# FY2022 FINANCIAL RESULTS
ENDED MARCH 31, 2023

**Naoki Okamura**
**President and CEO**
**Astellas Pharma Inc.**
**April 27, 2023**

# CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION



In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

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# TOWARD ACHIEVEMENT OF CSP2021

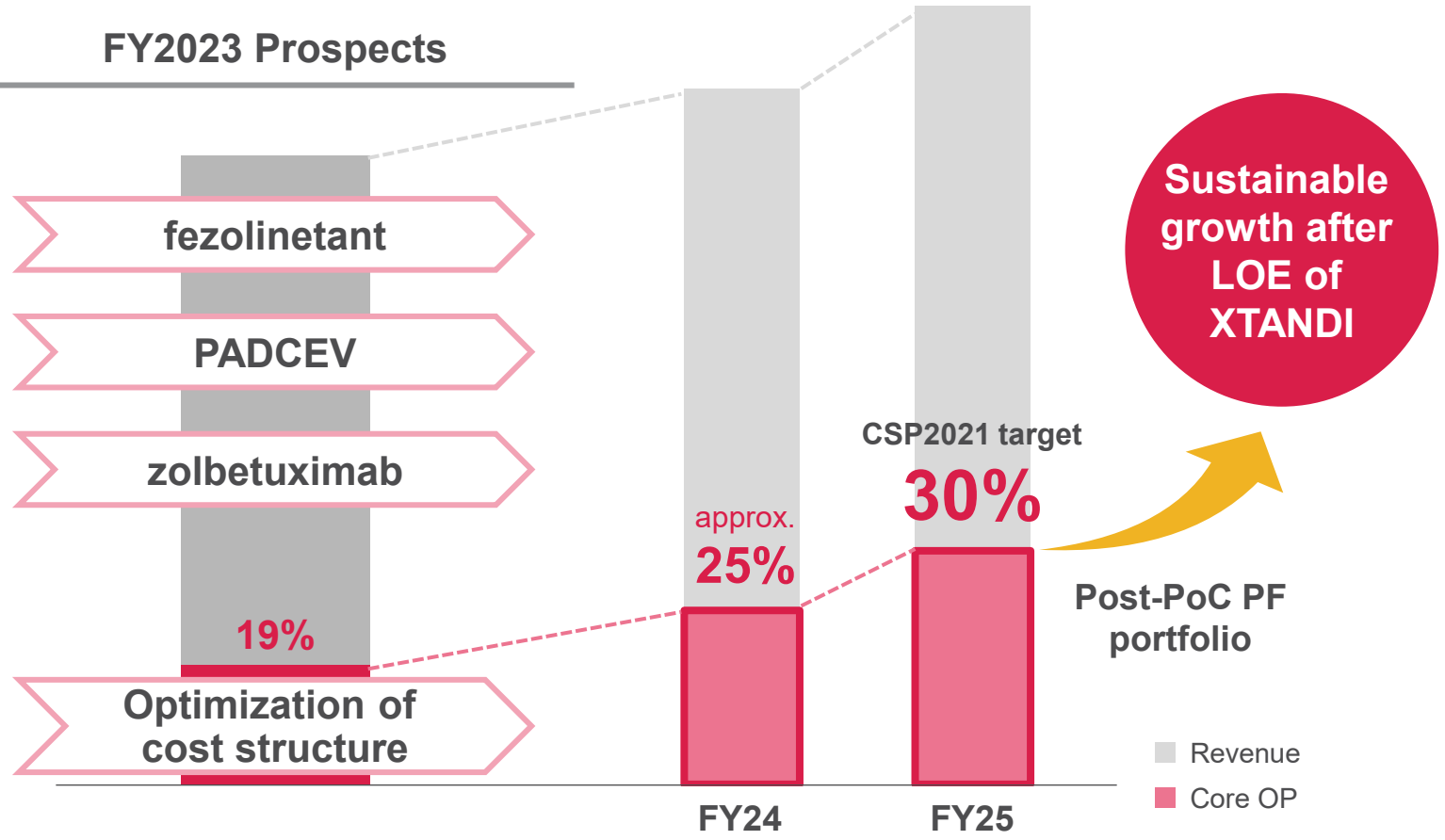


- *Continue commitment to CSP2021*
- *FY2023 is the turning point to ensure growth from FY2024 onwards*

## FY2022 Review

- Core results in line with expectations, but slightly behind full-year forecast
- fezolinetant NDA, PADCEV sBLA, successful zolbetuximab Phase 3 studies
- Established new PF "Targeted Protein Degradation"
- No PoC obtained in FA projects

## FY2023 Prospects




Approval of PADCEV sBLA for first-line metastatic urothelial cancer in US is Apr 2023.
CSP: Corporate Strategic Plan, NDA: New Drug Application, sBLA: Supplemental Biologics License Application, PF: Primary Focus, PoC: Proof of concept, FA: Focus Area, LOE: Loss of exclusivity

# AGENDA



I FY2022 Consolidated Financial Results

II Initiatives for Sustainable Growth

III FY2023 Forecasts and Key Expected Events

# FY2022 FINANCIAL RESULTS: OVERVIEW



*Revenue increased 17% YoY and was in line with expectations, but slightly behind full-year forecast*
*XTANDI, PADCEV and XOSPATA expanded as expected with full-year forecasts*

*Cost items*

- Cost of sales ratio was as expected
- SG&A expenses were on track and decreased YoY when excluding FX impact
- R&D expenses were on track

*Operating profit*

- Core OP increased 17% YoY and was in line with expectations, but slightly behind full-year forecast

# FY2022 FINANCIAL RESULTS



| (billion yen) | FY2021 | FY2022 | Change | Change (%) | FY2022 FCST [1] | Achievement | FX impact (YoY) |
|---|---|---|---|---|---|---|---|
| **Revenue** | **1,296.2** | **1,518.6** | **+222.5** | **+17.2%** | **1,529.0** | **99.3%** | +164.4 bil. yen |
| Cost of sales | 253.0 | 288.4 | +35.3 | +14.0% | | | +16.5 bil. yen (Incl. the impact of elimination of unrealized profit remaining in Q4/FY2021: +7.8 bil.yen) |
| % of revenue | 19.5% | 19.0% | -0.5 ppt | | | | |
| SG&A expenses | 548.8 | 630.3 | +81.4 | +14.8% | 642.0 | 98.2% | +80.3 bil. yen |
| US XTANDI co-pro fee | 139.3 | 175.5 | +36.2 | +26.0% | 186.0 | 94.3% | |
| SG&A excl. the above | 409.5 | 454.8 | +45.3 | +11.1% | 456.0 | 99.7% | +50.4 bil. yen |
| R&D expenses | 246.0 | 276.1 | +30.1 | +12.2% | 278.0 | 99.3% | +27.5 bil. yen |
| Amortisation of intangible assets | 28.3 | 38.4 | +10.2 | +35.9% | | | |
| Gain on divestiture of intangible assets | 24.2 | 0.2 | -24.0 | -99.1% | | | |
| **Core operating profit** | **244.7** | **286.9** | **+42.2** | **+17.2%** | **290.0** | **98.9%** | +40.1 bil. yen |
| <Full basis> | | | | | | | |
| Other income | 15.3 | 3.6 | -11.6 | -76.1% | | | |
| Other expenses | 104.3 | 157.5 | +53.2 | +51.0% | | | |
| **Operating profit** | **155.7** | **133.0** | **-22.7** | **-14.6%** | **137.0** | **97.1%** | |
| Profit before tax | 156.9 | 132.4 | -24.5 | -15.6% | 135.0 | 98.0% | |
| **Profit** | **124.1** | **98.7** | **-25.4** | **-20.4%** | **105.0** | **94.0%** | |

**Ref. Other expenses (booked in Q4/FY2022)**

- Fair value increase of contingent consideration(zolbetuximab) [2]:38.6 bil. yen
- Impairment losses on intangible assets :60.3 bil. yen(EVRENZO:47.1 bil. yen, FX-322:8.6 bil. yen, Adaptimmune:4.6 bil. yen)

1. FY22 FCST were announced in Oct 2022, provided that full basis is the revised forecast announced on April 11, 2023.
2. Booked in Q4/FY2022 due to internal decision-making to submit for approval of zolbetuximab

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# FY2022 FINANCIAL RESULTS: MAIN PRODUCTS



*XTANDI, PADCEV, XOSPATA showed solid growth in line with full-year forecast*

| (billion yen) | FY2022 Act | YoY | FY2022 FCST* | Achievement against FCST | |
|---|---|---|---|---|---|
| Xtandi® (enzalutamide) | 661.1 | +126.8 (+24%)<br>Excl. FX impact<br>[ +45.4 (+9%) ] | 670.0 | 99% | ✓ Global sales showed growth in line with FCST<br>✓ US: Total demand growth offset by affordability challenges including fluctuating PAP rates and generic competitor share<br>Despite the challenging environment, XTANDI continues to be the leading branded NHT across all indications<br>✓ Europe: Strong demand increase, achieved the upwardly revised FCST |
| PADCEV® enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials | 44.4 | +22.7 (+104%)<br>[ +17.2 (+79%) ] | 45.4 | 98% | ✓ Global sales expanded significantly, driven by Europe and Japan<br>✓ US: Despite steady growth in actual demand, revenue from clinical orders was below expectations, resulting in underachieving the FCST<br>✓ Europe: Launched countries increased to 21 and obtained reimbursement in 7 countries |
| XOSPATA® gilteritinib 40mg tablets | 46.6 | +12.5 (+37%)<br>[ +6.6 (+19%) ] | 45.8 | 102% | ✓ Global sales achieved FCST<br>✓ Sales expanded in all regions, performance in line with expectations<br>✓ High market share in US, Europe and Japan |
| Evrenzo® roxadustat | 3.2 | +0.6 (+23%) | 5.0 | 64% | ✓ Progress was significantly behind FCST<br>✓ Japan: Market share was lower than expected due to competitive pressure<br>✓ Europe: Launched with reimbursement in Italy in Q4 |

* Announced in Oct 2022
FCST: Full-year forecast, PAP: Patient Assistance Program, NHT: Novel Hormonal Therapy

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# FY2022 FINANCIAL RESULTS: COST ITEMS



*Cost of sales ratio was as expected*
*SG&A expenses were on track and decreased YoY when excluding FX impact*
*R&D expenses were on track*

**Core basis: YoY comparison, ratio to revenue, and achievement against FCST, for major cost items**

| Cost Items | YoY change | Ratio to Revenue | Achievement against FCST | |
|---|---|---|---|---|
| **Cost of sales** | +14.0% | 19.0% (-0.5ppt YoY) | - | ✓ Cost of sales ratio was as expected |
| **SG&A expenses** **excl. US XTANDI co-pro fee** | +11.1% (-1.3% excl. FX impact) | 29.9% (-1.6ppt YoY) | 99.7% | ✓ Optimization of commercial-related personnel globally (YoY approx. -8.0 bil. yen)<br>✓ Reduction of mature products-related costs (approx. -8.0 bil. yen)<br>✓ Investment for new product launch readiness (approx. +12.0 bil. yen)<br>✓ Cost reduction progressed as expected, actively making necessary investments<br>✓ As a result, SG&A expenses were on track |
| **R&D expenses** | +12.2% (+1.1% excl. FX impact) | 18.2% (-0.8ppt YoY) | 99.3% | ✓ Booked one-time expense for using PRV in Q1 for the application of fezolinetant (13.7 bil. yen)<br>✓ In line with full-year forecast, including the expense above |

PRV: Priority Review Voucher

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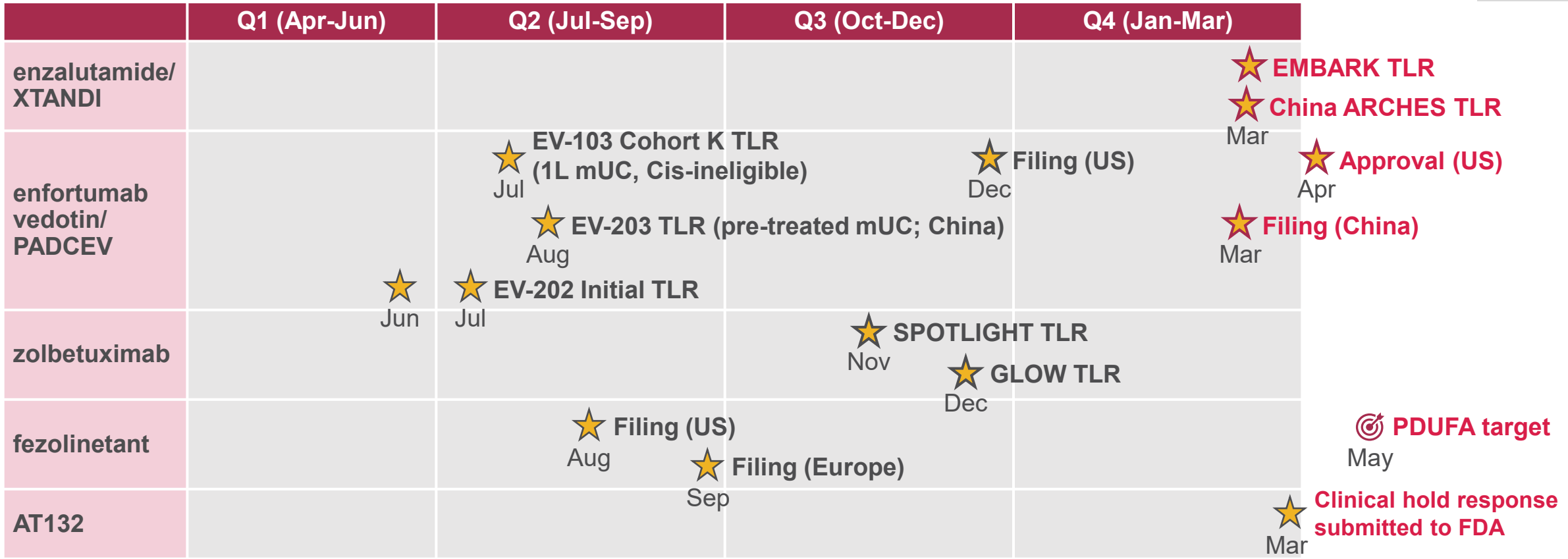
# XTANDI & STRATEGIC PRODUCTS: KEY EVENTS IN FY2022






As of Apr 2023

**<Other updates>**

- zolbetuximab: SPOTLIGHT study results published in The Lancet in Apr 2023
- fezolinetant: SKYLIGHT 1 study results published in The Lancet in Mar 2023
  TLR obtained in STARLIGHT (Japan Phase 2b) study in Mar 2023
- gilteritinib/XOSPATA: TLR obtained in MORPHO study (Post-HSCT maintenance) in Mar 2023

TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer, Cis: Cisplatin, PDUFA: Prescription Drug User Fee Act, FDA: Food and Drug Administration, HSCT: Hematopoietic stem cell transplant

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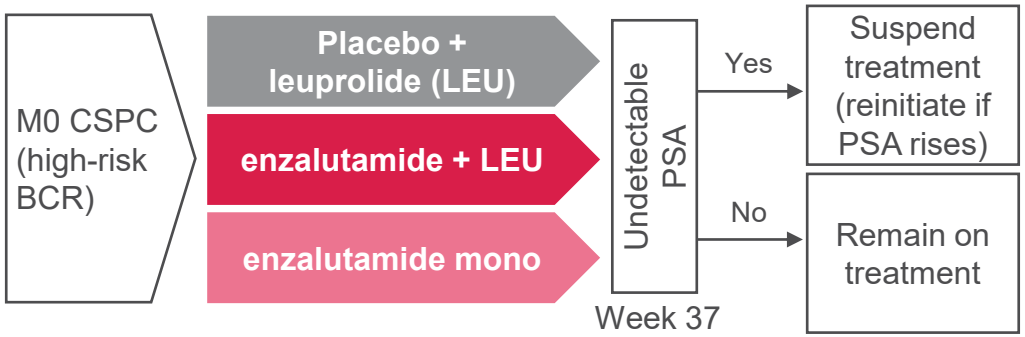
# ENZALUTAMIDE/XTANDI: LATEST STATUS



- *Aiming for regulatory submission in US as well as Europe, based on the positive topline results from EMBARK study*
- *Revised potential peak sales upward to 700 billion yen*

## EMBARK study

- Study design




- Topline results
  - ➢ Met primary endpoint of MFS (enzalutamide + LEU vs. placebo + LEU)
  - ➢ Positive trend in key secondary endpoint of OS (not yet mature)
  - ➢ Met other key secondary endpoints
    - MFS (enzalutamide mono vs. placebo + LEU)
    - Time to PSA progression
    - Time to first use of new antineoplastic therapy

## Future plan

- EMBARK data presentation: AUA 2023 on Apr 29
- Regulatory submission: targeting mid-2023 in US and 2H FY2023 in Europe

## Update of sales forecast

- Updated sales forecast by incorporating sales trend so far, M0 CSPC submission plan in Europe and FX rate trend
- Potential peak sales: over 700 billion yen*
  - ➢ Sales contribution from M0 CSPC: 40-50 billion yen

* Previous forecast: 600-700 billion yen

M0 CSPC: Non-metastatic castration-sensitive prostate cancer, BCR: Biochemical recurrence, PSA: Prostate-specific antigen, MFS: Metastasis-free survival, OS: Overall survival, AUA: American Urological Association

# PROGRESS IN FOCUS AREA APPROACH (1/2): CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

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

| Primary Focus | Biology/Modality/Technology [1] | Project | Current status | No. of projects aiming PoC by end FY25 [2] |
|---|---|---|---|---|
| Genetic Regulation | Gene replacement (AAV) | AT132 | ASPIRO study put on clinical hold by FDA in Sep 2021 | 2 |
| | | AT845 | **Activities to restart FORTIS study commenced in Feb 2023**<br>**Preliminary data from FORTIS study presented at WORLD*Symposium* in Feb 2023** | |
| | Gene regulation (AAV) | | | |
| Immuno-Oncology | Checkpoint | ASP1570 | Phase 1 study ongoing | 7 |
| | Artificial adjuvant vector cell (aAVC) | ASP7517 | **Terminated** | |
| | | ASP0739 | **Terminated** | |
| | Oncolytic virus (intratumoral) | ASP9801 | **Terminated** | |
| | Oncolytic virus (systemic) | | | |
| | Bispecific immune cell engager | ASP2138 | Phase 1 study ongoing | |
| | | ASP2074 | **FSFT in Phase 1 study in Mar 2023** | |
| | | ASP1002 | **FSFT in Phase 1 study in Mar 2023** | |
| | Cancer cell therapy (UDC) | | | |
| Blindness & Regeneration | Cell replacement | ASP7317 | Screening and enrollment in Phase 1b study restarted in Aug 2022 | 3 |
| | Cell replacement (UDC) | | | |
| | Gene regulation (AAV) | | | |
| Mitochondria | Gene regulation & mitochondrial biogenesis | ASP0367 | Phase 2/3 study in PMM ongoing<br>Phase 1b study in DMD terminated due to operational reasons | 3 |
| | Mitochondrial stress | ASP8731 | **Terminated** | |
| | Mitochondrial transfer | | | |
| Targeted Protein Degradation | Protein degradation | ASP3082 | Phase 1 study ongoing.<br>**Fast Track Designation granted by FDA in Feb 2023 (pancreatic adenocarcinoma)** | 1 |
| Primary Focus Candidate | Immune modulating/regulatory cells | | | - |
| | Tissue-specific immune regulation | | | |
| | | | **Total** | **24 → 16** |

Modality
- Small molecule
- Antibody
- Gene
- Cell
- Other

1. Not exhaustively listed.
2. Estimated based on standard development timelines, assuming 100% probability of success (as of Apr 2023). Total number indicates change from Apr 2022.

AAV: Adeno-associated virus, UDC: Universal donor cell, FDA: Food and Drug Administration, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

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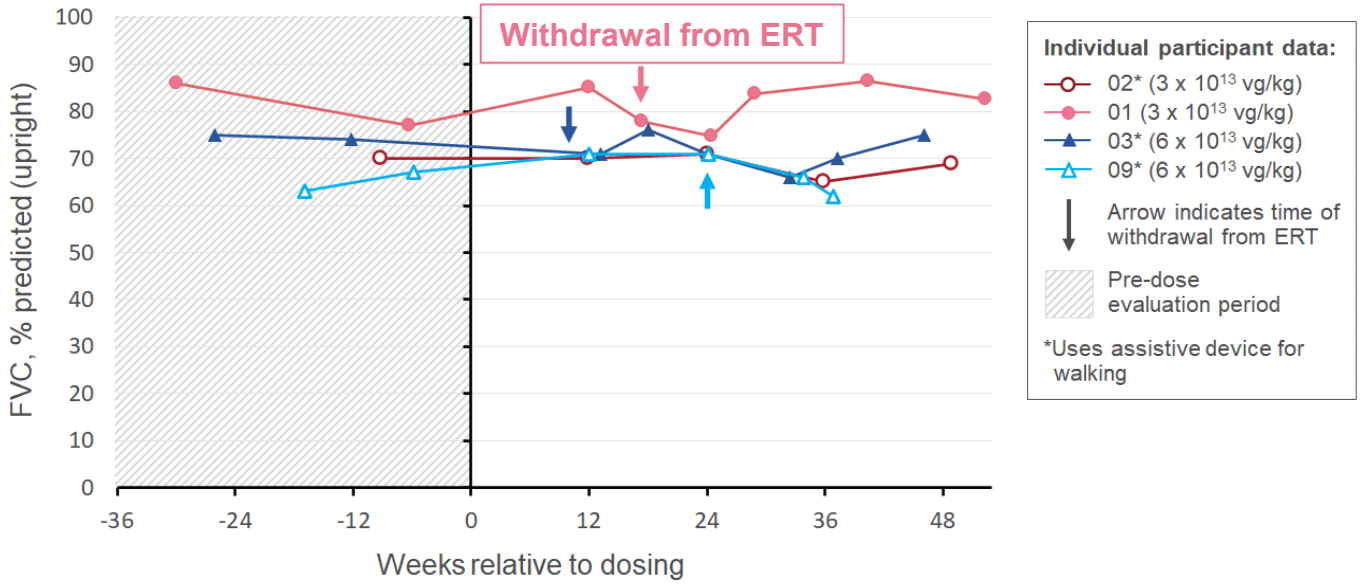
# PROGRESS IN FOCUS AREA APPROACH (2/2): AT845 PRELIMINARY DATA FROM FORTIS STUDY



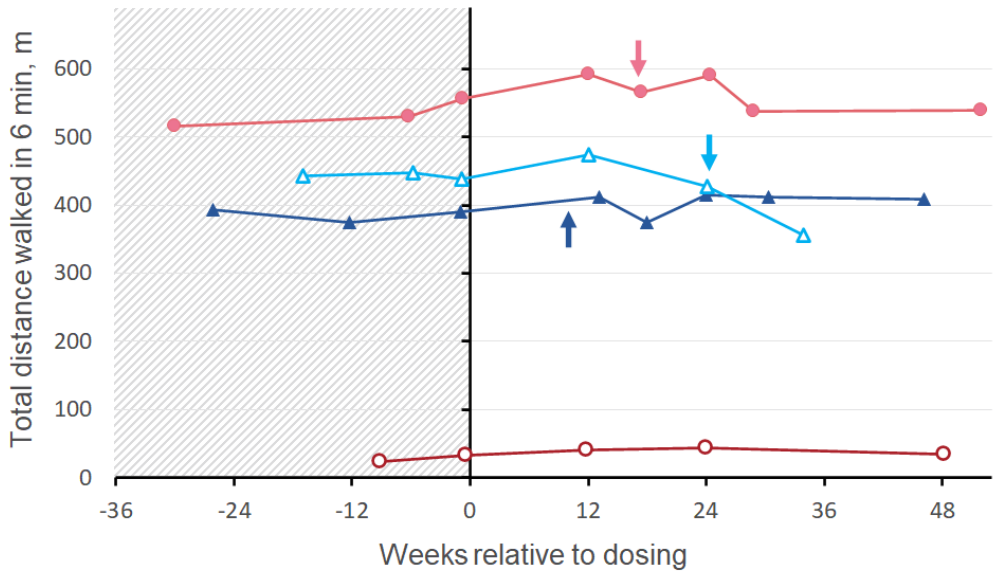
- *Three of four participants have discontinued enzyme replacement therapy (ERT)* following administration of AT845* [1]
- *Their measured functional outcomes have been stable while off ERT*

*ERT: only approved treatment for Pompe disease; a chronic treatment delivered in bi-weekly infusions

<Forced vital capacity (FVC)>




<6-minute walk test>




Note: The last two time points for Participant 09 (△) occurred after the development of peripheral polyneuropathy

- Activities to restart FORTIS study commenced in Feb 2023, with dosing anticipated to resume in Q2 FY2023

1. As of Sep 15, 2022

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# PROGRESS IN Rx+ PROGRAM: SUMMARY OF FY2022

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



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

| Category | Program | Event | Progress |
|---|---|---|---|
| Digital health<br>Other services | EG Holter | Initiation of pilot marketing | Jun 2022: Initiated sales pilot |
| Digital therapeutics | BlueStar | Initiation of clinical study (Japan) | Jan 2023: Partnership agreement with Roche Diabetes Care Japan, aiming for approval as a combined medical product with a blood glucose monitoring system<br>Initiation of clinical study in Japan planned in FY2023 |
| Drug-device combination | pudexacianinium chloride (ASP5354) | FSFT in Phase 3 study | Jan 2023: Collaboration on exclusive commercialization in US with Stryker, a medical device company with strengths in surgical visualization technology<br>Preparation to initiate Phase 3 trials in FY2023 |

FSFT: First subject first treatment

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# FY2023 FORECAST: OVERVIEW



- *Revenue to be the same level as previous fiscal year*
  *Sales contributions of fezolinetant and PADCEV offsetting decrease in sales of Lexiscan*
  - ✓ *SG&A expenses to increase YoY mainly due to investment in fezolinetant and zolbetuximab*
  - ✓ *Implementation of continued pursuit of operational excellence to achieve Core OP margin of 30% in FY2025*
  - ✓ *R&D expenses to decrease YoY due to decrease in development costs for Strategic products while continued investment to be made in Primary Focus*
- *As a result, Core OP to be the same level as previous fiscal year*
- *In anticipation of our growth from FY2024 onwards, dividend per share is forecasted at 70 yen, an increase of 10 yen*

# FY2023 FORECAST



| (billion yen) | FY2022 actual | FY2023 forecast | Change (%) |
|---|---|---|---|
| **Revenue** | **1,518.6** | **1,520.0** | **+0.1%** |
| SG&A expenses | 630.3 | 661.0 | +4.9% |
| US XTANDI co-pro fee | 175.5 | 176.0 | +0.3% |
| SG&A excl. the above | 454.8 | 485.0 | +6.6% |
| R&D expenses | 276.1 | 251.0 | -9.1% |
| **Core operating profit** | **286.9** | **290.0** | **+1.1%** |
| **<Full basis>** | | | |
| **Operating profit** | **133.0** | **288.0** | **+116.5%** |
| **Profit** | **98.7** | **227.0** | **+130.0%** |

FY2023 FCST (FX rate)
USD: 130 yen
EUR: 140 yen

FX impact: -40.8 bil. yen

FX impact: -8.7 bil. yen

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# FY2023 FORECAST: MAIN PRODUCTS



*Expect continued growth led by PADCEV, with sales contribution from fezolinetant*

| (billion yen) | FY2023 FCST | YoY | Main growth factors |
|---|---|---|---|
| Xtandi® (enzalutamide) | 669.9 | **+8.8 (+1%)**<br>Excl. FX impact*<br>[ +30.7 (+5%) ] | ✓ US: Expect continued growth within the current indication; and potential approval of M0 CSPC additional indication by the end of FY2023<br>✓ Japan: Expect sales growth driven by M1 CSPC<br>✓ China: Reimbursement for M0 CRPC additional indication started in Mar 2023 |
| PADCEV® enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials | 66.7 | **+22.3 (+50%)**<br>[ +23.5 (+54%) ] | ✓ US: Expect substantial growth driven by the additional indication of 1L mUC<br>✓ Europe: Expect increases in countries with reimbursement<br>✓ Japan: Expect continued growth within the current indication |
| XOSPATA® gilteritinib 40mg tablets | 49.3 | **+2.7 (+6%)**<br>[ +4.3 (+10%) ] | ✓ US and Europe: Expect continued growth in the large markets<br>✓ International Markets: Expect sales to expand from the increase of launched countries and reimbursement start |

- fezolinetant: Factored into FY2023 forecast (40-50 billion yen), detailed guidance will be provided after approval

Regional forecasts for XTANDI and PADCEV are on slides 31-32, * Aligning the exchange rate to FY2023 forecast exchange rate
M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer 1L: First Line, mUC: Metastatic urothelial cancer,
International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc

# FY2023 FORECAST: COST ITEMS



*Allocate limited resources in a disciplined manner to drive sustainable growth from FY2024 onwards*

**FY2024 and beyond**
**Accelerating future growth,**
**Optimize cost structure**

Main factors for increase/decrease (YoY)

**SG&A expenses**
**(excl. US XTANDI co-pro fee)**
485.0 billion yen (+30.2 billion yen YoY)
Ratio to revenue: 31.9%

- Investments in fezolinetant and zolbetuximab (approx. +50.0 bil. yen)
- Reduction of mature products-related costs (approx. -8.0 bil. yen)

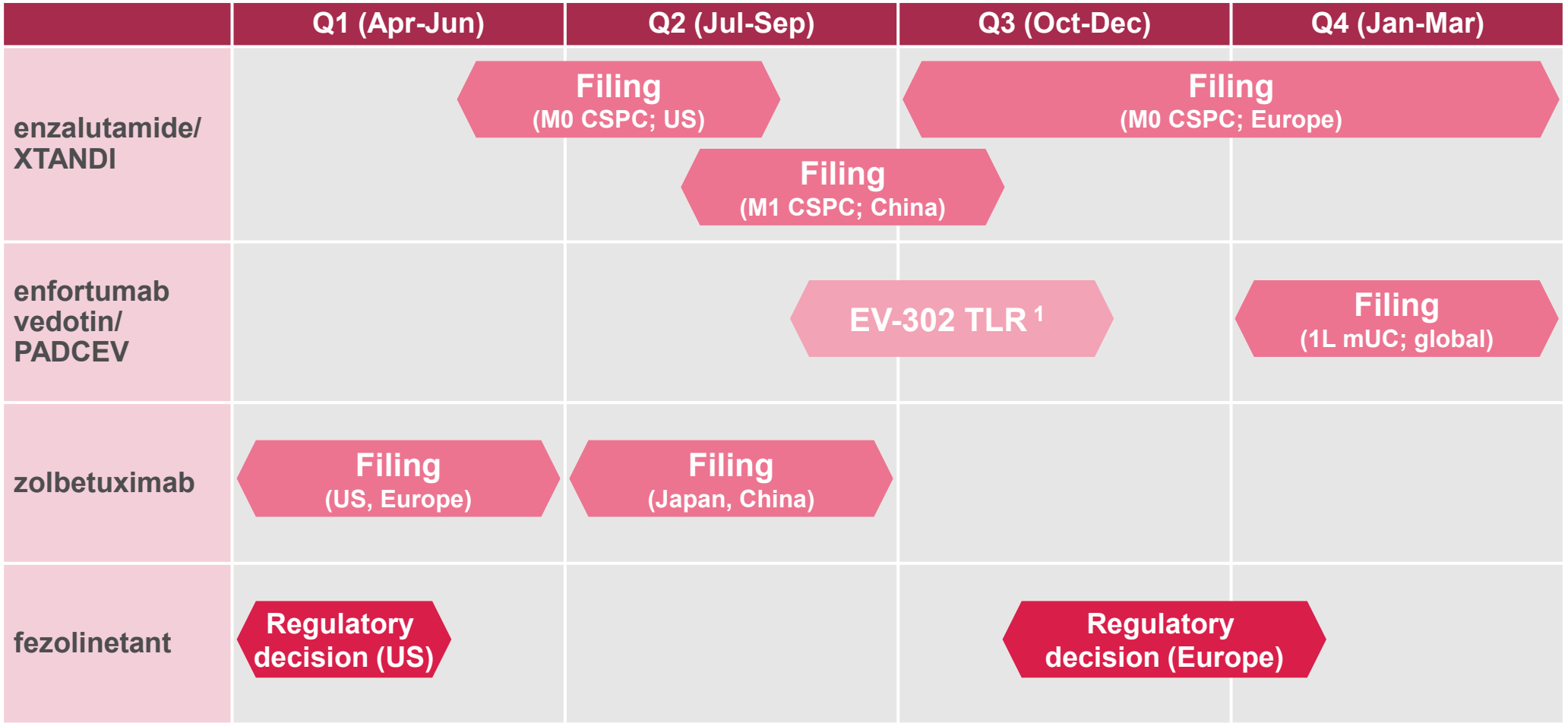
Continued pursuit of operational excellence

**R&D expenses**
251.0 billion yen (-25.1 billion yen YoY)
Ratio to revenue: 16.5%

- Increase in Primary Focus-related costs (approx. +8.0 bil. yen)
- One-time expense for PRV in FY22 (-13.7 bil. yen)
- Decrease in development costs for Strategic products (approx. -6.0 bil. yen)

# XTANDI & STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2023






As of Apr 2023

1. The timeline of TLR is subject to shift due to its event-driven nature.
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, M1: Metastatic, TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer

# FOCUS AREA APPROACH: KEY EVENTS EXPECTED IN FY2023



*Expecting Phase 1 entry in 4 projects and several progress in Phase 1 studies toward PoC judgment*

| Primary Focus | IND | Phase 1 | |
|---|---|---|---|
| | | Early data readout [1] | Dosing resumption |
| Genetic Regulation | 1 project | | AT845 |
| Immuno-Oncology | 2 projects | ASP1570<br>ASP2138 | |
| Blindness & Regeneration | | | ASP7317 |
| Targeted Protein Degradation | 1 project (pan-KRAS) | ASP3082 | |

1. Dose escalation/monotherapy

PoC: Proof of concept, IND: Investigational New Drug

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# NEW R&D OPERATING MODEL



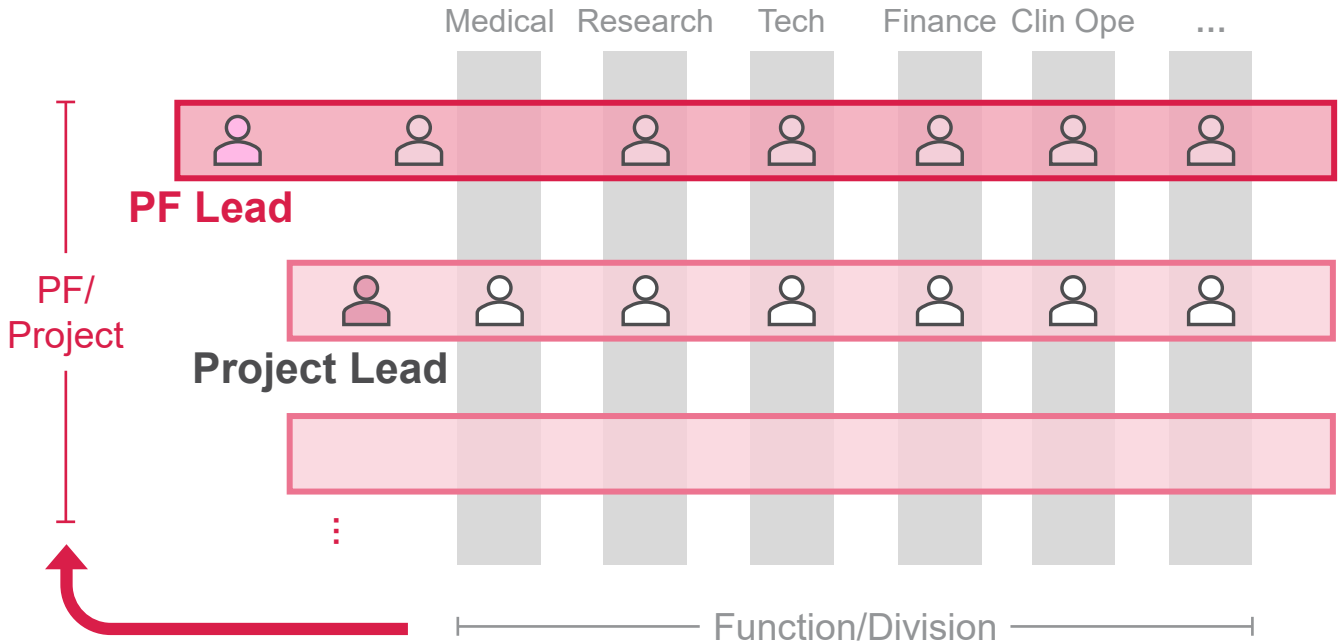
*To achieve meaningful PoC as early as possible, enable agile decision making by empowering projects and Primary Focuses throughout the project lifecycle*

**Kachi Committee**

- Cross-Primary Focus (PF) / cross-project prioritization
- Decision making focusing on key development milestones

Chaired by CXOs

Empower projects and PFs




**PF Leadership Team**

- PF strategy development & execution
- Budget management in place of divisions

**Project Team**

- Project strategy development & execution
- Day-to-day decisions within project

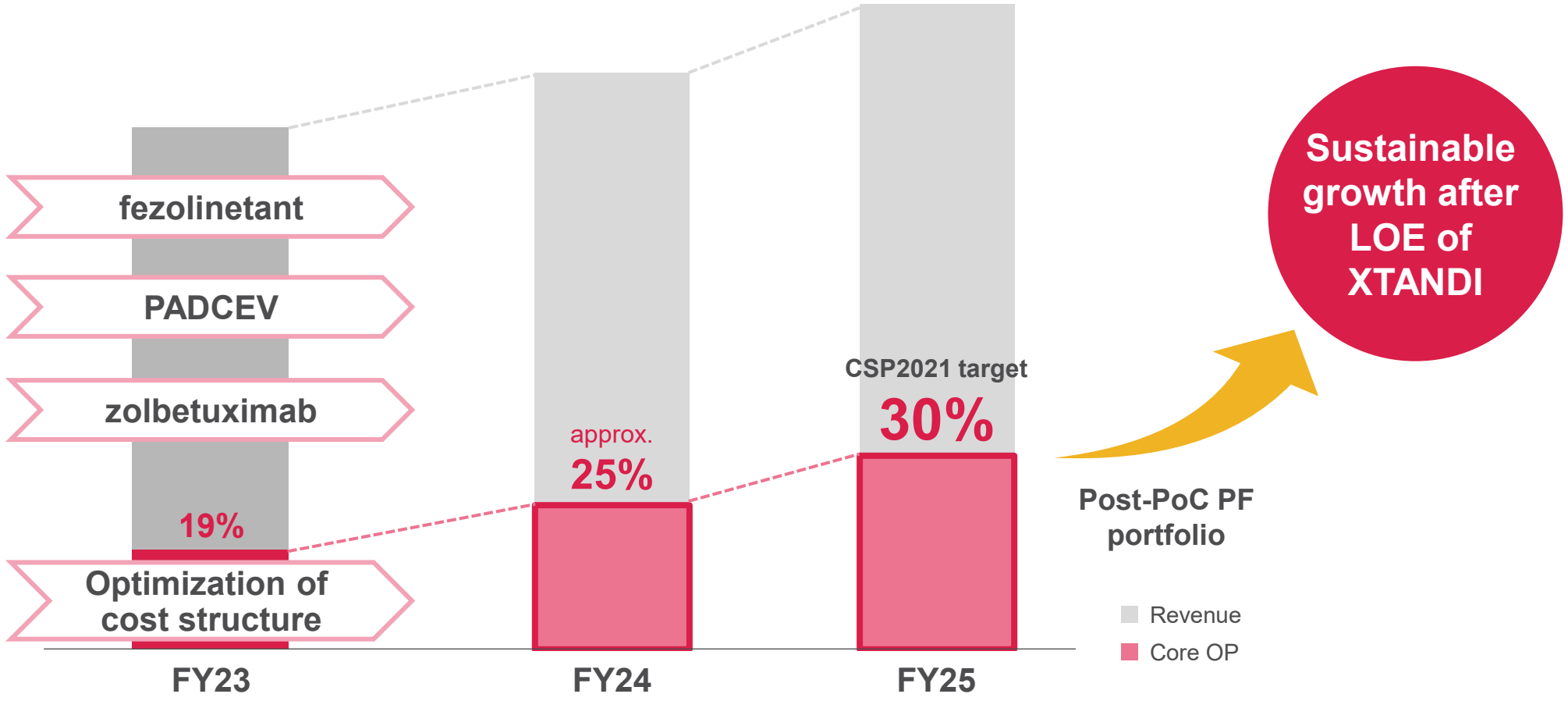
Agile decision making

PoC: Proof of concept

# TOWARD ACHIEVEMENT OF CSP2021



- *Continue commitment to CSP2021*
- *FY2023 is the turning point to ensure growth from FY2024 onwards*




CSP: Corporate Strategic Plan, PoC: Proof of concept, PF: Primary Focus, LOE: Loss of exclusivity

**fezolinetant Meeting**

- To be held after approval
  (Details will be delivered later)

# APPENDIX

# CHANGE EXCHANGE RATES USED FOR ELIMINATION OF UNREALIZED PROFIT ON INVENTORIES（PRO FORMA FIGURES）



- Pro forma figures when calculating the cost of sales at exchange rate after the change (average rate) is as shown in red font in the table below

| (billion yen) | Quarterly | | | | | | | | Year to Date | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Q1/FY21 | Q2/FY21 | Q3/FY21 | Q4/FY21 | Q1/FY22 | Q2/FY22 | Q3/FY22 | Q4/FY22 | FY21 | FY22 | Change (%) |
| **Revenue** | **326.1** | **325.5** | **340.6** | **303.9** | **381.8** | **380.4** | **402.2** | **354.3** | **1,296.2** | **1,518.6** | **+17.2%** |
| Cost of sales | 61.0 | 63.2 | 66.6 | 54.5 | 76.1 | 75.5 | 74.4 | 62.3 | 245.2 | 288.4 | +17.6% |
| % of revenue | 18.7% | 19.4% | 19.6% | 17.9% | 19.9% | 19.9% | 18.5% | 17.6% | 18.9% | 19.0% | +0.0ppt |
| SG&A expenses | 137.1 | 133.4 | 135.9 | 142.4 | 153.4 | 154.6 | 163.0 | 159.3 | 548.8 | 630.3 | +14.8% |
| US XTANDI co-pro fee | 34.5 | 36.6 | 37.6 | 30.6 | 43.1 | 46.5 | 48.6 | 37.3 | 139.3 | 175.5 | +26.0% |
| SG&A excl. the above | 102.6 | 96.8 | 98.3 | 111.8 | 110.3 | 108.0 | 114.4 | 122.0 | 409.5 | 454.8 | +11.1% |
| R&D expenses | 58.3 | 60.7 | 58.6 | 68.4 | 74.0 | 65.2 | 66.9 | 70.1 | 246.0 | 276.1 | +12.2% |
| Amortisation of intangible assets | 6.0 | 6.4 | 7.9 | 8.0 | 10.7 | 9.2 | 9.2 | 9.3 | 28.3 | 38.4 | +35.9% |
| Gain on divestiture of intangible assets | - | - | 24.1 | 0.1 | 0.2 | 0.0 | 0.0 | 0.0 | 24.2 | 0.2 | -99.1% |
| **Core operating profit** | **64.1** | **61.8** | **97.5** | **29.2** | **68.1** | **77.3** | **88.3** | **53.2** | **252.5** | **286.9** | **+13.6%** |
| **(Ref) Impact on Core OP*1** | **+1.2** | **-0.7** | **+2.8** | **+4.5** | **+12.8*2** | **-12.8** | **-** | **-** | **+7.8** | **-** | **-** |

*1: Impact on Core OP when this change is applied
*2: The impact of elimination of unrealized profit, which was disclosed as 13.3 billion yen in Q1/FY22 financial results, was 12.8 billion yen after careful examination

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# FY2022: REVENUE BY REGION



| (billion yen) | FY2021 | FY2022 | Change (%) |
|---|---|---|---|
| Japan | 258.8 | 262.3 | +1.4% |
| United States | 537.5 | 652.4 | +21.4% |
| Established Markets | 306.5 | 358.4 | +16.9% |
| Greater China | 66.3 | 80.0 | +20.7% |
| International Markets | 118.7 | 144.7 | +21.9% |

Established Markets: Europe, Canada  Greater China: China, Hong Kong, Taiwan
International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc.
Commercial segment of Australia was changed from Established Markets to International Markets in FY2022. Disclosed numbers reflect this change

# FY2022: SALES OF MAIN PRODUCTS



| (billion yen) | FY2021 | FY2022 | Change | CER growth | FY2022 FCST* |
|---|---|---|---|---|---|
| XTANDI | 534.3 | 661.1 | +23.7% | +8.5% | 670.0 |
| PADCEV | 21.7 | 44.4 | +104.4% | +79.2% | 45.4 |
| XOSPATA | 34.1 | 46.6 | +36.7% | +19.3% | 45.8 |
| EVRENZO | 2.6 | 3.2 | +23.0% | +20.8% | 5.0 |
| mirabegron | 172.3 | 188.6 | +9.5% | -3.4% | 195.0 |
| Prograf | 185.4 | 198.8 | +7.2% | -1.7% | 200.3 |

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

* Announced in Oct 2022

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# FY2022 ACTUAL: FX RATE



**Average rate for the period**

| Currency | FY2021 | FY2022 | Change |
|---|---|---|---|
| USD | 112 yen | 135 yen | -23 yen |
| EUR | 131 yen | 141 yen | -10 yen |

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

| Currency | FY2021 | FY2022 |
|---|---|---|
| USD | -11 yen | -11 yen |
| EUR | -5 yen | -9 yen |

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

- 164.4 billion yen increase in revenue, 40.1 billion yen increase in core OP

# FY2023 FORECAST: FX RATE & FX SENSITIVITY



| Exchange rate<br>Average for the period | FY2022 | FY2023 FCST | Change |
|---|---|---|---|
| USD | 135 yen | 130 yen | +5 yen |
| EUR | 141 yen | 140 yen | +1 yen |

**Estimated FX sensitivity of FY2023 forecasts by 1 yen appreciation**

| Currency | Average rate<br>1 yen higher than assumption | |
|---|---|---|
| | Revenue | Core OP |
| USD | Approx. -6.6 bil. yen | Approx. -2.8 bil. yen |
| EUR | Approx. -1.1 bil. yen | Approx. -1.2 bil. yen |

# FY2023 FORECAST: XTANDI (REGION)



| (billion yen) | FY2023 FCST | YoY | Main growth factors |
|---|---|---|---|
| Xtandi® (enzalutamide) | **669.9** | **+8.8 (+1%)**<br>Excl. FX impact*<br>(+30.7 (+5%)) | ✓ Expect continued growth globally in actual business excluding FX impact<br>✓ Expect sales growth in all regions |
| **US (Unit: $)** | $2,635M | +112 (+4%) | ✓ Despite the challenging conditions of PAP and generic competitor, expect continued growth within the current indication with a mid-single-digit growth in demand<br>✓ Expect approval of future growth driver M0 CSPC additional indication by the end of FY2023 |
| **Established Markets (Unit: €)** | €1,419M | +14 (+1%) | ✓ Expect mid-single-digit growth in demand driven by the growth of M1 CSPC indication<br>✓ On the other hand, expect negative impact from increased competitive and pricing pressure |
| **Japan** | 58.2 | +3.5 (+6%) | ✓ Expect sales to expand mainly driven by the growth of M1 CSPC indication, despite anticipated impact of increased competitive pressure |
| **Greater China** | 14.5 | +3.4 (+31%) | ✓ Reimbursement for M0 CRPC additional indication started in Mar 2023, expect sales contribution |
| **International Markets** | 55.9 | +0.3 (+0%) | ✓ Expect double-digit growth excluding FX impact from the increase in countries with approval and reimbursement start for the additional indication of M1 CSPC |

* Aligning the exchange rate to FY2023 forecast exchange rate
M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, Established Markets: Europe, Canada, Greater China: China, Hong Kong, Taiwan, International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc

# FY2023 FORECAST: PADCEV (REGION)



| (billion yen) | FY2023 FCST | YoY | Main growth factors |
|---|---|---|---|
| PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials | 66.7 | +22.3 (+50%)<br>Excl. FX impact*<br>[ +23.5 (+54%) ] | ✓ Expect strong growth, driven by the contribution of 1L mUC indication in the US<br>✓ Sales growth in all regions |
| **US (Unit: $)** | $341M | +126 (+59%) | ✓ Obtained approval for 1L mUC additional indication in Apr 2023, Expect significant contribution as a growth driver |
| **Established Markets (Unit: €)** | €82M | +34 (+70%) | ✓ Anticipate obtaining reimbursement in large markets such as Germany, France, Italy and Spain |
| **Japan** | 9.9 | +1.5 (+18%) | ✓ Expect continued growth within the current indication |
| **International Markets** | 0.9 | +0.8 (+887%) | ✓ Expect sales contribution from the increase of launched countries and reimbursement start |

* Aligning the exchange rate to FY2023 forecast exchange rate, 1L: First Line, mUC: Metastatic urothelial cancer
Established Markets: Europe, Canada, Greater China: China, Hong Kong, Taiwan,
International Markets: Russia, Latin America, Middle East, Africa, Southeast Asia, South Asia, Korea, Australia, Export sales, etc.

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# BALANCE SHEET & CASH FLOW HIGHLIGHTS



| (billion yen) | FY2021 end | FY2022 end |
|---|---|---|
| Total assets | 2,332.4 | 2,456.5 |
| Cash and cash equivalents | 316.0 | 376.8 |
| Total equity attributable to owners of the parent | 1,460.3 | 1,508.0 |
| Equity ratio (%) | 62.6% | 61.4% |

| (billion yen) | FY2021 | FY2022 |
|---|---|---|
| Cash flows from operating activities | 257.4 | 327.8 |
| Cash flows from investing activities | -62.4 | -84.5 |
| Free cash flows | 195.0 | 243.3 |
| Cash flows from financing activities | -216.3 | -195.6 |
| Increase/decrease in short-term borrowings and CP | -30.0 | -15.0 |
| Proceeds from issuance of bonds and long-term borrowings | - | 50.0 |
| Redemption of bonds and repayments of long-term borrowings | -30.0 | -50.0 |
| Acquisition of treasury shares | -50.7 | -60.6 |
| Dividends paid | -85.2 | -100.4 |

Balance of bonds (Incl. CP) and borrowings : 125.0 billion yen

CP: Commercial Paper

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# CAPITAL ALLOCATION

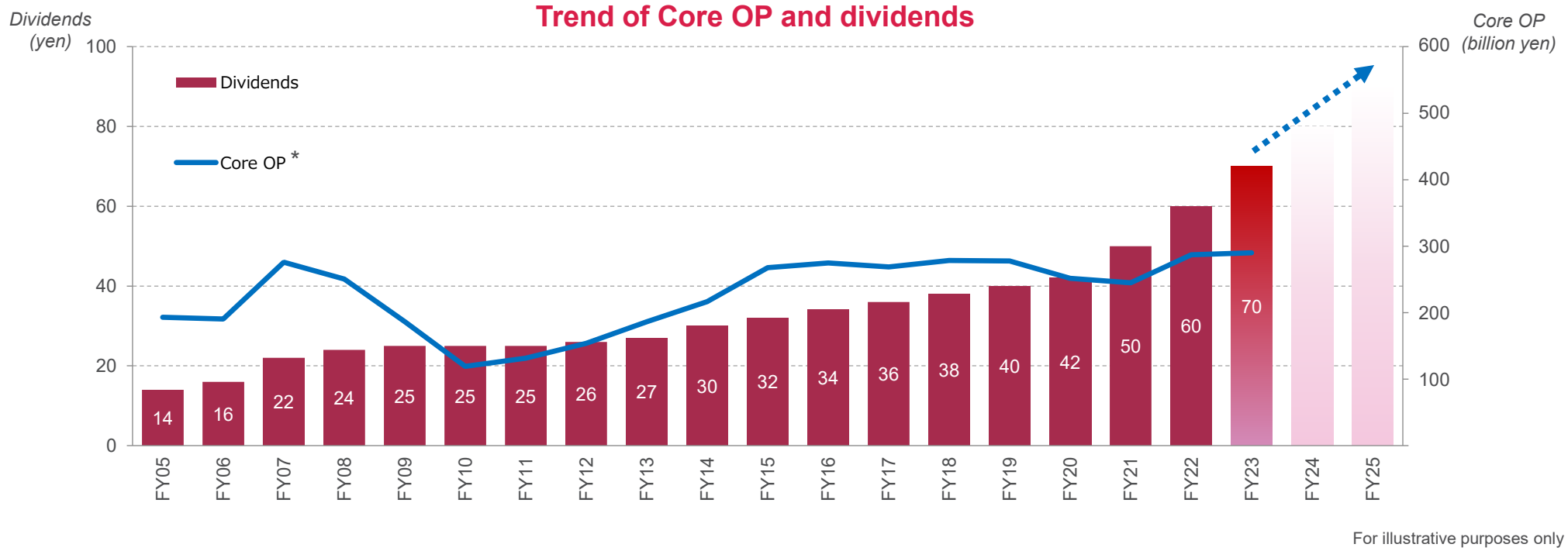


1. Top priority is investment for business growth
2. Raise dividend level aligned with profit / cashflow plan and actual performance throughout CSP2021 period
3. Flexibly execute share buyback by excess cash

**Acquisition of own shares announced in Feb. 2023**

- From Feb 7 to Mar 15, 2023
- 26.18 million shares
- 50.0 billion yen

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




For illustrative purposes only

* 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)
- ASP1570
- ASP2138
- ASP2074
- ASP1002
- ASP7317
- bocidelpar/ASP0367 (Duchenne muscular dystrophy)
- AT845
- ASP3082
- ASP0598
- ASP8062

## Phase 2

- enfortumab vedotin (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- fezolinetant (VMS due to menopause: Japan)
- resamirigene bilparvovec /AT132 (XLMTM)
- bocidelpar/ASP0367 (Primary mitochondrial myopathies)
- isavuconazole (Pediatric use: US)

## Phase 3

- enzalutamide (M0 CSPC, M1 CSPC: China)
- enfortumab vedotin (mUC previously untreated, MIBC)
- gilteritinib (Earlier-stage AML, pediatric use)
- zolbetuximab (Gastric and GEJ adenocarcinoma)
- fezolinetant (VMS due to menopause: China)
- mirabegron (Pediatric use: Europe)

## Submitted/Filed

- enfortumab vedotin (mUC pretreated: China)
- fezolinetant (VMS due to menopause: US, Europe)
- peficitinib (Rheumatoid arthritis: China)

XTANDI and Strategic products

Projects with Focus Area approach

Others

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, XLMTM: X-linked myotubular myopathy, 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

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# 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 |
|---|---|---|---|---|
| | | | **enfortumab vedotin** Locally advanced or metastatic urothelial cancer who received prior treatment with a PD-1/L1 inhibitor and platinum-based chemotherapy: China | **enfortumab vedotin** Locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy: US |

**Discontinuation**

**ASP9801:** Cancer (Phase 1)
**ASP7517:** Acute myeloid leukemia and myelodysplastic syndrome (Phase 2), solid tumor (Phase 1)
**ASP0739:** Cancer (Phase 1)
**ASP8731:** Sickle cell disease (Phase 1)
**FX-322:** Sensorineural hearing loss (Phase 2)

Note: Phase 1 entry is defined as confirmation of IND open.
Phase transition is defined by approval of company decision body for entering to next clinical phase.
Filing is defined as submission of application to health authorities.
Discontinuation is defined by the decision of company decision body.

IND: Investigational New Drug

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# XTANDI & STRATEGIC PRODUCTS: STATUS UPDATE

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

| Project / Product | Indication | Current status |
|---|---|---|
| **enzalutamide / XTANDI** | M1 CSPC | • **Europe: Label update to include the OS data approved in Mar 2023**<br>• **China: Obtained topline results from Phase 3 China ARCHES study in Mar 2023** |
| | M0 CSPC | • **Obtained topline results from Phase 3 EMBARK study in Mar 2023. Results to be presented at AUA in Apr 2023** |
| **enfortumab vedotin / PADCEV** | Metastatic urothelial cancer | • **Previously untreated (first line):** Phase 3 study ongoing (enrollment completed). **sBLA approved (accelerated approval) in US in Apr 2023 (cisplatin-ineligible)**<br>• **Pretreated: BLA accepted in China in Mar 2023** |
| | Muscle-invasive bladder cancer | • Phase 3 studies ongoing |
| | Non-muscle-invasive bladder cancer | • Phase 1 study ongoing |
| | Other solid tumors | • Phase 2 study ongoing (enrollment completed) |
| **gilteritinib / XOSPATA** | Relapsed and refractory AML | • **China:** Phase 3 study stopped due to efficacy |
| | AML, post-HSCT maintenance | • **Obtained topline results from Phase 3 MORPHO study in Mar 2023** |
| | AML, newly diagnosed (HIC-eligible) | • Phase 3 study ongoing |
| | AML, newly diagnosed (HIC-ineligible) | • Phase 1 study ongoing |
| | AML, post-chemotherapy | • Obtained topline results from Phase 2 GOSSAMER study |
| **zolbetuximab** | Gastric & GEJ adenocarcinoma | • Obtained topline results from Phase 3 SPOTLIGHT and GLOW studies in Nov 2022 and Dec 2022, respectively. **Results from GLOW study presented at ASCO Plenary Series in Mar 2023. Results from SPOTLIGHT study published in The Lancet in Apr 2023** |
| | Pancreatic adenocarcinoma | • Phase 2 study ongoing |
| **fezolinetant** | VMS due to menopause | • **US & Europe**: NDA accepted in US in Aug 2022. MAA accepted in Europe in Sep 2022. Phase 3b DAYLIGHT study ongoing (enrollment completed). **Results from Phase 3 SKYLIGHT 1 study published in The Lancet in Mar 2023**<br>• **Asia:** LSLV in Phase 3 MOONLIGHT 1 study in Apr 2022. Obtained topline results from Phase 3 MOONLIGHT 3 study in Sep 2022<br>• **Japan: Obtained topline results from Phase 2b STARLIGHT study in Mar 2023** |
| **AT132 (resamirigene bilparvovec)** | X-linked myotubular myopathy | • ASPIRO study put on clinical hold by FDA due to a serious adverse event |

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, OS: Overall survival, AUA: American Urological Association, (s)BLA: (Supplemental) Biologics License Application, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, GEJ: Gastroesophageal junction, ASCO: American Society of Clinical Oncology, VMS: Vasomotor symptoms, NDA: New Drug Application, MAA: Marketing Authorization Application, LSLV: Last subject last visit, FDA: Food and Drug Administration

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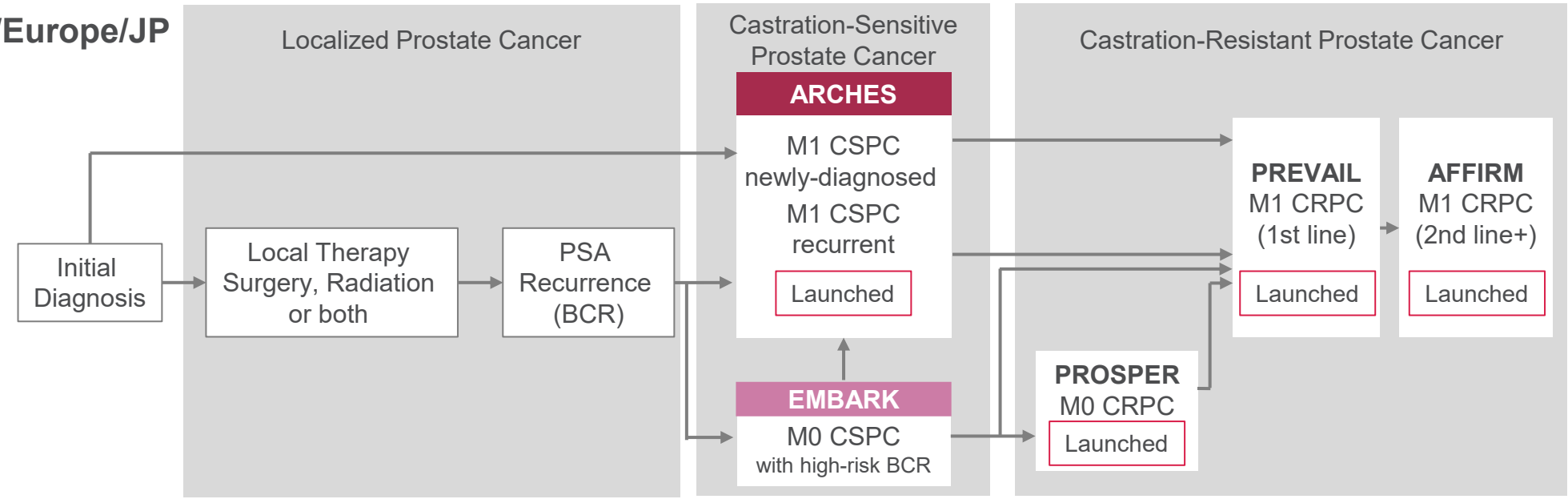
# ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

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






| | | | | | |
|---|---|---|---|---|---|
| **P3: ARCHES** | NCT02677896 | **M1 CSPC** | ENZA + ADT vs. placebo + ADT | n=1,150 | Approved in US in Dec 2019, in JP in May 2020, and in Europe in Apr 2021<br>Label update to include the OS data approved in US in Sep 2022, CHMP positive opinion received in Mar 2022 and **approved in Europe in Mar 2023** |
| **P3: EMBARK** | NCT02319837 | **M0 CSPC** | ENZA + ADT vs. placebo + ADT vs. ENZA mono | n=1,068 | **Topline results obtained in Mar 2023** |

**China**

- **M1 CSPC: Topline results obtained in Mar 2023** in Phase 3 China ARCHES study (NCT04076059)

BCR: Biochemical recurrence, M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ENZA: enzalutamide, ADT: Androgen deprivation therapy, OS: Overall survival, CHMP: Committee for Medicinal Products for Human Use, mono: Monotherapy

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

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

*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 | ✓ 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) | ✓ HR 0.66 | ✓ HR 0.67 | ✓ HR 0.73 | ✓ HR 0.77 | ✓ HR 0.63 |
| DoT | (Ongoing) | ✓ 40.2 months | ✓ 29.5 months | ✓ 33.9 months | ✓ 17.5 months | ✓ 8.3 months |

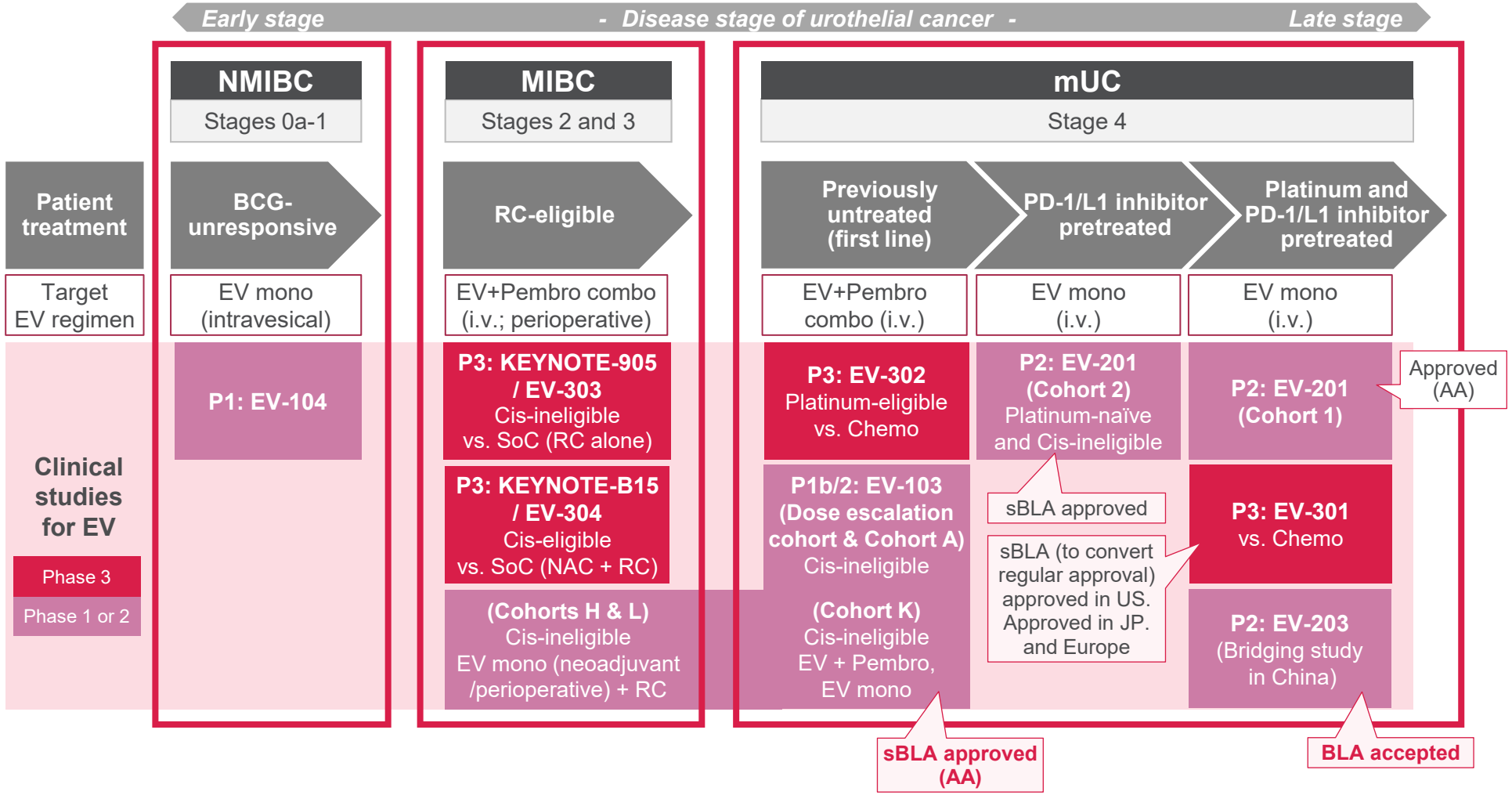
✓: Data obtained, *: Prespecified interim analysis

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

# ENFORTUMAB VEDOTIN (EV) (1/4): NECTIN-4 TARGETED ADC OVERALL UC PROGRAM

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






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, i.v.: Intravenous, Cis: Cisplatin, SoC; Standard of care, NAC: Neoadjuvant chemotherapy, Chemo: Chemotherapy, sBLA: Supplemental Biologics License Application, AA: Accelerated Approval

# ENFORTUMAB VEDOTIN (EV) (2/4): CLINICAL STUDIES

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



## For urothelial cancer

| | | | | | |
|---|---|---|---|---|---|
| **P3: EV-301** | NCT03474107 | mUC, Platinum and PD-1/L1 inhibitor pretreated;<br>EV mono vs. Chemo | n=608 | sBLA (to convert regular approval) approved in US in Jul 2021.<br>Approved in JP in Sep 2021, in Europe in Apr 2022 |
| **P3: EV-302** | NCT04223856 | mUC, Previously untreated, Platinum-eligible;<br>EV + Pembro vs. Chemo | n=990 | Enrollment completed |
| **P3: EV-303 /KEYNOTE-905** | NCT03924895 | MIBC, Cis-ineligible;<br>Pembro +/- EV (perioperative) + RC vs. RC alone | n=857 | FSFT in Pembro + EV arm: Dec 2020 |
| **P3: EV-304 /KEYNOTE-B15** | NCT04700124 | MIBC, Cis-eligible; EV + Pembro (perioperative) + RC<br>vs. Chemo (neoadjuvant) + RC | n=784 | FSFT: May 2021 |
| **P2: EV-201** | NCT03219333 | 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)<br>Cohort 2: sBLA approved in US in Jul 2021 |
| **P1b/2: EV-103** | NCT03288545 | Cohorts A - G and K (mUC):<br>A-G: Combo with Pembro and other chemo<br>K: EV mono, 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=348 | Dose Escalation/Cohort A and Cohort K: **sBLA approved (accelerated approval) in US in Apr 2023**<br>Enrollment completed |
| **P2: EV-203** | NCT04995419 | <Bridging study in China><br>mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono | n=40 | **BLA accepted in China in Mar 2023** |
| **P1: EV-104** | NCT05014139 | NMIBC, High-risk BCG-unresponsive; Intravesical EV mono | n=58 | FSFT: Jan 2022 |

## For other solid tumors

| | | | | |
|---|---|---|---|---|
| **P2: EV-202** | NCT04225117 | HR+/HER2- breast cancer, Triple-negative breast cancer,<br>Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer,<br>Gastric adenocarcinoma or esophageal adenocarcinoma or GEJ<br>adenocarcinoma, Esophageal squamous cell carcinoma; EV mono | n=280 | Enrollment completed<br>Initial topline results obtained in Jun 2022 |

mUC: Metastatic urothelial cancer, mono: Monotherapy, Chemo: Chemotherapy, sBLA: Supplemental Biologics License Application, Pembro: Pembrolizumab, FSFT: First subject first treatment, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, RC: Radical cystectomy, NMIBC: Non-muscle-invasive bladder cancer, BCG: Bacillus Calmette-Guerin, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer, GEJ: Gastroesophageal junction

# ENFORTUMAB VEDOTIN (EV) (3/4): STUDY DATA BY DISEASE STAGE OF UC



| 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 & 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 | 784 (2 arms) | 857 (3 arms) | 990 (2 arms) | 76 | 73 | 45 | 89 | 125 | 608 (2 arms) |
| EV regimen | Combo w/ Pembro (perioperative) | Combo w/ Pembro (perioperative) | Combo w/ Pembro | Combo w/ Pembro | Mono | Combo w/ Pembro | Mono | Mono | Mono |
| Control | Chemo (neoadjuvant) | SoC | Chemo | n/a | n/a | n/a | n/a | n/a | Chemo |
| Primary endpoint | pCR & EFS | pCR & EFS | PFS & OS | ✓ ORR 64% (CR 11%) | ✓ ORR 45% (CR 4%) | ✓ ORR 73% ** (CR 16% **) | ✓ ORR 51% ** (CR 22% **) | ✓ ORR 44% (CR 12%) | ✓ OS HR 0.70 * |
| OS | (Ongoing) | (Ongoing) | (Ongoing) | (Ongoing) | (Ongoing) | ✓ (26.1 mos **) | ✓ (14.7 mos) | ✓ (12.4 mos **) | ✓ HR 0.70 * (12.9 mos vs.9.0 mos) |
| PFS | (Ongoing) | (Ongoing) | (Ongoing) | (Ongoing) | (Ongoing) | ✓ (12.3 mos **) | ✓ (5.8 mos) | ✓ (5.8 mos) | ✓ HR 0.62 * (5.6 mos vs.3.7 mos) |
| ORR | (Ongoing) | (Ongoing) | (Ongoing) | ✓ 64% (CR 11%) | ✓ 45% (CR 4%) | ✓ 73% ** (CR 16% **) | ✓ 52% (CR 20%) | ✓ 44% (CR 12%) | ✓ 41% vs.18% * (CR 4.9% vs.2.7%) |
| DoR | (Ongoing) | (Ongoing) | (Ongoing) | (Ongoing) | ✓ 13.2 mos | ✓ 25.6 mos ** | ✓ 13.8 mos ** | ✓ 7.6 mos | ✓ 7.4 mos vs. 8.1 mos * |

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

(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer, cis: Cisplatin, 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

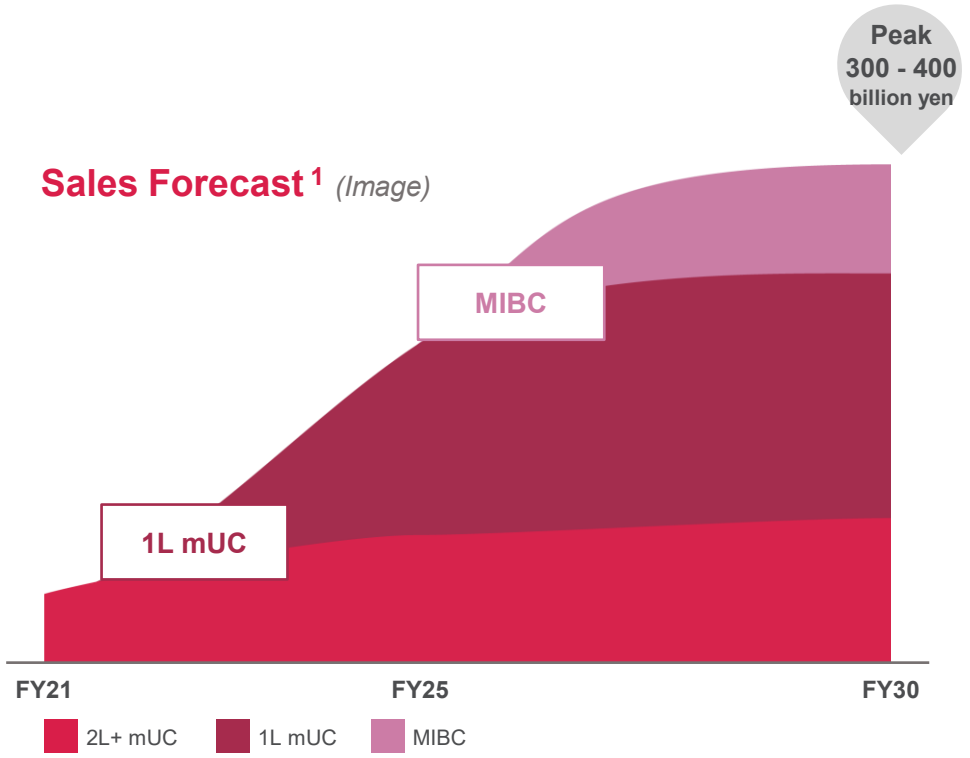
# ENFORTUMAB VEDOTIN (EV) (4/4): FUTURE OUTLOOK

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



- *The most significant growth driver is 1L mUC indication, which is expected to account for more than half of total sales in the future*
- *Success in NMIBC and other solid tumors will provide further growth potential*

**Sales Forecast** [1] *(Image)*




<Already approved / pivotal phase>

| Patient segment | | Pivotal study (PADCEV regimen) | Target filing timing | Number of eligible patients [2] |
|---|---|---|---|---|
| MIBC | Cis-ineligible | **EV-303** (combo w/ Pembro) | **FY2025 or later** | **10,000** |
| | Cis-eligible | **EV-304** (combo w/ Pembro) | **FY2025 or later** | **37,000** |
| 1L mUC | | **EV-302**<br>**EV-103 Cohorts** [Phase 1b/2 for AA in US] (combo w/ Pembro) | **FY2024**<br>**Approved** [AA in US] | **76,000** (incl. US, Cis-ineligible: **8,000-9,000**) |
| 2L+ mUC | PD-1/L1 inhibitor pretreated & Cis-ineligible | **EV-201 Cohort 2** [Phase 2] (monotherapy) | **Approved** | **1,600** (US, Cis-ineligible) |
| | Platinum & PD-1/L1 inhibitor pretreated | **EV-301**<br>**EV-201 Cohort 1** [Phase 2 for AA in US] (monotherapy) | **Approved** | **38,000** |

<Early clinical phase>

| Patient segment | Study (PADCEV regimen) |
|---|---|
| **NMIBC High-risk BCG-unresponsive** | **EV-104** [Phase 1] (monotherapy, intravesical) |
| **Other solid tumors** | **EV-202** [Phase 2]* (monotherapy) |

* 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

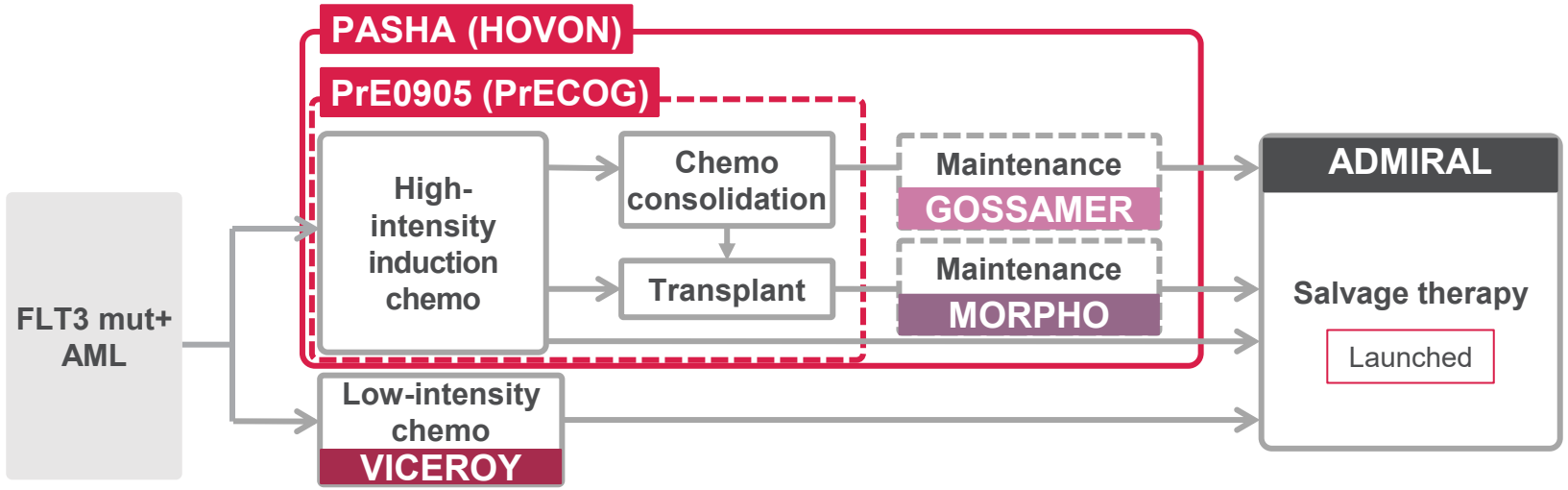
1. Global. 2. Based on internal estimates

mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder, 1L: First line, 2L+: Second or later line, Cis: Cisplatin, Pembro: Pembrolizumab, AA: Accelerated Approval, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer, GEJ: Gastroesophageal junction

# GILTERITINIB: FLT3 INHIBITOR

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



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|---|---|---|---|---|---|---|
| | Relapsed or refractory | **P3: ADMIRAL** | NCT02421939 | Monotherapy vs. salvage chemo (2:1) | n=371 | Launched in US, JP, and Europe |
| | Newly diagnosed (HIC-eligible) | **P3: PASHA (HOVON)** | NCT04027309 | Combo with high intensity chemo gilteritinib vs. midostaurin (1:1) | n=768 | FSFT: Dec 2019 (Sponsor: HOVON) |
| | | **P2: PrE0905 (PrECOG)** | NCT03836209 | | n=179 | FSFT: Dec 2019 (Sponsor: PrECOG, LLC.) |
| | Post-HSCT maintenance | **P3: MORPHO** | NCT02997202 | Monotherapy vs. placebo (1:1) | n=356 | **Topline results obtained in Mar 2023** Collaborating with BMT-CTN |
| | Post-chemo maintenance | **P2: GOSSAMER** | NCT02927262 | Monotherapy vs. placebo (2:1) | n=98 | Topline results obtained in Aug 2021 |
| | Newly diagnosed (HIC-ineligible) | **P1: VICEROY** | NCT05520567 | Combo with venetoclax and azacitidine | n=70 | FSFT in Jan 2023 |

**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

FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, 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, R/R: Relapsed or refractory

# 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: 38%
  - ✓ ~60% of primary pancreatic adenocarcinomas; ~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 ~6% five-year survival rate at Stage IV and treatment options are limited

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| | **Gastric and GEJ adenocarcinoma** | **P3: SPOTLIGHT** | NCT03504397 | First line, Combo with mFOLFOX6, DB, vs. placebo | n=566 | Topline results obtained in Nov 2022 |
| | | **P3: GLOW** | NCT03653507 | First line, Combo with CAPOX, DB, vs. placebo | n=507 | Topline results obtained in Dec 2022 |
| | | **P2: ILUSTRO** | NCT03505320 | 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<br>Cohort 4: First line, Combo with mFOLFOX6 and nivolumab | n=116 | FSFT: Sep 2018 |
| | **Pancreatic adenocarcinoma** | **P2** | NCT03816163 | First line, Combo with nab-paclitaxel and gemcitabine, open | n=369 | FSFT: May 2019 |

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

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# FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

**(Red: Updates 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 [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 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 Europe

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|---|---|---|---|---|---|
| | P3: SKYLIGHT 1 | NCT04003155 | Moderate to severe VMS associated with menopause;<br>The first 12 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)<br>The last 40 weeks: Active extension treatment period, 30 mg or 45 mg | n=527 | NDA accepted in US in Aug 2022<br>MAA accepted in Europe in Sep 2022 |
| | P3: SKYLIGHT 2 | NCT04003142 | | n=501 | |
| | P3: SKYLIGHT 4 | NCT04003389 | VMS associated with menopause;<br>52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1) | n=1,831 | |
| | P3b: DAYLIGHT | NCT05033886 | Moderate to severe VMS associated with menopause, unsuitable for HRT;<br>24 weeks, DB, 45 mg vs. placebo (1:1) | n=453 | Enrollment completed |

### Asia (except for Japan)

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|---|---|---|---|---|---|
| | **P3: MOONLIGHT 1** | NCT04234204 | 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=302 | Primary endpoints not met (12w DB period topline results) |
| | **P3: MOONLIGHT 3** | NCT04451226 | VMS associated with menopause; open label, 30 mg for 52 weeks | n=150 | Topline results obtained in Sep 2022 |

### Japan

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|---|---|---|---|---|---|
| | **P2b: STARLIGHT** | NCT05034042 | Peri- and post-menopausal patients with mild to severe VMS;<br>12 weeks: DB, 2 doses vs. placebo (1:1:1) | n=147 | **Topline results obtained in Mar 2023** |

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, QoL: Quality of life, HRT: Hormone replacement therapy, DB: Double-blind, NDA: New Drug Application, MAA: Marketing Authorization Application, LSLV: Last subject last visit

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# AT132 (RESAMIRIGENE BILPARVOVEC): rAAV8-Des-hMTM1



## Characteristics of AT132

- Delivers 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
  - ✓ <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)** | NCT03199469 | n=26 | Study put on clinical hold by FDA due to a serious adverse event. Investigation on the event ongoing |

(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

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# ON THE FOREFRONT OF HEALTHCARE CHANGE