

Q3/FY2023 FINANCIAL RESULTS

ENDED DECEMBER 31, 2023



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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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AGENDA

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I

Q3/FY2023 Consolidated Financial Results
FY2023 Revised Forecasts

II

Initiatives for Sustainable Growth

Q3/FY2023 FINANCIAL RESULTS: OVERVIEW

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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)
Revenue	1,164.4	1,189.1	+24.7	+2.1%	1,608.0	+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			
SG&A expenses	471.0	547.0	+76.0	+16.1%	737.0	+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
R&D expenses	206.1	216.3	+10.3	+5.0%	290.0	+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	-		
Core operating profit	233.7	149.6	-84.0	-36.0%	199.0	+13.8 bil. yen
< Full basis >						
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
Operating profit	181.3	74.1	-107.2	-59.1%	123.0	
Profit before tax	180.2	73.6	-106.6	-59.1%	121.0	
Profit	144.8	50.3	-94.5	-65.3%	85.0	

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

XTANDI & XOSPATA: BUSINESS UPDATE

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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



560.0

+48.1
(+9%)

719.8

- ✓ Global sales are in line with the full-year forecast revised upward in Q2
- ✓ ~5% growth even excluding FX impact, still growing even 10+ years on the market
- ✓ Expect to achieve the full-year forecast
- ✓ Sales expanded in all regions
- ✓ US: Approval of M0 CSPC additional indication based on EMBARK study in Nov 2023
Steady growth in demand excluding PAP (demand YoY +3%)



41.3

+5.0
(+14%)

55.2

- ✓ Global sales are in line with the full-year forecast revised upward in Q2
- ✓ Near double-digit growth even excluding FX impact
- ✓ Expect to achieve the full-year forecast

PADCEV: BUSINESS UPDATE

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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
 PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	55.6	+22.5 (+68%)	85.2

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:

(Previous forecast)
300 - 400 billion yen



(Latest forecast)
400 - 500 billion yen

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

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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



3.6 bil. yen

7.1 bil. yen

- ✓ DTC activities have been effective, however, it is taking longer to impact the demand increase
- ✓ Based on market research, HCP's perception of the current payer coverage progress is "insufficient to actively prescribe VEOZAH" which is impacting the uptake
- ✓ 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

Only US
(\$ basis)

\$25M

\$50M

<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

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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)

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

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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	
Cost of sales	-3.0%	18.4% (-1.0 ppt YoY)	-	Cost of sales ratio was as expected
SG&A expenses excl. US XTANDI co-pro fee	+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)
R&D expenses	+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

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- *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
Revenue	1,608.0	1,562.0	-46.0	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
Core operating profit	199.0	164.0	-35.0	

<Full basis>

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

AGENDA

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I

Q3/FY2023 Consolidated Financial Results
FY2023 Revised Forecasts

II

Initiatives for Sustainable Growth

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

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	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)
enzalutamide/ XTANDI		Acceptance (M0 CSPC*; US) ★ Aug	★ Approval (M0 CSPC*; US) Nov Acceptance (M0 CSPC*; Europe, M1 CSPC; China) Sep	
enfortumab vedotin/ PADCEV		EV-302 TLR ★ Sep	★ Acceptance (1L mUC; US) ★ Nov ★ Approval (US) ★ Dec	★ Acceptance (1L mUC; Europe, Japan) Jan
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) ★	★ 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

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

	Indication	Region	
 Xtandi (enzalutamide)	M0 CSPC with BCR at high risk for metastasis	US	✓ First novel hormonal therapy for the indication ✓ Approved for monotherapy as well as combination with GnRH analog
 PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	Locally advanced or metastatic urothelial cancer (combination with pembrolizumab)	US	✓ New treatment option to transform the current standard of care for decades ✓ Approval in a remarkably short period of time • 3 months after TLR readout in EV-302 study • 2 weeks after sBLA acceptance
 VEOZA fezolinetant	Moderate to severe VMS associated with menopause	Europe	✓ First-in-class nonhormonal treatment option ✓ Expansion of opportunities to address unmet medical needs worldwide
 CRESEMBA (isavuconazonium sulfate) 372 mg for injection 74.5 mg - 186 mg capsules	Invasive aspergillosis and invasive mucormycosis in pediatric patients	US	✓ High unmet medical needs in pediatric patients ✓ Extension of market exclusivity period by 6 months granted

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

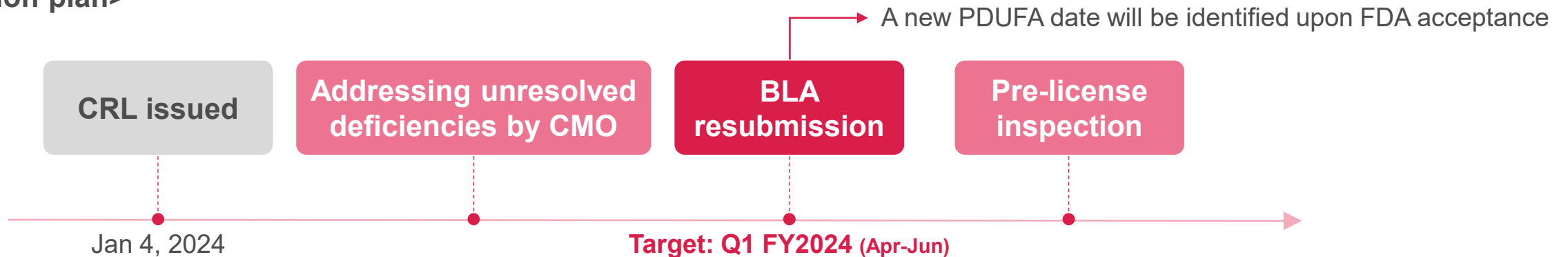
ZOLBETUXIMAB: LATEST STATUS

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<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

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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

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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



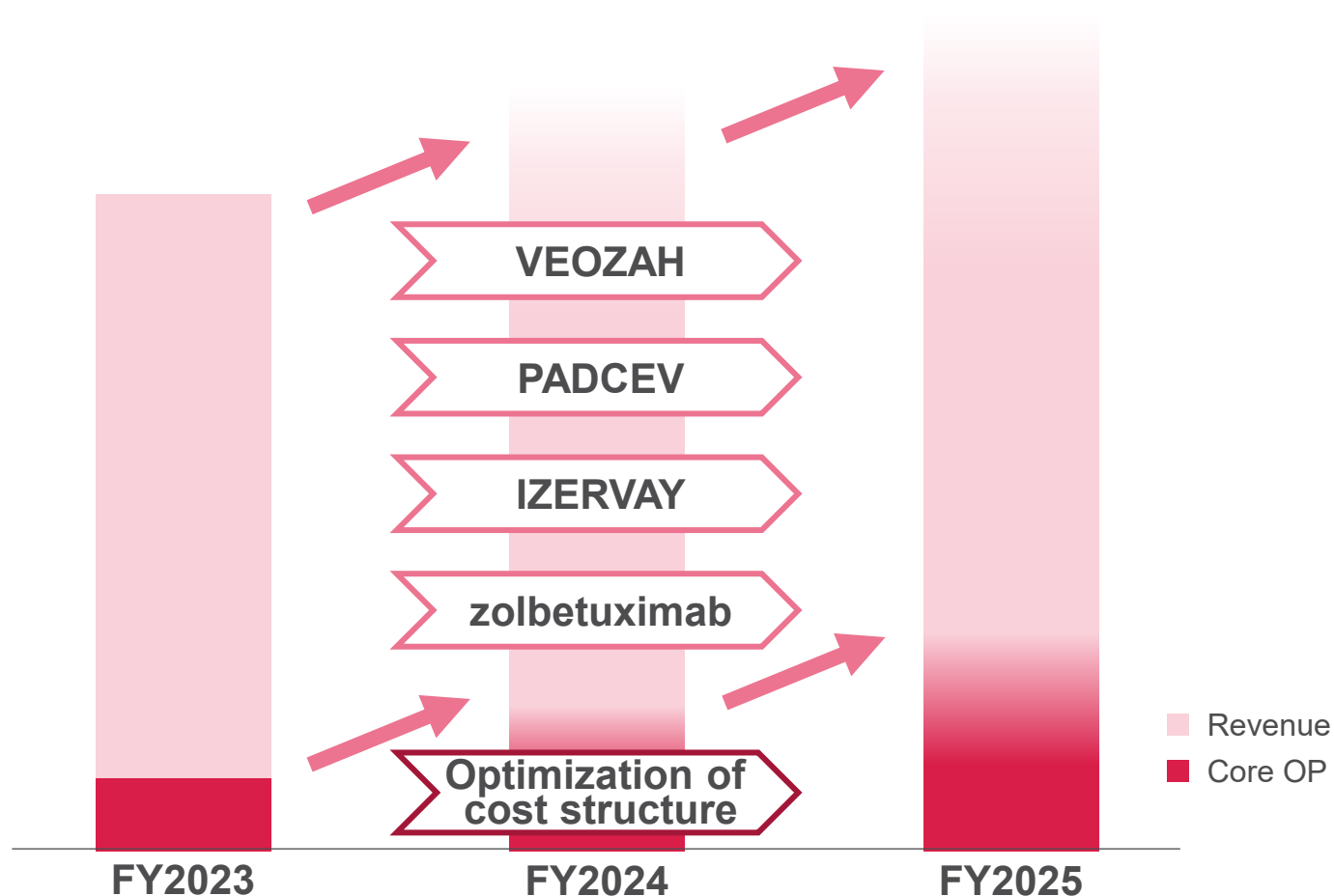
PROGRESS IN FY2023 AND FUTURE OUTLOOK

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- *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



APPENDIX



Q3/FY2023: REVENUE BY REGION

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(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

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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

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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

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(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)

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	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

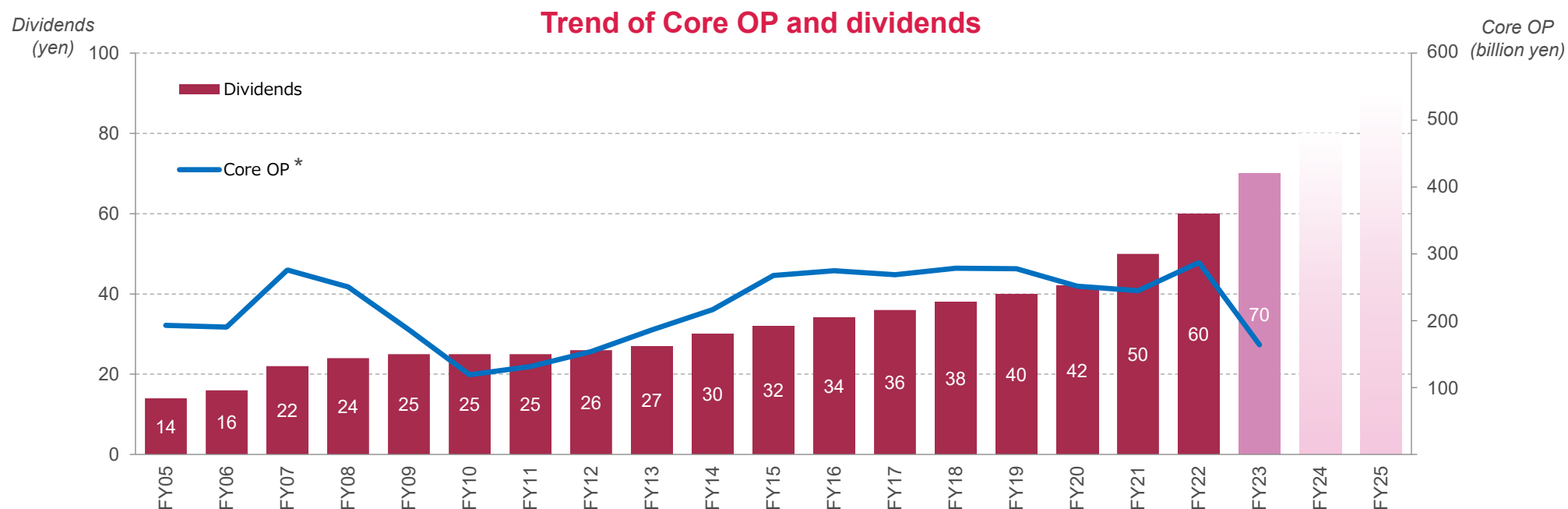
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1 Top priority is investment for business growth

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

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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



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)

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Project / Product	Indication	Current status
enzalutamide/ XTANDI	M1 CSPC	• NDA accepted in China in Sep 2023
	M0 CSPC with BCR at high risk for metastasis	• Approved in US in Nov 2023. Type II variation accepted in Europe in Sep 2023
enfortumab vedotin/ PADCEV	Metastatic urothelial cancer	• Previously untreated (first line): Approved in US in Dec 2023. Type II variation/sNDA accepted in Europe/Japan in Jan 2024 • Pretreated: BLA accepted in China in Mar 2023
	Muscle-invasive bladder cancer	• Phase 3 studies ongoing. Enrollment completed in Phase 3 EV-304 study
	Non-muscle-invasive bladder cancer	• Phase 1 study ongoing
	Other solid tumors	• Phase 2 study ongoing
gilteritinib/ XOSPATA	Relapsed and refractory AML	• China: Phase 3 study stopped due to efficacy
	AML, post-HSCT maintenance	• Development based on Phase 3 MORPHO study discontinued
	AML, newly diagnosed (HIC-eligible)	• Phase 3 study ongoing (enrollment completed)
	AML, newly diagnosed (HIC-ineligible)	• Phase 1 study ongoing
zolbetuximab	AML, post-chemotherapy	• Obtained topline results from Phase 2 GOSSAMER study
	Gastric & GEJ adenocarcinoma	• NDA accepted in Japan in Jun 2023. BLA/MAA accepted in Europe and China in Jul 2023. Received complete response letter in US in Jan 2024
	Pancreatic adenocarcinoma	• Phase 2 study ongoing
fezolinetant/ VEOZAH	VMS due to menopause	• Europe: Approved in Dec 2023 • China: Obtained topline results from Phase 3 MOONLIGHT 1 and MOONLIGHT 3 studies • Japan: Phase 3 studies under preparation to start in Q4 FY2023
avacincaptad pegol/ IZERVAY	GA secondary to AMD	• MAA accepted in Europe in Aug 2023. sNDA for label update submitted in US in Jan 2024.
	Stargardt disease	• Phase 2b study ongoing

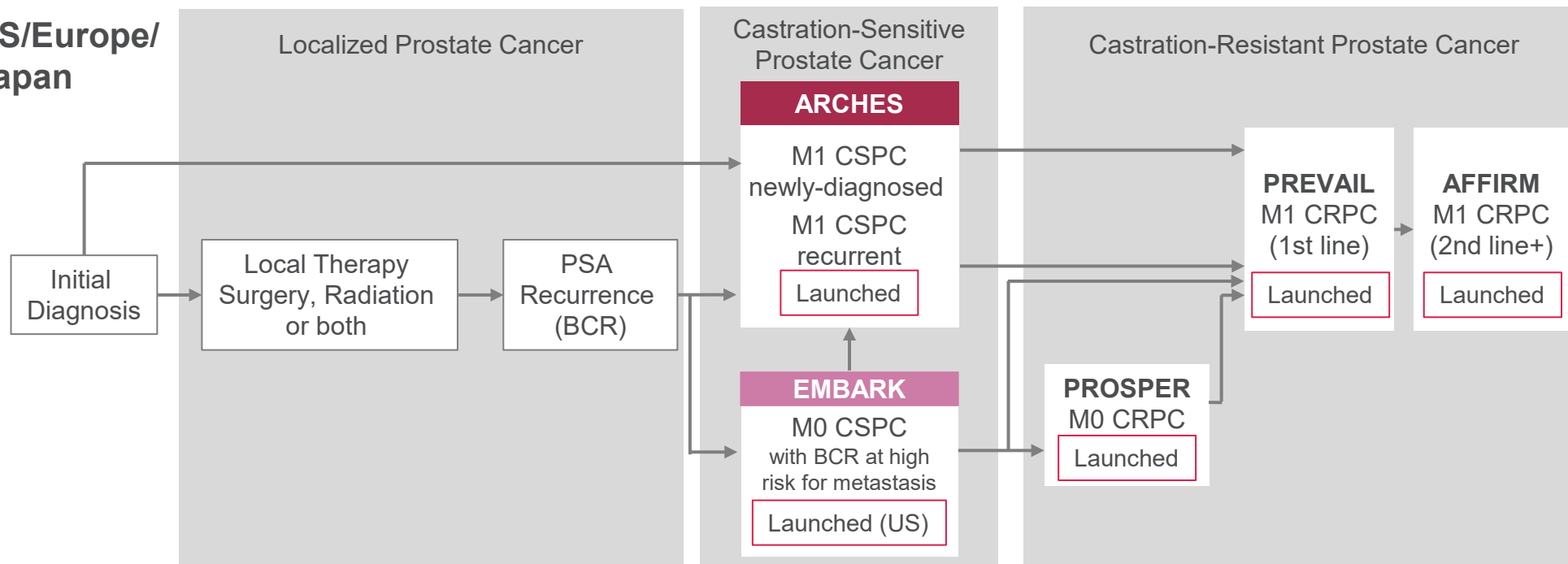
VEOZAH: Approved as "VEOZA" in Europe. M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, BCR: Biochemical recurrence, (s)NDA: (Supplemental) New Drug Application, BLA: Biologics License Application, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: 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)

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US/Europe/
Japan



P3: EMBARK

[NCT02319837](#)

M0 CSPC

ENZA + ADT vs. placebo + ADT vs. ENZA mono

n=1,068

Approved in US in Nov 2023

Type II variation accepted in Europe in Sep 2023

China

• M1 CSPC: NDA accepted in Sep 2023

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

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

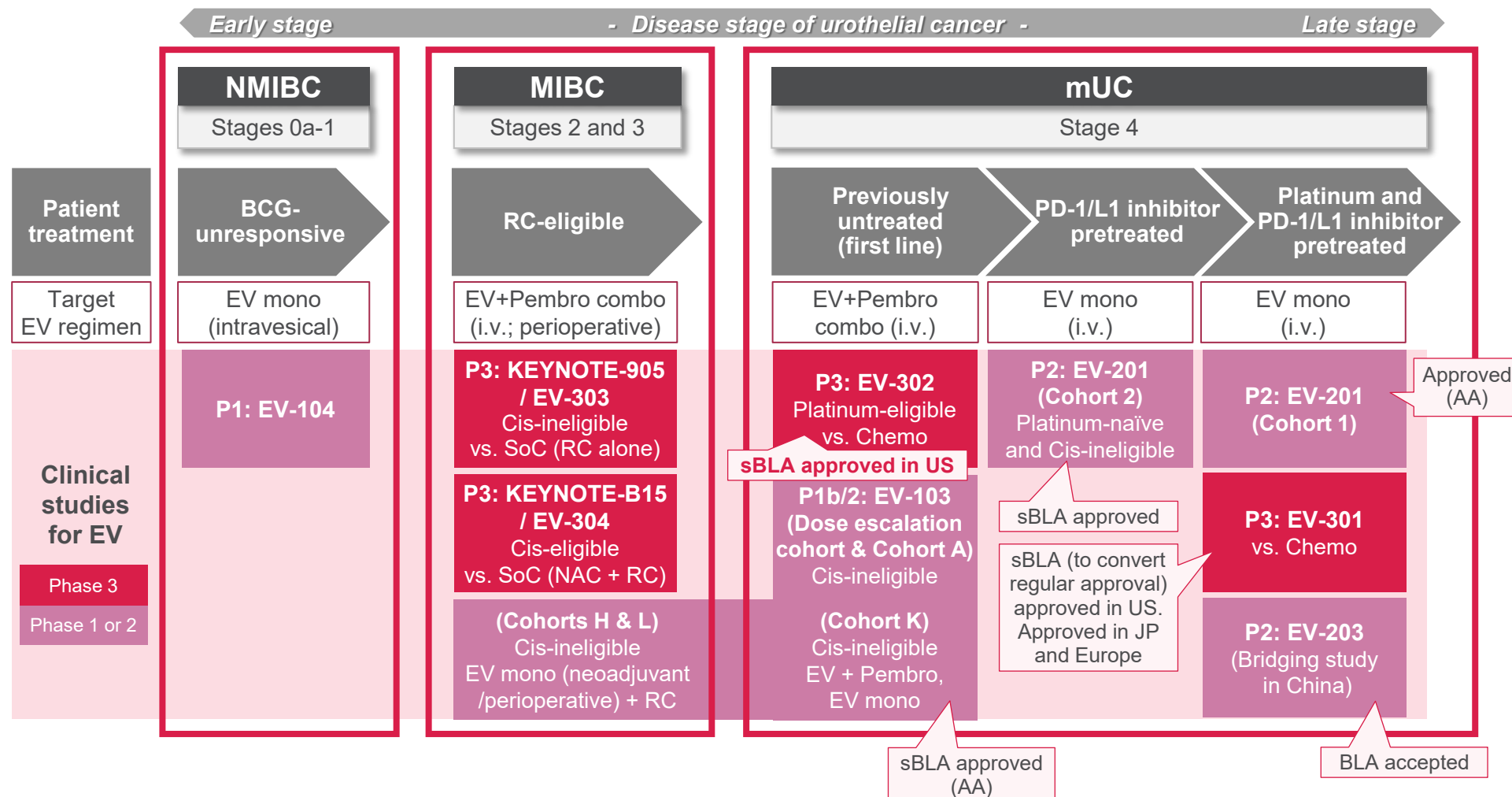
Disease stage	Early stage			Late stage		
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	EMBARK	ARCHES	ENZAMET	PROSPER	PREVAIL	AFFIRM
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary endpoint	✓ MFS HR 0.42	✓ 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)

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

(Red: Updates since the last financial results announcement)

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For urothelial cancer

P3: EV-301	NCT03474107	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
P3: EV-302	NCT04223856	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=990	Approved in US in Dec 2023. Type II variation/sNDA accepted in Europe/Japan in Jan 2024
P3: EV-303 /KEYNOTE-905	NCT03924895	MIBC, Cis-ineligible; 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 vs. Chemo (neoadjuvant) + RC	n=784	Enrollment completed
P2: EV-201	NCT03219333	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
P1b/2: EV-103	NCT03288545	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
P2: EV-203	NCT04995419	<Bridging study in China> 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, 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

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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)

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- 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	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 EV-103 Cohorts [Phase 1b/2 for AA in US] (combo w/ Pembro)	Approved 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 (monotherapy)	Approved	1,600 (US, Cis-ineligible)
	Platinum & PD-1/L1 inhibitor pretreated	EV-301 EV-201 Cohort 1 [Phase 2 for AA in US] (monotherapy)	Approved	38,000

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

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

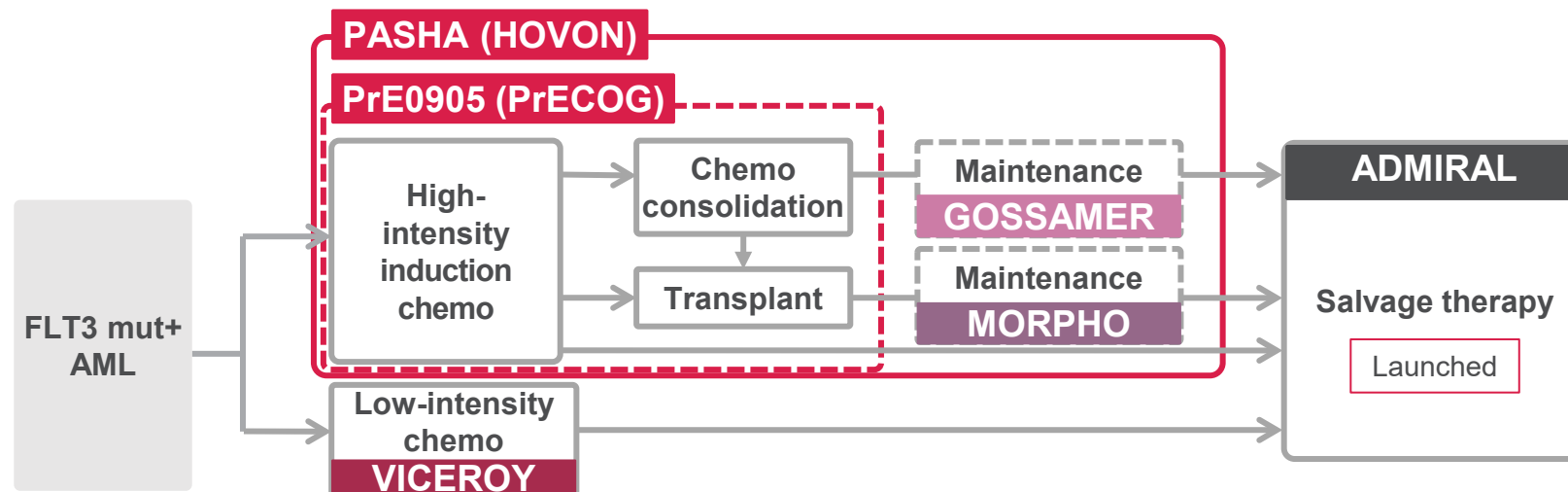
**Combo w/ Pembro:

Head and neck squamous cell carcinoma

GILTERITINIB: FLT3 INHIBITOR

(Red: Updates since the last financial results announcement)

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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	n=766	Enrollment completed (Sponsor: HOVON)
	P2: PrE0905 (PrECOG)	NCT03836209	gilteritinib vs. midostaurin (1:1)	n=179	Enrollment completed (Sponsor: PrECOG, LLC.)
Post-HSCT maintenance	P3: MORPHO	NCT02997202	Monotherapy vs. placebo (1:1)	n=356	Development based on MORPHO study discontinued
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

ZOLBETUXIMAB: ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

(Red: Updates since the last financial results announcement)

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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	NCT03504397	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. Received complete response letter in US in Jan 2024
	P3: GLOW	NCT03653507	First line, Combo with CAPOX, DB, vs. placebo	n=507	
	P2: ILUSTRO	NCT03505320	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 Cohort 5: Perioperative, Combo with FLOT	n=143	FSFT: Sep 2018
Pancreatic adenocarcinoma	P2	NCT03816163	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)

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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

P3: SKYLIGHT 1	NCT04003155	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. Approved in Europe in Dec 2023
P3: SKYLIGHT 2	NCT04003142	The last 40 weeks: Active extension treatment period, 30 mg or 45 mg	n=501	
P3: SKYLIGHT 4	NCT04003389	VMS associated with menopause; 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; 24 weeks, DB, 45 mg vs. placebo (1:1)	n=453	Topline results obtained in Jun 2023

China

P3: MOONLIGHT 1	NCT04234204	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)
P3: MOONLIGHT 3	NCT04451226	VMS associated with menopause; open label, 30 mg for 52 weeks	n=150	Topline results obtained in Sep 2022

Japan

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

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)

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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 ¹
- Approximately 75% of people living with GA in the US are believed to be undiagnosed ²
- Without timely treatment, an estimated 66% of people with GA may become blind or severely visually impaired ³

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	NCT02686658	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. sNDA for label update submitted in US in Jan 2024
	P3: GATHER2	NCT04435366	2 mg vs. Sham	n=448	
Stargardt disease	P2b	NCT03364153	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

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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

