td>
<td>EV-103 Cohort K TLR&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Filing (1L mUC; US)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>EV-203 TLR (pre-treated mUC; China)&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>fezolinetant</td>
<td></td>
<td></td>
<td>SPOTLIGHT TLR&lt;sup&gt;1&lt;/sup&gt;</td>
<td>GLOW TLR&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>AT132</td>
<td></td>
<td></td>
<td>Response to FDA clinical hold</td>
<td></td>
</tr>
</tbody>
</table>

1. The timeline of TLR is subject to shift due to its event-driven nature.

TLR: Topline results, M0 CSPC: Non-metastatic castration-sensitive prostate cancer, 1L: First line, mUC: Metastatic urothelial cancer, NDA: New Drug Application, FDA: Food and Drug Administration
ENFORTUMAB VEDOTIN (EV) (1/2): TOPLINE RESULTS FOR EV-103 STUDY COHORT K

Positive topline results obtained, showing consistent efficacy and safety with previous data.

- First-line treatment for advanced urothelial cancer (cis-ineligible, combination with pembrolizumab)
- Plan to discuss results with FDA aiming sBLA submission in 2022 under Accelerated Approval

<table>
<thead>
<tr>
<th>Early stage</th>
<th>Disease stage of urothelial cancer</th>
<th>Late stage</th>
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</thead>
<tbody>
<tr>
<td>NMIBC</td>
<td>Stages 0a-1</td>
<td>MIBC</td>
</tr>
<tr>
<td></td>
<td>Stages 2 and 3</td>
<td>mUC</td>
</tr>
<tr>
<td></td>
<td>First line</td>
<td>PD-1/L1 inhibitor pretreated</td>
</tr>
<tr>
<td></td>
<td>Second or later line</td>
<td>cis-eligible</td>
</tr>
<tr>
<td>cis-eligible</td>
<td>Platnum and PD-1/L1 inhibitor pretreated</td>
<td></td>
</tr>
</tbody>
</table>

**Patient segment**
- Patients with unresectable la/mUC who are unable to receive cisplatin-based chemotherapy in the first-line setting

**Study arm**
- EV + pembrolizumab combo (n=76)
- EV monotherapy (n=73)

**Primary endpoint**
- ORR (per BICR)

**Secondary endpoint**
- DoR, PFS, OS, safety, etc.

**<Cohort K in EV-103 study>**

**<Topline results (Combo arm)>**

<table>
<thead>
<tr>
<th>ORR [95% CI]</th>
<th>64.5% [52.7 to 75.1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>DoR</td>
<td>Not reached (median cannot be calculated due to continued response in many subjects)</td>
</tr>
<tr>
<td>Safety</td>
<td>Tolerable and manageable, and no new safety concerns emerged</td>
</tr>
</tbody>
</table>

[Ref] Previously reported ORR data for gemcitabine + carboplatin treatment in first-line setting: 42-46%
ENFORTUMAB VEDOTIN (2/2): OVERVIEW

The most significant growth driver is 1L mUC indication, which is expected to account for more than half of total sales in the future.

<table>
<thead>
<tr>
<th>Patient segment</th>
<th>Pivotal study</th>
<th>Mono/Combo</th>
<th>OS</th>
<th>PFS</th>
<th>ORR</th>
<th>DoR</th>
<th>Target filing timing</th>
<th>Number of eligible patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIBC</td>
<td>EV-303</td>
<td>Combo</td>
<td>(Ongoing)</td>
<td>FY2025 or later</td>
<td>10,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cis-eligible</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cis-ineligible</td>
<td>EV-304</td>
<td>Combo</td>
<td>(Ongoing)</td>
<td>FY2025 or later</td>
<td>37,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mUC, previously untreated (1L)</td>
<td>EV-302</td>
<td>Combo</td>
<td>(Ongoing)</td>
<td>FY2024</td>
<td>76,000</td>
<td></td>
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<tr>
<td>EV-103 Cohort K</td>
<td></td>
<td>Combo</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>EV-103 dose escalation cohort &amp; Cohort A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platinum &amp; PD-1/L1 inhibitor pretreated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD-1/L1 inhibitor pretreated</td>
<td>EV-201</td>
<td>Mono</td>
<td>14.7 mos</td>
<td>5.8 mos</td>
<td>52%</td>
<td>13.8 mos</td>
<td>Approved</td>
<td>1.600 (US, cis-ineligible)</td>
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<tr>
<td>EV-201 Cohort 2</td>
<td></td>
<td>Mono</td>
<td>12.9 mos</td>
<td>5.6 mos</td>
<td>41%</td>
<td>7.4 mos</td>
<td>Approved</td>
<td>38,000</td>
</tr>
</tbody>
</table>

Clinical studies in other patient segments are also ongoing:

- Non-muscle-invasive bladder cancer (NMIBC): EV-104 (Phase 1)
- Other solid tumors: EV-202 (Phase 2)
FEZOLINETANT: LATEST STATUS

<Regulatory submission> NDA submitted to US FDA on June 22

<Data presentation> Latest data presented at ACOG and ENDO
- SKYLIGHT 1 study 12-w data: Consistent results with those of SKYLIGHT 2 study
- SKYLIGHT 2 study 52-w data:
  ✓ Maintained improvement in VMS frequency and severity throughout 52 weeks
  ✓ Reduction in VMS frequency and severity after re-randomization from placebo to fezolinetant
  ✓ Consistent safety profile with that of 12-week placebo-controlled period

<VMS education and awareness activities (US)>
- HCP: Sequentially launched VMS educational/awareness website (KnowVMS.com) and omni-channel online and in-person approach
  ✓ Reached 132k unique HCPs
- Consumer: Launching DSA (Disease State Awareness) campaign in August (TV from October)

<Upcoming events>
- SKYLIGHT 4 study 52-week data to be presented at NAMS in October
- Conference call after NAMS presentation will be held on October 17

NAMS: North American Menopause Society
# PROGRESS IN FOCUS AREA APPROACH (1/4):
## CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL
(Red: Updates since the last financial results announcement)

<table>
<thead>
<tr>
<th>Primary Focus</th>
<th>Biology/Modality/Technology</th>
<th>Project</th>
<th>Current status</th>
<th>No. of projects aiming PoC by end FY25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic Regulation</td>
<td>Gene replacement (AAV)</td>
<td>AT132</td>
<td>ASPIRO study put on clinical hold by FDA in Sep 2021</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Gene regulation (AAV)</td>
<td>AT845</td>
<td>FORTIS study put on clinical hold by FDA in Jun 2022</td>
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</tr>
<tr>
<td></td>
<td>Checkpoint</td>
<td>ASP1570</td>
<td>Phase 1 study ongoing</td>
<td></td>
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<tr>
<td></td>
<td>Artificial adjuvant vector cell (aAVC)</td>
<td>ASP7517</td>
<td>Phase 2 study in R/R AML and MDS ongoing</td>
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<tr>
<td></td>
<td></td>
<td>ASP0739</td>
<td>Phase 1 study in advanced solid tumors ongoing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oncolytic virus (intranuclear)</td>
<td>ASP9801</td>
<td>Phase 1 study ongoing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oncolytic virus (systemic)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bispecific immune cell engager</td>
<td>ASP2138</td>
<td>FSFT in Phase 1 study in Jun 2022</td>
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<tr>
<td></td>
<td>Cancer cell therapy (UDC)</td>
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<td></td>
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<td></td>
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<tr>
<td>Immuno-Oncology</td>
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<td></td>
</tr>
<tr>
<td>Cell replacement</td>
<td>ASP7317</td>
<td>Screening and enrollment in Phase 1b study anticipated to restart in Aug 2022</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Cell replacement (UDC)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gene replacement (AAV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mitochondria</td>
<td>Gene regulation &amp; mitochondrial biogenesis</td>
<td>ASP0367</td>
<td>Phase 2/3 study in PMM ongoing</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Mitochondrial stress</td>
<td>ASP8731</td>
<td>Phase 1b study in DMD ongoing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mitochondrial transfer</td>
<td></td>
<td>Phase 1 study ongoing</td>
<td></td>
</tr>
<tr>
<td>Primary Focus Candidates</td>
<td>Immune modulating/regulatory cells</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tissue-specific immune regulation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Targeted protein degradation</td>
<td>ASP3082</td>
<td>FSFT in Phase 1 study in Jun 2022</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>24</td>
<td></td>
</tr>
</tbody>
</table>

1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Jul 2022)

FORTIS study placed on clinical hold by FDA, following the reporting of an SAE of peripheral sensory neuropathy

Remain committed to the safe and effective development of AT845 for Pompe disease, and to gene therapy

PROGRESS IN FOCUS AREA APPROACH (2/4): AT845

- SAE reported by investigator
- Follow-up with regulatory authorities
- FDA clinical hold letter received
- Actions to respond to FDA clinical hold comments:
  - Develop overall plan
  - Scientific investigation
  - Gather key clinical data
  - KOL consultation
  - Protocol modification

1. Participant dosed in Nov 2021 with AT845 $6 \times 10^{13}$ vg/kg
2. Assumes no new nonclinical study or analysis of existing nonclinical samples necessary
**PROGRESS IN FOCUS AREA APPROACH (3/4): ASP7317**

*Clinical study of ASP7317, the lead program of cell therapy, anticipated to restart*

- **ASP7317**
  - Human embryonic stem cell-derived retinal pigment epithelial cells
  - Target disease: Geographic atrophy secondary to age-related macular degeneration, Stargardt disease
- The clinical study was voluntarily put on hold due to the manufacturing process changes and the introduction of new cutting-edge analytical methods for product release in accordance with technology advancements in a cell-therapy field
- Established capabilities enabling supply of cells that meet the high quality standard through activities for resumption

<table>
<thead>
<tr>
<th>Establishment of PSC line</th>
<th>Master cell bank</th>
<th>Working cell bank</th>
<th>Differentiation to desired cells</th>
<th>Drug substance</th>
</tr>
</thead>
</table>

- **Manufacturing**: Improving ratio of cells with desired characteristics
- **Analysis**: Quality testing with high sensitivity and reproducibility
- **Specification setting**: Building rationale based on multiple preclinical data

- Screening and enrollment anticipated to restart in Aug 2022
- Acceleration of research and development for subsequent cell therapy programs
  - Expected to be able to provide cells with higher quality for clinical studies without delay, by leveraging established capabilities

PSC: pluripotent stem cell
Degradation of target protein with technology enabling access to “Undruggable target”

**Protein degrader**: degrades target protein through intrinsic mechanism

**Conventional target** vs **Undruggable target**
- **Active site**:
  - Conventional target: Able to control its function through binding to active site, conformational change, etc.
  - Undruggable target: Not able to sufficiently control its function by just binding, due to lack of apparent active sites, etc., considered hard to be a target of drug

**KRAS G12D**
- Binding to target protein and E3 ligase, and bringing them adjacent to each other
- Ubiquitylation of target protein by E2/E3 ligase complex
- Degradation of ubiquitinated protein by proteasome

**ASP3082 (Protein degrader)**
- Target protein: KRAS G12D mutant
  - One of the most frequently mutated oncogenes in cancer, involved in cancer cell growth signaling
  - Have been considered an “Undruggable target” for which inhibitors are difficult to develop
- Target disease: Cancers harboring KRAS G12D mutation
- Primary Focus Candidate: Targeted Protein Degradation

<table>
<thead>
<tr>
<th>Percentage with KRAS G12D mutation (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic ductal adenocarcinoma</td>
<td>33.8</td>
</tr>
<tr>
<td>Rectum adenocarcinoma</td>
<td>12.0</td>
</tr>
<tr>
<td>Bile duct carcinoma</td>
<td>10.9</td>
</tr>
<tr>
<td>Colon adenocarcinoma</td>
<td>10.3</td>
</tr>
<tr>
<td>Endometrium carcinoma</td>
<td>5.3</td>
</tr>
<tr>
<td>Lung adenocarcinoma</td>
<td>3.6</td>
</tr>
<tr>
<td>Ovarian carcinoma</td>
<td>3.5</td>
</tr>
</tbody>
</table>

KRAS: Kirsten rat sarcoma viral oncogene homologue
## PROGRESS IN Rx+ PROGRAM

### Key events expected in FY2022 (announced in Apr 2022)

<table>
<thead>
<tr>
<th>Category</th>
<th>Program</th>
<th>Event</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital health</td>
<td>EG Holter/AI Software</td>
<td>Initiation of sales pilot</td>
<td>Achieved (Jun 2022)</td>
</tr>
<tr>
<td>Other services</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digital therapeutics</td>
<td>BlueStar</td>
<td>Initiation of clinical study (Japan)</td>
<td></td>
</tr>
<tr>
<td>Drug-device combination</td>
<td>pudexacianinium chloride (ASP5354)</td>
<td>FSFT in Phase 3 study</td>
<td></td>
</tr>
</tbody>
</table>

- Implantable medical devices (iota):
  - Prepare for IDE submission in FY2022, toward initiation of clinical study in FY2023

---

AI: Artificial intelligence, IDE: Investigational Device Exemption, FSFT: First subject first treatment
**PROGRESS TOWARD ACHIEVING CSP2021**

### Revenue, Pipeline Value

1. **XTANDI and Strategic products:** ≥ ¥1.2T in FY2025
   - Sales growth on track
   - PADCEV: Obtained TLR from EV-103 Cohort K and EV-202
   - fezolinetant: NDA submission in US, VMS education/awareness activities for HCP rolled out

2. Post-PoC projects from Primary Focuses
3. Multiple technology platforms
4. Focus Area projects: ≥ ¥0.5T in FY2030
   - ASP7317: Phase 1b study anticipated to restart
   - ASP2138, ASP3082: FSFT in Phase 1 study
   - Gene therapy: Opening of new manufacturing facility in Sanford
   - AT845: Clinical hold

### Core OP

5. Flat SG&A in absolute terms
6. Sufficient R&D investments
7. Core OP margin of ≥ 30% in FY2025
8. Steady increase in dividends

### Future growth

8. Rx+: Breakeven by FY2025
9. **Sustainability**
   - Selected for the FTSE4Good Index Series for 11 consecutive years

---

Strategic products: PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132
fezolinetant meeting
➢ Oct 17th 2022, 9:30-10:45 (JST)

Enfortumab Vedotin meeting (EV-103 Cohort K)
➢ To be announced
Overview of cost of sales

<table>
<thead>
<tr>
<th>Beginning inventory</th>
<th>Cost of sales</th>
<th>Ending inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfg cost / Purchase</td>
<td>Unrealized profit</td>
<td>Mfg cost / Purchase</td>
</tr>
</tbody>
</table>

 elimination of unrealized profit

Record cost of sales

Profit from intra-group transactions

Theoretically no impacts on P/L as the cost of sales offset the intra-group profit

(example of unrealized intercompany profit) Co. A sold product to Co. B. At the year-end, the product had not yet been sold to 3rd parties.

Company A

Sales 100

COGs 30

Profit from intra-group transactions 70

Company B

Inventory 100

Unrealized profit 70

COGs 30

Unrealized profit

Profit from intra-group transactions

FX impacts related to inventories held by foreign affiliates

Local currency

Unrealized profit

Record cost of sales

Profit from intra-group transactions

Translated to yen

JPY

@current rate

Profit from intra-group transactions

@average rate

(1) In case current rate (@120) is weaker than average rate (@110)

8,400 yen > 7,700 yen

Recorded COGs is larger → COGs +700 yen

(2) In case current rate (@100) is stronger than average rate (@110)

7,000 yen < 7,700 yen

Recorded COGs is smaller → COGs -700 yen

Impacts on FY22Q1
Group consolidation (JPY) : cost of sales +9.1 billion yen
Sub-consolidation at ABV (euro) : cost of sales +4.2 billion yen (mainly due to stronger RUB)
Q1/FY2022: REVENUE BY REGION

<table>
<thead>
<tr>
<th>Region</th>
<th>Q1/FY21 (billion yen)</th>
<th>Q1/FY22 (billion yen)</th>
<th>Change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>67.5</td>
<td>66.8</td>
<td>-1.0%</td>
</tr>
<tr>
<td>United States</td>
<td>133.6</td>
<td>160.9</td>
<td>+20.4%</td>
</tr>
<tr>
<td>Established Markets</td>
<td>78.0</td>
<td>88.7</td>
<td>+13.7%</td>
</tr>
<tr>
<td>Greater China</td>
<td>16.4</td>
<td>23.2</td>
<td>+41.0%</td>
</tr>
<tr>
<td>International Markets</td>
<td>27.8</td>
<td>31.8</td>
<td>+14.5%</td>
</tr>
</tbody>
</table>

Established Markets: Europe, Canada, Australia
Greater China: China, Hong Kong, Taiwan
International Markets: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.
Q1/FY2022: SALES OF MAIN PRODUCTS

<table>
<thead>
<tr>
<th>Product</th>
<th>Q1/FY21</th>
<th>Q1/FY22</th>
<th>Change</th>
<th>CER growth</th>
<th>FY22 Initial FCST</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTANDI</td>
<td>132.9</td>
<td>162.4</td>
<td>+22.2%</td>
<td>+9.3%</td>
<td>642.5</td>
</tr>
<tr>
<td>PADCEV</td>
<td>4.2</td>
<td>10.6</td>
<td>+151.6%</td>
<td>+122.9%</td>
<td>36.5</td>
</tr>
<tr>
<td>XOSPATA</td>
<td>8.3</td>
<td>10.5</td>
<td>+26.3%</td>
<td>+12.1%</td>
<td>46.2</td>
</tr>
<tr>
<td>EVRENZO</td>
<td>0.6</td>
<td>0.7</td>
<td>+19.3%</td>
<td>+18.8%</td>
<td>9.9</td>
</tr>
<tr>
<td>mirabegron</td>
<td>44.0</td>
<td>47.9</td>
<td>+9.0%</td>
<td>-2.2%</td>
<td>178.7</td>
</tr>
<tr>
<td>Prograf</td>
<td>45.2</td>
<td>51.8</td>
<td>+14.6%</td>
<td>+5.8%</td>
<td>190.7</td>
</tr>
</tbody>
</table>

PADCEV (US): Co-promotion revenue from Seagen
mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL
### Average rate for the period

<table>
<thead>
<tr>
<th>Currency</th>
<th>Q1/FY21</th>
<th>Q1/FY22</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>109 yen</td>
<td>130 yen</td>
<td>-20 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>132 yen</td>
<td>138 yen</td>
<td>-6 yen</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Currency</th>
<th>Q1/FY21</th>
<th>Q1/FY22</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>+0 yen</td>
<td>-14 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>-2 yen</td>
<td>-8 yen</td>
</tr>
</tbody>
</table>

<Impact of exchange rate on financial results>

- 35.5 billion yen increase in revenue, 7.4 billion yen decrease in core OP
- FX impact on elimination of unrealized profit: COGs ratio +3.2 ppt
## FY2022 FCST: FX RATE & FX SENSITIVITY

### Average rate for the period

<table>
<thead>
<tr>
<th>Currency</th>
<th>FY2021</th>
<th>FY2022 FCST</th>
<th>change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>112 yen</td>
<td>120 yen</td>
<td>+8 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>131 yen</td>
<td>135 yen</td>
<td>+4 yen</td>
</tr>
</tbody>
</table>

### Change in closing rate from the previous FY end

<table>
<thead>
<tr>
<th>Currency</th>
<th>FY2021</th>
<th>FY2022 FCST</th>
<th>change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>+11 yen</td>
<td>-2 yen</td>
<td></td>
</tr>
<tr>
<td>EUR</td>
<td>+5 yen</td>
<td>0 yen</td>
<td></td>
</tr>
</tbody>
</table>

### Estimated FX sensitivity of FY2022 forecast by 1 yen depreciation

<table>
<thead>
<tr>
<th>Currency</th>
<th>Average rate 1 yen lower than assumption</th>
<th>Year-end rate 1 yen lower than assumption</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Revenue</td>
<td>Core OP</td>
</tr>
<tr>
<td>USD</td>
<td>Approx. +6.6 bil. yen</td>
<td>Approx. +1.1 bil. yen</td>
</tr>
<tr>
<td>EUR</td>
<td>Approx. +2.8 bil. yen</td>
<td>Approx. +1.2 bil. yen</td>
</tr>
</tbody>
</table>
## BALANCE SHEET & CASH FLOW HIGHLIGHTS

### Balance Sheet

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>FY21 end</th>
<th>Jun 30, 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total assets</td>
<td>2,332.4</td>
<td>2,481.8</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>316.0</td>
<td>313.0</td>
</tr>
<tr>
<td>Total equity attributable to owners of the parent</td>
<td>1,460.3</td>
<td>1,539.1</td>
</tr>
<tr>
<td>Equity ratio (%)</td>
<td>62.6%</td>
<td>62.0%</td>
</tr>
</tbody>
</table>

### Cash Flows

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q1/FY21</th>
<th>Q1/FY22</th>
<th>FY21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flows from operating activities</td>
<td>40.1</td>
<td>48.8</td>
<td>257.4</td>
</tr>
<tr>
<td>Cash flows from investing activities</td>
<td>-21.1</td>
<td>-19.1</td>
<td>-62.4</td>
</tr>
<tr>
<td>Free cash flows</td>
<td>19.0</td>
<td>29.7</td>
<td>195.0</td>
</tr>
<tr>
<td>Cash flows from financing activities</td>
<td>-44.7</td>
<td>-46.6</td>
<td>-216.3</td>
</tr>
<tr>
<td>Bonds and short-term borrowings</td>
<td>-</td>
<td>+15.0</td>
<td>-30.0</td>
</tr>
<tr>
<td>Acquisition of treasury shares</td>
<td>-0.7</td>
<td>-10.6</td>
<td>-50.7</td>
</tr>
<tr>
<td>Dividends paid</td>
<td>-38.9</td>
<td>-45.7</td>
<td>-85.2</td>
</tr>
</tbody>
</table>

Balance of bonds and borrowings: 155.0 billion yen
(Increased by 15.0 billion yen from FY2021 end)
1. Top priority is investment for business growth

2. Raise dividend level aligned with profit / cashflow plan and actual performance throughout CSP2021 period

3. Flexibly execute share buyback by excess cash

Aiming for higher level of dividends increase during CSP2021 aligned with the robust profit growth forecast

Trend of Core OP and dividends

* Prior to FY2012, operating profit is in accordance with J-GAAP
CSP: Corporate Strategic Plan
## ROBUST PIPELINE OF ASTELLAS

### Phase 1
- **enfortumab vedotin** (NMIBC)
- gilteritinib (Newly diagnosed AML, HIC-ineligible)
- ASP9801
- ASP7517 (Solid tumors)
- ASP0739
- ASP7317
- bocidelpar/ASP0367 (Duchenne muscular dystrophy)
- AT845
- ASP0598
- ASP1570
- ASP2138
- ASP8731
- ASP3082
- ASP08062

### Phase 2
- **enfortumab vedotin** (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- roxadustat (Chemotherapy-induced anemia)
- fezolinetant (VMS associated with menopause: Japan)
- resamirigene bilparvovec /AT132 (XLTM)
- ASP7517 (AML and MDS)
- bocidelpar/ASP0367 (Primary mitochondrial myopathies)
- FX-322 (Sensorineural hearing loss)
- isavuconazole (Pediatric use: US)

### Phase 3
- **enazlutamide** (M0 CSPC, M1 CSPC: China)
- **enfortumab vedotin** (mUC previously untreated, MIBC)
- gilteritinib (Earlier-stage AML, pediatric use)
- zolbetuximab (Gastric and GEJ adenocarcinoma)
- fezolinetant (VMS associated with menopause: Europe, China)
- peficitinib (Rheumatoid arthritis: China)
- mirabegron (Pediatric use: Europe)
- ASP9801
- ASP7517
- ASP0739
- ASP7317
- bocidelpar/ASP0367
- FX-322
- isavuconazole

### Submitted
- fezolinetant (VMS associated with menopause: US)

---

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

**NMIBC:** Non-muscle-invasive bladder cancer, **AML:** Acute myeloid leukemia, **HIC:** High-intensity chemotherapy, **XLTM:** X-linked myotubular myopathy, **MDS:** Myelodysplastic syndrome, **M0:** Non-metastatic, **M1:** Metastatic, **CSPC:** Castration-sensitive prostate cancer, **mUC:** Metastatic urothelial cancer, **MIBC:** Muscle-invasive bladder cancer, **GEJ:** Gastroesophageal junction, **VMS:** Vasomotor symptoms
PROGRESS IN OVERALL PIPELINE
Phase 1 Entry to Approval since the Last Financial Results Announcement

Phase 1 Entry ▶ Phase 2 Entry ▶ Phase 3 Entry ▶ Filing ▶ Approval

**fezolinetant**
Vasomotor symptoms associated with menopause: US

---

**Discontinuation**
ASP8062: Opioid use disorder (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.
### XTANDI & STRATEGIC PRODUCTS: STATUS UPDATE

(Read: Updates since the last financial results announcement)

<table>
<thead>
<tr>
<th>Project / Product</th>
<th>Indication</th>
<th>Current status</th>
</tr>
</thead>
</table>
| **enzalutamide / XTANDI** | M1 CSPC | • US: Filed label update to include the OS data in Dec 2021  
EU: CHMP positive opinion received for label update to include the OS data in Mar 2022  
China: Phase 3 study ongoing (enrollment completed) |
| | M0 CSPC | Phase 3 study ongoing (enrollment completed) |
| **enfortumab vedotin / PADCVE** | Metastatic urothelial cancer | • Previously untreated (first line): Phase 3 study ongoing. OBTAINED TOPLINE RESULTS FROM COHORT K IN EV-103 STUDY IN JUL 2022  
China: Phase 2 bridging study ongoing (enrollment completed)  
Muscle-invasive bladder cancer | Phase 3 studies ongoing  
Non-muscle-invasive bladder cancer | Phase 1 study ongoing  
Other solid tumors | Phase 2 study ongoing. OBTAINED INITIAL TOPLINE RESULTS IN JUN 2022 |
| **gilteritinib / XOSPATA** | Relapsed and refractory AML | • China: Phase 3 study stopped due to efficacy  
AML, post-HSCT maintenance | Phase 3 study ongoing (enrollment completed)  
AML, newly diagnosed (HIC-eligible) | Phase 3 study ongoing  
AML, newly diagnosed (HIC-ineligible) | Phase 1 study under preparation to start in Q4 FY2022  
AML, post-chemotherapy | Obtained topline results from Phase 2 GOSSAMER study |
| **zolbetuximab** | Gastric & GEJ adenocarcinoma | Phase 3 studies ongoing (enrollment completed)  
Pancreatic adenocarcinoma | Phase 2 study ongoing |
| **roxadustat / EVRENZO** | Chemotherapy-induced anemia | Obtained topline results from Phase 2 study |
| **fezolinetant** | VMS associated with menopause | • US & EU: NDA submitted in US in Jun 2022. Phase 3b DAYLIGHT study ongoing. 12w data from Phase 3 SKYLIGHT 1 study presented at ACOG in May 2022. 52w data from Phase 3 SKYLIGHT 2 study presented at ENDO in Jun 2022. 52w data from Phase 3 SKYLIGHT 4 study to be presented at NAMS in Oct 2022  
Asia: Phase 3 MOONLIGHT 1 study in Apr 2022. LSLV in Phase 3 MOONLIGHT 3 study in Jun 2022  
Japan: Phase 2b STARLIGHT study ongoing |
| **AT132** (resamirigene bilparvovec) | X-linked myotubular myopathy | • ASPIRO study put on clinical hold by FDA due to a serious adverse event |
ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

US/Europe/JP

- **Initial Diagnosis**
  - Active Surveillance
- **Definitive Therapy**
  - Surgery
  - Radiation
- **Castration-Sensitive**
  - ARCHES
    - M1 CSPC newly-diagnosed
    - M1 CSPC recurrent
      - Launched
  - EMBARK
    - M0 CSPC
- **Castration-Resistant**
  - PREVAIL
    - M1 CRPC (1st line)
    - Launched
  - AFFIRM
    - M1 CRPC (2nd line+)
    - Launched

**P3: ARCHES**
- M1 CSPC: Combo with ADT, vs. placebo
- n=1,150
- Approved in US in Dec 2019, in JP in May 2020, and in Europe in Apr 2021
- Filed label update to include the OS data in US and Europe in Dec 2021. CHMP positive opinion received in Mar 2022

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

**China**
- M1 CSPC: Enrollment completed in Phase 3 China-ARCHES study

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy, OS: Overall survival, CHMP: Committee for Medicinal Products for Human Use
### 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>
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<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 (Ongoing)</td>
<td>HR 0.66</td>
<td>HR 0.67</td>
</tr>
<tr>
<td>DoT (Ongoing)</td>
<td>40.2 months</td>
<td>29.5 months</td>
</tr>
</tbody>
</table>

- ✔: Data obtained, *: Prespecified interim analysis

M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, NSAA: Non-steroidal antiandrogen, HR: Hazard ratio, MFS: Metastasis-free survival, rPFS: Radiographic progression-free survival, OS: Overall survival, DoT: Duration of treatment
ENFORTUMAB VEDOTIN (EV) (1/3): NECTIN-4 TARGETED ADC OVERALL UC PROGRAM

**NMIBC**
- Stages 0a-1
  - Target EV regimen

  - Clinical studies for EV
    - Phase 3
    - Phase 1 or 2

**MIBC**
- Stages 2 and 3
  - RC-eligible
    - EV+Pembro combo (i.v.; perioperative)
      - P3: KEYNOTE-905 / EV-303
        - Cis-ineligible vs. SoC (RC alone)
      - P3: KEYNOTE-B15 / EV-304
        - Cis-eligible vs. SoC (NAC + RC)
        - (Cohorts H & L)
          - Cis-ineligible
            - EV mono (neoadjuvant /perioperative) + RC

**mUC**
- Stage 4
  - Previously untreated (first line)
    - EV+Pembro combo (i.v.)
      - P3: EV-302
        - Platinum-eligible vs. Chemo
  - PD-1/L1 inhibitor pretreated
    - EV mono (i.v.)
      - P2: EV-201
        - Platinum-naïve and cis-ineligible
        - (Cohort 2)
      - P2: EV-201 (Cohort 1)
        - PD-1/L1 inhibitor pretreated
          - Approved (AA)

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

**Clinical stage**
- Disease stage of urothelial cancer

**Phases**
- Early stage
- Late stage

**Abbreviations**
- ADC: Antibody-drug conjugate
- mUC: Metastatic urothelial cancer
- NMIBC: Non-muscle-invasive bladder cancer
- MIBC: Muscle-invasive bladder cancer
- BCG: Bacillus Calmette-Guerin
- RC: Radical cystectomy
- mono: Monotherapy
- Pembro: Pembrolizumab
- SoC: Standard of care
- NAC: Neoadjuvant chemotherapy
- Chemo: Chemotherapy
- sBLA: Supplemental Biologics License Application
- AA: Accelerated Approval
ENFORTUMAB VEDOTIN (EV) (2/3):  
CLINICAL STUDIES

(Red: Updates since the last financial results announcement)

For urothelial cancer

| P3: EV-301 | mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono vs. Chemo | n=608 | sBLA (to convert regular approval) approved in US in Jul 2021. Approved in JP in Sep 2021, in Europe in Apr 2022 |
| P3: EV-302 | mUC, Previously untreated, Platinum-eligible; EV + Pembrolizumab vs. Chemo | n=860 | FSFT: Apr 2020 |
| P3: EV-303 /KEYNOTE-905 | MIBC, Cis-ineligible; Pembrolizumab +/- EV (perioperative) + RC vs. RC alone | n=836 | FSFT in Pembrolizumab + EV arm: Dec 2020 |
| P3: EV-304 /KEYNOTE-B15 | MIBC, Cis-eligible; EV + Pembrolizumab (perioperative) + RC vs. Chemo (neoadjuvant) + RC | n=784 | FSFT: May 2021 |
| P2: EV-201 | mUC, PD-1/L1 inhibitor pretreated; EV mono Cohort 1: Platinum pretreated Cohort 2: Platinum naive and cis-ineligible | n=219 | Cohort 1: Approved (under the Accelerated Approval program) Cohort 2: sBLA approved in US in Jul 2021 |
| P2: EV-203 | <Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono | n=40 | Enrollment completed in Jan 2022 |
| P1: EV-104 | NMIBC, High-risk BCG-unresponsive; Intravesical EV mono | n=58 | FSFT: Jan 2022 |

For other solid tumors

| P2: EV-202 | HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric adenocarcinoma or esophageal adenocarcinoma or GEJ adenocarcinoma, Esophageal squamous cell carcinoma; EV mono | n=280 | FSFT: Mar 2020 Initial topline results obtained in Jun 2022 |

## ENFORTUMAB VEDOTIN (EV) (3/3): STUDY DATA BY DISEASE STAGE OF UC

*(Red: Updates since the last financial results announcement)*

### Disease stage

<table>
<thead>
<tr>
<th>Early stage</th>
<th>MIBC</th>
<th>mUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery eligible</td>
<td>Previously untreated (first line)</td>
<td>PD-1/L1 inhibitor pretreated</td>
</tr>
<tr>
<td>Cis-eligible</td>
<td>Platinum eligible</td>
<td>Cis-ineligible</td>
</tr>
<tr>
<td>Study phase</td>
<td>Phase 3</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Study No.</td>
<td>KN-B15 / EV-304</td>
<td>KN-905 / EV-303</td>
</tr>
<tr>
<td>No. of subjects</td>
<td>784 (2 arms)</td>
<td>836 (3 arms)</td>
</tr>
<tr>
<td>EV regimen</td>
<td>Combo w/ Pembrolizumab (perioperative)</td>
<td>Combo w/ Pembrolizumab (perioperative)</td>
</tr>
<tr>
<td>Control</td>
<td>Chemo (neoadjuvant)</td>
<td>SoC</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>pCR &amp; EFS</td>
<td>pCR &amp; EFS</td>
</tr>
<tr>
<td>OS</td>
<td>(Ongoing)</td>
<td>(Ongoing)</td>
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<tr>
<td>PFS</td>
<td>(Ongoing)</td>
<td>(Ongoing)</td>
</tr>
<tr>
<td>ORR</td>
<td>(Ongoing)</td>
<td>(Ongoing)</td>
</tr>
<tr>
<td>DoR</td>
<td>(Ongoing)</td>
<td>(Ongoing)</td>
</tr>
</tbody>
</table>

✓: Data obtained, *: Prespecified interim analysis, **: Updated data

GILTERITINIB: FLT3 INHIBITOR

(Red: Updates since the last financial results announcement)

FLT3 mut+ AML

- **Relapsed or refractory**
  - P3: ADMIRAL
    - Monotherapy vs. salvage chemo (2:1)
    - n=371
    - Launched in US, JP, and Europe
- **Newly diagnosed (HIC-eligible)**
  - P3: PASHA (HOVON)
    - Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)
    - n=768
    - FSFT: Dec 2019 (Sponsor: HOVON)
  - P2: PrE0905 (PrECOG)
    - n=179
    - FSFT: Dec 2019 (Sponsor: PrECOG, LLC.)
- **Post-HSCT maintenance**
  - P3: MORPHO
    - Monotherapy vs. placebo (1:1)
    - n=346
    - Enrollment completed
      - Collaborating with BMT-CTN
- **Post-chemo maintenance**
  - P2: GOSSAMER
    - Monotherapy vs. placebo (2:1)
    - n=98
    - Topline results obtained in Aug 2021
- **Newly diagnosed (HIC-ineligible)**
  - P1
    - Combo with venetoclax and azacitidine
    - TBD
    - To start in Q4 FY2022

China

- **R/R AML**: Conditional approval obtained in Jan 2021, based on ADMIRAL study data (full approval contingent on COMMODORE study data) and launched in Apr 2021. Phase 3 COMMODORE study (including China and other countries) stopped due to efficacy based on the planned interim analysis.

**Abbreviations**
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
  - Prevalence of patients with high expression of Claudin 18.2 is substantial: 33% - 37%
  - ~60% of primary pancreatic adenocarcinomas; approx. 20% of these meet the eligibility criteria for the ongoing Phase 2 study

**Gastric and (GEJ) adenocarcinoma**
- Target patient population:
  - HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma
- Metastatic gastric cancer is an area of significant unmet need, especially in advanced stages with ~4% five-year survival rate at Stage IV and limited treatment options have been limited

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Patient Population</th>
<th>n</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P3: SPOTLIGHT</strong></td>
<td>First line, Combo with mFOLFOX6, DB, vs. placebo</td>
<td>HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma</td>
<td>550</td>
<td>Enrollment completed</td>
</tr>
<tr>
<td><strong>P3: GLOW</strong></td>
<td>First line, Combo with CAPOX, DB, vs. placebo</td>
<td>HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma</td>
<td>500</td>
<td>Enrollment completed</td>
</tr>
<tr>
<td><strong>P2: ILUSTRO</strong></td>
<td>Cohort 1: Third or later line, zolbetuximab monotherapy</td>
<td>HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma</td>
<td>116</td>
<td>FSFT: Sep 2018</td>
</tr>
<tr>
<td></td>
<td>Cohort 2: First line, Combo with mFOLFOX6</td>
<td>HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cohort 3: Third or later line, Combo with pembrolizumab</td>
<td>HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cohort 4: First line, Combo with mFOLFOX6 and nivolumab</td>
<td>HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pancreatic adenocarcinoma</strong></td>
<td>First line, Combo with nab-paclitaxel and gemcitabine, open</td>
<td>HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma</td>
<td>369</td>
<td>FSFT: May 2019</td>
</tr>
</tbody>
</table>

GEJ: Gastroesophageal junction, HER2-: HER2 negative, Claudin 18.2+: Claudin 18.2 positive, mFOLFOX6: 5-FU, leucovorin and oxaliplatin, DB: Double-blind, CAPOX: Capecitabine and oxaliplatin, FSFT: First subject first treatment
**FEZOLINETANT: NK3 RECEPTOR ANTAGONIST**

(Updated since the last financial results announcement)

### VMS has a significant negative impact on QoL
- Physical symptoms include hot flashes and night sweats, which can impact sleep
- Physical symptoms may 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 breast cancer
- Since WHI’s findings, use of HRT has dropped
- Although subsequent analysis of the WHI data have demonstrated that HRT is safe and effective when initiated in the appropriate patient in the appropriate manner (i.e. right time, formulation, dose and duration), prescriptions have not rebounded, leaving some women with minimal options to satisfactorily manage their VMS

### US and EU

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Duration</th>
<th>Treatment Regimen</th>
<th>Follow-Up</th>
<th>Primary Endpoint</th>
<th>LSLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: SKYLIGHT 1</td>
<td>Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)</td>
<td>12 weeks</td>
<td>DB, 30 mg and 45 mg vs. placebo (1:1:1)</td>
<td>FSFT: Nov 2021</td>
<td>Primary endpoints not met (12w DB period topline results)</td>
<td>Apr 2022</td>
</tr>
<tr>
<td>P3: SKYLIGHT 2</td>
<td>Moderate to severe VMS associated with menopause; The last 40 weeks: Active extension treatment period, 30 mg or 45 mg</td>
<td>40 weeks</td>
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<tr>
<td>P3: SKYLIGHT 3</td>
<td>VMS associated with menopause; 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)</td>
<td>52 weeks</td>
<td>DB, 30 mg and 45 mg vs. placebo (1:1)</td>
<td></td>
<td></td>
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<tr>
<td>P3b: DAYLIGHT</td>
<td>Moderate to severe VMS associated with menopause, unsuitable for HRT; 24 weeks, DB, 45 mg vs. placebo (1:1)</td>
<td>24 weeks</td>
<td>DB, 45 mg vs. placebo (1:1)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Asia (except for Japan)

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Duration</th>
<th>Treatment Regimen</th>
<th>Follow-Up</th>
<th>Primary Endpoint</th>
<th>LSLV</th>
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</thead>
<tbody>
<tr>
<td>P3: MOONLIGHT 1</td>
<td>Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg vs. placebo (1:1)</td>
<td>12 weeks</td>
<td>DB, 30 mg vs. placebo (1:1)</td>
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<tr>
<td>P3: MOONLIGHT 2</td>
<td>Moderate to severe VMS associated with menopause; The last 12 weeks: Active extension treatment period, 30 mg</td>
<td>12 weeks</td>
<td>Active extension treatment period, 30 mg</td>
<td>FSFT: Nov 2021</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P3: MOONLIGHT 3</td>
<td>VMS associated with menopause; open label, 30 mg for 52 weeks</td>
<td>52 weeks</td>
<td>30 mg</td>
<td></td>
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</tr>
</tbody>
</table>

### Japan

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Duration</th>
<th>Treatment Regimen</th>
<th>Follow-Up</th>
<th>Primary Endpoint</th>
<th>LSLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>P2b: STARLIGHT</td>
<td>Peri- and post-menopausal patients with mild to severe VMS; 12 weeks: DB, 2 doses vs. placebo (1:1:1)</td>
<td>12 weeks</td>
<td>DB, 2 doses vs. placebo (1:1:1)</td>
<td>FSFT: Nov 2021</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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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 transfet and express myotubularin in skeletal muscle cells
- Regulatory designations granted:
  - <US> RMAT, Rare Pediatric Disease, Fast Track, and Orphan Drug designations
  - <Europe> 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
  - Up to 24 hours of invasive mechanical ventilation, 60% of patients require tracheostomy
  - > 80% require gastrostomy tube placement
  - Motor milestones substantially delayed
  - No treatment available; supportive care only

ASPIRO (clinical study for registration in XLMTM patients) n=26
- Study put on clinical hold by FDA due to a serious adverse event.
- Investigation on the event ongoing

FOCUS AREA APPROACH:
CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS

Expecting PoC judgement in 2 projects, Phase 1 entry in 5 projects (lead and follow-on projects)

<table>
<thead>
<tr>
<th>Primary Focus</th>
<th>Biology/Modality/Technology</th>
<th>Lead project</th>
<th>FY22</th>
<th>FY23</th>
<th>FY24-25</th>
<th>No. of projects aiming PoC by end FY25</th>
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<tbody>
<tr>
<td>Genetic regulation</td>
<td>Gene replacement (AAV)</td>
<td>AT132</td>
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<td>AT845</td>
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<td>PoC</td>
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<td>Gene regulation (AAV)</td>
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<td>Immuno-Oncology</td>
<td>Checkpoint</td>
<td>ASP1570</td>
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<td>Artificial adjuvant vector cell (aAVC)</td>
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<td>Oncolytic virus (systemic)</td>
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<td>Bispecific immune cell engager</td>
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<td>Cancer cell therapy (UDC)</td>
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<td>Blindness &amp; Regeneration</td>
<td>Cell replacement</td>
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<td>Cell replacement (UDC)</td>
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<td>Gene regulation (AAV)</td>
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<td>Mitochondria</td>
<td>Gene regulation &amp; mitochondrial biogenesis</td>
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<td>Mitochondrial stress</td>
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<td>Mitochondrial transfer</td>
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<td>Primary Focus Candidates</td>
<td>Immune modulating/regulatory cells</td>
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<td>Tissue-specific immune regulation</td>
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</tr>
</tbody>
</table>

Total: 24

1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Jul 2022)

PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

Notes:
- AT845: Updated timeline for PoC judgement is under discussion
- AT845: Updated timeline for PoC judgement is under discussion
- AT845: Updated timeline for PoC judgement is under discussion
ON THE FOREFRONT OF HEALTHCARE CHANGE