# FY2020 FINANCIAL RESULTS
ENDED MARCH 31, 2021

**Kenji Yasukawa, Ph.D.**
**President and CEO**
**Astellas Pharma Inc.**
**April 27, 2021**

# 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 FY2020 Consolidated Financial Results
FY2021 Forecasts

II Initiatives for Sustainable Growth

III Review of Corporate Strategic Plan 2018

# FY2020 FINANCIAL RESULTS



| (billion yen) | FY2019 | FY2020 | Change | Change (%) | FY2020 FCST | Achieve-ment |
|---|---|---|---|---|---|---|
| **Revenue** | **1,300.8** | **1,249.5** | **-51.3** | **-3.9%** | **1,256.5** | **99.4%** |
| Cost of sales | 276.7 | 246.1 | -30.7 | -11.1% | | |
| % of revenue | 21.3% | 19.7% | -1.6 ppt | | | |
| SG&A expenses | 499.3 | 504.3 | +5.0 | +1.0% | | |
| R&D expenses | 224.2 | 224.5 | +0.3 | +0.1% | 233.5 | 96.1% |
| Amortisation of intangible assets | 21.2 | 23.8 | +2.6 | +12.3% | | |
| **Core operating profit** | **277.8** | **251.4** | **-26.4** | **-9.5%** | **251.0** | **100.1%** |
| **<Full basis>** | | | | | | |
| Other income | 12.2 | 7.6 | -4.5 | - | | |
| Other expense | 45.9 | 123.0 | +77.0 | - | | |
| **Operating profit** | **244.0** | **136.1** | **-107.9** | **-44.2%** | **210.5** | **64.6%** |
| Profit before tax | 245.4 | 145.3 | -100.0 | -40.8% | 209.5 | 69.4% |
| **Profit** | **195.4** | **120.6** | **-74.8** | **-38.3%** | **169.5** | **71.1%** |

# FY2020 FINANCIAL RESULTS: YEAR-ON-YEAR COMPARISON



- *Revenue and Core operating profit decreased, YoY*
  - ✓ Sales of growth drivers steadily increased
  - ✓ Sales decreased due to termination of sales and distribution in Japan and loss of exclusivity
  - ✓ Negatively impacted by COVID-19 mainly during Q1/FY2020
  - ✓ SG&A expenses slightly increased, and R&D expenses were almost flat

- *Full basis: Operating profit and Profit decreased, YoY*
  - ✓ Booked impairment losses on intangible asset as other expense:
    - − Termination of development for ASP8374 (Q2/FY2020: 30.2 billion yen)
    - − Decrease in asset value due to review of AT132 development plan (Q4/FY2020: 58.8 billion yen)

# FY2020 FINANCIAL RESULTS: COMPARISON WITH FORECAST



- *Revenue was slightly behind forecast, but achieved when adjusted to exclude FX impact.*
  *Core operating profit achieved*
  - ✓ FX impact (Revenue: -11.8 billion yen,  Core OP: -6.5 billion yen）
  - ✓ Steady performance for main oncology products
  - ✓ In China, revenue was behind forecast due to delayed reimbursement start and the impact of Volume Based Procurement
  - ✓ R&D expenses were slightly behind forecast

- *Full basis: Operating profit and Profit were behind forecast*
  - ✓ Booked impairment losses on intangible asset, not included into full-year forecast
    - − Decrease in asset value due to review of AT132 development plan (Q4/FY2020: 58.8 billion yen)

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# FY2020 FINANCIAL RESULTS: REVENUE



*Main oncology products continue to grow strongly*

| **FY2020 actual** (billion yen) | | YoY |
|---|---|---|
| **XTANDI** | **458.4** | **+58.4** |
| **XOSPATA** | **23.8** | **+9.6** |
| **PADCEV** | **12.8** | **+11.0** |
| **Evrenzo** | **1.1** | **+0.9** |
| **mirabegron** | **163.6** | **+2.0** |
| **New products in Japan** | **70.5** | **+9.3** |

Xtandi (enzalutamide) 40 mg capsules
XOSPATA gilteritinib 40mg tablets
PADCEV enfortumab vedotin-ejfv Injection for IV infusion 20 mg & 30 mg vials

**Total sales of 3 oncology products, YoY**

**+79.0 billion yen**

Consolidated revenue for FY2020: -51.3 billion yen, YoY

Main decrease items:

- ✓ Sales decreases due to termination of sales and distribution in Japan (-36.3 billion yen) and loss of exclusivity (-55.7 billion yen)
- ✓ Negatively impacted by COVID-19 mainly during Q1/FY2020

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Loss of exclusivity (LOE) products: Products with LOE in FY2019 or FY2020 (Vesicare, Tarceva, Celecox, MYCAMINE/Funguard)
Terminated products in Japan: Micardis-family, Symbicort, KM Bio products
New products in Japan: Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf

# FY2020 FINANCIAL RESULTS: BUSINESS UPDATE FOR MAIN PRODUCTS



| | |
|---|---|
| **XTANDI** | Global sales excl. FX impact achieved full-year forecast. US sales were slightly behind forecast due to COVID-19 (slowdown of new patients' diagnosis and treatment initiation), but demand grew approx. 20% YoY and continued growth is expected. In China, reimbursement for M1 CRPC indication has started from Mar 2021 |
| **XOSPATA** | Sales in US and EU steadily expanded and global sales exceeded full-year forecast. Launched in Singapore (Feb 2021) and China (Apr 2021). Reimbursement has started in Italy from Mar 2021 in addition to UK and Germany |
| **PADCEV** | Revenue grew steadily through rapid market penetration and achieved full-year forecast on a local currency basis. EV-301 study results published in New England Journal of Medicine. The NCCN updated its guidelines, changing PADCEV's listing from a Category 2A to a Category 1 recommendation. This category is for treatment with the highest level of evidence |
| **Evrenzo** | Following expansion of the indication in Japan to include patients who are not dialysis dependent in Nov 2020 and the subsequent lifting of the 2-week prescribing restriction in Dec 2020, sales have steadily increased, driven by large scale adoption in new institutions. Evrenzo is now the market leading HIF-PHI in Japan |
| **mirabegron** | Global sales increased slightly behind full-year forecast due to demand impact of COVID-19.<br>In China, NRDL reimbursement started from Mar 2021. The FDA granted pediatric exclusivity for Myrbetriq, resulting in an additional 6-month period of market exclusivity in US |
| **New products in Japan** | Sales of EVENITY and Suglat-Family increased, but progress against forecast was behind due to the impact of COVID-19 such as restrictions on promotion activities, reduction of hospital/clinic visits by patients, etc. |

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M1 CRPC: Metastatic castration-resistant prostate cancer, NCCN：National Comprehensive Cancer Network,
HIF-PHI: Hypoxia-inducible factor prolyl hydroxylase inhibitor, NRDL: National Reimbursement. Drug List, FDA: Food and Drug Administration
New products in Japan: Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf

# FY2021 FORECAST



| (billion yen) | FY2020 actual | FY2021 forecast | Change (%) |
|---|---|---|---|
| **Revenue** | **1,249.5** | **1,323.0** | **+5.9%** |
| SG&A expenses | 504.3 | 541.0 | +7.3% |
| R&D expenses | 224.5 | 242.0 | +7.8% |
| **Core operating profit** | **251.4** | **270.0** | **+7.4%** |
| **Core profit** | **209.9** | **213.0** | **+1.5%** |
| **<Full basis>** | | | |
| **Operating profit** | **136.1** | **265.0** | **+94.8%** |
| **Profit** | **120.6** | **209.0** | **+73.3%** |

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# FY2021 FORECAST: OVERVIEW



- *Revenue and Profit to increase in FY2021*
  *Core OP margin for FY2021 to be 20%*

- *Main products and new products continue to grow.*
  *Growth to more than offset the impact of the LOE, termination of sales and distribution, transfer of products and NHI price revision*
  - ✓ Increase factors: XTANDI, XOSPATA, PADCEV, Evrenzo, mirabegron
  - ✓ Decrease factors: Vesicare Japan, MYCAMINE/Funguard, termination of sale and distribution, transfer of products (Celecox, Lipitor, Eligard, legacy products in EU, etc.), reversal of product transfer value (Dificlir, Protopic), NHI price revision in Japan

- *Resource allocation to key strategic areas such as R&D investment for Primary Focus and launch costs for new products, while reviewing costs not contributing to competitiveness and increase of value*

- *Dividends per share: Forecasted 8 yen increase to 50 yen*

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LOE: Loss of exclusivity, NHI: National Health Insurance

# FY2021 FORECAST: MAIN GROWTH DRIVERS



| | FY2021 Forecast | FY2021 initiatives and growth factors |
|---|---|---|
| **XTANDI** | **557.2 billion yen**<br>**+98.8, YoY (+21.5%)** | • Drive market share in earlier stages of prostate cancer<br>• Expand sales in the additional indication (M1 CSPC) in Established markets and International markets<br>• Continued growth in China with M1 CRPC reimbursed launch |
| **XOSPATA** | **36.7 billion yen**<br>**+12.8 (+53.8%)** | • Maintain market leadership US/Japan and drive market share growth in other markets<br>• Expect sales contribution from China launched in Apr 2021<br>• Increase product awareness and FLT3 testing rates |
| **PADCEV** | **20.1 billion yen**<br>**+7.3 (+57.1%)** | • Solidify the position as the preferred treatment option in the current indication in US. Expect to penetrate new patient segment with additional indication<br>• Successfully launch in Japan and Established markets |
| **Evrenzo** | **8.6 billion yen**<br>**+7.4 (+661.0%)** | • Drive class growth in Japan whilst maintaining leadership within the HIF-PHI class<br>• Successfully launch in Established markets and International markets |

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M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer,
HIF-PHI: Hypoxia-inducible factor prolyl hydroxylase inhibitor

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# KEY POST-POC PROJECTS: STATUS UPDATE

(Underlined: Updates since Q3/FY2020 Financial Results Announcement in Jan 2021)



## enzalutamide

### M0 CRPC

- **EU:** CHMP positive opinion received in Jan 2021 for label update to include the OS data

### M1 CSPC

- **EU:** CHMP positive opinion received in Mar 2021
- **China:** Phase 3 study ongoing

### M0 CSPC

- Phase 3 study ongoing

## gilteritinib

### R/R AML

- **China:** Conditional approval obtained in Jan 2021 (full approval contingent on COMMODORE study data). Phase 3 COMMODORE study stopped due to efficacy based on the planned interim analysis

### Earlier-stage AML

- Phase 3 studies ongoing

## enfortumab vedotin

### mUC

- **Pretreated:** Filed in US (2 sBLAs) in Feb 2021, and in EU and JP in Mar 2021. Data of EV-301 study data presented at ASCO GU 2021 and published in NEJM. EV-201 study Cohort 2 data presented at ASCO GU 2021
- **Previously untreated (first line; combo with pembrolizumab):** Phase 3 study ongoing
- **China:** Currently under preparation to start clinical studies

### MIBC (combo with pembrolizumab)

- Phase 3 studies ongoing

### Other solid tumors

- Phase 2 study ongoing

## zolbetuximab

### Gastric & GEJ adenocarcinoma

- Phase 3 studies ongoing

### Pancreatic adenocarcinoma

- Phase 2 study ongoing

## roxadustat

### Anemia associated with CKD

- **EU:** Filed in Apr 2020

### Chemotherapy-induced anemia

- Phase 2 study ongoing

## fezolinetant

### VMS associated w/ menopause

- **US & EU:** Phase 3 studies ongoing. Primary endpoints (12w DB period topline results) met in both Phase 3 pivotal studies, SKYLIGHT 1 and 2
- **Asia:** Phase 3 studies ongoing

## AT132 (resamirigene bilparvovec) XLMTM

- Clinical trial re-start activities underway. Discussions planned on the path forward toward global registration filings

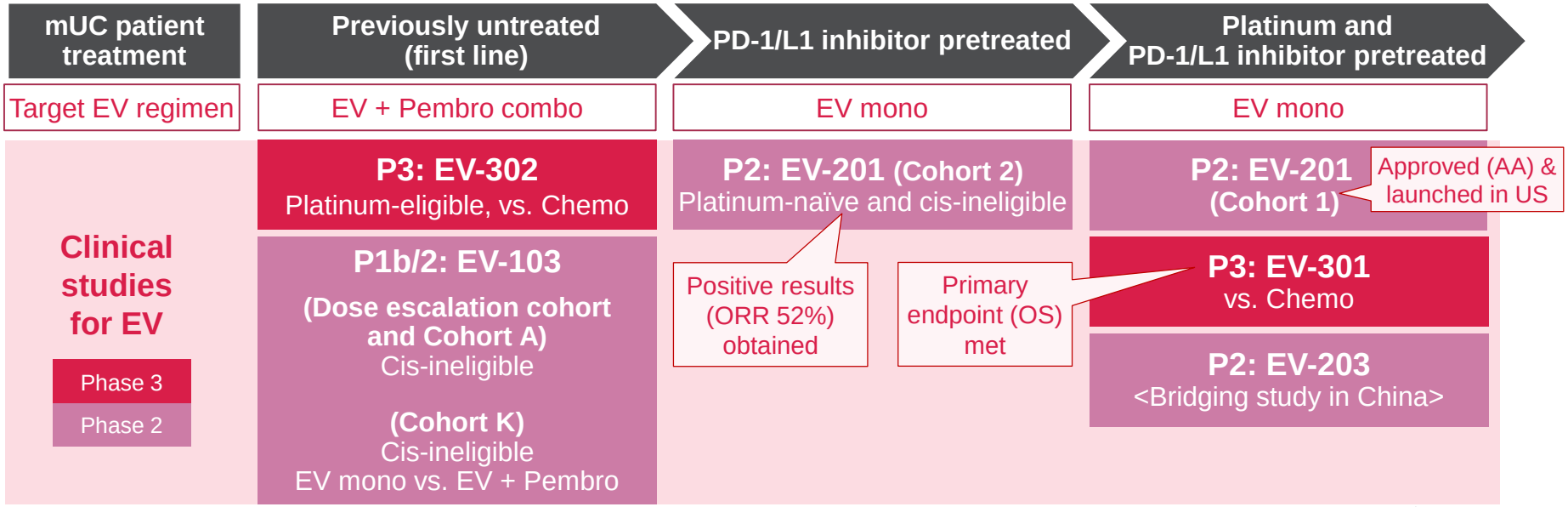
PoC: Proof of concept, M0: Non-metastatic, M1: Metastatic, CRPC: Castration-resistant prostate cancer, CSPC: Castration-sensitive prostate cancer, CHMP: Committee for Medicinal Products for Human Use, OS: Overall survival, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, mUC: Metastatic urothelial cancer, sBLA: Supplemental Biologics License Application, ASCO GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium, NEJM: New England Journal of Medicine, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, CKD: Chronic kidney disease, VMS: Vasomotor symptoms, DB: Double blind, XLMTM: X-linked myotubular myopathy

# ENFORTUMAB VEDOTIN (EV) (1/2): mUC PROGRAM REGULATORY STATUS



## *Filed in US, EU and Japan*

- US: Filed (2 sBLAs) in Feb 2021 and PDUFA set on Aug 17, 2021 [a]
  1. To convert “Accelerated Approval” to “Regular Approval”, based on EV-301 study results
  2. To expand the indication to include mUC, PD-1/L1 inhibitor pretreated and cis-ineligible, based on EV-201 study Cohort 2 results
- EU: Filed in Mar 2021, based on EV-301 study results [b]
- JP: Filed in Mar 2021, based on EV-301 study and EV-201 study results




a: Priority Review granted, Real-Time Oncology Review pilot program and Project Orbis applied
b: Accelerated Assessment granted

mUC: Metastatic urothelial cancer, sBLA: Supplemental Biologics License Application, mono: Monotherapy, Pembro: Pembrolizumab, Cis: Cisplatin, Chemo: Chemotherapy, AA: Accelerated Approval, ORR: Objective response rate, OS: Overall survival

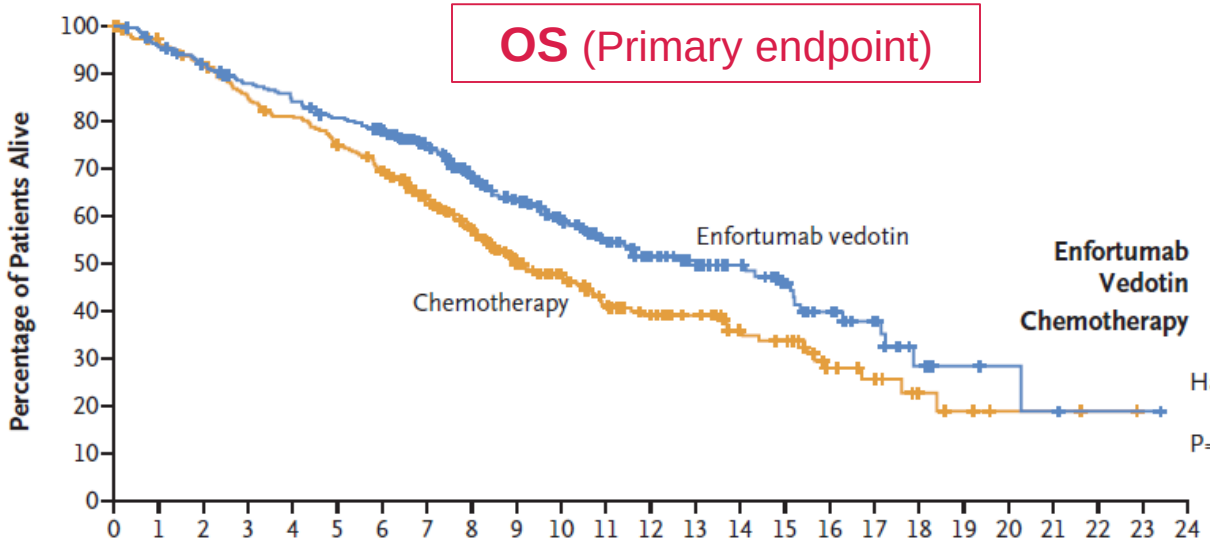
# ENFORTUMAB VEDOTIN (EV) (2/2): mUC PROGRAM PHASE 3 EV-301 STUDY RESULTS



*In patients with advanced UC who had previously received platinum-based chemotherapy and a PD-1/L1 inhibitor,*

- ✓ *EV monotherapy showed superior OS, compared with chemotherapy*
- ✓ *Safety profile was consistent with prior EV studies*

**OS** (Primary endpoint)




| | No. of Deaths/ No. of Patients | Median Overall Survival (95% CI) |
|---|---|---|
| | | *mo* |
| Enfortumab Vedotin | 134/301 | 12.88 (10.58–15.21) |
| Chemotherapy | 167/307 | 8.97 (8.05–10.74) |

Hazard ratio for death, 0.70 (95% CI, 0.56–0.89)
P=0.001

| No. at Risk | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Enfortumab vedotin | 301 | 286 | 272 | 257 | 246 | 234 | 222 | 190 | 158 | 130 | 105 | 85 | 63 | 52 | 42 | 33 | 23 | 15 | 7 | 4 | 3 | 2 | 1 | 1 | 0 |
| Chemotherapy | 307 | 288 | 274 | 250 | 238 | 219 | 198 | 163 | 131 | 101 | 84 | 66 | 51 | 44 | 32 | 29 | 16 | 11 | 6 | 4 | 2 | 2 | 1 | 0 | 0 |

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Powels T, *et al.*, NEJM. 2021

(m)UC: (metastatic) Urothelial cancer, OS: Overall survival, CI: Confidence interval, NEJM: New England Journal of Medicine

# PROGRESS IN FOCUS AREA APPROACH: GENETIC REGULATION



*To build our position as a global leader in the field of genetic regulation*

## "Astellas Gene Therapies" as Gene Therapy Center of Excellence of Astellas

- Established (effective Apr 1, 2021), integrating our wholly owned subsidiary, Audentes Therapeutics, to achieve more effective and efficient operations for gene therapy programs
- Consists of three divisions specializing in gene therapies including research and technical operations, medical and development, and commercial

## Status of AT132 for XLMTM

- ASPIRO study re-start activities underway
  - ✓ To resume dosing at the lower dose of AT132 in Q1/FY2021
- Discussions planned on the path forward toward global registration filings
  - ✓ Next meeting with FDA planned in Q1/FY2021
  - ✓ Meeting with EMA planned in Q2/FY2021

## Status of AT845 for Pompe disease

- First-in-human Phase 1/2 FORTIS study in adult patients with late onset Pompe disease started
  - ✓ First subject dosed in Mar 2021

XLMTM: X-linked myotubular myopathy, FDA: Food and Drug Administration, EMA: European Medicines Agency

# KEY EVENTS EXPECTED IN FY2021



| | | |
|---|---|---|
| **Regulatory decision** | enzalutamide | M1 CSPC (EU) |
| | enfortumab vedotin | mUC, PD-1/L1 inhibitor pretreated and cisplatin ineligible (US [a]) |
| | | mUC, platinum and PD-1/L1 inhibitor pretreated (US [a,b], EU [c]) |
| | | mUC, progressed after anti-cancer medication (JP) |
| | roxadustat | Anemia associated with CKD (EU) |
| **Regulatory submission** | gilteritinib | R/R AML (China [d]) |
| **Data readout** | fezolinetant | 52-week safety results from Phase 3 SKYLIGHT 1, 2 and 4 studies |

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

a: Priority Review granted, Real-Time Oncology Review pilot program and Project Orbis applied
b: sBLA to convert Accelerated Approval to regular approval
c: Accelerated Assessment granted
d: sNDA to convert conditional approval to full approval

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M1 CSPC: Metastatic castration-sensitive prostate cancer, mUC: Metastatic urothelial cancer, CKD: Chronic kidney disease,
R/R AML: Relapsed or refractory acute myeloid leukemia, sBLA: Supplemental Biologics License Application, sNDA: Supplemental New Drug Application

# PROGRESS IN Rx+ PROGRAM (1/2): DEVELOPMENT OF AI-BASED PROGRAM FOR HOLTER ANALYSIS DEVICES



*Developed an AI-based data analysis algorithm for Holter ECG test through research collaboration with M. Heart*

- Developed an efficient analytical algorithm with low computer load (patent pending)
- Data described in accordance with MFER, an international standard, can be analyzed in the cloud regardless of type of Holter monitor
- Received certification as a medical device program in Mar 2021 and scheduled to be commercialized (implemented into ECG analysis service of M. Heart) in FY2021
- The next version with improved accuracy and efficiency will be developed through deep learning utilizing ECG data obtained clinically


| | |
|---|---|
| **Brand name** | My Holter II |
| **Classification** | Class II (Controlled medical devices) |
| **Certification No.** | 303AGBZX00015000 |

M. Heart

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AI: Artificial intelligence, ECG: Electrocardiography, MFER: Medical waveform Format Encoding Rules

# PROGRESS IN Rx+ PROGRAM (2/2): KEY EVENTS EXPECTED IN FY2021



| Sphere * | Program | Expected key event |
|---|---|---|
| Chronic disease progression prevention | Fitness service for exercise support (Fit-eNce) | Initiation of pilot marketing for at-home service |
| | Smartphone game application for exercise support | Initiation of pilot marketing |
| | BlueStar | Initiation of clinical study (Japan) |
| | Program for Holter analysis devices (My Holter II) | Commercialization of service |
| Patient outcome maximization | ASP5354 | Topline results for Phase 2 study |

* Business areas to focus on for realization of Rx+ Story

# SUSTAINABILITY: ACCESS TO HEALTH



*A new collaborative research agreement with TB Alliance to identify lead compounds for the treatment of tuberculosis*

- Astellas and TB Alliance have conducted joint research for exploration of new compounds for *Mycobacterium tuberculosis* since Oct 2017
- This new joint research aims to identify lead compounds with improved pharmacological activity, pharmacokinetics, and safety by utilizing multiple hit compounds obtained from the exploration research
- Funded by the Global Health Innovative Technology Fund

## Position on Access to Health

- Efforts to create innovative medicines and medical solution, and deliver them to patients
- Identified four areas, “creating innovation”, “enhancing availability”, “strengthening healthcare system” and “improving health literacy”

## Other initiatives for “creating innovation”

- Participated in a project regarding the development of pediatric formulation for schistosomiasis as a research and development project pursuing social benefits
- Working on various initiatives to improve Access to Health through collaboration with external partners

## Acceleration to drive Access to Health activities

- “Sustainability” will form one of the strategic goals in the new Corporate Strategic Plan, and Access to Health will be the core piece

TB Alliance: Non-profit organization dedicated to finding faster-acting and affordable drug regimens to fight tuberculosis

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# REVIEW OF CORPORATE STRATEGIC PLAN 2018 (STRATEGIC PART)



*Initiatives aiming at 3 Strategic Goals advancing as planned.*
*Building a foundation to create innovative treatments*

## Strategic Goal 1

**Maximizing Product VALUE and Operational Excellence**

**Maximizing Product VALUE**

- ✓ Sales of XTANDI and mirabegron steadily increased. XTANDI's growth exceeded original expectations
- ✓ Continued launches of new products in Japan
- ✓ 6 post-PoC projects: Achieved important milestones as planned. Successful launches of XOSPATA, PADCEV, Evrenzo and positive initial uptake

**Operational Excellence**

- ✓ Prioritize sales promotion expenses and promote global procurement efficiencies and travel cost reduction (Approx. 50.0 bil. yen* profit improvement)

* Cumulative total of FY2018-FY2020

## Strategic Goal 2

**Evolving How We Create VALUE - With Focus Area Approach -**

- ✓ Progressed clinical programs in the designated Primary Focus
- ✓ Strengthened capabilities by collaborations and acquisitions to continuously produce innovative projects
- ✓ Enhanced utilization of innovative platforms among multiple Primary Focus and produced multiple promising projects

## Strategic Goal 3

**Developing Rx+ Programs**

- ✓ Progressed toward establishment of a foundation for Rx+ business
- ✓ Achieved partnerships with various technologies from different fields
- ✓ Successfully advanced multiple programs toward commercialization

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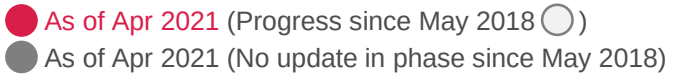
PoC: Proof of concept

# PROGRESS IN 6 POST-POC PROJECTS



*Achieved all the targeted submission goals in Strategic Plan 2018 and obtained the global approvals*



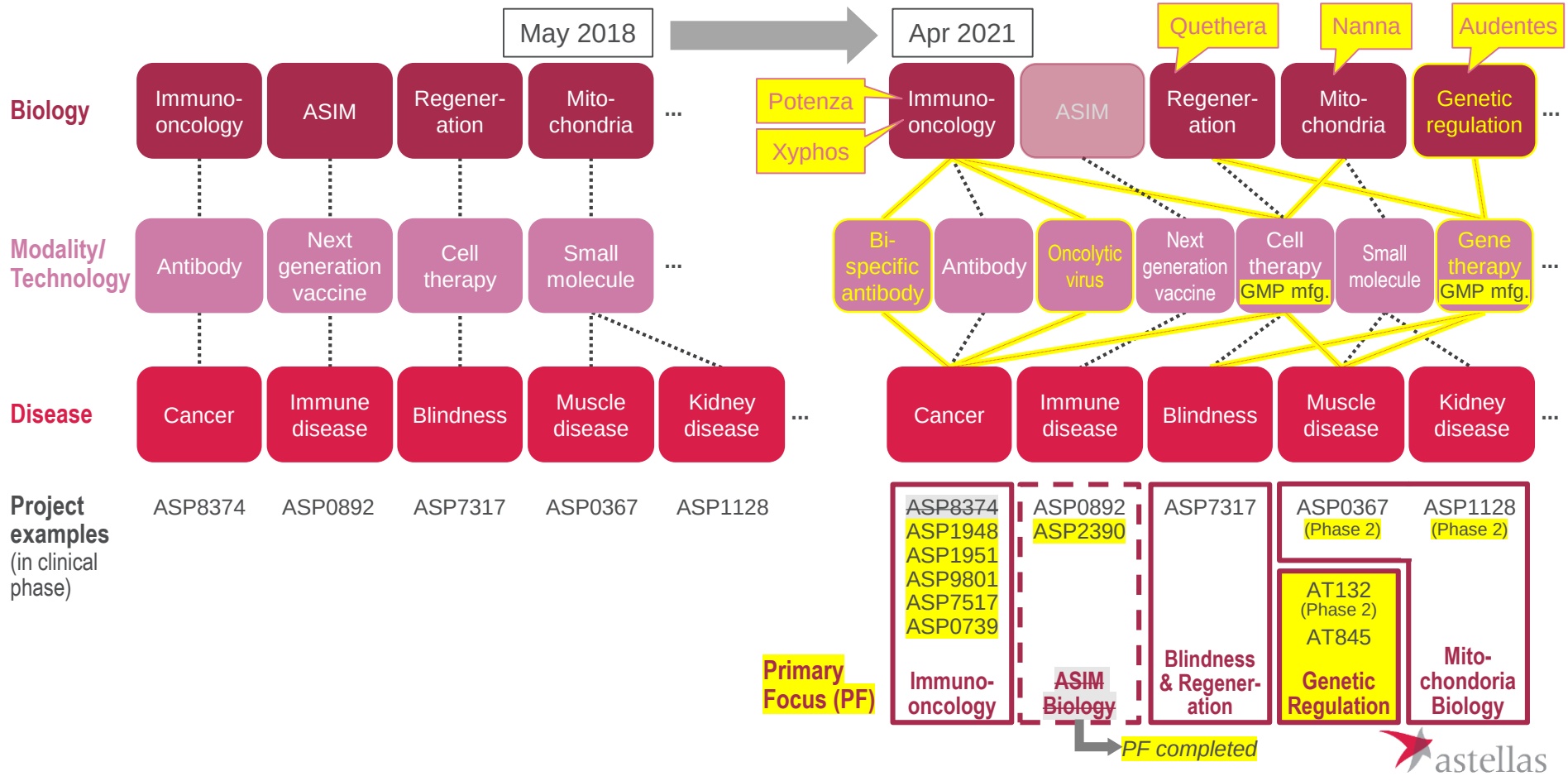

| Project | Indication | Phase 2 | Phase 3 | Filed | Approved |
|---|---|---|---|---|---|
| **enzalutamide** | M1 CRPC | | | | CN |
| | M0 CRPC | | | | US, EU, CN |
| | M1 CSPC | | | EU | US, JP |
| | M0 CSPC | | | | |
| **gilteritinib** | Refractory and relapsed AML | | | | JP, US, EU, CN |
| | AML, 1st line, intensive chemo eligible | | | | |
| | AML, 1st line, intensive chemo ineligible | | Phase 3 study stopped due to futility | | |
| | AML, post-HSCT maintenance | | | | |
| | AML, post-chemo maintenance | | | | |
| **enfortumab vedotin** | mUC, pretreated | | | EU, JP | US |
| | mUC, previously untreated (1st line) | | | | |
| | Muscle-invasive bladder cancer | | | | |
| | Other solid tumors | | | | |
| **zolbetuximab** | Gastric and GEJ adenocarcinoma | | | | |
| | Pancreatic adenocarcinoma | | | | |
| **roxadustat** | Anemia associated with CKD | | | EU | JP |
| | Chemotherapy-induced anemia | | | | |
| **fezolinetant** | VMS associated with menopause | | Primary endpoints met in US & EU pivotal studies | | |

PoC: Proof of concept, M1: Metastatic, M0: Nonmetastatic, CRPC: Castration-resistant prostate cancer, CSPC: Castration-sensitive prostate cancer, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplantation, mUC: Metastatic urothelial cancer, GEJ: Gastroesophageal junction, CKD: Chronic kidney disease, VMS: Vasomotor symptoms

# PROGRESS IN FOCUS AREA APPROACH (1/2):
## ORGANIC APPLICATION AMONG MULTIPLE PRIMARY FOCUS



*Enhanced utilization of innovative platforms among multiple Primary Focus and produced multiple promising projects*




GMP: Good Manufacturing Practice, ASIM: Antigen-specific immuno-modulation

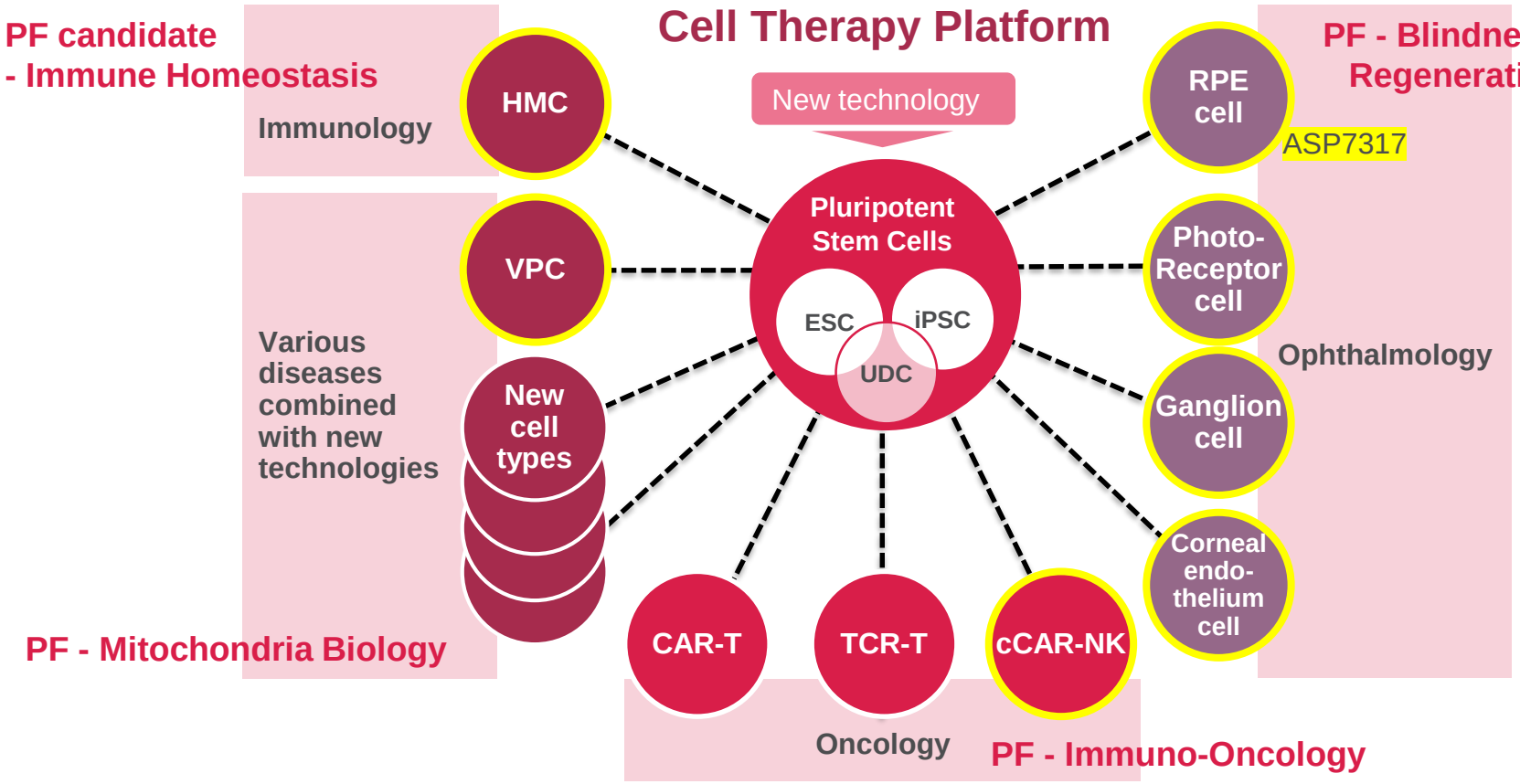
Yellow: Updates since May 2018

: Acquired since May 2018

# PROGRESS IN FOCUS AREA APPROACH (2/2): ORGANIC APPLICATION OF CELL THERAPY PLATFORM TO REALIZE MULTIPLE PF STRATEGY



*Established cell differentiation protocols in multiple projects*




Yellow: Cell differentiation protocols established

PF: Primary Focus, ESC: Embryonic stem cell, iPSC: Induced pluripotent stem cell, UDC: Universal donor cell, RPE: Retinal pigment epithelium, HMC: Hemangioblast-derived mesenchymal stem cell, VPC: Vascular progenitor cell, CAR: Chimeric antigen receptor, TCR: T-cell receptor, cCAR: *convertible*CAR, NK: Natural killer

# PROGRESS IN Rx+ PROGRAM



*Steadily progressed to establish a solid foundation*

- ✓ Formulated Rx+ Story (strategic direction of Rx+ business creation)
- ✓ Established a US base for Rx+ business

*Successfully advanced multiple programs toward commercialization*

**Chronic disease progression prevention**

### Service and smartphone application for exercise support

- Initiated pilot marketing of a science-based exercise support service “Fit-eNce”
- Entered into agreement with BANDAI NAMCO Entertainment to co-develop and co-commercialize smartphone exercise support application
- Launched “Health Mock Lab.”, a virtual framework for industry-academia collaboration

### Digital therapeutics

- Entered into a strategic alliance with Welldoc to develop and commercialize digital therapeutics

### Support ecosystem for patients with heart disease

- Developed a program for Holter analysis devices “My Holter II” through research collaboration with M. Heart and received certification as a class II medical device program

**Patient outcome maximization**

### Image-guided precision surgery

- ASP5354: FSFT in Phase 2 study (US)
- ASP5354: Received FDA Fast Track Designation

### Theranostics* utilizing radioisotope-labeled antibodies

- Entered into a research collaboration for molecular targeted radiotherapies with Actinium Pharmaceuticals

**Across all Spheres**

### Ultra-small implantable medical devices

- Completed acquisition of iota Biosciences

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* The term that combines “Therapeutics” and “Diagnostics”. Treatment protocol or concept in which healthcare professionals assess lesion sites and simultaneously determine the appropriate treatment for each patient
FSFT: First subject first treatment, FDA: Food and Drug Administration

# REVIEW OF CORPORATE STRATEGIC PLAN 2018 (FINANCIAL PART) (1/2)



*Revenue was behind original forecast, but achieved Core OP margin including investment for sustainable growth*

(billion yen)

| Indicators | FY2017 ACT | FY2020 ACT | FY2020 Guidance (Announced in May 2018) |
|---|---|---|---|
| Revenue | 1,300.3 | 1,249.5 | × FY2017 level |
| R&D investment | 220.8 | 224.5 | ○ More than 200.0 billion yen |
| Core OP | 268.7<br>20.7% | 251.4<br>20.1% | ○ Core OP margin 20% |
| Core EPS | 100.64 yen | 113.03 yen | ○ Exceed FY2017 |

# REVIEW OF CORPORATE STRATEGIC PLAN 2018 (FINANCIAL PART) (2/2)

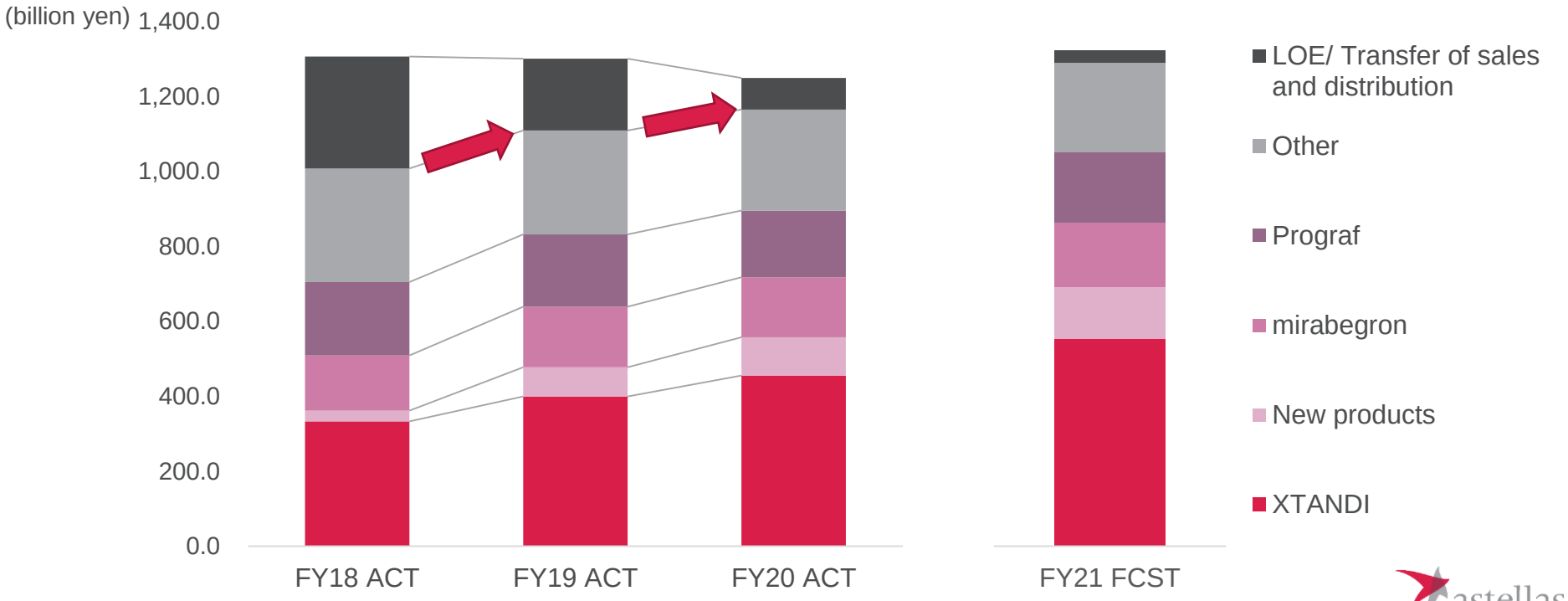


*Product portfolio has changed in 3 years and sales of main products and new products grew significantly.*

*Negative impact from LOE/ transfer of sales and distribution has almost ended.*

*Aiming for mid- to long-term growth trend during the next corporate strategic plan*

**Revenue trend**




LOE: Loss of exclusivity
LOE products/ Transfer of sales and distribution: Vesicare, Tarceva, MYCAMINE/ Funguard, Celecox, Symbicort, KM bio products, Micardis, etc.
New products: XOSPATA, PADCEV, Evrenzo, New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

# APPENDIX

# FY2020: REVENUE BY REGION



| (billion yen) | FY2019 | FY2020 | Change (%) |
|---|---|---|---|
| Japan | 345.4 | 279.1 | -19.2% |
| United States | 443.5 | 473.2 | +6.7% |
| Established Markets | 296.1 | 293.2 | -1.0% |
| Greater China | 60.4 | 59.3 | -1.8% |
| International Markets | 134.8 | 111.1 | -17.6% |

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.

# FY2020: SALES OF MAIN PRODUCTS



| (billion yen) | FY2019 | FY2020 | Change | CER growth | FY2020 FCST * |
|---|---|---|---|---|---|
| XTANDI | 400.0 | 458.4 | +14.6% | +15.3% | 464.6 |
| XOSPATA | 14.3 | 23.8 | +67.2% | +68.3% | 23.1 |
| PADCEV | 1.8 | 12.8 | +607.3% | - | 13.0 |
| Evrenzo | 0.2 | 1.1 | - | - | |
| mirabegron | 161.6 | 163.6 | +1.2% | +2.3% | 167.9 |
| New products in Japan | 61.2 | 70.5 | +15.3% | - | |
| Prograf | 192.9 | 182.7 | -5.3% | -5.9% | 182.0 |

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

*Announced in Aug 2020

# FY2020 ACTUAL: FX RATE



**Average rate for the period**

| Currency | FY2019 | FY2020 | Change |
|---|---|---|---|
| USD | 109 yen | 106 yen | -3 yen |
| EUR | 121 yen | 124 yen | +3 yen |

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

| Currency | FY2019 | FY2020 |
|---|---|---|
| USD | -2 yen | +2 yen |
| EUR | -5 yen | +10 yen |

**<Impact of exchange rate on financial results>**

- 4.6 billion yen decrease in revenue, 7.3 billion yen decrease in core OP
- FX impact on elimination of unrealized gain: COGs ratio +0.8 ppt

FX: Foreign exchange, COGs: Cost of goods sold

# FY2021 FCST: FX RATE & FX SENSITIVITY



**Average rate for the period**

| Currency | FY2020 | FY2021 FCST | change |
|---|---|---|---|
| USD | 106 yen | 110 yen | +4 yen |
| EUR | 124 yen | 130 yen | +6 yen |

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

| Currency | FY2020 | FY2021 FCST |
|---|---|---|
| USD | +2 yen | -1 yen |
| EUR | +10 yen | +0 yen |

**Estimated FX sensitivity of FY2021 forecast by 1 yen appreciation**

| Currency | Average rate 1 yen higher than assumption | | Year-end rate 1 yen higher than assumption |
|---|---|---|---|
| | Revenue | Core OP | Core OP |
| USD | Approx. -6.3 bil. yen | Approx. -1.3 bil. yen | Approx. +0.6 bil. yen |
| EUR | Approx. -2.9 bil. yen | Approx. -1.4 bil. yen | Approx. +0.3 bil. yen |

# BALANCE SHEET & CASH FLOW HIGHLIGHTS



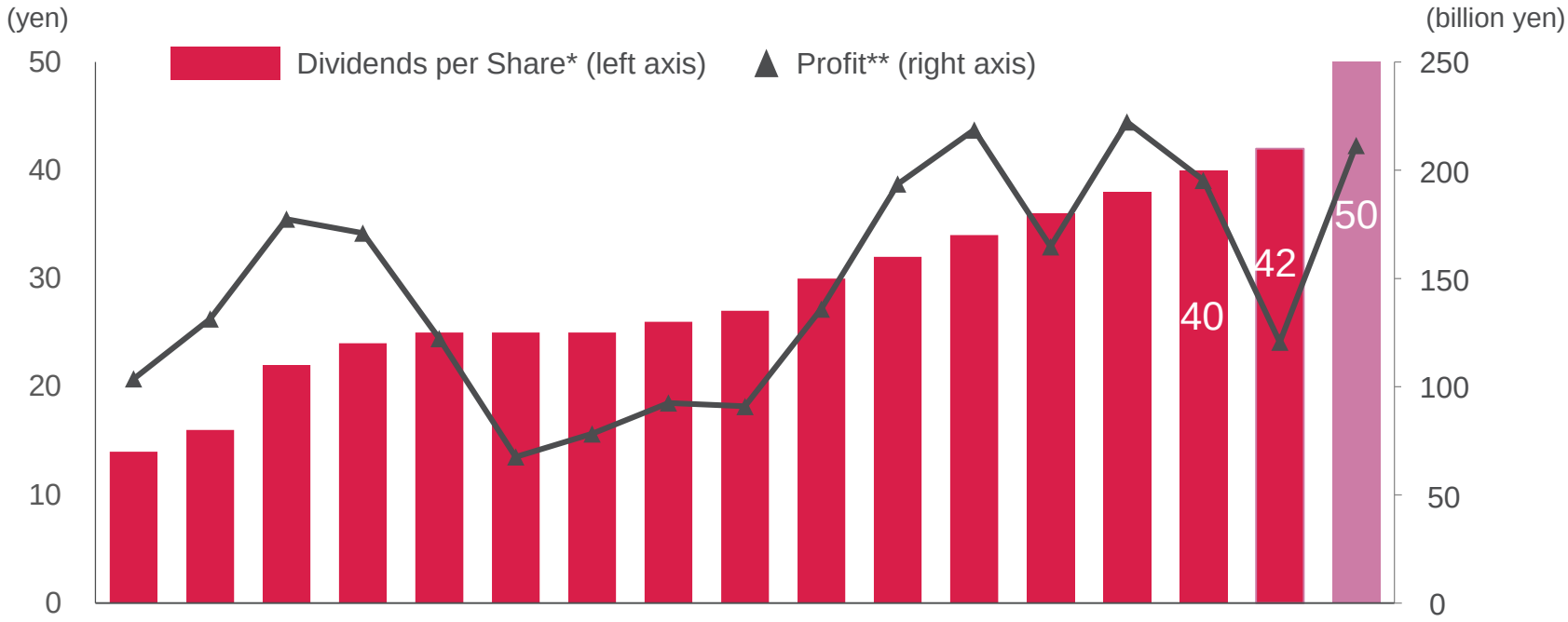
| (billion yen) | FY2019 end | FY2020 end |
|---|---|---|
| Total assets | 2,315.2 | 2,273.6 |
| Cash and cash equivalents | 318.4 | 326.1 |
| Total equity attributable to owners of the parent | 1,289.2 | 1,386.1 |
| Equity ratio (%) | 55.7% | 61.0% |

| (billion yen) | FY2019 | FY2020 |
|---|---|---|
| Cash flows from operating activities | 222.0 | 306.8 |
| Cash flows from investing activities | -389.8 | -81.9 |
| Free cash flows | -167.8 | 224.9 |
| Cash flows from financing activities | 181.1 | -229.5 |
| Bonds and short-term borrowings | 326.0 | -206.0 |
| Proceeds from long-term borrowings | - | 80.0 |
| Dividends paid | -73.5 | -76.2 |

Balance of bonds and borrowings：200.0 billion yen
(Decreased by 126.0 billion yen from FY2019 end)

# DETAILS OF SHAREHOLDER RETURNS






| (billion yen) | FY05 | FY06 | FY07 | FY08 | FY09 | FY10 | FY11 | FY12 | FY13 | FY14 | FY15 | FY16 | FY17 | FY18 | FY19 | FY20 | FY21 (FCST) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total dividends | 39.3 | 42.3 | 55.2 | 56.9 | 58.2 | 57.7 | 57.7 | 59.4 | 60.6 | 66.0 | 68.5 | 71.3 | 72.1 | 72.4 | 75.0 | 78.1 | 93.0 |
| Acquisition of own share | 46.2 | 219.9 | 81.8 | 123.4 | 27.0 | - | - | 49.4 | 30.0 | 58.2 | 119.3 | 91.4 | 130.0 | 160.0 | 50.0 | - | |
| Total return ratio (%) | 82 | 200 | 77 | 106 | 70 | 85 | 74 | 118 | 100 | 92 | 97 | 74 | 123 | 105 | 64 | 65 | |

* The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014, Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal year 2005.
** From fiscal year 2013, figures are in accordance with International Financial Reporting Standards (IFRS)

# ROBUST PIPELINE OF ASTELLAS



## Phase 1

- ASP1948/PTZ-329
- ASP1951/PTZ-522
- ASP9801
- ASP7517
- ASP0739
- ASP7317
- ASP0892
- ASP0367/MA-0211 (Duchenne muscular dystrophy)
- ASP2390
- ASP0598
- AT845
- ASP8062 (Alcohol use disorder)
- ASP1617

## Phase 2

- zolbetuximab (Pancreatic adenocarcinoma)
- enfortumab vedotin (Other solid tumors)
- ASP1128/MA-0217 (Acute kidney injury)
- ASP3772 (Pneumococcal disease)
- FX-322 (Sensorineural hearing loss)
- resamirigene bilparvovec /AT132 (XLMTM)
- ASP0367/MA-0211 (Primary mitochondrial myopathies)
- bleselumab (rFSGS)
- roxadustat (Chemotherapy-induced anemia)
- isavuconazole (Pediatric use: US)
- ASP8062 (Opioid use disorder)

## Phase 3

- enzalutamide (M0 CSPC, M1 CSPC: China)
- gilteritinib (Earlier-stage AML, Pediatric use)
- enfortumab vedotin (mUC previously untreated, MIBC)
- zolbetuximab (Gastric and GEJ adenocarcinoma)
- peficitinib (Rheumatoid arthritis: China)
- mirabegron (Pediatric use: EU)
- fezolinetant (VMS associated with menopause)

## Filed

- enzalutamide (M1 CSPC: EU)
- enfortumab vedotin (mUC, pretreated: US [sBLA], EU, JP)
- roxadustat (Anemia associated with CKD: EU)
- tacrolimus (Lung transplantation: US)

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

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

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XLMTM: X-linked myotubular myopathy, rFSGS: Recurrence of focal segmental glomerulosclerosis, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, AML: Acute myeloid leukemia, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms, sBLA: Supplemental Biologics License Application, CKD: Chronic kidney disease

# PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since Q3/FY2020 Financial Results Announcement in Jan 2021



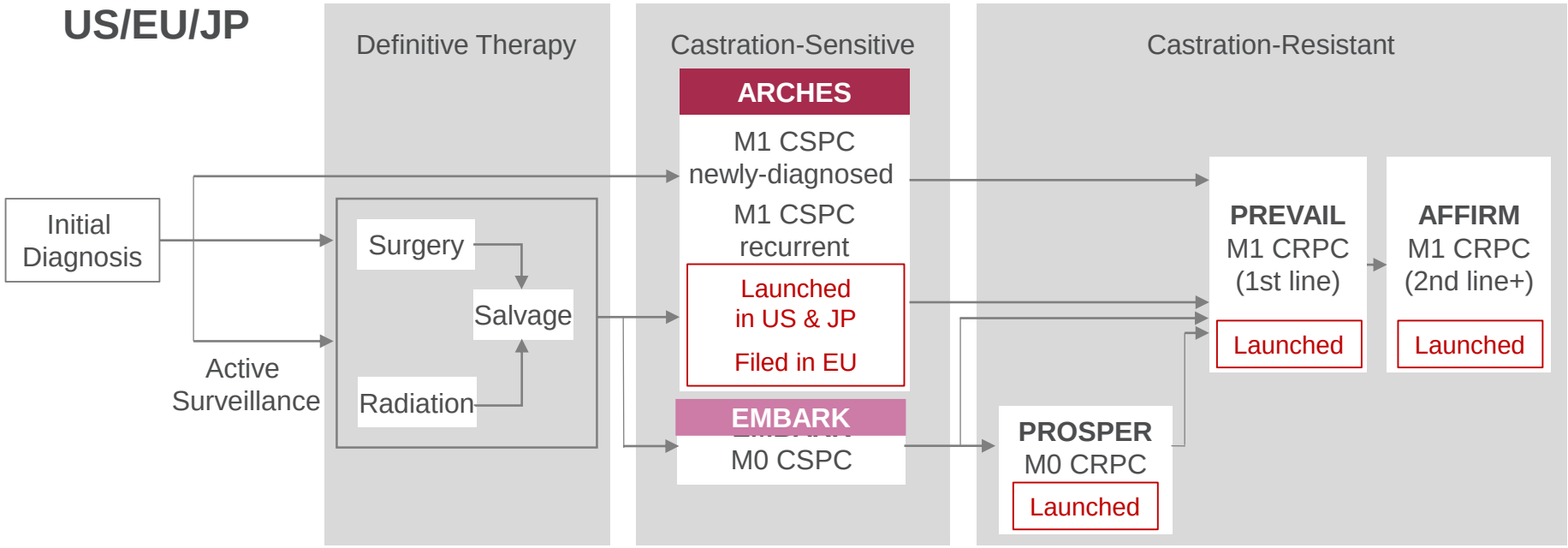
| Phase 1 Entry | Phase 2 Entry | Phase 3 Entry | Filing | Approval |
|---|---|---|---|---|
| | **ASP8062**<br>Opioid use disorder | | **enfortumab vedotin**<br>Locally advanced or metastatic urothelial cancer, PD-1/PD-L1 inhibitor pretreated and cisplatin-ineligible:<br>US<br><br>**enfortumab vedotin**<br>Locally advanced or metastatic urothelial cancer, PD-1/PD-L1 inhibitor and platinum-containing chemotherapy pretreated:<br>EU<br><br>**enfortumab vedotin**<br>Locally advanced or metastatic urothelial cancer, progressed after anti-cancer medication:<br>JP | **gilteritinib**<br>Relapsed or refractory acute myeloid leukemia with a FLT3 mutation:<br>China<br><br>**mirabegron**<br>Neurogenic detrusor overactivity in pediatric patients aged three years and older:<br>US |

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)






| | | | | | |
|---|---|---|---|---|---|
| | **P3: ARCHES** | **M1 CSPC** | Combo with ADT, vs. placebo | n=1,150 | Approved in US in Dec 2019 and in JP in May 2020<br>Filed in EU in Jul 2019 and CHMP positive opinion received in Mar 2021 |
| | **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:** Approved in Nov 2020
- **M1 CSPC:** Enrollment completed in Phase 3 China-ARCHES study

Underlined: Updates since Q3/FY2020 financial results announcement in Jan 2021
M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy

# ENZALUTAMIDE (2/2): PHASE 3 STUDY DATA BY DISEASE STAGE

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

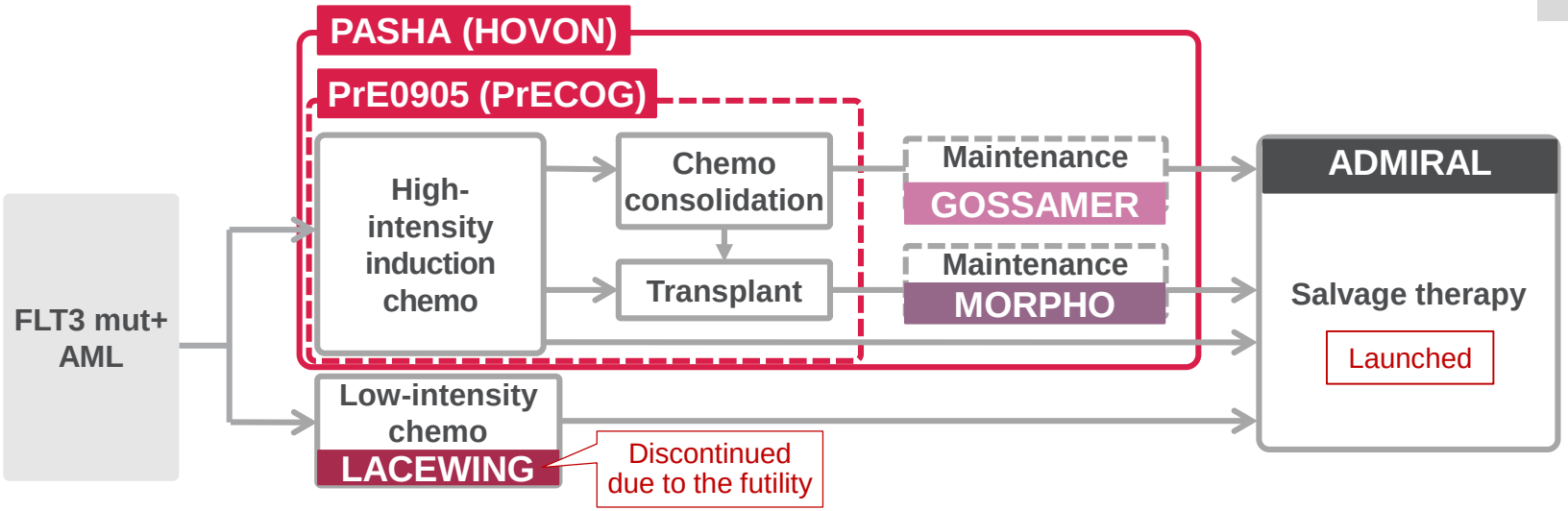
| Disease stage | Early stage → Late stage | | | | | |
|---|---|---|---|---|---|---|
| | Castration-sensitive (CSPC) | | | Castration-resistant (CRPC) | | |
| | M0 | M1 | | M0 | M1 (pre-chemo) | M1 (post-chemo) |
| Phase 3 study | **EMBARK** | **ARCHES** | **ENZAMET** | **PROSPER** | **PREVAIL** | **AFFIRM** |
| Control | Placebo | Placebo | Conventional NSAA | Placebo | Placebo | Placebo |
| Primary endpoint | MFS (Ongoing) | ✔ rPFS HR 0.39 | ✔ OS HR 0.67 | ✔ MFS HR 0.29 | ✔ rPFS HR 0.17<br>✔ OS HR 0.71* | ✔ OS HR 0.63 |
| OS | (Ongoing) | (Not reached) | ✔ HR 0.67 | ✔ HR 0.73 | ✔ HR 0.77 | ✔ HR 0.63 |
| DoT | (Ongoing) | (Not reached) | ✔ 29.5 months | ✔ 33.9 months | ✔ 17.5 months | ✔ 8.3 months |

✔: 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

# GILTERITINIB: FLT3 INHIBITOR






| | | | | |
|---|---|---|---|---|
| Relapsed or refractory (R/R) | **P3: ADMIRAL** | Monotherapy vs salvage chemo (2:1) | n=371 | Launched in US, JP, and EU |
| Newly diagnosed (intensive chemo 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.) |
| Newly diagnosed (intensive chemo ineligible) | **P3: LACEWING** | Combo with azacitidine vs. azacitidine alone (2:1) | n=146 | Discontinued due to the futility based on the planned interim analysis |
| Post-HSCT maintenance | **P3: MORPHO** | Monotherapy vs. placebo (1:1) | n=346 | Enrollment completed<br>Collaborating with BMT-CTN |
| Post-chemo maintenance | **P2: GOSSAMER** | Monotherapy vs. placebo (2:1) | n=98 | Enrollment completed |

**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

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Underlined: Updates since Q3/FY2020 financial results announcement in Jan 2021
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

# ENFORTUMAB VEDOTIN (EV) : NECTIN-4 TARGETED ADC (1/9)



## For urothelial cancer

| | | | |
|---|---|---|---|
| **P3: EV-301** | mUC, Platinum and PD-1/L1 inhibitor pretreated;<br>EV mono vs. Chemo | n=608 | Primary endpoint (OS) met (data presented at ASCO GU 2021 and published in NEJM). Filed in US (sBLA) in Feb 2021, in EU and JP in Mar 2021 |
| **P3: EV-302** | mUC, Previously untreated, Platinum-eligible;<br>EV + Pembro vs. Chemo | n=760 | FSFT: Apr 2020 |
| **P3: EV-303 /KEYNOTE-905** | MIBC, Cis-ineligible;<br>Pembro +/- EV (perioperative) + RC vs. RC alone | n=836 | FSFT in Pembro + EV arm: Dec 2020 |
| **P3: EV-304 /KEYNOTE-B15** | MIBC, Cis-eligible; EV+Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC | n=784 | To start in Q1 FY2021 |
| **P2: EV-201** | mUC, PD-1/L1 inhibitor pretreated; EV mono<br>Cohort 1: Platinum pretreated<br>Cohort 2: Platinum naïve and cis-ineligible | n=219 | Cohort 1: Approved (under the Accelerated Approval program) and launched in US in Dec 2019<br>Cohort 2: Obtained positive ORR (data presented at ASCO GU 2021). Filed in US (sBLA) in Feb 2021 |
| **P1b/2: EV-103** | Cohorts A - G and K (mUC):<br>A-G: Combo with Pembro and other chemo<br>K: EV mono vs. EV + Pembro<br>Cohorts H, J and L (MIBC, Cis-ineligible, + RC):<br>H: EV mono (neoadjuvant)<br>J (optional): EV+Pembro (neoadjuvant)<br>L: EV mono (perioperative) | n=457 | Enrollment ongoing in Cohort K and L |
| **P2: EV-203** | <Bridging study in China><br>mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono | n≈40 | Currently under preparation (IND approved) |

## 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, gastroesophageal junction or esophageal cancer; EV mono | n=240 | FSFT: Mar 2020 |

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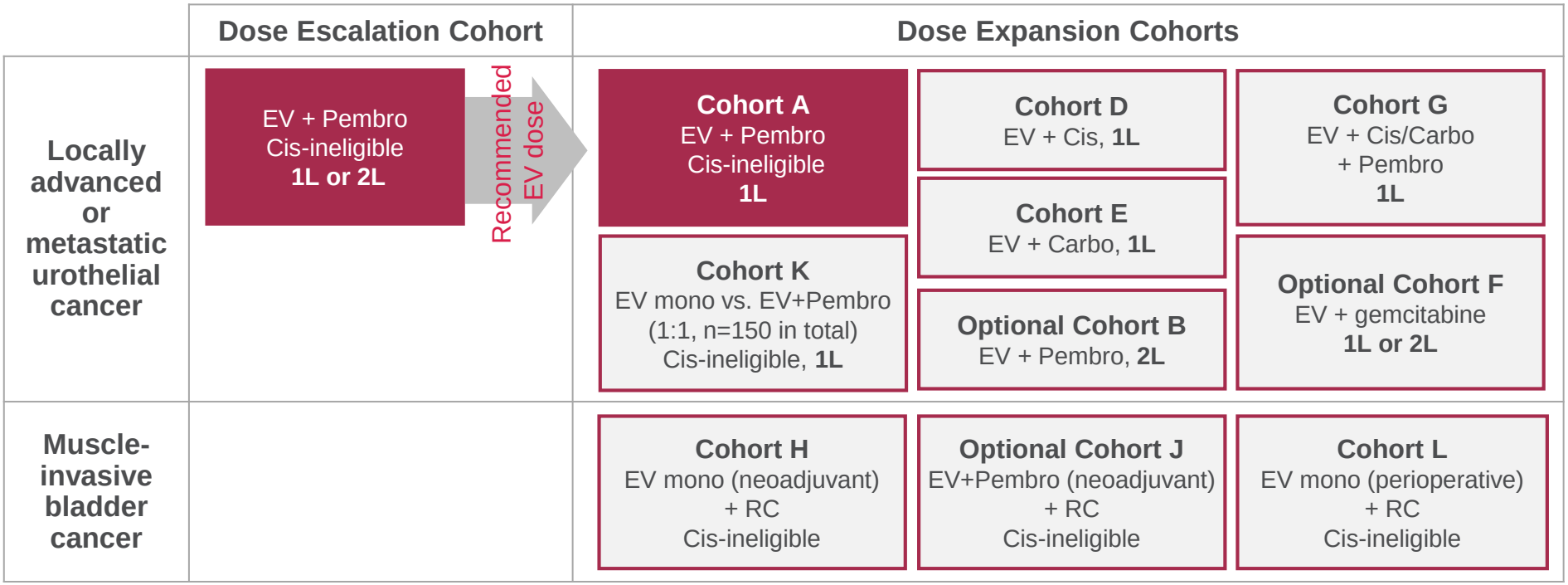
Underlined: Updates since Q3/FY2020 financial results announcement in Jan 2021

ADC: Antibody-drug conjugate, mUC: Metastatic urothelial cancer, mono: Monotherapy, Chemo: Chemotherapy, OS: Overall survival, ASCO GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium, NEJM: New England Journal of Medicine, sBLA: Supplemental Biologics License Application, Pembro: Pembrolizumab, FSFT: First subject first treatment, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, RC: Radical cystectomy, ORR: Objective response rate, IND: Investigational New Drug application, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer

# ENFORTUMAB VEDOTIN (EV) (2/9): PHASE 1b/2 EV-103 STUDY DESIGN






Results from cis-ineligible and 1L in these cohorts presented at ESMO 2019 and ASCO GU 2020

*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*

Seagen

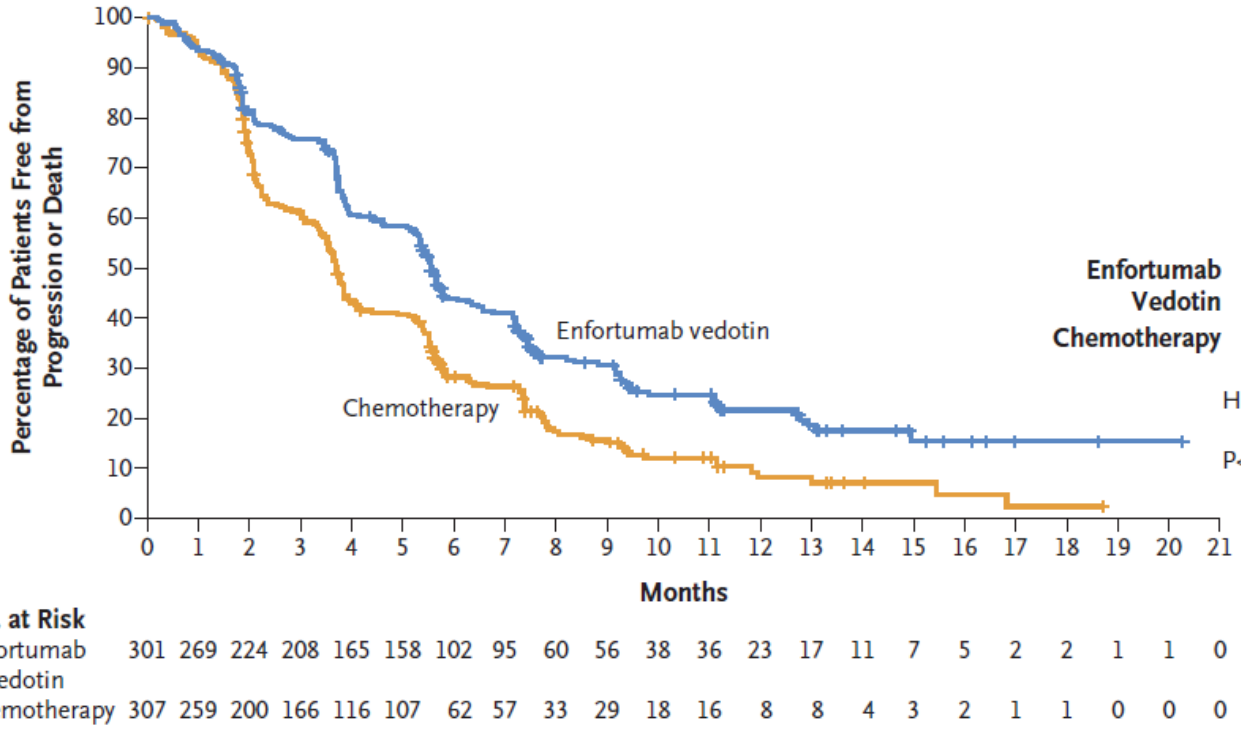
(EV-103 study is sponsored by Seagen) astellas

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 (3/9): PHASE 3 EV-301 STUDY RESULTS - EFFICACY



**PFS** (Secondary endpoint)




| | No. of Events/ No. of Patients | Median Progression-free Survival (95% CI) |
|---|---|---|
| | | *mo* |
| Enfortumab Vedotin | 201/301 | 5.55 (5.32–5.82) |
| Chemotherapy | 231/307 | 3.71 (3.52–3.94) |

Hazard ratio for disease progression or death, 0.62 (95% CI, 0.51–0.75)
P<0.001

Powels T, *et al.*, NEJM. 2021
PFS: Progression-free survival, CI: Confidence interval, NEJM: New England Journal of Medicine

# ENFORTUMAB VEDOTIN (EV) (4/9): PHASE 3 EV-301 STUDY RESULTS - SAFETY



*Safety profile was consistent with prior EV studies*

| **TRAE** Any grade in ≥ 20% of patients and ≥ Grade 3 in ≥ 5% of patients | **No. of patients** (%) | | | |
|---|---|---|---|---|
| | **EV** (n=296) | | **Chemo** (n=291) | |
| | Any grade | ≥ Grade 3 | Any grade | ≥ Grade 3 |
| **Any adverse event** | **278 (93.9)** | **152 (51.4)** | **267 (91.8)** | **145 (49.8)** |
| Alopecia | 134 (45.3) | 0 | 106 (36.4) | 0 |
| Peripheral sensory neuropathy | 100 (33.8) | 9 (3.0) | 62 (21.3) | 6 (2.1) |
| Pruritus | 95 (32.1) | 4 (1.4) | 13 (4.5) | 0 |
| Fatigue | 92 (31.1) | 19 (6.4) | 66 (22.7) | 13 (4.5) |
| Decreased appetite | 91 (30.7) | 9 (3.0) | 68 (23.4) | 5 (1.7) |
| Diarrhea | 72 (24.3) | 10 (3.4) | 48 (16.5) | 5 (1.7) |
| Dysgeusia | 72 (24.3) | 0 | 21 (7.2) | 0 |
| Nausea | 67 (22.6) | 3 (1.0) | 63 (21.6) | 4 (1.4) |
| Maculopapular rash | 48 (16.2) | 22 (7.4) | 5 (1.7) | 0 |
| Anemia | 34 (11.5) | 8 (2.7) | 59 (20.3) | 22 (7.6) |
| Decreased neutrophil count | 30 (10.1) | 18 (6.1) | 49 (16.8) | 39 (13.4) |
| Neutropenia | 20 (6.8) | 14 (4.7) | 24 (8.2) | 18 (6.2) |
| Decrease white-cell count | 16 (5.4) | 4 (1.4) | 31 (10.7) | 20 (6.9) |
| Febrile neutropenia | 2 (0.7) | 2 (0.7) | 16 (5.5) | 16 (5.5) |

- ≥ Grade 3 TRAEs were experienced by approx. 50% of patients in both arms
- Adverse events of special interest (e.g., skin reactions, peripheral neuropathy, and hyperglycemia) were generally mild/moderate in severity and consistent with those reported in prior studies

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Powels T, *et al.*, NEJM. 2021

TRAE: Treatment-related adverse event, Chemo: Chemotherapy, NEJM: New England Journal of Medicine

# ENFORTUMAB VEDOTIN (5/9):
## PHASE 2 EV-201 STUDY COHORT 2 RESULTS - EFFICACY (1)



**ORR** (Primary endpoint)

| **ORR per RECIST v1.1 assessed by BICR** | **Patients** (%) (n=89) |
|---|---|
| **Confirmed ORR** | **52** |
| 95% CI | (40.8, 62.4) |
| **Best Overall Response per RECIST v1.1** | |
| Complete response | 20 |
| Partial response | 31 |
| Stable disease | 30 |
| Progressive disease | 9 |
| Not evaluable * | 9 |

* Includes five subjects who did not have response assessment post-baseline, two subjects whose post-baseline assessment did not meet the minimum interval requirement for stable disease, and one subject whose response cannot be assessed due to incomplete anatomy.

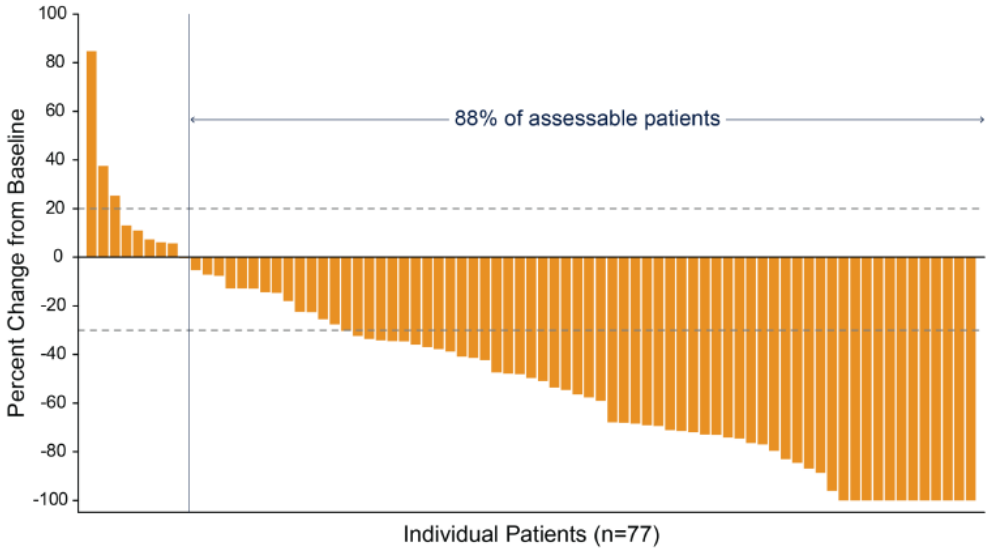
Barlar AV, *et al.*, ASCO GU 2021
ORR: Objective response rate, RECIST: Response evaluation criteria in solid tumors, BICR: Blind independent central review, CI: Confidence interval, ASCO GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium

# ENFORTUMAB VEDOTIN (6/9):
## PHASE 2 EV-201 STUDY COHORT 2 RESULTS - EFFICACY (2)

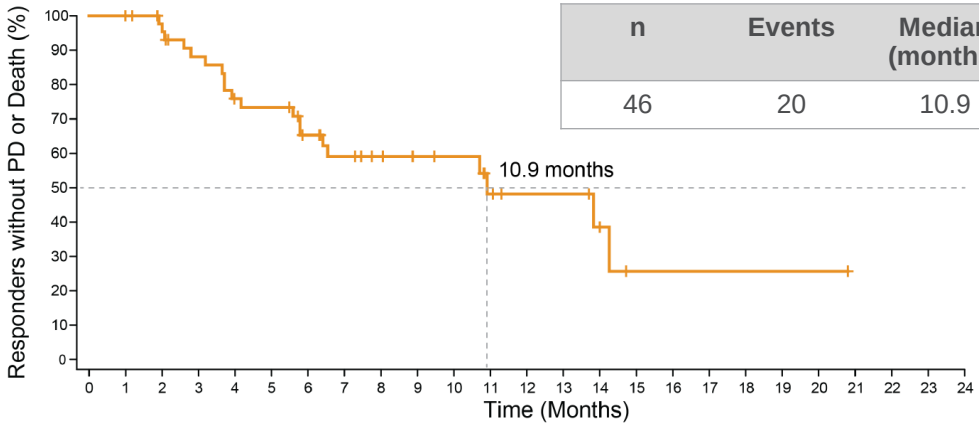


**Change in tumor measurements per BICR**

Data are not available for 12 subjects due to no response assessment post-baseline (n=5), incomplete assessment of target lesions post-baseline (n=1), or no measurable disease at baseline per BICR (n=6)




**DoR per BICR**




| n | Events | Median (months) | 95% CI |
|---|---|---|---|
| 46 | 20 | 10.9 | (5.78, -) |

Barlar AV, *et al.*, ASCO GU 2021
BICR: Blinded Independent Central Review, DoR: Duration of response, PD: Progressive disease, CI: Confidence interval, ASCO GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium

# ENFORTUMAB VEDOTIN (EV) (7/9): PHASE 2 EV-201 STUDY COHORT 2 RESULTS - SAFETY



*Safety profile was consistent with prior EV studies*

| **TRAE** Any grade in ≥ 20% of patients and ≥ Grade 3 in ≥ 5% of patients | **No. of patients** (%) (n=89) | |
|---|---|---|
| | Any grade | ≥ Grade 3 |
| **Overall TRAEs** | **86 (97)** | **49 (55)** |
| Alopecia | 45 (51) | - |
| Peripheral sensory neuropathy | 42 (47) | 3 (3) |
| Fatigue | 30 (34) | 6 (7) |
| Decreased appetite | 29 (33) | 5 (6) |
| Pruritus | 27 (30) | 3 (3) |
| Rash maculo-papular | 27 (30) | 7 (8) |
| Dysgeusia | 24 (27) | - |
| Weight decreased | 23 (26) | 1 (1) |
| Anemia | 22 (25) | 5 (6) |
| Diarrhea | 20 (22) | 5 (6) |
| Nausea | 20 (22) | 1 (1) |
| Neutropenia | 11 (12) | 8 (9) |
| Hyperglycemia | 8 (9) | 5 (6) |
| Lipase increased | 7 (8) | 5 (6) |

- ≥ Grade 3 TRAEs of interest included skin reactions (17%), peripheral neuropathy (8%) and hyperglycemia (6%)
- Four deaths were reported as treatment-related by investigators in patients aged 75 years and older with multiple comorbidities

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Barlar AV, et al., ASCO GU 2021

TRAE: Treatment-related adverse event, ASCO GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium

# ENFORTUMAB VEDOTIN (EV) (8/9): STUDY DATA BY DISEASE STAGE



| Disease stage | Early stage → Late stage | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | MIBC | | mUC | | | | | |
| | Surgery eligible | | Previously untreated (first line) | | | PD-1/L1 inhibitor pretreated | | |
| | Cis-eligible | Cis-ineligible | Platinum eligible | Cis-ineligible | | Platinum naïve and cis-ineligible | Platinum pretreated | |
| Study phase | Phase 3 | Phase 3 | Phase 3 | Phase 1b/2 | Phase 1b/2 | Phase 2 | Phase 2 | Phase 3 |
| Study No. | **KN-B15 / EV-304** | **KN-905 / EV-303** | **EV-302** | **EV-103 Cohort K** | **EV-103 Cohort A & Others** | **EV-201 Cohort 2** | **EV-201 Cohort 1** | **EV-301** |
| No. of subjects | 734 (2 arms) | 836 (3 arms) | 760 (2 arms) | 150 (2 arms) | 45 | 89 | 125 | 608 (2 arms) |
| EV regimen | Combo w/ Pembro (perioperative) | Combo w/ Pembro (perioperative) | Combo w/ Pembro | Mono vs. Combo w/ Pembro | Combo w/ Pembro | Mono | Mono | Mono |
| Control | Chemo (neoadjuvant) | SoC | Chemo | n/a | n/a | n/a | n/a | Chemo |
| Primary endpoint | pCR & EFS | pCR & EFS | PFS & OS | ORR | ✔ ORR ** 73% (CR 16%) | ✔ ORR 52% (CR 20%) | ✔ ORR 44% (CR 12%) | ✔ OS * HR 0.70 |
| OS | (To be started soon) | (Ongoing) | (Ongoing) | (Ongoing) | (Not reached) | ✔ (14.7 mos) | ✔ (12.4 mos) ** | ✔ HR 0.70 * (12.9 mos vs.9 mos) |
| PFS | (To be started soon) | (Ongoing) | (Ongoing) | (Ongoing) | (Not reached) | ✔ (5.8 mos) | ✔ (5.8 mos) | ✔ HR 0.62 * (5.6 mos vs.3.7 mos) |
| ORR | (To be started soon) | (Ongoing) | (Ongoing) | (Ongoing) | ✔ 73% ** (CR 16%) | ✔ 52% (CR 20%) | ✔ 44% (CR 12%) | ✔ 41% vs.18% * (CR 4.9% vs.2.7%) |
| DoR | (To be started soon) | (Ongoing) | (Ongoing) | (Ongoing) | (Not reached) | ✔ 10.9 mos | ✔ 7.6 mos | ✔ 7.39 mos vs. 8.11 mos * |

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✔: Data obtained, *: Prespecified interim analysis, **: Updated data, Yellow: Data recently disclosed

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MIBC: Muscle-invasive bladder cancer, mUC: Metastatic urothelial cancer, Pembro: Pembrolizumab, mono: Monotherapy, Chemo: Chemotherapy, pCR: Pathologic complete response, EFS: Event-free survival, ORR: Objective response rate, CR: Complete response, OS: Overall survival, HR: Hazard ratio, PFS: Progression-free survival, DoR: Duration of response

# ENFORTUMAB VEDOTIN (9/9): NUMBER OF UC PATIENTS



| Urothelial cancer (Annual) | All stages (Incidence) | MIBC | mUC | | |
|---|---|---|---|---|---|
| | | Post-cystectomy | Total (Incident + Newly recurrent) | Drug treated (1L) | Drug treated (2L+*) |
| **US** | 83,000 | 20,000 | 20,700 | 15,600 | 8,500 |
| **EU5** | 120,000 | 32,000 | 29,600 | 28,000 | 13,600 |
| **JP** | 46,000 | 11,500 | 10,500 | 7,500 | 3,800 |
| **China (urban)** | 54,000 | 14,000 | 30,000 | 25,000 | 12,300 |

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

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* 2L+: Platinum and/or PD-1/L1 inhibitor pretreated

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Kantar Health - 2021 incident and newly recurrent patients updated Dec 2020
Underlined: Updated figures from the ones presented at Q3/FY2020 financial results announcement in Jan 2021
(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer

# 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 [1]
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20% [2,3]
- Median overall survival for Stage IV gastric cancer is 10-15 months [4,5]

| | | | | | |
|---|---|---|---|---|---|
| | **Gastric and GEJ adenocarcinoma** | **P3: SPOTLIGHT** | First line, combo with mFOLFOX6, vs. placebo | n=550 | FSFT: Oct 2018 |
| | | **P3: GLOW** | First line, combo with CAPOX, vs. placebo | n=500 | FSFT: Jan 2019 |
| | | **P2: ILUSTRO** | Cohort 1: Third or later line, zolbetuximab monotherapy<br>Cohort 2: First line, combo with mFOLFOX6<br>Cohort 3: Third or later line, combo with pembrolizumab | n=112 | FSFT: Sep 2018 |
| | **Pancreatic adenocarcinoma** | **P2** | Combo with nab-paclitaxel and gemcitabine, vs. placebo | n=141 | FSFT: May 2019 |

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1: WHO Cancer Fact Sheet - Globocan 2018, 2: Pennathur A, *et al*., 2013, 3: Sahin U, *et al*., 2008, 4: 2017 RDPAC survey, 5: Iizumi S, *et al*. 2018
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 [1]

## Women's Health Initiative (WHI) Study [2]

- 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 significant unmet medical needs

### US and EU

| | | | | |
|---|---|---|---|---|
| **P3: SKYLIGHT 1** | Moderate to severe VMS associated with menopause;<br>The first 12 weeks: DB, 30 mg vs. 45 mg vs. placebo (1:1:1)<br>The last 40 weeks: Active extension treatment period, 30 mg or 45 mg | | n=527 | Primary endpoints met (12w DB period topline results) |
| **P3: SKYLIGHT 2** | | | n=501 | Primary endpoints met (12w DB period topline results) |
| **P3: SKYLIGHT 4** | VMS associated with menopause;<br>52 weeks: DB, 30 mg vs. 45 mg vs. placebo (1:1:1) | | n=1,833 | Enrollment completed |

### Asia (except for Japan)

| | | | |
|---|---|---|---|
| **P3: MOONLIGHT 1** | Moderate to severe VMS associated with menopause;<br>The first 12 weeks: DB, 30 mg vs. placebo (1:1)<br>The last 12 weeks: Active extension treatment period, 30 mg | n=300 | FSFT: Apr 2020 |
| **P3: MOONLIGHT 3** | VMS associated with menopause; open label, 30 mg for 52 weeks | n=150 | FSFT: Aug 2020 |

**JP:** Independent development plan under preparation

Underlined: Updates since Q3/FY2020 financial results announcement in Jan 2021

1: DelveInsight, Epidemiology Forecast, Jun 2018, 2: Data Source - IMS NPA (2000-2016), IMS NSP (2000-2016). (3 HTs and SSRI) NAMS 2015 Position Statement.

VMS: Vasomotor symptoms, HRT: Hormone replacement therapy, DB: Double-blind, LSLV: Last subject last visit, FSFT: First subject first treatment

# 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 transfect 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)** | n=26 | Clinical hold lifted by FDA in Dec 2020. Clinical trial re-start activities underway<br>Discussions planned on the path forward toward global registration filings |

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(r)AAV: (recombinant) Adeno-associated virus, Des: Desmin promoter, hMTM1: Human myotubularin gene,
RMAT: Regenerative Medicine Advanced Therapy, PRIME: PRIority Medicines, FDA: Food and Drug Administration

# PROGRESS IN FOCUS AREA APPROACH:
## MANUFACTURING CAPABILITY - CELL THERAPY & GENE THERAPY



### Cell Therapy: Astellas Institute for Regenerative Medicine (AIRM)


**April 2020 in operation**

**Westborough, Massachusetts, US**

- A complex of research, CMC/manufacturing, and clinical development, optimized for the promotion of cell therapy
- CMC/GMP manufacturing occupy half of 24,000 $m^2$
- 7 GMP clean rooms complied with US/EU/JP regulations. Expandable for future demands
- Independent air controlling system for clean rooms, enabling production of different cell types in parallel

**Cell Drug Substance Manufacturing**

- 10 years' experiences of PSC-derived cell therapy and GMP manufacturing cultivated as a pioneer
- Accumulated regulatory know-how accumulated through interactions with regulatory authorities
- Now promoting GMP manufacturing with protocols optimized for each cell type

**Cell Drug Product Manufacturing**

- Experience in supplying CTM to US and UK
- Plans to expand our capabilities as a center of future supply chain (DP shipping)

### Gene Therapy: Astellas Gene Therapies (Audentes Therapeutics)


**South San Francisco, California, US**

- Internal AAV manufacturing capability provides self sufficiency from research to commercial
- Capabilities to expand to support future AAV manufacturing and supply chain needs

**AAV Drug Substance Manufacturing**

- Suspension bioreactor systems at 1,000L (2x500L) scale
- AAV production supports clinical-stage GMP material with preparations in place for AT132 commercial launch

**AAV Drug Product (DP) Manufacturing**

- All AAV DP batches filled in-house (no CMO reliance)
- Capacity to support all CoE programs in the future

This fully approved capital project is currently under construction in Sanford, North Carolina.
Scheduled to be operational and GMP ready by mid 2022.
First phase provides 4,000L of bioreactor capacity

CMC: Chemistry, manufacturing and control, GMP: Good Manufacturing Practice. PSC: Pluripotent stem cell, CTM: Clinical trial material, DP: Drug product, AAV: Adeno-associated virus, L: Liter, CMO: Contract manufacturing organization, CoE: Center of excellence

# ON THE FOREFRONT OF HEALTHCARE CHANGE