

# **Q3/FY2023 FINANCIAL RESULTS**

## **ENDED DECEMBER 31, 2023**



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**Astellas Pharma Inc.**  
**February 5, 2024**

# CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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

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# AGENDA

I

Q3/FY2023 Consolidated Financial Results  
FY2023 Revised Forecasts

II

Initiatives for Sustainable Growth

# Q3/FY2023 FINANCIAL RESULTS: OVERVIEW

*Revenue increased YoY, however, behind the full-year forecast*

- XTANDI & XOSPATA: In line with the full-year forecast revised upward in Q2
- PADCEV: In line with the full-year forecast revised significantly upward in Q2  
Potential peak sales revised upward incorporating the robust results of EV-302 study
- VEOZAH: Overall initiatives are progressing, however, demand trails internal expectations  
Full-year forecast revised downward
- IZERVAY: Encouraging first full quarter performance since launch, expect further growth

*Cost items*

- SG&A and R&D expenses were on track

*Operating profit*

- Core OP behind the full-year forecast mainly due to the performance of VEOZAH

Full-year forecast for revenue and operating profit revised downward incorporating VEOZAH's current progress

# Q3/FY2023 FINANCIAL RESULTS



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(billion yen)	Q3/FY22	Q3/FY23	Change	Change (%)	FY23 FCST	FX impact (YoY)
<b>Revenue</b>	<b>1,164.4</b>	<b>1,189.1</b>	<b>+24.7</b>	<b>+2.1%</b>	<b>1,608.0</b>	+58.8 bil. yen
Cost of sales	226.1	219.3	-6.8	-3.0%		+10.2 bil. yen
% of revenue	19.4%	18.4%	-1.0 ppt			
<b>SG&amp;A expenses</b>	<b>471.0</b>	<b>547.0</b>	<b>+76.0</b>	<b>+16.1%</b>	<b>737.0</b>	+26.1 bil. yen
US XTANDI co-pro fee	138.2	146.2	+8.0	+5.8%	187.0	+6.9 bil. yen
SG&A excl. the above	332.7	400.7	+68.0	+20.4%	555.0	+19.2 bil. yen
<b>R&amp;D expenses</b>	<b>206.1</b>	<b>216.3</b>	<b>+10.3</b>	<b>+5.0%</b>	<b>290.0</b>	+6.9 bil. yen
Amortisation of intangible assets	29.2	66.2	+37.0	+126.8%		Note) Amortisation of IZERVAY's intangible assets started from Q2
Gain on divestiture of intangible assets	0.2	9.7	+9.5	-		
<b>Core operating profit</b>	<b>233.7</b>	<b>149.6</b>	<b>-84.0</b>	<b>-36.0%</b>	<b>199.0</b>	+13.8 bil. yen
<b>&lt; Full basis &gt;</b>						
Other income	2.5	8.5	+6.0	+236.6%		Other expenses
Other expenses	54.9	84.0	+29.1	+52.9%		• Organizational restructuring cost on a global scale: approx. 18.4 bil. yen
<b>Operating profit</b>	<b>181.3</b>	<b>74.1</b>	<b>-107.2</b>	<b>-59.1%</b>	<b>123.0</b>	
Profit before tax	180.2	73.6	-106.6	-59.1%	121.0	
<b>Profit</b>	<b>144.8</b>	<b>50.3</b>	<b>-94.5</b>	<b>-65.3%</b>	<b>85.0</b>	

Full-year forecast revised in Nov 2023, Exchange rate assumption: 140 yen/USD, 152 yen/EUR

# XTANDI & XOSPATA: BUSINESS UPDATE


*Performance in line with the full-year forecast upwardly revised in Q2, expect to achieve the full-year forecast*

(billion yen)	Q3/FY2023 YTD	YoY	FY2023 FCST	
 <b>Xtandi</b> (enzalutamide)	<b>560.0</b>	<b>+48.1</b> <b>(+9%)</b>	<b>719.8</b>	<ul style="list-style-type: none"> <li>✓ Global sales are in line with the full-year forecast revised upward in Q2</li> <li>✓ ~5% growth even excluding FX impact, still growing even 10+ years on the market</li> <li>✓ Expect to achieve the full-year forecast</li> <li>✓ Sales expanded in all regions</li> <li>✓ US: Approval of M0 CSPC additional indication based on EMBARK study in Nov 2023 Steady growth in demand excluding PAP (demand YoY +3%)</li> </ul>
 <b>XOSPATA</b> gilteritinib 40mg tablets	<b>41.3</b>	<b>+5.0</b> <b>(+14%)</b>	<b>55.2</b>	<ul style="list-style-type: none"> <li>✓ Global sales are in line with the full-year forecast revised upward in Q2</li> <li>✓ Near double-digit growth even excluding FX impact</li> <li>✓ Expect to achieve the full-year forecast</li> </ul>

Full-year forecast revised in Nov 2023, Exchange rate assumption: 140 yen/USD, 152 yen/EUR  
 M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, PAP: Patient Assistance Program

# PADCEV: BUSINESS UPDATE

Peak sales revised upward to 400 - 500 billion yen incorporating the robust results of EV-302 study

(billion yen)	Q3/FY2023 YTD	YoY	FY2023 FCST
	<b>55.6</b>	<b>+22.5</b> <b>(+68%)</b>	<b>85.2</b>

## Latest progress & outlook

### <US>

- ✓ Performance in line with full-year forecast revised significantly upward in Q2, driven by the penetration of 1L mUC based on EV-103 study (cis-ineligible) approved in April 2023
- ✓ Approval of 1L mUC additional indication based on EV-302 study (both cis-eligible and ineligible) in Dec 2023 at an incredible speed, only two weeks after the FDA filing acceptance
  - Expect significant sales contribution in FY2024 and beyond, driven by the robust data and further expansion of eligible patient population

### <Europe>

- ✓ Reimbursement started in 3 new countries including Spain, a total of 13 countries as of now. Expect further sales growth

## Update of potential peak sales

- ✓ Updated sales forecast incorporating the robust results of EV-302 study which exceeded initial expectations
- ✓ **Upward revision of potential peak sales:**



**Aim for the upper end of 500 billion yen**

- Peak sales is disclosed as “in-market sales,” not Astellas revenue
- Indications in early clinical phase are not included (NMIBC and other solid tumors)

(Reference) Image of economic conditions with Pfizer

- ✓ Intended for approx. 50:50 profit split globally

	Pfizer	Astellas
Americas*	Pfizer books sales	Receive 50% of gross profit (recognize in product sales as PADCEV related revenue)
Ex-Americas	Receive 50% of gross profit	Astellas books sales

Note) Receipt/payment percentage and schemes vary by region (profit sharing or royalty payment)

Full-year forecast revised in Nov 2023, Exchange rate assumption: 140 yen/USD, 152 yen/EUR

\*Americas includes the US, Canada and Latin America, 1L: First line, mUC: Metastatic urothelial cancer, Cis: Cisplatin, FDA: Food and Drug Administration

# VEOZAH: BUSINESS UPDATE

Overall initiatives are progressing, however, demand trails internal expectations

Downward revision of full-year forecast, reassessed the timing and pace of the FY2023 demand ramp to delay

	Q3/FY2023 YTD	FY2023 Revised FCST	Factors for the downward revision
 <p>VEOZAH™ (fezolinetant) tablets 45 mg</p>	<b>3.6 bil. yen</b>	<b>7.1 bil. yen</b>	<ul style="list-style-type: none"> <li>✓ DTC activities have been effective, however, it is taking longer to impact the demand increase</li> <li>✓ Based on market research, HCP's perception of the current payer coverage progress is "insufficient to actively prescribe VEOZAH" which is impacting the uptake</li> <li>✓ As a result, full-year forecast has been revised downward by incorporating the above factors and reassessing the timing and pace of demand ramp to delay which was expected particularly in Q4</li> </ul>
Only US (\$ basis)	<b>\$25M</b>	<b>\$50M</b>	

### <Latest progress>

#### Market Access

- ✓ Total lives covered (payer coverage) expanded to ~35%
- ✓ Expect over 50% by the end of FY2023

#### Reach

- ✓ DTC campaign has reached an estimated ~56M women

#### Awareness

- ✓ Consumer: **53%** increase (Sep: ~15% vs Dec: ~25%)
- ✓ HCP: **40%** increase (Sep: ~50% vs Dec: ~70%)

#### Activation

- ✓ Consumer: **70%** of women reported "**High Intent**" to ask HCP about VEOZAH (40% increase from Oct)
- ✓ HCP: **76%** of HCP's report they are "**Extremely Willing**" to prescribe VEOZAH (19% increase from Sep)

#### DTC Impact\*

### <Future initiatives & outlook>

- ✓ Sales force to continue driving rapid and widescale awareness of VEOZAH and educate HCPs on the expanding payer coverage
- ✓ VEOZAH TV spot during the Super Bowl in the US
- ✓ In FY2024, expect % of lives covered (payer coverage) to increase and continued momentum from commercial investments
- ✓ Mid- to long-term and peak sales outlook will be reviewed based on the progress of overcoming HCP's perception that coverage is insufficient

### Update on Europe


- ✓ Approval in Dec 2023, launched in 7 countries including Germany and UK

Note) Approved as "VEOZA" in Europe,  
Exchange rate assumption: 140 yen/USD, 152 yen/EUR , \*Market Research December 2023, DTC: Direct-to-consumer, HCP: Healthcare professional



# IZERVAY: BUSINESS UPDATE

*Encouraging first full quarter performance since launch in the US, expect significant growth in FY2024*

(billion yen)	Q3/FY2023 YTD	FY2023 FCST
	5.3	11.0

## Progress since launch

- ✓ Encouraging performance despite being only the first full quarter since launch, as well as before permanent J-Code and label update
- ✓ 17,000+\* vials shipped and available in 920+ Retina accounts since launch through Q3, representing ~70% of accounts
- ✓ Accelerated growth in IZERVAY usage following the GATHER2 data release at AAO 2023 (nonpromoted use)
- ✓ Estimate market share in the Q3 period to be ~20% based on reported volume shipments
- ✓ Safety profile so far has been consistent with clinical trial results

## DTC activities to increase awareness (as of Dec 2023)

- ✓ Branded campaign for IZERVAY:
  - Achieved 55% brand awareness among GA patients post-launch
- ✓ Disease awareness campaign for GA:
  - Contributed to 56% awareness of GA among dry AMD patients



**Disease awareness campaign** with two-time Emmy® Award-winning actor Eric Stonestreet, who shared his personal connection with GA in a national PR effort ([askaboutGA.com](http://askaboutGA.com))

## Future outlook

- ✓ Expect significant growth in FY2024 driven by upcoming milestones;
  - Received confirmation of permanent J-Code effective Apr 1 which will be a driver of reimbursement confidence and accelerant of demand
  - Anticipate approval of label update within FY2024

Note) Screenshot is from the US Disease education campaign and is intended for US audiences only  
Exchange rate assumption: 140 yen/USD, 152 yen/EUR, \*Excluding clinical trial vials. The figure disclosed in Q2/FY2023 earnings (10K units) was inclusive of clinical trial vials  
GA: Geographic atrophy, AMD: Age-related macular degeneration, AAO: American Academy of Ophthalmology

## Q3/FY2023 FINANCIAL RESULTS: COST ITEMS

*SG&A expenses increased YoY due to the impact of the acquisition of Iveric Bio and the investment in VEOZAH, however, progress in line with expectations*

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

Cost Items	YoY change	Ratio to Revenue	Progress against FCST	
<b>Cost of sales</b>	-3.0%	18.4% (-1.0 ppt YoY)	-	Cost of sales ratio was as expected
<b>SG&amp;A expenses excl. US XTANDI co-pro fee</b>	+20.4% (+14.6% excl. FX impact)	33.7% (+5.1 ppt YoY)	72.9%	YoY increase excl. FX impact: approx. +49.0 bil. yen ✓ Impact of Iveric Bio acquisition (approx. +20.0 bil. yen. YoY) ✓ Increase in VEOZAH-related costs (approx. +30.0 bil. yen YoY) ✓ Reduction of mature products-related costs (approx. -6.0 bil. yen YoY)
<b>R&amp;D expenses</b>	+5.0% (+1.6% excl. FX impact)	18.2% (+0.5 ppt YoY)	74.6%	Impact of Iveric Bio acquisition: approx. +8.0 bil. yen

# FY2023 REVISED FORECAST

- *Revenue: Downward revision*
  - ✓ *VEOZAH: Full-year forecast revised downward incorporating current progress*
  - ✓ *No change has been made on exchange rates and other products' full-year forecast*
- *Core OP: Downward revision*
  - ✓ *Profit also revised downward aligned with VEOZAH's downward revision*
  - ✓ *Partially mitigated by the review of cost items*

(billion yen)	FY2023 FCST*	FY2023 Revised FCST	Change	Main items of revision
<b>Revenue</b>	<b>1,608.0</b>	<b>1,562.0</b>	<b>-46.0</b>	Downward revision of VEOZAH: 53.3 bil. yen → 7.1 bil. yen (US only: \$375M → \$50M)
SG&A expenses	737.0	731.0	-6.0	Review of VEOZAH investment timing aligned with reassessing the timing and pace of demand ramp-up
R&D expenses	290.0	286.0	-4.0	Applied accounting treatment recognizing IZERVAY's production cost (R&D expenses) as inventory assets
<b>Core operating profit</b>	<b>199.0</b>	<b>164.0</b>	<b>-35.0</b>	

<Full basis>

<b>Operating profit</b>	<b>123.0</b>	<b>83.0</b>	<b>-40.0</b>	
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\*Revised in Nov 2023, Exchange rate assumption: 140 yen/USD, 152 yen/EUR

# AGENDA

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Q3/FY2023 Consolidated Financial Results  
FY2023 Revised Forecasts

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Initiatives for Sustainable Growth

# INITIATIVES FOR SUSTAINABLE GROWTH: OVERVIEW

## *XTANDI and Strategic products*

- enzalutamide / XTANDI : Approval of additional indication for M0 CSPC\* (US)
- enfortumab vedotin / PADCEV : Approval (US) and filing (Europe, Japan) of additional indication for 1L mUC
- zolbetuximab : Complete response letter issued (US)
- fezolinetant / VEOZAH : Approval (Europe), Phase 3 studies to start (Japan)
- avacincaptad pegol / IZERVAY : Submission for label update (US)

## *Focus Area approach*

- Clinical studies ongoing:  
Early data readout in Phase 1 studies expected in FY2023 for ASP1570, ASP2138 and ASP3082

## *Others*

- Open innovation initiatives:  
Open labs in Tsukuba and Kashiwa-no-ha area, strategic collaboration with Mass General Brigham

VEOZAH: Approved as "VEOZA" in Europe

\*with biochemical recurrence at high risk for metastasis

M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, 1L: First line, mUC: Metastatic urothelial cancer

# XTANDI AND STRATEGIC PRODUCTS: KEY EVENTS EXPECTED IN FY2023

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)
enzalutamide/ XTANDI		Acceptance (M0 CSPC*; US) ★ Aug	Acceptance (M0 CSPC*; Europe, M1 CSPC; China) ★ Sep	Approval (M0 CSPC*; US) ★ Nov
enfortumab vedotin/ PADCEV		EV-302 TLR ★ Sep	Acceptance (1L mUC; US) ★ Nov	Approval (US) ★ Dec
zolbetuximab	Acceptance (Japan) ★ Jun	Acceptance (US, Europe, China) ★ Jul		Complete response (US) ★ Jan
fezolinetant/ VEOZAH	Approval (US) ★ May	CHMP positive opinion (Europe) ★	Approval (Europe) ★ Dec	
avacincaptad pegol/ IZERVAY	Approval (US) Acceptance (Europe) ★	Acceptance (Europe) ★ Aug	GATHER2 TLR (24 month) ★ Sep	Submission (Label update; US) ★ Jan

As of Feb 2024

### <Other updates>




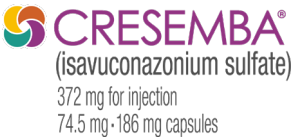
- fezolinetant / VEOZAH: Phase 3 studies in Japan (STARLIGHT 2 and STARLIGHT 3) to start in Q4
- gilteritinib / XOSPATA: Development for post-HSCT maintenance acute myeloid lymphoma based on MORPHO study discontinued

VEOZAH: Approved as "VEOZA" in Europe

\*with biochemical recurrence at high risk for metastasis. M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, M1: Metastatic, TLR: Topline results, 1L: First line, mUC: Metastatic urothelial cancer, CHMP: Committee for Medicinal Products for Human Use, HSCT: Hematopoietic stem cell transplant

# PROGRESS IN LATE-STAGE PIPELINE

*4 regulatory approvals for new indication or region received during the quarter*

	Indication	Region	
	M0 CSPC with BCR at high risk for metastasis	US	<ul style="list-style-type: none"> <li>✓ First novel hormonal therapy for the indication</li> <li>✓ Approved for monotherapy as well as combination with GnRH analog</li> </ul>
	Locally advanced or metastatic urothelial cancer (combination with pembrolizumab)	US	<ul style="list-style-type: none"> <li>✓ New treatment option to transform the current standard of care for decades</li> <li>✓ Approval in a remarkably short period of time                             <ul style="list-style-type: none"> <li>• 3 months after TLR readout in EV-302 study</li> <li>• 2 weeks after sBLA acceptance</li> </ul> </li> </ul>
	Moderate to severe VMS associated with menopause	Europe	<ul style="list-style-type: none"> <li>✓ First-in-class nonhormonal treatment option</li> <li>✓ Expansion of opportunities to address unmet medical needs worldwide</li> </ul>
	Invasive aspergillosis and invasive mucormycosis in pediatric patients	US	<ul style="list-style-type: none"> <li>✓ High unmet medical needs in pediatric patients</li> <li>✓ Extension of market exclusivity period by 6 months granted</li> </ul>

VEOZAH: Approved as "VEOZA" in Europe

M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, BCR: Biochemical recurrence, GnRH: gonadotropin-releasing hormone, TLR: Topline results,

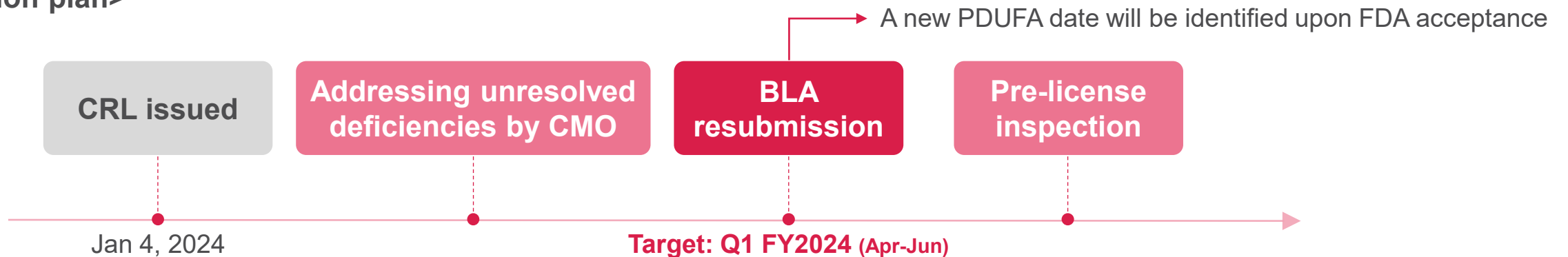
sBLA: Supplemental Biologics License Application, VMS: Vasomotor symptoms

# ZOLBETUXIMAB: LATEST STATUS

## <Complete response letter (CRL) by FDA>

- Unresolved deficiencies following pre-license inspection of a third-party manufacturing facility
- FDA has not raised any concerns related to the clinical data, and is not requesting additional clinical studies

## <Action plan>



## <Note>

- Reviews of applications outside of the US are continuing as planned
  - ✓ Regulatory agencies around the world conduct their reviews independently, and the review decisions are based on the different requirements and expectations of each regulatory agency
- No other Astellas products are affected



# PROGRESS IN FOCUS AREA APPROACH: CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

Primary Focus	Biology/Modality/Technology*	Project	Mechanism of Action	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	MTM1 gene	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	GAA gene	Phase 1 study ongoing
	Gene regulation (AAV)			
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing toward early data readout in FY2023
	Bispecific immune cell engager	ASP2138	Anti-Claudin 18.2 and anti-CD3	Phase 1 study ongoing toward early data readout in FY2023
		ASP2074	Anti-TSPAN8 and anti-CD3	Phase 1 study ongoing
		ASP1002	Undisclosed	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	Phase 1 study under preparation to start in Q4/FY2023
	Cancer cell therapy			
Blindness & Regeneration	Cell replacement	ASP7317	RPE cells	Phase 1b study ongoing
	Cell replacement (UDC)			
	Gene regulation (AAV)			
Mitochondria	Gene regulation & mitochondrial biogenesis	ASP0367	PPARδ modulator	PMM: Phase 2/3 study ongoing DMD: Next step under discussion
Targeted Protein Degradation	Protein degradation	ASP3082	KRAS G12D degrader	Phase 1 study ongoing toward early data readout in FY2023
Primary Focus Candidate	Immune modulating/regulatory cells			
	Tissue-specific immune regulation			

Modality

- Small molecule
- Antibody
- Gene
- Cell

\*Not exhaustively listed. AAV: Adeno-associated virus, MTM1: Myotubularin 1, FDA: Food and Drug Administration, GAA: Acid alpha-glucosidase, DGK: Diacylglycerol kinase, TSPAN8: Tetraspanin-8, IL-2: Interleukin-2, RPE: Retinal pigment epithelium, UDC: Universal donor cell, PPAR: Peroxisome proliferator-activated receptor, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy, KRAS: Kirsten rat sarcoma viral oncogene homologue

# OPEN INNOVATION INITIATIVES

*Advancing open innovation in life science ecosystems globally and accelerating early R&D*

## Activities at research stage

- Focused on incorporating external innovation and co-creation through collaborations with academia and other companies, while contributing to life science ecosystems
- Leverage open laboratories as part of these efforts: Started activities of SakuLab™-Tsukuba and TME iLab in Tsukuba and Kashiwa-no-ha area



### SakuLab™-Tsukuba



- ✓ Located at Astellas' Tsukuba Research Center
- ✓ Available for academia and start-ups



### TME iLab

- ✓ Open innovation hub for TME research

## Activities at early development stage

### Mass General Brigham

- Five-year strategic collaboration with one of the leading biomedical research organizations in US
- Aim to advance translational medicine and accelerate early development of novel therapies
- Initial focus in key areas of R&D investment for Astellas: oncology, rare disease, cell and gene therapy
- Expected to better understand diseases and modalities and optimize clinical trials
- Further reinforces Astellas' presence in the Greater Boston innovation ecosystem

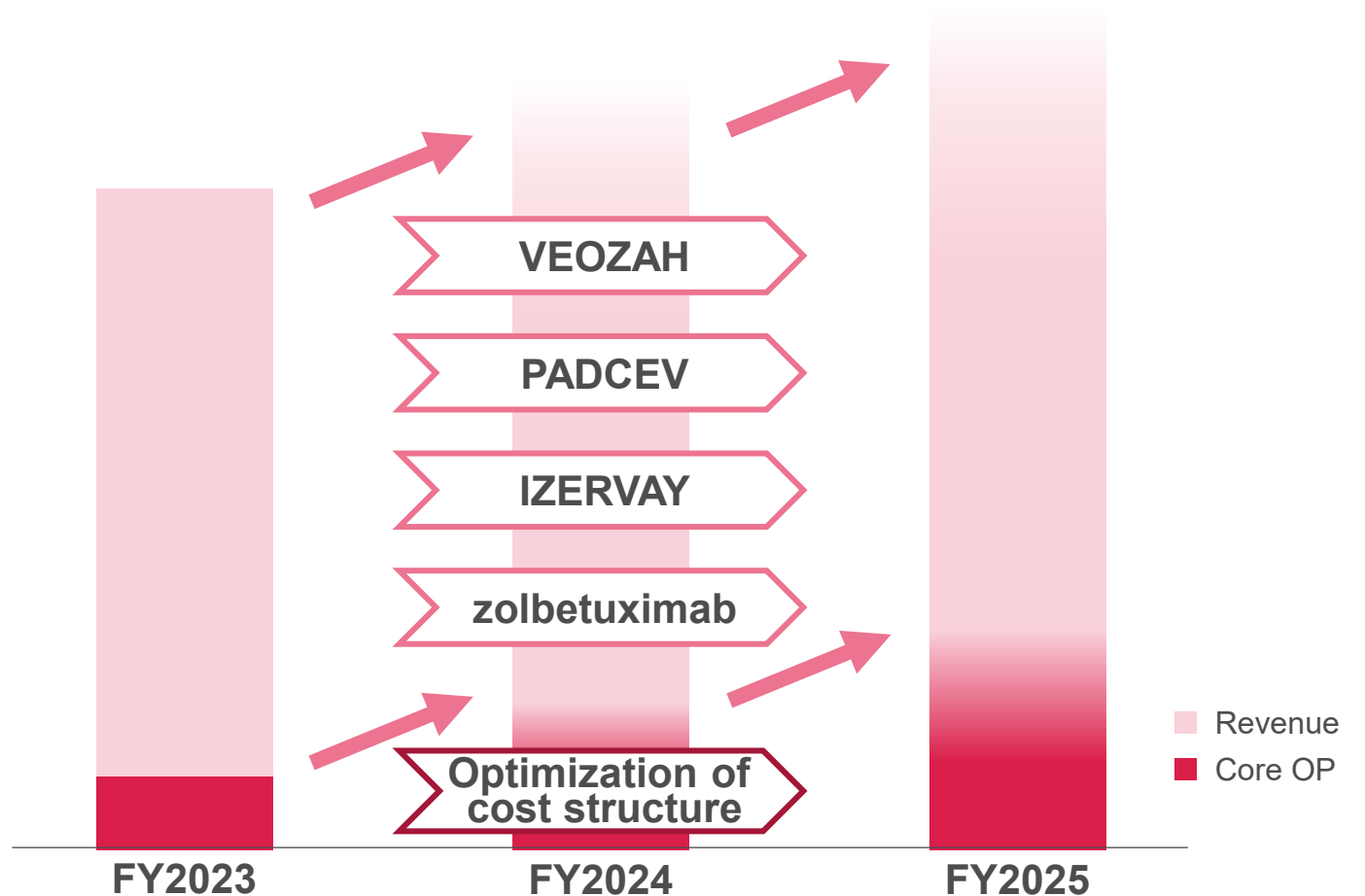


# PROGRESS IN FY2023 AND FUTURE OUTLOOK

- *Achieved many key milestones including new product launches and additional indications in FY2023*
- *Expecting Revenue and Profit to increase in FY2024 through contribution of VEOZAH, PADCEV and IZERVAY as growth drivers*

## Major progress in FY2023 contributing to future growth

- **VEOZAH**: launch in US and Europe
- **PADCEV** (1L mUC): positive results from EV-302 study, approval in US, filing in Europe and Japan
- **IZERVAY**: launch in US, filing in Europe, positive additional results from GATHER2 study
- **zolbetuximab**: global filing



VEOZAH: Approved as "VEOZA" in Europe  
1L: First line, mUC: Metastatic urothelial cancer

# APPENDIX



## Q3/FY2023: REVENUE BY REGION

(billion yen)	Q3/FY2022	Q3/FY2023	Change (%)
Japan	204.5	211.0	+3.2%
United States	501.1	481.4	-3.9%
Established Markets	272.2	306.3	+12.5%
Greater China	65.2	67.3	+3.3%
International Markets	104.2	118.8	+14.0%

Established Markets: Europe, Canada, etc., Greater China: China, Hong Kong, Taiwan,  
International Markets: Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Korea, Australia, Export sales, etc.

## Q3/FY2023 ACTUAL: FX RATE

### Average rate for the period

Currency	Q3/FY2022	Q3/FY2023	Change
USD	137 yen	143 yen	+7 yen
EUR	141 yen	155 yen	+15 yen

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

- 58.8 billion yen increase in revenue, 13.8 billion yen increase in core OP

# FY2023 FORECAST: FX RATE & FX SENSITIVITY

Exchange rate Average for the period	FY2023 Initial FCST	FY2023 Revised FCST*	Change
USD	130 yen	140 yen	+10 yen
EUR	140 yen	152 yen	+12 yen

Forecast rates Q3/FY2023 onwards: 140 yen/USD, 150 yen/EUR

## Estimated FX sensitivity (Q3 onwards) of FY2023 revised forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption	
	Revenue	Core OP
USD	Approx. +3.2 bil. yen	Approx. +0.1 bil. yen
EUR	Approx. +1.4 bil. yen	Approx. +0.6 bil. yen

# BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY2022 end	Dec 31, 2023
Total assets	2,456.5	3,368.7
Cash and cash equivalents	376.8	254.0
Total equity attributable to owners of the parent	1,508.0	1,503.3
Equity ratio (%)	61.4%	44.6%
(billion yen)	Q3/FY2022	Q3/FY2023
Cash flows from operating activities	212.2	100.5
Cash flows from investing activities	-61.8	-823.6
Free cash flows	150.4	-723.1
Cash flows from financing activities	-91.1	583.1
Increase/decrease in short-term borrowings and CP	-15.0	263.2
Proceeds from issuance of bonds and long-term borrowings	50.0	471.6
Acquisition of treasury shares	-10.6	-10.7
Dividends paid	-100.4	-116.7

As of end of December, Balance of bonds (Incl. CP) and borrowings : 871.0 billion yen



## MAIN INTANGIBLE ASSETS (AS OF DEC 31, 2023)

	Bil. yen	Foreign currency*
AT132	15.3	USD 109M
AT845	10.2	USD 73M
Other gene therapy related program**	92.5	USD 656M
Gene therapy related technology**	68.1	USD 483M
VEOZAH	90.0	EUR 566M
EVRENZO	21.4	-
zolbetuximab	64.0	EUR 493M
IZERVAY (US)	702.6	USD 4,981M
IZERVAY (Ex-US)	155.2	USD 1,100M

\* VEOZAH, zolbetuximab: foreign currency is a reference value based on the currency at the time of acquisition of the intangible asset

\*\* Acquired during the acquisition of Audentes (now Astellas Gene Therapies)

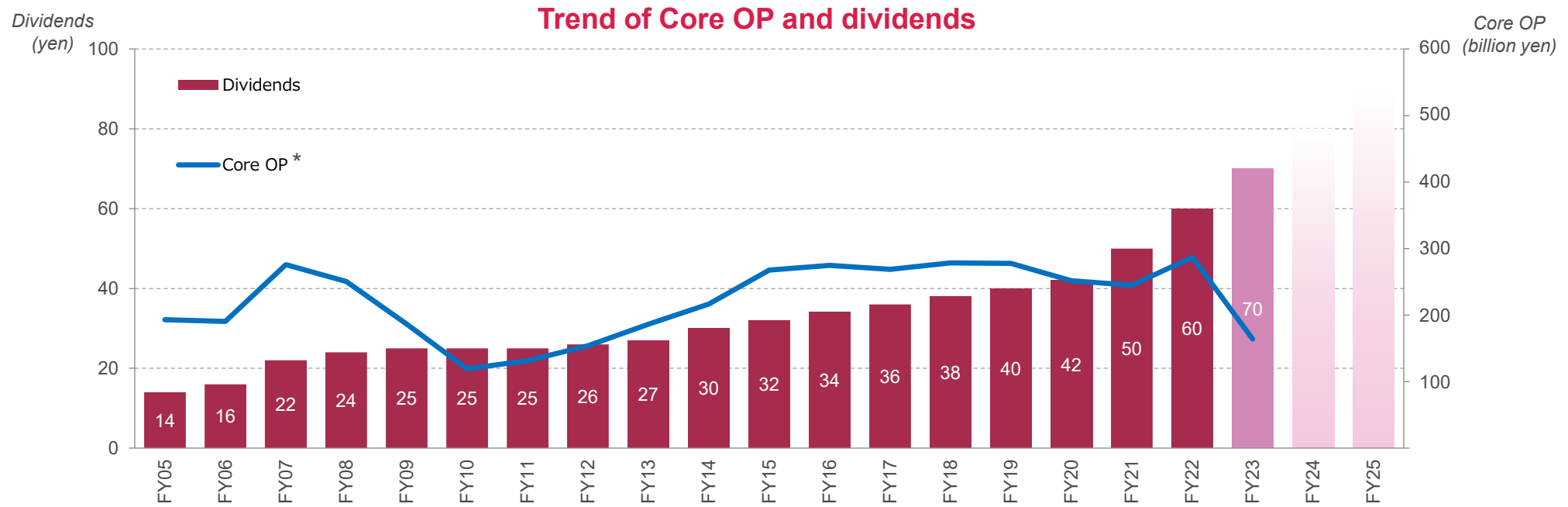
# CAPITAL ALLOCATION

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

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
ASP1012
ASP7317
bocidelpar/ASP0367 (Duchenne muscular dystrophy)
zocaglusagene nuzaparvovec/ AT845
ASP3082
abiraterone decanoate/ PRL-02/ASP5541

## Phase 2

enfortumab vedotin (Other solid tumors)
zolbetuximab (Pancreatic adenocarcinoma)
resamirigene bilparvovec/ AT132 (XLMTM)
avacincaptad pegol (Stargardt disease)
bocidelpar/ASP0367 (Primary mitochondrial myopathies)

## Phase 3

enfortumab vedotin (MIBC)
gilteritinib (Earlier-stage AML, pediatric use)
fezolinetant (VMS due to menopause: China, Japan)
roxadustat (Anemia associated with CKD, pediatric use: Europe)
mirabegron (Neurogenic detrusor overactivity, pediatric use: Europe)

## Submitted/Filed

enzalutamide (M0 CSPC*: Europe, M1 CSPC: China)
enfortumab vedotin (mUC previously untreated: Europe, Japan; mUC pretreated: China)
zolbetuximab (Gastric and GEJ adenocarcinoma: Japan, US, Europe, China)
avacincaptad pegol (GA secondary to AMD: 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.

\*with biochemical recurrence at high risk for metastasis. NMIBC: Non-muscle-invasive bladder cancer, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, XLMTM: X-linked myotubular myopathy, MIBC: Muscle-invasive bladder cancer, VMS: Vasomotor symptoms, CKD: Chronic kidney disease, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, mUC: Metastatic urothelial cancer, GEJ: Gastroesophageal junction, GA: Geographic atrophy, AMD: Age-related macular degeneration



# PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since the Last Financial Results Announcement

28



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

# XTANDI AND STRATEGIC PRODUCTS: STATUS UPDATE

(Red: Updates since the last financial results announcement)

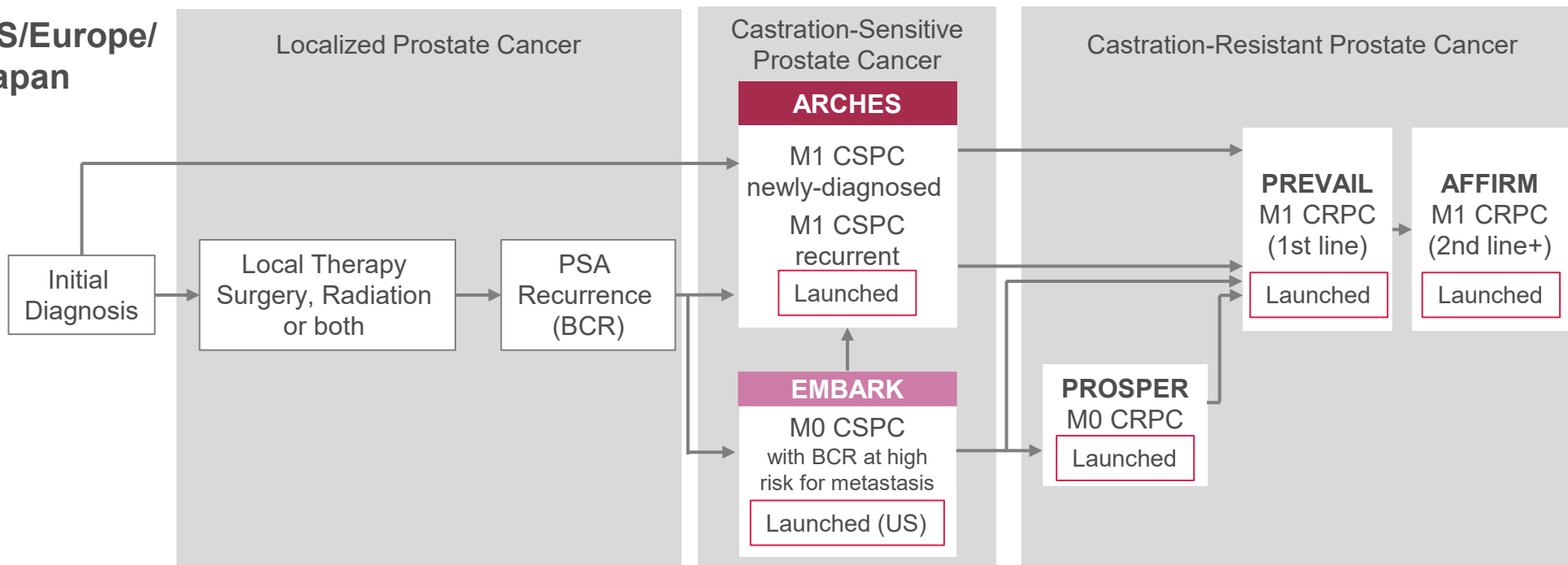
Project / Product	Indication	Current status
enzalutamide/ XTANDI	M1 CSPC	<ul style="list-style-type: none"> <li>NDA accepted in China in Sep 2023</li> </ul>
	M0 CSPC with BCR at high risk for metastasis	<ul style="list-style-type: none"> <li><b>Approved in US in Nov 2023.</b> Type II variation accepted in Europe in Sep 2023</li> </ul>
enfortumab vedotin/ PADCEV	Metastatic urothelial cancer	<ul style="list-style-type: none"> <li><b>Previously untreated (first line): Approved in US in Dec 2023. Type II variation/sNDA accepted in Europe/Japan in Jan 2024</b></li> <li>Pretreated: BLA accepted in China in Mar 2023</li> </ul>
	Muscle-invasive bladder cancer	<ul style="list-style-type: none"> <li>Phase 3 studies ongoing. <b>Enrollment completed in Phase 3 EV-304 study</b></li> </ul>
	Non-muscle-invasive bladder cancer	<ul style="list-style-type: none"> <li>Phase 1 study ongoing</li> </ul>
	Other solid tumors	<ul style="list-style-type: none"> <li>Phase 2 study ongoing</li> </ul>
gilteritinib/ XOSPATA	Relapsed and refractory AML	<ul style="list-style-type: none"> <li>China: Phase 3 study stopped due to efficacy</li> </ul>
	AML, post-HSCT maintenance	<ul style="list-style-type: none"> <li><b>Development based on Phase 3 MORPHO study discontinued</b></li> </ul>
	AML, newly diagnosed (HIC-eligible)	<ul style="list-style-type: none"> <li>Phase 3 study ongoing (enrollment completed)</li> </ul>
	AML, newly diagnosed (HIC-ineligible)	<ul style="list-style-type: none"> <li>Phase 1 study ongoing</li> </ul>
zolbetuximab	Gastric & GEJ adenocarcinoma	<ul style="list-style-type: none"> <li>NDA accepted in Japan in Jun 2023. BLA/MAA accepted in Europe and China in Jul 2023. <b>Received complete response letter in US in Jan 2024</b></li> </ul>
	Pancreatic adenocarcinoma	<ul style="list-style-type: none"> <li>Phase 2 study ongoing</li> </ul>
fezolinetant/ VEOZAH	VMS due to menopause	<ul style="list-style-type: none"> <li><b>Europe: Approved in Dec 2023</b></li> <li>China: Obtained topline results from Phase 3 MOONLIGHT 1 and MOONLIGHT 3 studies</li> <li><b>Japan: Phase 3 studies under preparation to start in Q4 FY2023</b></li> </ul>
avacincaptad pegol/ IZERVAY	GA secondary to AMD	<ul style="list-style-type: none"> <li>MAA accepted in Europe in Aug 2023. <b>sNDA for label update submitted in US in Jan 2024.</b></li> </ul>
	Stargardt disease	<ul style="list-style-type: none"> <li>Phase 2b study ongoing</li> </ul>

VEOZAH: Approved as "VEOZA" in Europe. M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, BCR: Biochemical recurrence, (s)NDA: (Supplemental) New Drug Application, BLA: Biologics License Application, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, GEJ: Gastroesophageal junction, MAA: Marketing Authorization Application, VMS: Vasomotor symptoms, GA: Geographic atrophy, AMD: Age-related macular degeneration

# ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR

(Red: Updates since the last financial results announcement)

US/Europe/  
Japan



<b>P3: EMBARK</b>	<a href="#">NCT02319837</a>	<b>M0 CSPC</b>	ENZA + ADT vs. placebo + ADT vs. ENZA mono	n=1,068	<b>Approved in US in Nov 2023</b> Type II variation accepted in Europe in Sep 2023
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**China** • **M1 CSPC:** NDA accepted in Sep 2023



BCR: Biochemical recurrence, M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ENZA: enzalutamide, ADT: Androgen deprivation therapy, mono: Monotherapy



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

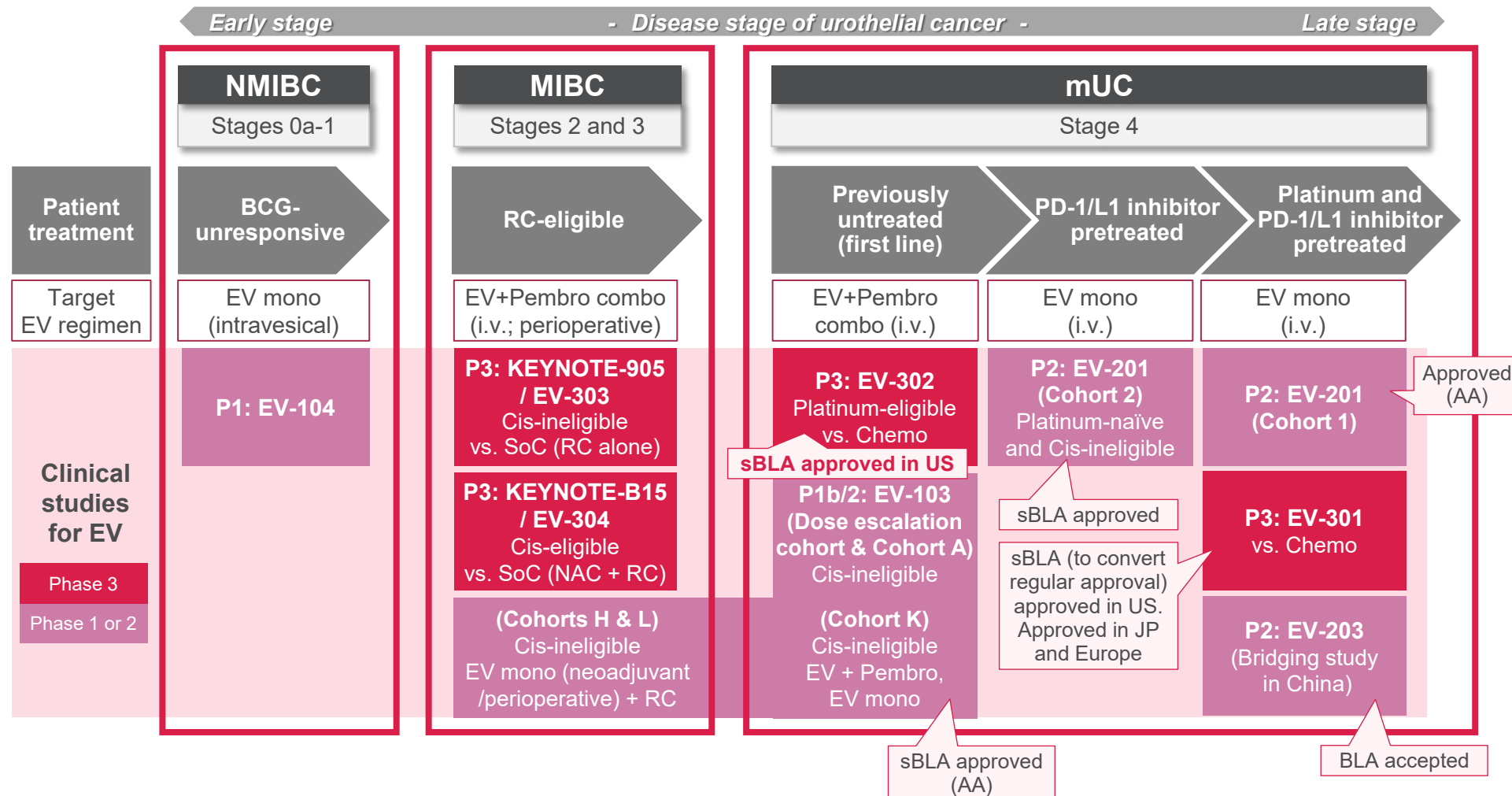
Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

Disease stage	Early stage			Late stage		
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	<b>EMBARK</b>	<b>ARCHES</b>	<b>ENZAMET</b>	<b>PROSPER</b>	<b>PREVAIL</b>	<b>AFFIRM</b>
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary endpoint	✓ MFS HR 0.42	✓ rPFS HR 0.39	✓ OS HR 0.67	✓ MFS HR 0.29	✓ rPFS HR 0.17 ✓ 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	✓ 32.4 months**	✓ 40.2 months	✓ 29.5 months	✓ 33.9 months	✓ 17.5 months	✓ 8.3 months

✓: Data obtained, \*: Prespecified interim analysis, \*\*: excluding treatment suspension period

# 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

<b>P3: EV-301</b>	<a href="#">NCT03474107</a>	mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono vs. Chemo	n=608	sBLA (to convert regular approval) approved in US in Jul 2021. Approved in Japan in Sep 2021, in Europe in Apr 2022
<b>P3: EV-302</b>	<a href="#">NCT04223856</a>	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=990	<b>Approved in US in Dec 2023.</b> <b>Type II variation/sNDA accepted in Europe/Japan in Jan 2024</b>
<b>P3: EV-303 /KEYNOTE-905</b>	<a href="#">NCT03924895</a>	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=857	FSFT in Pembro + EV arm: Dec 2020
<b>P3: EV-304 /KEYNOTE-B15</b>	<a href="#">NCT04700124</a>	MIBC, Cis-eligible; EV + Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=784	<b>Enrollment completed</b>
<b>P2: EV-201</b>	<a href="#">NCT03219333</a>	mUC, PD-1/L1 inhibitor pretreated; EV mono Cohort 1: Platinum pretreated Cohort 2: Platinum naïve and Cis-ineligible	n=219	Cohort 1: Approved (under the Accelerated Approval program) Cohort 2: sBLA approved in US in Jul 2021
<b>P1b/2: EV-103</b>	<a href="#">NCT03288545</a>	Cohorts A - G and K (mUC): A-G: Combo with Pembro and other chemo K: EV mono, EV + Pembro Cohorts H, J and L (MIBC, Cis-ineligible, + RC): H: EV mono (neoadjuvant) J (optional): EV + Pembro (neoadjuvant) L: EV mono (perioperative)	n=348	Dose Escalation/Cohort A and Cohort K: sBLA approved (under the Accelerated Approval program) in US in Apr 2023. Enrollment completed
<b>P2: EV-203</b>	<a href="#">NCT04995419</a>	<Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono	n=40	BLA accepted in China in Mar 2023
<b>P1: EV-104</b>	<a href="#">NCT05014139</a>	NMIBC, High-risk BCG-unresponsive; Intravesical EV mono	n=58	FSFT: Jan 2022

## For other solid tumors

<b>P2: EV-202</b>	<a href="#">NCT04225117</a>	HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric adenocarcinoma or esophageal adenocarcinoma or GEJ adenocarcinoma, Esophageal squamous cell carcinoma; EV mono Head and neck squamous cell carcinoma; EV + Pembro	n=320	Enrollment completed for EV mono cohorts. Initial topline results obtained in Jun 2022
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# 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: HR 0.45 ✓ OS: HR 0.47	✓ 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)	✓ HR 0.47 (31.5 mos vs.16.1 mos)	(Ongoing)	✓ (21.7 mos)	✓ (26.1 mos **)	✓ (14.7 mos)	✓ (12.4 mos **)	✓ HR 0.70 * (12.9 mos vs.9.0 mos)
PFS	(Ongoing)	(Ongoing)	✓ HR 0.45 (12.5 mos vs.6.3 mos)	(Ongoing)	✓ (8.2 mos)	✓ (12.7 mos **)	✓ (5.8 mos)	✓ (5.8 mos)	✓ HR 0.62 * (5.6 mos vs.3.7 mos)
ORR	(Ongoing)	(Ongoing)	✓ 67.7% vs. 44.4% (CR 29.1% vs. 12.5%)	✓ 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	✓ 22.1 mos **	✓ 13.8 mos **	✓ 7.6 mos	✓ 7.4 mos vs. 8.1 mos *

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

# 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

<Already approved / pivotal phase> (Included in potential peak sales)

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

<Early clinical phase> (Not included in potential peak sales)

Patient segment	Study (EV regimen)
<b>NMIBC High-risk BCG-unresponsive</b>	<b>EV-104</b> [Phase 1] (monotherapy, intravesical)
<b>Other solid tumors</b>	<b>EV-202</b> [Phase 2] (monotherapy* / combo w/ Pembro**)

\*Monotherapy:

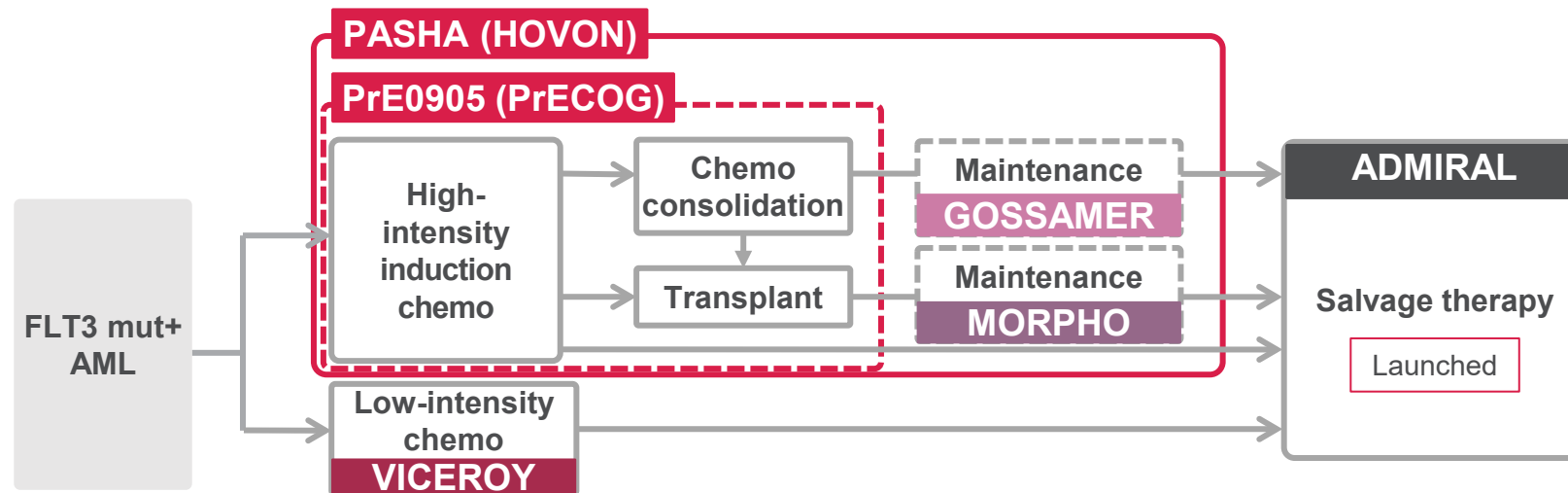
HR+/HER2- breast cancer,  
Triple-negative breast cancer,  
Squamous NSCLC,  
Non-squamous NSCLC,  
Head and neck cancer,  
Gastric adenocarcinoma or esophageal adenocarcinoma or  
GEJ adenocarcinoma,  
Esophageal squamous cell carcinoma

\*\*Combo w/ Pembro:

Head and neck squamous cell carcinoma

# GILTERITINIB: FLT3 INHIBITOR

(Red: Updates since the last financial results announcement)



Relapsed or refractory	<b>P3: ADMIRAL</b>	<a href="#">NCT02421939</a>	Monotherapy vs. salvage chemo (2:1)	n=371	Launched in US, JP, and Europe
Newly diagnosed (HIC-eligible)	<b>P3: PASHA (HOVON)</b>	<a href="#">NCT04027309</a>	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=766	Enrollment completed (Sponsor: HOVON)
	<b>P2: PrE0905 (PrECOG)</b>	<a href="#">NCT03836209</a>		n=179	Enrollment completed (Sponsor: PrECOG, LLC.)
Post-HSCT maintenance	<b>P3: MORPHO</b>	<a href="#">NCT02997202</a>	Monotherapy vs. placebo (1:1)	n=356	<b>Development based on MORPHO study discontinued</b>
Post-chemo maintenance	<b>P2: GOSSAMER</b>	<a href="#">NCT02927262</a>	Monotherapy vs. placebo (2:1)	n=98	Topline results obtained in Aug 2021
Newly diagnosed (HIC-ineligible)	<b>P1: VICEROY</b>	<a href="#">NCT05520567</a>	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

# ZOLBETUXIMAB: ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

(Red: Updates since the last financial results announcement)

## 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

Gastric and GEJ adenocarcinoma	P3: SPOTLIGHT	<a href="#">NCT03504397</a>	First line, Combo with mFOLFOX6, DB, vs. placebo	n=566	NDA accepted in Japan in Jun 2023. BLA/MAA accepted in Europe and China in Jul 2023. <b>Received complete response letter in US in Jan 2024</b>
	P3: GLOW	<a href="#">NCT03653507</a>	First line, Combo with CAPOX, DB, vs. placebo	n=507	
	P2: ILUSTRO	<a href="#">NCT03505320</a>	Cohort 1: Third or later line, zolbetuximab monotherapy Cohort 2: First line, Combo with mFOLFOX6 Cohort 3: Third or later line, Combo with pembrolizumab Cohort 4: First line, Combo with mFOLFOX6 and nivolumab <b>Cohort 5: Perioperative, Combo with FLOT</b>	<b>n=143</b>	
Pancreatic adenocarcinoma	P2	<a href="#">NCT03816163</a>	First line, Combo with nab-paclitaxel and gemcitabine, open	n=369	FSFT: May 2019

# 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 <sup>1</sup>

## Women’s Health Initiative (WHI) Study <sup>2</sup>

- 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

<b>P3: SKYLIGHT 1</b>	<a href="#">NCT04003155</a>	Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)	n=527	Approved in US in May 2023. <b>Approved in Europe in Dec 2023</b>
<b>P3: SKYLIGHT 2</b>	<a href="#">NCT04003142</a>	The last 40 weeks: Active extension treatment period, 30 mg or 45 mg	n=501	
<b>P3: SKYLIGHT 4</b>	<a href="#">NCT04003389</a>	VMS associated with menopause; 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)	n=1,831	
<b>P3b: DAYLIGHT</b>	<a href="#">NCT05033886</a>	Moderate to severe VMS associated with menopause, unsuitable for HRT; 24 weeks, DB, 45 mg vs. placebo (1:1)	n=453	

### China

<b>P3: MOONLIGHT 1</b>	<a href="#">NCT04234204</a>	Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg vs. placebo (1:1) The last 12 weeks: Active extension treatment period, 30 mg	n=302	Primary endpoints not met (12w DB period topline results)
<b>P3: MOONLIGHT 3</b>	<a href="#">NCT04451226</a>	VMS associated with menopause; open label, 30 mg for 52 weeks	n=150	Topline results obtained in Sep 2022

### Japan

<b>P3: STARLIGHT 2</b>	<a href="#">NCT06206408</a>	<b>Mild to severe VMS associated with menopause; 12 weeks: DB, 2 doses vs. placebo (1:1:1)</b>	<b>n=390</b>	<b>Under preparation to start in Q4 FY2023</b>
<b>P3: STARLIGHT 3</b>	<a href="#">NCT06206421</a>	<b>VMS associated with menopause; 52 weeks: DB, vs. placebo (1:1)</b>	<b>n=260</b>	<b>Under preparation to start in Q4 FY2023</b>

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



# AVACINCAPTAD PEGOL (ACP): COMPLEMENT C5 INHIBITOR / PEGYLATED RNA APTAMER

(Red: Updates since the last financial results announcement)

## Geographic atrophy (GA)

- Advanced form of dry age-related macular degeneration (AMD)
- Globally, approximately 5 million people are estimated to have GA at least in one eye <sup>1</sup>
- Approximately 75% of people living with GA in the US are believed to be undiagnosed <sup>2</sup>
- Without timely treatment, an estimated 66% of people with GA may become blind or severely visually impaired <sup>3</sup>

## Characteristics of ACP

- Pegylated RNA aptamer (Chemically synthesized)
- ACP inhibits complement C5, and slows inflammation and cell death associated with development and progression of GA

GA secondary to AMD	P2/3: GATHER1	<a href="#">NCT02686658</a>	Part 1: 1 mg, 2 mg vs. Sham (n=77) Part 2: 2 mg, 4 mg vs. Sham (n=209)	n=286	MAA accepted in Europe in Aug 2023. <b>sNDA for label update submitted in US in Jan 2024</b>
	P3: GATHER2	<a href="#">NCT04435366</a>	2 mg vs. Sham	n=448	
Stargardt disease	P2b	<a href="#">NCT03364153</a>	vs. Sham	n=120	FSFT: Jan 2018

1. Retina 37:819-835 (2017). 2. IQVIA Medical Claims (DX) data Jan '20-Dec '21: 24 Months. 3. JAMA Ophthalmol 139:743-750 (2021)

MAA: Marketing Authorization Application, sNDA: Supplemental New Drug Application, FSFT: First subject first treatment

# 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*	Dosing resumption
Genetic Regulation	1 project		✓ AT845
Immuno-Oncology	2 projects (✓ ASP1012)	ASP1570 ASP2138	
Blindness & Regeneration			✓ ASP7317
Targeted Protein Degradation	1 project (pan-KRAS)	ASP3082	

✓: Achieved

\*Dose escalation/monotherapy  
PoC: Proof of concept, IND: Investigational New Drug



# ON THE FOREFRONT OF HEALTHCARE CHANGE

