Q2 YTD/FY2024 FINANCIAL RESULTS

Naoki Okamura
President and CEO
Astellas Pharma Inc.
October 30, 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.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.

AGENDA

I Q2 YTD/FY2024 Consolidated Financial Results
FY2024 Revised Forecast

II Initiatives for Sustainable Growth

III Mid-term Initiatives and Latest Outlook

Q2 YTD/FY2024 FINANCIAL RESULTS: OVERVIEW

Revenue

- Increased YoY (+22%)
- Strategic Brands: Expanded to over **150.0 bil. yen**
  Significant growth of over **90.0 bil. yen** YoY, progress exceeded expectations

*SG&A expenses**

- Ratio to revenue **improved by 3.2ppt** YoY through continued cost management

Core operating profit

- Increased significantly YoY (+36%) driven by growth of Strategic Brands and continued cost management

Revised full-year forecast

- **Upward revision** of revenue and core operating profit based on the robust Q2 YTD progress
  - ✓ Change from profit decline initial forecast to **profit increase forecast**

Strategic Brands: PADCEV, IZERVAY, VEOZAH, VYLOY, XOSPATA
*Excl. US XTANDI co-pro fee

Q2 YTD/FY2024 FINANCIAL RESULTS

(billion yen)	Q2 YTD FY2023	Q2 YTD FY2024	Change	Change (%)	FY2024 Initial FCST	FX impact (YoY)
Revenue	**767.1**	**935.6**	**+168.5**	**+22.0%**	**1,650.0**	+54.8
Cost of sales	143.4	173.8	+30.5	+21.3%	326.0	+6.7
SG&A expenses	347.5	406.4	+58.9	+17.0%	757.0	+25.9
US XTANDI co-pro fee	93.0	126.0	+33.0	+35.5%	189.0	+9.5
SG&A excl. the above	254.4	280.4	+26.0	+10.2%	568.0	+16.4
(SG&A ratio*)	33.2%	30.0%	-3.2ppt		34.4%	
R&D expenses	141.9	172.3	+30.4	+21.4%	317.0	+8.5
(R&D ratio)	18.5%	18.4%	-0.1ppt		19.2%	
Core operating profit**	**134.4**	**183.1**	**+48.7**	**+36.2%**	**250.0**	+13.7
(Core OP margin)	17.5%	19.6%	+2.0ppt		15.2%	
＜Full basis＞						
Amortisation of intangible assets	33.7	69.2	+35.5	+105.2%		
Other income	7.1	4.5	-2.6	-36.9%		
Other expenses	61.7	26.9	-34.8	-56.4%		
Operating profit	**55.2**	**93.7**	**+38.6**	**+69.9%**	**48.0**	
Profit before tax	56.3	89.0	+32.7	+58.1%	43.0	
Profit	**35.8**	**73.5**	**+37.7**	**+105.3%**	**30.0**	

Note) Amortisation of IZERVAY's intangible assets started from Q2/FY2023

Other expenses (booked in Q2)

- Net foreign exchange losses: 12.2

FY2024 Initial FCST announced in Apr 2024. FX rates for initial FCST: 145 yen/USD, 155 yen/EUR. Actual FX rates for Q2 YTD/FY2024: 152 yen/USD, 166 yen/EUR
*Excl. US XTANDI co-pro fee, **The definition of core-basis was changed from Q1/FY2024. In addition to the old definition's adjustments, 'Amortisation of intangible assets', 'Gain on divestiture of intangible assets' and 'Share of profit (loss) of investments accounted for using equity method' were newly excluded as new adjustment items.

astellas

Q2 YTD/FY2024 FINANCIAL RESULTS: XTANDI AND STRATEGIC BRANDS

XTANDI progress continues to be strong, driven primarily by the US

(billion yen)	Q2 YTD/FY2024	YoY	FY2024 Initial FCST*	FY2024 Revised FCST	
Xtandi	451.7	+90.7 (+25%)	757.0	859.7 vs. Initial FCST (+102.7)	✓ US progress continues to be driven by EMBARK impact (M0 CSPC) and market growth ✓ Upward revision of FCST based on robust progress through Q2, despite the anticipated negative impact from US IRA Medicare Part D redesign in Q4 ($80-100M impact)

*Strategic Brands expanded to **over 150.0 bil. yen** (**+90.0** YoY). Upward revision by **over 40.0 bil. yen**, reflecting strong momentum*

(billion yen)	Q2 YTD/FY2024	YoY	FY2024 Initial FCST*	FY2024 Revised FCST	
PADCEV	75.4	+42.7 (+131%)	151.2	166.9 (+15.7)	✓ Global sales expanded significantly YoY, driven by the US and EST performance ✓ Upward revision of FCST, reflecting the strong global growth trend
izervay	28.1	+26.9	46.4	69.5 (+23.1)	✓ Performance exceeded expectations, driven by higher-than-expected new patient share ✓ Significant upward revision of FCST, based on robust momentum and outlook
VEOZAH	14.8	+13.5	28.3	31.6 (+3.3)	✓ Steady growth in global sales, implementing continued initiatives with a focus on ROI ✓ Upward revision of FCST, reflecting the solid demand trend in the US and EST
VYLOY	1.2	+1.2	3.7	5.1 (+1.4)	✓ Market penetration of CLDN18.2 testing faster than expected in Japan Expect sales contribution from the US and EST from Q3 onwards ✓ Upward revision of FCST, reflecting the strong Japan performance
XOSPATA	34.8	+8.5 (+32%)	60.0	64.7 (+4.7)	✓ Expansion of global sales exceeded expectations Increase in FLT3 testing rate suggests potential positive impact to US demand growth ✓ Upward revision of FCST, reflecting the solid progress

*Announced in Apr 2024. FX rates for initial FCST: 145 yen/USD,155 yen/EUR, FX rates for revised FCST: 149 yen/USD,160 yen/EUR (Q3 onwards: 145 yen/USD,155 yen/EUR)
M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, IRA: Inflation Reduction Act, ROI: Return On Investment, CLDN18.2: Claudin 18.2
VEOZAH: Approved as "VEOZA" in ex-US, EST (Established Markets): Europe, Canada, etc.

astellas

PADCEV: BUSINESS UPDATE

PADCEV™

Significant sales growth globally. Expect robust global growth momentum to continue moving forward

	Q2 YTD/FY2024	YoY	FY2024 Initial FCST*	FY2024 Revised FCST
Global sales	**75.4** bil. yen	**+42.7 (+131%)**	**151.2**	**169.9** vs. Initial FCST **(+15.7)**
US ($ basis)	$349M	+186 (+114%)	742	**767 (+25)**
EST (€ basis)	€90M	+57 (+171%)	182	**200 (+18)**
Japan・CN・INT	7.2 bil. yen	+2.7 (+158%)	15.5	**20.8 (+5.3)**

Global progress & outlook

- ✓ Launched countries: 39 (1L mUC approved countries: 11)
- ✓ More than double growth YoY, with strong progress against initial FCST
- ✓ Upward revision of FCST, reflecting the strong global growth trend
- ✓ While varying growth rates are anticipated by region, expect robust global growth momentum to continue

Regional progress

- **US :** Steady penetration of 1L mUC, with new patient share approaching 55%
  Expect a moderate growth moving forward
- **EST :** Approval of 1L mUC in Aug, demonstrating strong initial uptake
  Expect further sales growth moving forward
- **JP :** Approval of 1L mUC in Sep, expect sales contribution from Q3 onwards
- **CN :** Approval of 2L+ mUC in Aug, expect 1L mUC approval in 1H/CY2025
- **INT :** Approval of 1L mUC in multiple countries, contributing to sales growth
  Expect further new launches and 1L mUC approvals from Q3 onwards

Future growth drivers

- ✓ Expect substantial 1L mUC sales contribution from ex-US in FY2025
- ✓ Next potential growth driver is the anticipated additional indication of MIBC, with TLR expected in FY2025 and contribution expected after approval

*Announced in Apr 2024. FX rates for initial FCST: 145 yen/USD,155 yen/EUR, FX rates for revised FCST: 149 yen/USD,160 yen/EUR (Q3 onwards: 145 yen/USD,155 yen/EUR)
1L: First line, mUC: Metastatic urothelial cancer, 2L+: Second or later line, MIBC: Muscle-invasive bladder cancer, TLR: Topline results, EST (Established Markets): Europe, Canada, etc.
CN (China): China, Hong Kong, INT (International Markets): Latin America, Middle East, Africa, Southeast Asia, South Asia, Russia, Taiwan, Korea, Australia, Export sales, etc.

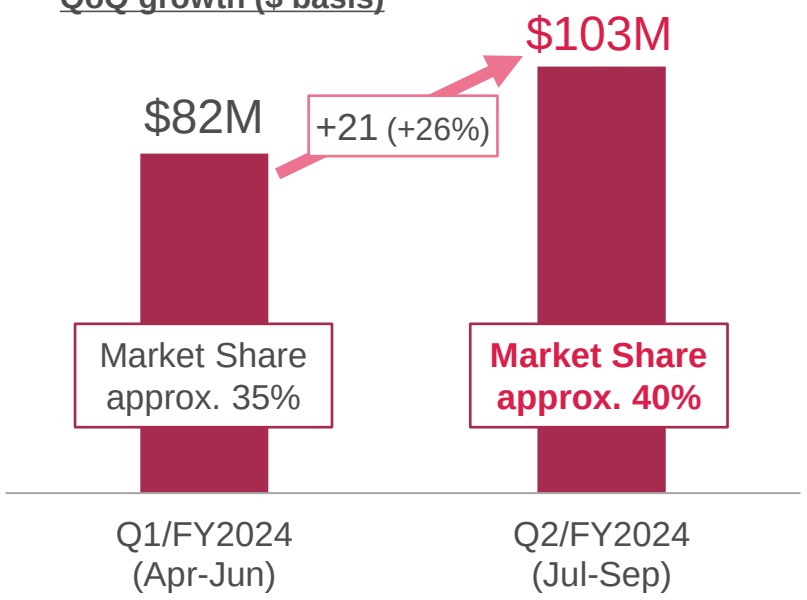
astellas

IZERVAY: BUSINESS UPDATE (US)

Performance continues to exceed expectations, expect further sales growth from Q3 onward

	Q2 YTD/FY2024	YoY	FY2024 Initial FCST*	FY2024 Revised FCST
	28.1 bil. yen	**+26.9**	**46.4**	**69.5** vs. Initial FCST (+23.1)
$ basis	$184M	+176	318	**467** (+149)

QoQ growth ($ basis)



Progress through Q2

- ✓ Continues to exceed expectations, driven by higher-than-expected new patient share
- ✓ Market share estimated at **~40%** and new patient share estimated at **~60%** in Q2 (Jul-Sep)
- ✓ Over **143,000 vials** shipped since launch as of Q2 (excl. clinical trials)
- ✓ Available in over 1,300 Retina accounts
- ✓ Post-marketing safety profile remains consistent with clinical trial results

DTC campaign

- ✓ New campaign launched across major channels incl. TV ad and social media, from Sep 30
- ✓ Aim to raise awareness of GA and highlight the importance of early treatment with IZERVAY

Future outlook

- ✓ Expect market growth from Q3 onward driven by DTC campaign
  Aim for 50% market share by the end of FY2024
- ✓ Significant upward revision of FCST (+$149M), based on robust momentum and outlook

*Announced in Apr 2024. FX rates for initial FCST: 145 yen/USD,155 yen/EUR, FX rates for revised FCST: 149 yen/USD,160 yen/EUR (Q3 onwards: 145 yen/USD,155 yen/EUR)
DTC: Direct-to-consumer, GA: Geographic atrophy

Q2 YTD/FY2024 FINANCIAL RESULTS: SG&A AND R&D EXPENSES

SG&A ratio to revenue improved by 3.2ppt YoY through continued cost management

Core basis: YoY comparison and ratio to revenue

(billion yen)

Cost Items	YoY change	Ratio to Revenue	
SG&A expenses **excl. US XTANDI co-pro fee**	+10.2% (+3.8% excl. FX impact)	SG&A ratio: 30.0% **(-3.2ppt YoY)**	YoY increase excl. FX impact: approx. +10.0 ✓ Strategic Brands-related expenses mainly IZERVAY (approx. +19.0 YoY) ✓ Reduction of mature products-related expenses (approx. -6.0 YoY) ✓ Global organizational restructuring in FY2023 (approx. -5.0 YoY)
R&D expenses	+21.4% (+15.4% excl. FX impact)	R&D ratio: 18.4% (-0.1ppt YoY)	YoY increase excl. FX impact: approx. +22.0 ✓ Primary Focus and enhanced R&D functions (approx. +13.0 YoY) ✓ One-time co-development cost payments in Q1

ROI: Return On Investment

FY2024 REVISED FORECAST

- *Upward revision of revenue and core operating profit based on the robust Q2 YTD progress*
- *Change from profit decline initial forecast to profit increase forecast*

Exchange rates for revised forecast: 149 yen/USD, 160 yen/EUR
(Forecast rates Q3 onwards: 145 yen/USD, 155 yen/EUR)

(billion yen)	FY2023 Actual	FY2024 Initial FCST	FY2024 Revised FCST	FY2024 Change	Main items of revision
Revenue	**1,603.7**	**1,650.0**	**1,800.0**	**+150.0**	• FX impact: approx. +30.0 • XTANDI and Strategic Brands: approx. +120.0
SG&A expenses	740.1	757.0	823.0	+66.0	• FX impact: approx. +15.0 • Increase in US pharma fee, etc.
US XTANDI co-pro fee	194.9	189.0	229.0	+40.0	
SG&A excl. the above	545.2	568.0	594.0	+26.0	
(SG&A ratio*)	34.0%	34.4%	33.0%	-1.4ppt	
R&D expenses	294.2	317.0	341.0	+24.0	• FX impact: approx. +5.0 • Faster patient enrollment of VYLOY (pancreatic) & VEOZAH (Japan)
(R&D ratio)	18.3%	19.2%	18.9%	-0.3ppt	
Core operating profit**	**276.9**	**250.0**	**300.0**	**+50.0**	• FX impact: approx. +7.0
(Core OP margin)	17.3%	15.2%	16.7%	+1.5ppt	

＜Full basis＞

Operating profit	**25.5**	**48.0**	**80.0**	**+32.0**

FY2024 Initial FCST announced in Apr 2024. FX rates for initial FCST: 145 yen/USD, 155 yen/EUR
*Excl. US XTANDI co-pro fee, **The definition of core-basis was changed from Q1/FY2024. In addition to the old definition's adjustments, 'Amortisation of intangible assets', 'Gain on divestiture of intangible assets' and 'Share of profit (loss) of investments accounted for using equity method' were newly excluded as new adjustment items.

astellas

AGENDA

I Q2 YTD/FY2024 Consolidated Financial Results
FY2024 Revised Forecast

II Initiatives for Sustainable Growth

III Mid-term Initiatives and Latest Outlook

INITIATIVES FOR SUSTAINABLE GROWTH: OVERVIEW OF QUARTERLY UPDATES

Strategic Brands

- enfortumab vedotin / PADCEV : Approval for 1L mUC (Europe, Japan) and 2L+ mUC (China)
- zolbetuximab / VYLOY : Approval (Europe, US)
- avacincaptad pegol / IZERVAY : Withdrawal of Marketing Authorization Application (Europe)
- fezolinetant / VEOZAH : Phase 3 study for additional indication initiated

Focus Area approach

- Data presentation : ASP3082 (Targeted Protein Degradation), ASP1570 (Immuno-Oncology)
- First subject first treatment : ASP5502 (Immune Homeostasis)
- Partnering : AviadoBio (Genetic Regulation)

Rx+ program

- DIGITIVA (digital health solution for heart failure management) : FDA listed, pilot launch under preparation
- Implantable device for underactive bladder (iota Biosciences) : IDE approval for early feasibility study by FDA

VEOZAH: Approved as “VEOZA” in ex-US.
See slide 33 for overview of collaboration with AviadoBio.
1L: First line, mUC: Metastatic urothelial cancer, 2L+: Second or later line, FDA: Food and Drug Administration, IDE: Investigational Device Exemption

astellas

XTANDI AND STRATEGIC BRANDS: FY2024 KEY EXPECTED EVENTS

(Blue: Updates since the last financial results announcement)

	Q1 (Apr-Jun)	Q2 (Jul-Sep)	Q3 (Oct-Dec)	Q4 (Jan-Mar)
enzalutamide/ XTANDI	Jun	Approval (M1 CSPC; China)		
enfortumab vedotin/ PADCEV		Aug Approval (2L+ mUC; China, 1L mUC; Europe)	Sep Approval (1L mUC; Japan)	
zolbetuximab/ VYLOY	May Resubmission acknowledgment (US)	Sep Approval (Europe)	Oct Approval (US)	NMPA Decision (China) TLR* (Pancreatic)
avacincaptad pegol/ IZERVAY		Withdrawal of MAA (Europe)	Nov PDUFA date (Label update; US) Oct	

Regulatory decision

Data readout

<Other updates>

- fezolinetant / VEOZAH: FSFT in Phase 3 study for VMS in women with breast cancer receiving adjuvant endocrine therapy (HIGHLIGHT 1) in Aug 2024

As of Oct 2024. VEOZAH: Approved as “VEOZA” in ex-US. *The timeline of TLR is subject to shift due to its event-driven nature. M1: Metastatic, CSPC: Castration-sensitive prostate cancer, 2L+: Second or later line, mUC: Metastatic urothelial cancer, 1L: First line, NMPA: National Medical Products Administration, TLR: Topline results, PDUFA: Prescription Drug User Fee Act, MAA: Marketing Authorization Application, FSFT: First subject first treatment, VMS: Vasomotor symptoms

astellas

PROGRESS IN FOCUS AREA APPROACH: CURRENT STATUS OF PROGRAMS IN CLINICAL TRIAL

(Blue: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology	Program	Mechanism of Action	Current status
Immuno-Oncology	Checkpoint	ASP1570	DGKζ inhibitor	Phase 1 study ongoing. **Initial data presented at ESMO in Sep 2024**
	Bispecific immune cell engager	★ ASP2138	Anti-CLDN18.2 and anti-CD3	Phase 1 study ongoing
		ASP1002	Anti-CLDN4 and anti-CD137	Phase 1 study ongoing
	Oncolytic virus (systemic)	ASP1012	Leptin-IL-2	Phase 1 study ongoing
	Cancer cell therapy	ASP2802	CD20 *convertible* CAR-T (autologous)	Phase 1 study under preparation to start in Q3/FY2024
Targeted Protein Degradation	Protein degradation	★ ASP3082	KRAS G12D degrader	Phase 1 study ongoing. **Initial data presented at ESMO in Sep 2024** (Link)
		ASP4396	KRAS G12D degrader	Phase 1 study ongoing
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
		ASP2016	FXN gene	Phase 1 study under preparation to start in Q3/FY2024. **Rare pediatric disease designation and orphan drug designation granted by FDA in Aug 2024 and Sep 2024, respectively**
Blindness & Regeneration	Cell replacement	★ ASP7317	RPE cells	Phase 1b study ongoing
Immune Homeostasis (PF Candidate)	Immune modulation	ASP5502	STING inhibitor	**FSFT in Phase 1 study in Sep 2024**
Others (Non-PF)	Long-acting abiraterone prodrug	ASP5541 (PRL-02)	CYP17 lyase inhibitor	Phase 1 study ongoing

Modality
- Small molecule
- Antibody
- Gene
- Cell

★: Flagship program (See slides 31 & 32 for overview)

DGK: Diacylglycerol kinase, ESMO: European Society for Medical Oncology, CLDN: Claudin, IL-2: Interleukin-2, CAR: Chimeric antigen receptor, KRAS: Kirsten rat sarcoma viral oncogene homologue, AAV: Adeno-associated virus, MTM1: Myotubularin 1, FDA: Food and Drug Administration, GAA: Acid alpha-glucosidase, FXN: Frataxin, RPE: Retinal pigment epithelial, PF: Primary Focus, STING: Stimulator of interferon genes, FSFT: First subject first treatment

astellas

AGENDA

I Q2 YTD/FY2024 Consolidated Financial Results
FY2024 Revised Forecast

II Initiatives for Sustainable Growth

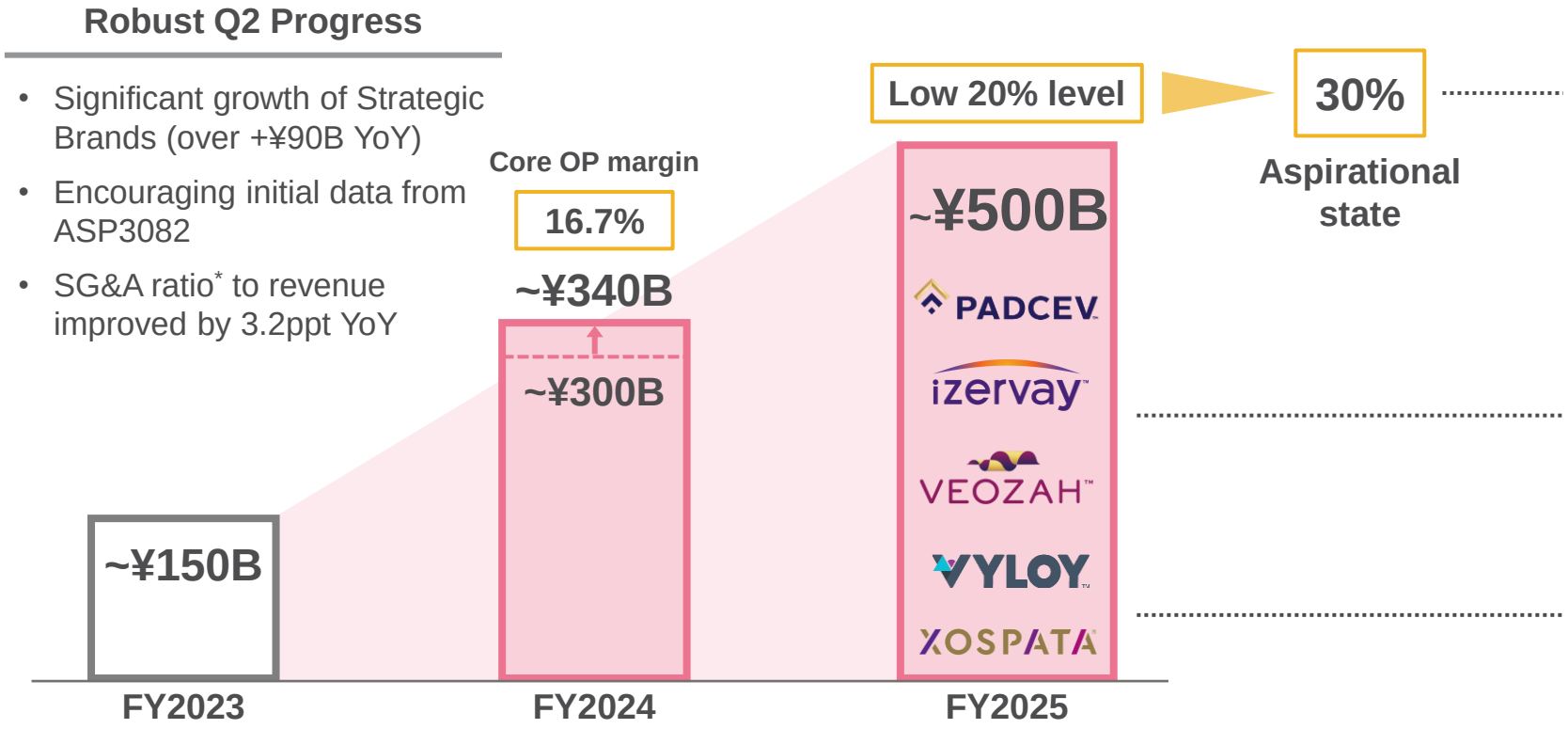
III Mid-term Initiatives and Latest Outlook

OVERVIEW OF ONGOING INITIATIVES AND LATEST OUTLOOK

Accelerate Three Enterprise Priorities to overcome XTANDI LOE and pursue further growth

Robust Q2 Progress

- Significant growth of Strategic Brands (over +¥90B YoY)
- Encouraging initial data from ASP3082
- SG&A ratio* to revenue improved by 3.2ppt YoY



PoC judgment of PF flagship programs

TPD: ASP3082, IO: ASP2138, GR: AT845, BR: ASP7317

Three Enterprise Priorities

Sustainable Margin Transformation

- Company-wide cost optimization before XTANDI LOE
- Fund growth investment and profit improvement

Growth Strategy

- New operating model by brand level to maximize brand performance
- Agile ways of working to promote faster decision-making

Bold Ambition

- Agile R&D model to accelerate from discovery to PoC, acquiring new assets, etc.
- Strengthening in-house capabilities for clinical trial execution and data-driven decision making

*Excl. US XTANDI co-pro fee
LOE: Loss of exclusivity, PoC: Proof of concept, PF: Primary Focus, IO: Immuno-Oncology, TPD: Targeted Protein Degradation, GR: Genetic Regulation, BR: Blindness & Regeneration

astellas

MAXIMIZE POTENTIAL OF STRATEGIC BRANDS

Accelerate growth of Strategic Brands by new operating model and LCM

Data readout timing
(registrational study)

VYLOY
Pancreatic cancer

PADCEV
MIBC

XOSPATA
Untreated AML

Other LCM opportunities

Potential contribution from LCM

FY2024 progress

- Launched new operating model in US accelerating sales performance

FY2023	FY2024	FY2025	FY2026 onwards
~¥150B	~¥340B ~¥300B Q2 YTD sales Over ¥150B	~¥500B PADCEV izervay VEOZAH VYLOY XOSPATA	

Growth momentum to continue

Expand new operating model globally to maximize brand potential

Growth Strategy

- New operating model by brand level to maximize brand performance
- Agile ways of working to promote faster decision-making

Bold Ambition

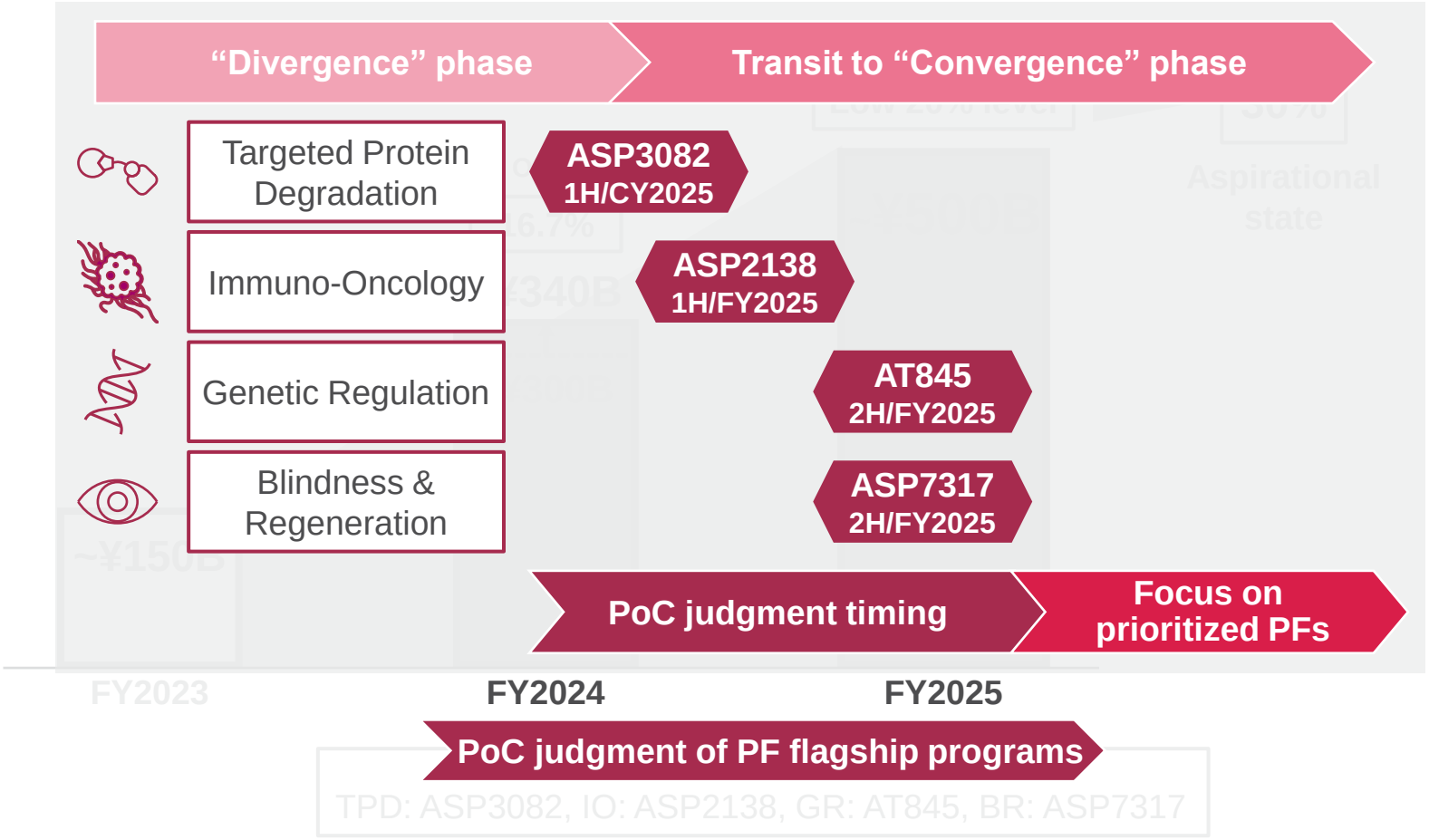
- Agile R&D model to accelerate from discovery to PoC, acquiring new assets, etc.
- Strengthening in-house capabilities for clinical trial execution and data-driven decision making

See slide 30 for details of LCM activities.
LCM: Lifecycle management, MIBC: Muscle-invasive bladder cancer, AML: Acute myeloid leukemia

astellas

ADVANCE FOCUS AREA APPROACH

- *Focus on prioritized Primary Focuses and increase pipeline value based on PoC judgment of flagship programs*
- *Continue exploratory research at the frontier with discipline, to generate new programs for future growth*



Expect sales contribution in 2030's

Bold Ambition

- Agile R&D model to accelerate from discovery to PoC, acquiring new assets, etc.
- Strengthening in-house capabilities for clinical trial execution and data-driven decision making

See slides 31 & 32 for overview of flagship programs.
PoC: Proof of concept, PF: Primary Focus

SUSTAINABLE MARGIN TRANSFORMATION

- *Company-wide cost optimization of 120-150 billion yen before XTANDI LOE*
- *Fund growth investment and profit improvement*

FY2024 → FY2027

Strengthen monitoring on priority initiatives

1. Build critical in-house capability to reduce outsourcing **: ¥15B+**
   - Strengthen in-house capabilities for clinical development operations
   - Reduce outsourcing and advisory service costs
2. Further efficiency of global operations **: ¥20B+**
   - Establish global capability centers to optimize global operations
   - Enhance company-wide efficiency with AI and digital tools
3. Optimize selling expenses with ROI focus **: ¥35B+**
   - Cost efficiency from global organizational restructuring in FY2023
   - Strengthen optimization for mature products
4. Continuous company-wide cost optimization **: ¥50B+**
   - Streamline OPEX with no sacred areas
   - Improve manufacturing cost by scaling up and yield enhancement

Recurring annual benefit

Range of ¥120-150B

FY2024 end ~¥40B

Growth Investment

Profit Improvement

Core OP margin

30%

Aspirational state

Maximize potential of Strategic Brands

Focus on post-PoC prioritized PF assets

Optimize a cost structure before XTANDI LOE

Sustainable Margin Transformation

- Company-wide cost optimization before XTANDI LOE
- Fund growth investment and profit improvement

LOE: Loss of exclusivity, ROI: Return On Investment, PoC: Proof of concept, PF: Primary Focus

TO OVERCOME XTANDI LOE AND PURSUE FURTHER GROWTH

Maximize potential of Strategic Brands, accelerate further growth with LCM contribution

Focus on prioritized PFs and increase pipeline value based on PoC judgment of flagship programs

Drive Sustainable Margin Transformation to fund growth investment and profit improvement

Three Enterprise Priorities

- Fund growth investment and profit improvement
- maximize brand performance
- Agile ways of working to promote faster
- Agile R&D model to accelerate from discovery to PoC, acquiring new assets, etc.
- Strengthening in-house capabilities for clinical trial execution and data-driven decision making

Core OP margin

16.7%

~¥500B

FY2023 FY2024 FY2025

PoC judgment of PF flagship programs

TPD: ASP3082, IO: ASP2138, GR: AT845, BR: ASP7317

LOE: Loss of exclusivity, LCM: Lifecycle management, PF: Primary Focus, PoC: Proof of concept

astellas

APPENDIX

XTANDI AND STRATEGIC BRANDS: POTENTIAL PEAK SALES (AS OF OCT 2024)

Brand	Potential Peak Sales *(Global, billions of yen)*
XTANDI (enzalutamide)	over 700.0
PADCEV (enfortumab vedotin) *	400.0 – 500.0
IZERVAY (avacincaptad pegol)	200.0 – 400.0
VEOZAH (fezolinetant)	150.0 – 250.0
VYLOY (zolbetuximab)	100.0 – 200.0
XOSPATA (gilteritinib)	100.0 – 200.0

Only indications undergoing pivotal studies are included for projection (as of Oct 2024), VEOZAH: Approved as “VEOZA” in ex-US
*Disclosed as “in-market sales,” not Astellas revenue. Sales for Americas are calculated based on the sales booked by Pfizer

Q2 YTD/FY2024 ACTUAL: FX RATE

Average rate for the period

Currency	Q2 YTD/FY2023	Q2 YTD/FY2024	Change
USD	141 yen	152 yen	+11 yen
EUR	153 yen	166 yen	+12 yen

<Impact of exchange rate on financial results>

- Revenue: +54.8 billion yen
- Core OP: +13.7 billion yen

FY2024 FORECAST: FX RATE & FX SENSITIVITY

Exchange rate Average for the period	FY2024 Initial FCST	FY2024 Revised FCST	Change
USD	145 yen	149 yen	+4 yen
EUR	155 yen	160 yen	+5 yen

Forecast rates Q3 onwards: 145 yen/USD, 155 yen/EUR

Estimated FX sensitivity (Q3 onwards) of FY2024 revised forecasts by 1 yen depreciation

Currency	Average rate 1 yen depreciation from assumption	
	Revenue	Core OP
USD	Approx. +3.5 bil. yen	Approx. +0.5 bil. yen
EUR	Approx. +1.6 bil. yen	Approx. +0.7 bil. yen

BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY2023 end	Sep 30, 2024
Total assets	3,569.6	3,462.2
Cash and cash equivalents	335.7	293.0
Total equity attributable to owners of the parent	1,596.0	1,529.8
Equity ratio (%)	44.7%	44.2%

(billion yen)	Q2 YTD/FY2023	Q2 YTD/FY2024
Cash flows from operating activities	53.2	77.4
Cash flows from investing activities	-787.5	-55.7
Free cash flows	-734.2	21.7
Cash flows from financing activities	670.2	-66.3
Increase/decrease in short-term borrowings and commercial papers	274.9	-159.9
Proceeds from issuance of bonds and long-term borrowings	470.5	200.0
Redemption of bonds and repayments of long-term borrowings	-	-26.0
Acquisition of treasury shares	-10.7	-7.0
Dividends paid	-53.9	-62.8

BALANCE OF BONDS AND BORROWINGS HIGHLIGHTS

（billion yen）	Jun 30, 2024	Sep 30, 2024
Balance of bonds and borrowings	992.7	927.5
Non-current liabilities	443.1	620.2
Bonds	250.0	350.0
Long-term borrowings	193.1	270.2
Current liabilities	549.6	307.3
Commercial papers	325.7	164.8
Short-term borrowings	170.4	91.8
Current portion of long-term borrowings	53.5	50.6

MAIN INTANGIBLE ASSETS (AS OF SEP 30, 2024)

	Bil. yen	Foreign currency*
AT132	15.6	$109M
AT845	10.4	$73M
Other gene therapy related program**	55.1	$384M
Gene therapy related technology**	64.6	$450M
VEOZAH	86.8	€535M
VYLOY	62.3	€480M
IZERVAY（US）	649.7	$4,523M
IZERVAY (Ex-US）	158.0	$1,100M

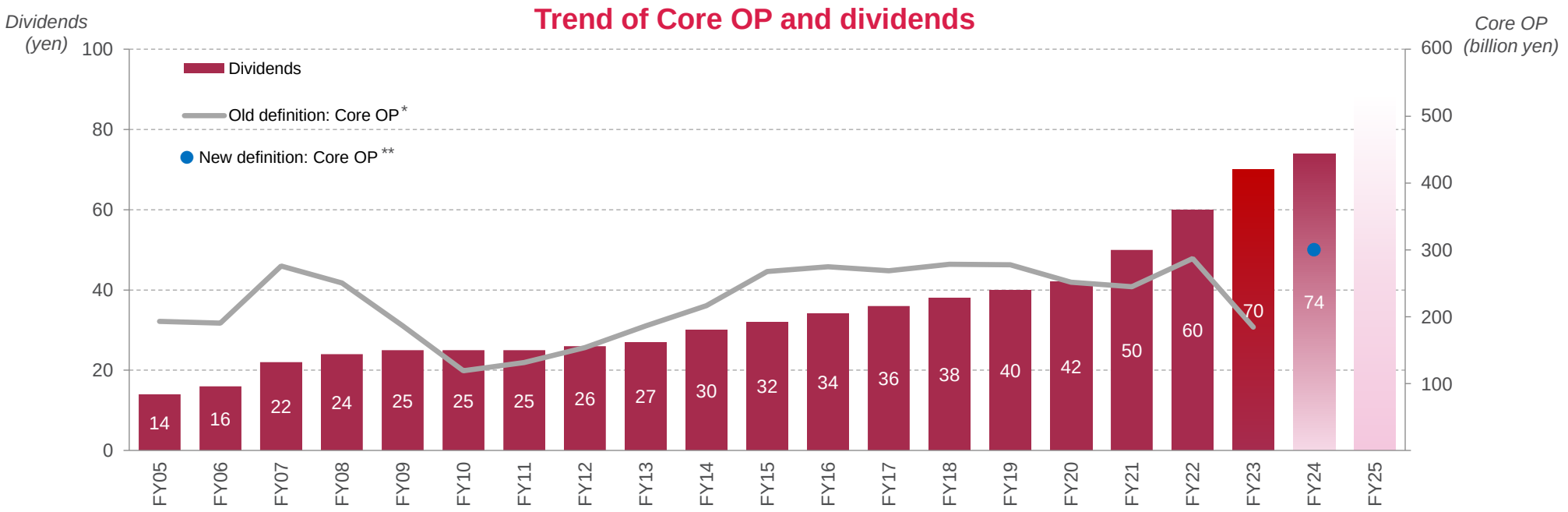
VEOZAH: Approved as “VEOZA” in ex-US
*VEOZAH, VYLOY: foreign currency is a reference value based on the currency at the time of acquisition of the intangible asset
**Acquired during the acquisition of Audentes (now Astellas Gene Therapies)

astellas

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

CSP: Corporate Strategic Plan
*Prior to FY2012, operating profit is in accordance with J-GAAP
**Change in definition of core basis from FY2024

astellas

CORE BASIS PERFORMANCE: CHANGES IN DEFINITIONS AND CONTEXT

Introduce New definition of core-based performance from FY2024

Financial Results (Full basis)

Revenue
- Cost of sales

Gross profit
- SG&A expenses
- R&D expenses
- Amortisation of Intangible assets
- Gain on divestiture of Intangible assets
- Share of profit (loss) of investments accounted for using equity method
- Other income
- Other expenses

Operating profit
- Finance income
- Finance expenses

Profit before tax
- Income tax expense

Profit

Financial Results (Old definition: Core basis)

Certain items reported in financial results on a full basis by the Company are excluded as non-core items from these financial results on a core basis. These adjusted items include impairment losses, gain/loss on sales of property, plant and equipment, restructuring costs, loss on disaster, a large amount of losses on compensation or settlement of litigations and other legal disputes

Core operating profit

Adjustments to 'Finance income' and 'Finance expenses'

Core profit

Financial Results (New definition: Core basis)

In addition to the old definition's adjustments, 'Amortisation of intangible assets', 'Gain on divestiture of intangible assets' and 'Share of profit (loss) of investments accounted for using equity method' are newly excluded in the new definition

Core operating profit

Adjustments to 'Finance income' and 'Finance expenses'

Core profit

LIFECYCLE MANAGEMENT OF STRATEGIC BRANDS

Product	Indication	Current status	Next milestone
PADCEV enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials	MIBC	Phase 3 EV-303 & EV-304 studies ongoing	TLR anticipated for FY2025
	NMIBC	Phase 1 EV-104 study ongoing	TLR anticipated for FY2025
	Head and neck cancer	2L+: Next step under discussion	(Under discussion)
		1L: Phase 2 EV-202 study ongoing	TLR anticipated for FY2025
izervay (avacincaptad pegol intravitreal solution) 2 mg	GA secondary to AMD	Japan: Under discussion with PMDA	(Under discussion)
		LCM opportunities under consideration (e.g. prefilled syringe, sustained release)	(Under discussion)
	Stargardt disease	Phase 2 study ongoing	TLR anticipated for FY2025
VEOZAH™ (fezolinetant) tablets 45 mg	VMS associated with menopause	Japan: Phase 3 STARLIGHT 2 & 3 studies ongoing	TLR anticipated for FY2026 or later
	VMS in breast cancer women	Phase 3 HIGHLIGHT 1 study ongoing	TLR anticipated for FY2027
VYLOY™ zolbetuximab for injection 100mg vial	Gastric and GEJ cancer	Phase 3 study in combo with CPI and chemotherapy under preparation	Study start in Q1/FY2025
	Pancreatic cancer	Registrational Phase 2 GLEAM study ongoing	TLR anticipated for Q4/FY2024
XOSPATA® gilteritinib 40mg tablets	Newly diagnosed AML (HIC-eligible)	Phase 3 PASHA study ongoing	TLR anticipated for FY2026

As of Oct 2024. Not exhaustively listed. VEOZAH: Approved as “VEOZA” in ex-US. MIBC: Muscle-invasive bladder cancer, TLR: Topline results, NMIBC: Non-muscle-invasive bladder cancer, GA: Geographic atrophy, AMD: Age-related macular degeneration, PMDA: Pharmaceuticals and Medical Devices Agency, LCM: Lifecycle management, VMS: Vasomotor symptoms, GEJ: Gastroesophageal junction, CPI: Checkpoint inhibitor, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy

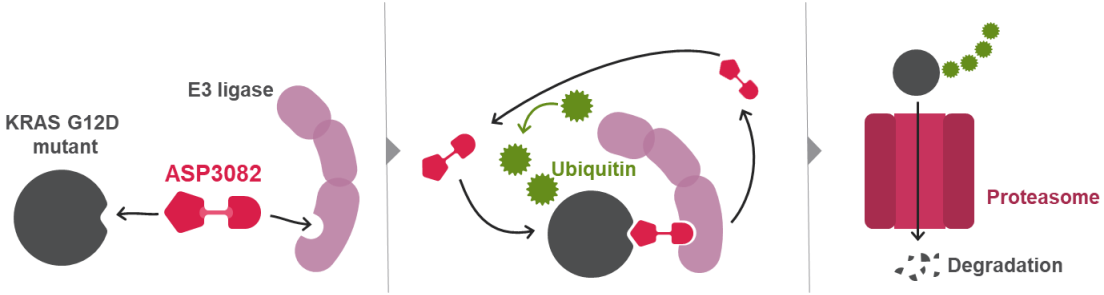
astellas

OVERVIEW OF PRIMARY FOCUS FLAGSHIP PROGRAMS (1/2)

ASP3082 (Targeted Protein Degradation)

Protein degrader targeting KRAS G12D mutant

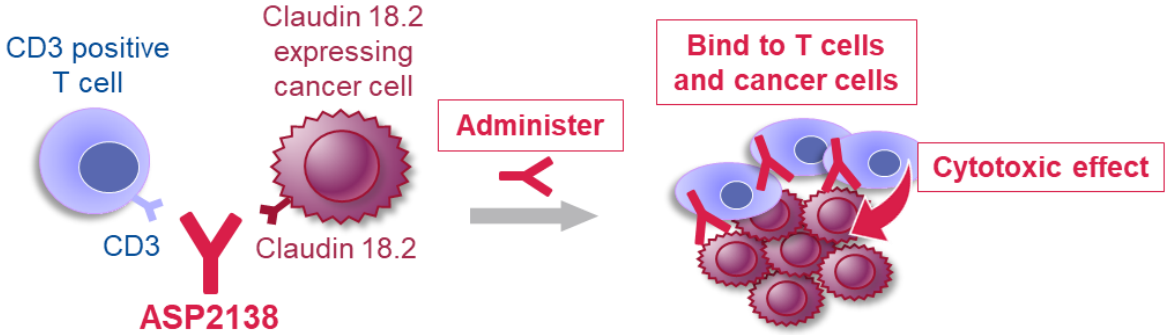
- Target disease: Cancers harboring KRAS G12D mutation
  - ✓ Rate of patients with KRAS G12D mutation: ~40% in PDAC, ~15% in CRC, ~5% in non-squamous NSCLC[1]
- Standard of care (metastatic PDAC): Chemotherapy
- Status: Phase 1 study ongoing (NCT05382559)
  - ✓ PDAC: 2L+ (monotherapy), 1L (combo with chemotherapy)
  - ✓ CRC: 2L+ (monotherapy, combo with cetuximab)
  - ✓ NSCLC: 2L+ (monotherapy)
- Anticipated PoC judgment timing: 1H/CY2025



ASP2138 (Immuno-Oncology)

Bispecific antibody targeting Claudin 18.2 and CD3

- Target disease: Gastric and GEJ (G/GEJ) adenocarcinoma, pancreatic adenocarcinoma
  - ✓ Rate of Claudin 18.2-positive patients*: ~70% in G/GEJ adenocarcinoma[2] and ~60% in pancreatic adenocarcinoma[3]
- Standard of care (HER2-, advanced G/GEJ adenocarcinoma)
  - ✓ 1L: chemotherapy +/- checkpoint inhibitor
  - ✓ 2L+: paclitaxel + ramucirumab
- Status: Phase 1 study ongoing (NCT05365581)
  - ✓ G/GEJ adenocarcinoma, 1L & 2L, monotherapy & combo
- Anticipated PoC judgment timing: 1H/FY2025



*Represents % of patients with any level of Claudin 18.2+ staining (≥1%). 1. npj Precis Oncol. 2022;6:91, 2. Gastric Cancer. 2024;27:1058, 3. Int J Cancer. 2013;134:731
KRAS: Kirsten rat sarcoma viral oncogene homologue, PDAC: Pancreatic ductal adenocarcinoma, CRC: Colorectal cancer, NSCLC: Non-small cell lung cancer, 2L+: Second or later line, 1L: First line, PoC: Proof of concept, GEJ: Gastroesophageal junction, HER2-: HER2 negative

astellas

OVERVIEW OF PRIMARY FOCUS FLAGSHIP PROGRAMS (2/2)

AT845 (Genetic Regulation)

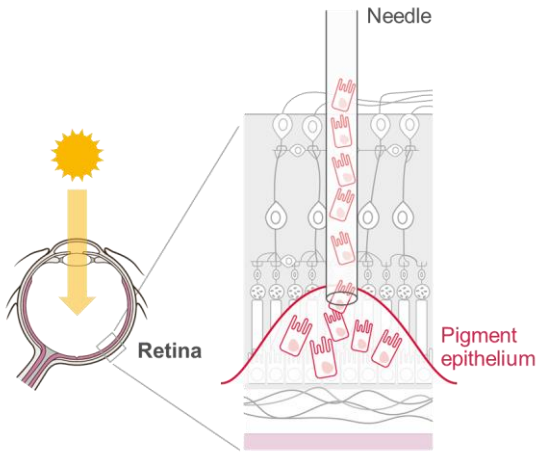
Recombinant AAV8 expressing hGAA gene specially in muscle

- Target disease: Pompe disease
  - ✓ Estimated incidence: 1 in ~40,000[1]
- Standard of care: Enzyme replacement therapy (ERT)
  - ✓ Chronic, repeated infusions every 2 weeks
  - ✓ Secondary disease progression after 2-3 years on ERT[2,3,4]
- Status: Phase 1/2 FORTIS study ongoing (NCT04174105)
  - ✓ Disease stability observed for up to 2 years while off ERT[5]
- Anticipated PoC judgment timing: 2H/FY2025

ASP7317 (Blindness & Regeneration)

Replacement therapy with retinal pigment epithelial cells aiming to maintain and restore visual functions

- Target disease: Geographic atrophy secondary to AMD
  - ✓ Estimated Number of patients: ~5 million worldwide[6]
- Standard of care: Complement inhibitors
  - ✓ Slows progression, does not improve vision
- Status: Phase 1b study ongoing (NCT03178149)
- Anticipated PoC judgment timing: 2H/FY2025



1. NORD (National Organization for Rare Disorders) at https://rarediseases.org/rare-diseases/pompe-disease/, 2. Neuromuscul Disord. 2021;31:91-100, 3. J Neurol. 2021;268:2482-2492, 4. Mol Genet Metab. 2012;106:301-309, 5. MDA Clinical & Scientific Conference 2024, 6. Retina. 2017;37:819-835
AAV: Adeno-associated virus, hGAA: Human acid alpha-glucosidase, PoC: Proof of concept, AMD: Age-related macular degeneration

astellas

COLLABORATION WITH AVIADOBIO

Potential expansion of portfolio in Primary Focus Gene Therapy

Overview of agreement

- Exclusive option and license agreement for AVB-101
  - ✓ Option to receive a worldwide exclusive license for the development and commercialization rights to AVB-101
  - ✓ Equity investment of $20 million and option upfront payments up to $30 million
  - ✓ License fees and milestone payments plus royalties if Astellas exercises its option

AVIADOBIO

AVB-101

- AAV-based gene therapy to deliver human progranulin gene
  - ✓ One-time infusion into the brain
- Target disease: Frontotemporal dementia with progranulin mutations (FTD-GRN)
  - ✓ Devastating form of early-onset dementia that typically leads to death within three to 13 years from diagnosis
  - ✓ Characterized by a rapid decline in executive function*, uncharacteristic behaviors, loss of language, apathy, and reduced mobility

    *attention control, working memory, problem-solving, etc.
  - ✓ No disease-modifying therapy currently available
- Phase 1/2 study ongoing (NCT06064890)

Ref. Int Rev Psychiatry. 2013;25:130-137, Neuropsychiatr Dis Treat. 2014;10:297-310, Neuroepidemiology. 2011;37:166-167, Dement Geriatr Cogn Disord. 2016;41:109-122
AAV: Adeno-associated virus

astellas

ROBUST PIPELINE OF ASTELLAS

Phase 1

- enfortumab vedotin (NMIBC)
- gilteritinib (Newly diagnosed AML, HIC-ineligible)
- ASP1570
- ASP2138
- ASP1002
- ASP1012
- ASP2802
- ASP3082
- ASP4396
- zocaglusagene nuzaparvovec/ AT845
- ASP2016
- ASP7317
- ASP5502
- abiraterone decanoate/ ASP5541 (PRL-02)

Phase 2

- enfortumab vedotin (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- avacincaptad pegol (Stargardt disease)
- resamirigene bilparvovec/ AT132 (XLMTM)

Phase 3

- enfortumab vedotin (MIBC)
- gilteritinib (Earlier-stage AML, pediatric use)
- fezolinetant (VMS due to menopause: China, Japan; Induced VMS in breast cancer patients on adjuvant endocrine therapy)
- zolbetuximab (Gastric and GEJ adenocarcinoma, combo with CPI and chemotherapy)
- mirabegron (NDO, pediatric use (aged 6 months to less than 3 years): Europe)
- roxadustat (Anemia associated with CKD, pediatric use: Europe)

Submitted/Filed

- enfortumab vedotin (mUC previously untreated: China)
- zolbetuximab (Gastric and GEJ adenocarcinoma, combo with chemotherapy: China)

Strategic Brands

Programs 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, MIBC: Muscle-invasive bladder cancer, VMS: Vasomotor symptoms, GEJ: Gastroesophageal junction, CPI: Checkpoint inhibitor, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, mUC: Metastatic urothelial cancer

astellas

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

Withdrawal of MAA

avacincaptad pegol: GA secondary to AMD (Europe)

enfortumab vedotin
Locally advanced or metastatic urothelial cancer after prior treatment with platinum-containing chemotherapy and PD-1 or PD-L1 inhibitors: China

Unresectable or metastatic urothelial cancer, previously untreated (first line): Europe, Japan

zolbetuximab
Gastric and gastroesophageal junction adenocarcinoma (combo with chemotherapy): Europe, US

mirabegron
Neurogenic detrusor overactivity in pediatric patients (aged 3 to less than 18 years): Europe

peficitinib
Rheumatoid arthritis: China

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, GA: Geographic atrophy, AMD: Age-related macular degeneration, MAA: Marketing Authorization Application

STRATEGIC BRANDS: STATUS UPDATE

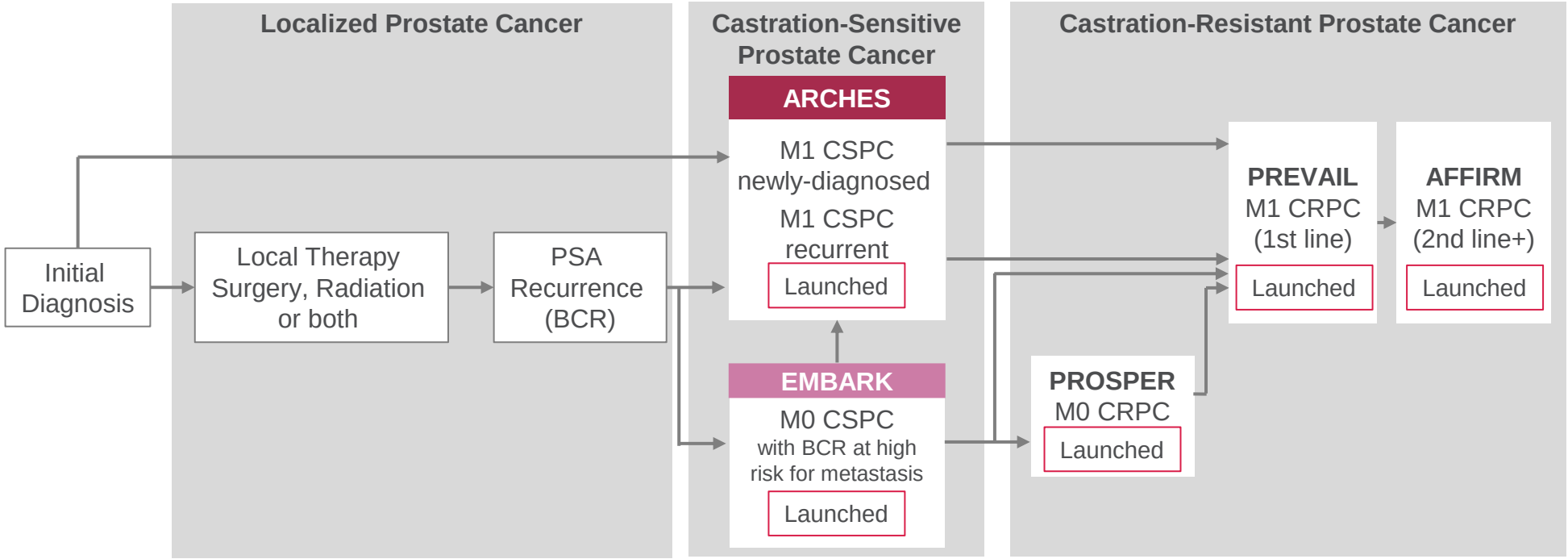
(Blue: Updates since the last financial results announcement)

Generic / Brand name	Indication	Current status
enfortumab vedotin / PADCEV	Metastatic urothelial cancer	• Previously untreated (first line): **Approved in Europe in Aug 2024, in Japan in Sep 2024** • Pretreated: **Approved in China in Aug 2024**
	Muscle-invasive bladder cancer	• Phase 3 studies ongoing (enrollment completed)
	Non-muscle-invasive bladder cancer	• Phase 1 study ongoing **(enrollment completed)**
	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	• 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
	AML, post-chemotherapy	• Obtained topline results from Phase 2 GOSSAMER study
zolbetuximab/ VYLOY	Gastric and GEJ adenocarcinoma	• BLA accepted in China in Jul 2023. **Approved in Europe in Sep 2024, in US in Oct 2024** • Phase 3 study in combo with CPI and chemotherapy under preparation to start in Q1/FY2025
	Pancreatic adenocarcinoma	• Phase 2 study ongoing (enrollment completed)
fezolinetant/ VEOZAH	VMS due to menopause	• China: Obtained topline results from Phase 3 MOONLIGHT 1 and MOONLIGHT 3 studies • Japan: Phase 3 studies ongoing
	VMS in breast cancer patients on adjuvant endocrine therapy	• **FSFT in Phase 3 HIGHLIGHT 1 study in Aug 2024**
avacincaptad pegol/ IZERVAY	GA secondary to AMD	• sNDA for label update accepted in US in Mar 2024 • **MAA withdrawn in Europe in Oct 2024**
	Stargardt disease	• Phase 2b study ongoing

VEOZAH: Approved as “VEOZA” in ex-US. AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, GEJ: Gastroesophageal junction, BLA: Biologics License Application, CPI: Checkpoint inhibitor, VMS: Vasomotor symptoms, FSFT: First subject first treatment, GA: Geographic atrophy, AMD: Age-related macular degeneration, sNDA: Supplemental New Drug Application, MAA: Marketing Authorization Application

astellas

ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR



PSA: Prostate-specific antigen, BCR: Biochemical recurrence, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, M0: Non-metastatic, CRPC: Castration-resistant prostate cancer

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

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

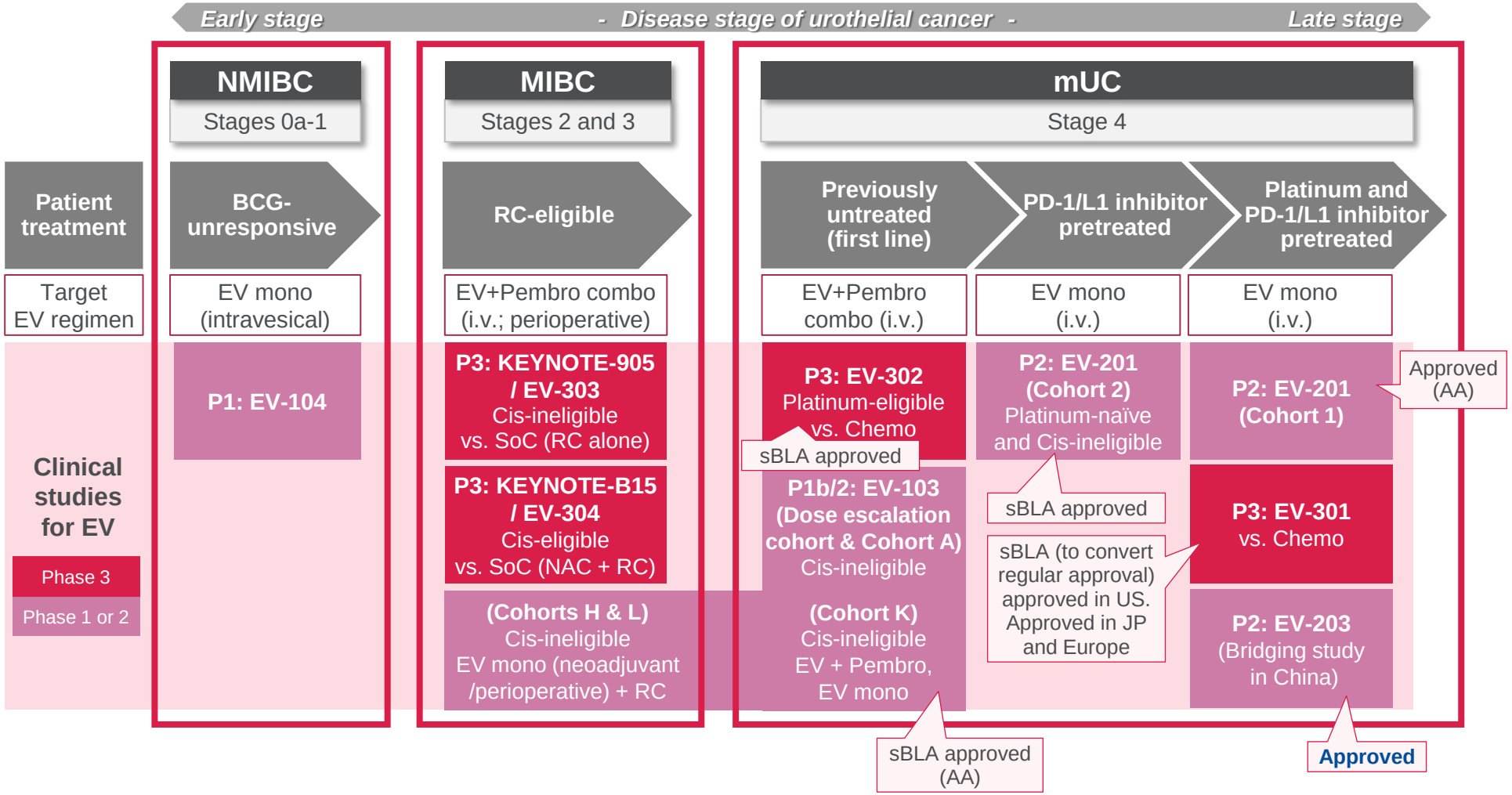
Disease stage	Early stage					Late stage
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	**EMBARK**	**ARCHES**	**ENZAMET**	**PROSPER**	**PREVAIL**	**AFFIRM**
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary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

CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, M0: Non-metastatic, M1: Metastatic, 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) (1/6): NECTIN-4 TARGETED ADC OVERALL UC PROGRAM

(Blue: 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) (2/6): CLINICAL STUDIES

(Blue: Updates since the last financial results announcement)

For urothelial cancer

	P3: EV-302	NCT04223856	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=886	Approved in US in Dec 2023, **in Europe in Aug 2024, in Japan in Sep 2024**. sBLA accepted in China in Mar 2024.
	P3: EV-303 /KEYNOTE-905	NCT03924895	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=595	Enrollment completed
	P3: EV-304 /KEYNOTE-B15	NCT04700124	MIBC, Cis-eligible; EV + Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=784	Enrollment completed
	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	**Approved in China in Aug 2024**
	P1: EV-104	NCT05014139	NMIBC, High-risk BCG-unresponsive; Intravesical EV mono	n=58	**Enrollment completed**

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 and esophageal adenocarcinoma including GEJ adenocarcinoma, Esophageal squamous cell carcinoma; EV mono Head and neck squamous cell carcinoma; EV + Pembro	n=329	**Enrollment completed**

mUC: Metastatic urothelial cancer, Pembro: Pembrolizumab, Chemo: Chemotherapy, (s)BLA: (Supplemental) Biologics License Application, MIBC: Muscle-invasive bladder cancer, Cis: Cisplatin, RC: Radical cystectomy, mono: Monotherapy, 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) (3/6): 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)	595 (3 arms)	886	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	EFS	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 *

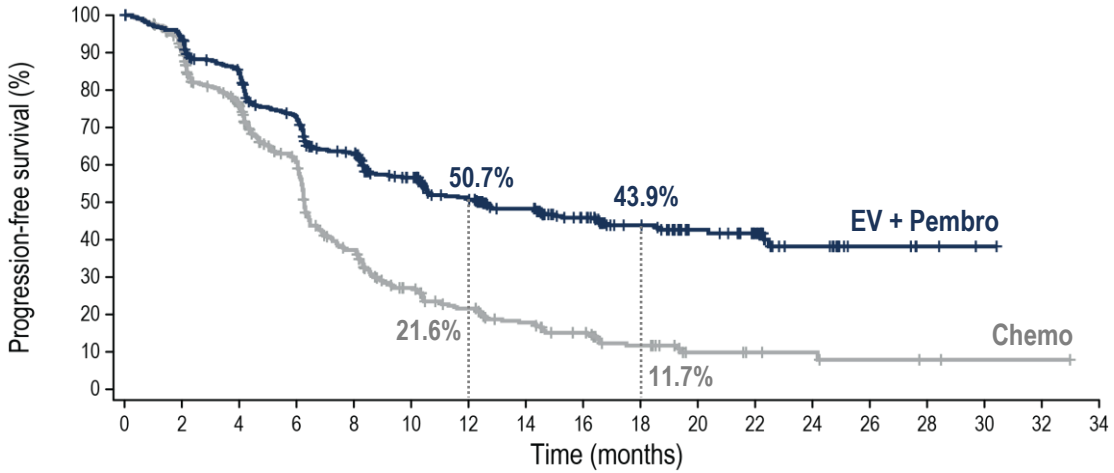
✓: Data obtained, *: Prespecified interim analysis, **: Updated data

(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer, cis: Cisplatin, Pembro: Pembrolizumab, mono: Monotherapy, Chemo: Chemotherapy, 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) (4/6): STUDY DATA IN 1L MUC (EV-302)

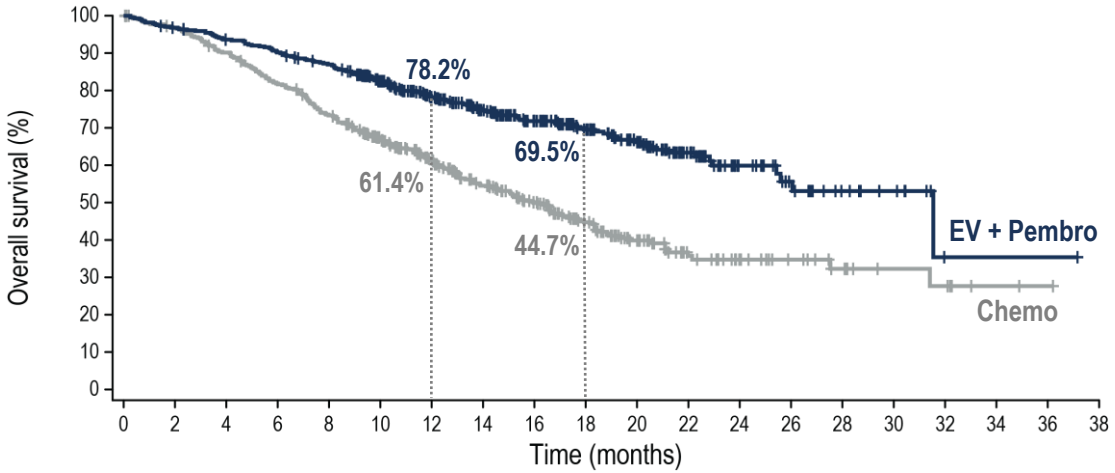
Statistically significant and clinically meaningful improvement over chemotherapy with nearly doubled mOS and mPFS

<Progression-free survival>



	N	Events (%)	HR (95% CI)	2-sided P value	mPFS (95% CI), months
EV + Pembro	442	223 (50.5)	0.45 (0.38-0.54)	<0.00001	12.5 (10.4-16.6)
Chemo	444	307 (69.1)			6.3 (6.2-6.5)

<Overall survival>



	N	Events (%)	HR (95% CI)	2-sided P value	mOS (95% CI), months
EV + Pembro	442	133 (30.1)	0.47 (0.38-0.58)	<0.00001	31.5 (25.4-NR)
Chemo	444	226 (50.9)			16.1 (13.9-18.3)

- Chemo: cisplatin or carboplatin + gemcitabine
- 30.4% of patients in Chemo arm received subsequent avelumab maintenance therapy

1L: First line, mUC: Metastatic urothelial cancer, (m)OS: (Median) Overall survival, PFS: Progression-free survival, Pembro: Pembrolizumab, Chemo: Chemotherapy, HR: Hazard ratio, CI: Confidence interval, NR: Not reached

ENFORTUMAB VEDOTIN (EV) (5/6): STUDY DATA IN SOLID TUMORS OTHER THAN UC (EV-202)

Cohort	Cancer type	n	ORR	
			Target*	Result
1	HR+/HER2- breast cancer	45	30%	**15.6%**
2	Triple-negative breast cancer	42	25%	**19.0%**
3	Squamous non-small cell lung cancer	23	17.5%	**4.3%**
4	Non-squamous non-small cell lung cancer	43	25%	**16.3%**
5	Head and neck cancer	46	17.5%	**23.9%**
7	Gastric and esophageal adenocarcinoma incl. GEJ adenocarcinoma	42	17.5%	**9.5%**
8	Esophageal squamous cell carcinoma	44	17.5%	**18.2%**
9	1L head and neck squamous cell carcinoma	Ongoing		

Cohorts 1-8: Second or later line, monotherapy
Cohort 9: First line, combo with pembrolizumab
*Minimum responders needed to declare promising antitumor activity

UC: Urothelial cancer, ORR: Objective response rate, HR+: Hormone receptor positive, HER2-: HER2 negative, GEJ: Gastroesophageal junction, 1L: First line

ENFORTUMAB VEDOTIN (EV) (6/6): FUTURE OUTLOOK

- *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	19,000**
MIBC	Cis-eligible	EV-304 (combo w/ Pembro)	FY2025 or later	64,000**
1L mUC		EV-302 EV-103 Cohorts [Phase 1b/2 for AA in US] (combo w/ Pembro)	Approved Approved [AA in US]	87,000
2L+ mUC	PD-1/L1 inhibitor pretreated & Cis-ineligible	EV-201 Cohort 2 (monotherapy)	Approved	1,500 (US, Cis-ineligible)
2L+ mUC	Platinum & PD-1/L1 inhibitor pretreated	EV-301 EV-201 Cohort 1 [Phase 2 for AA in US] (monotherapy)	Approved	46,000

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

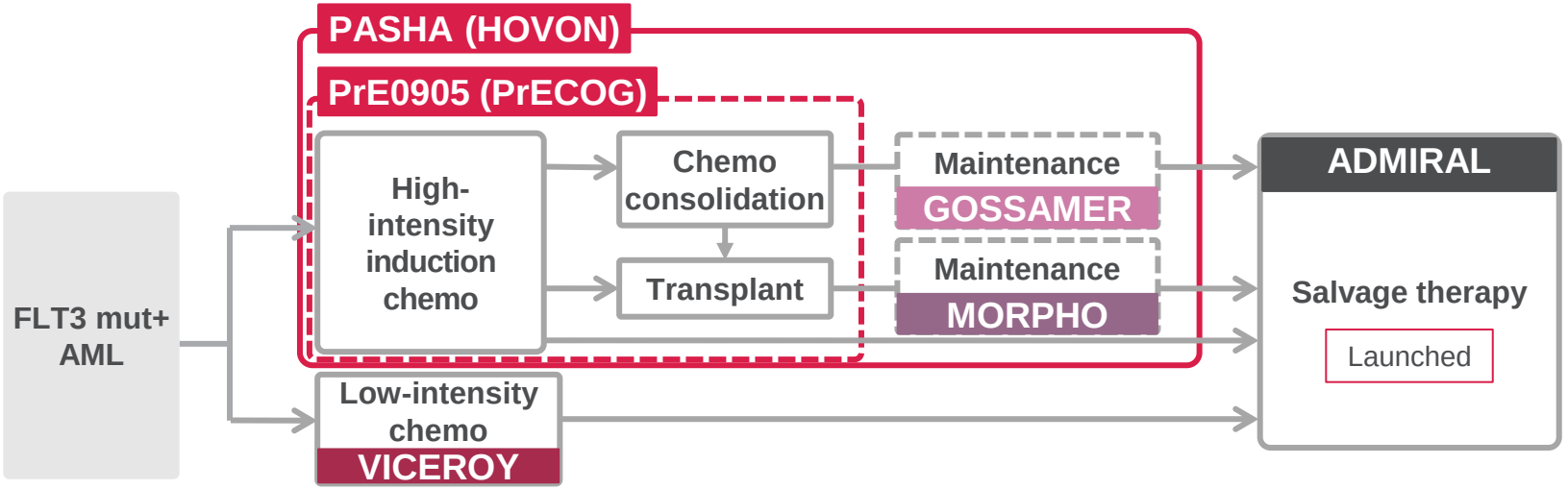
Patient segment	Study (EV regimen)
NMIBC High-risk BCG-unresponsive	EV-104 [Phase 1] (monotherapy, intravesical)
Other solid tumors	EV-202 [Phase 2] (monotherapy* / combo w/ Pembro**)

*Monotherapy:
- HR+/HER2- breast cancer
- Triple-negative breast cancer
- Squamous non-small cell lung cancer
- Non-squamous non-small cell lung cancer
- Head and neck cancer
- Gastric and esophageal adenocarcinoma including GEJ adenocarcinoma
- Esophageal squamous cell carcinoma

**Combo w/ Pembro:
- Head and neck squamous cell carcinoma

*US, Germany, France, Italy, Spain, UK, Japan, China (based on internal estimates) **Excluding China
mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, 1L: First line, 2L+: Second or later line, Cis: Cisplatin, Pembro: Pembrolizumab, AA: Accelerated Approval, HR+: Hormone receptor positive, HER2-: HER2 negative, BCG: Bacillus Calmette-Guerin, GEJ: Gastroesophageal junction

GILTERITINIB: FLT3 INHIBITOR



	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=766	Enrollment completed (Sponsor: HOVON)
		P2: PrE0905 (PrECOG)	NCT03836209		n=181	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)	P1/2: VICEROY	NCT05520567	Combo with venetoclax and azacitidine	n=70	FSFT: 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, R/R: Relapsed or refractory

astellas

ZOLBETUXIMAB: ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

(Blue: 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
- 38% of patients had CLDN18.2-positive tumors* in SPOTLIGHT and GLOW studies for gastric and GEJ adenocarcinoma
- **27.7% of patients had CLDN18.2-positive tumors* in GLEAM study for pancreatic adenocarcinoma**

Gastric and GEJ adenocarcinoma

- Five-year survival rate is ~6% for metastatic gastric cancer patients at Stage IV

Pancreatic adenocarcinoma

- Five-year survival rate is <5% for patients at the metastatic stage

Gastric and GEJ adenocarcinoma	**P3: SPOTLIGHT**	NCT03504397	First line, Combo with mFOLFOX6, DB, vs. placebo	n=566	BLA accepted in China in Jul 2023. Approved in Japan in Mar 2024, **in Europe in Sep 2024, in US in Oct 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	**Enrollment completed**
Pancreatic adenocarcinoma	**P2: GLEAM**	NCT03816163	First line, Combo with nab-paclitaxel and gemcitabine, open	n=393	Enrollment completed

*CLDN18.2 positivity is defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining
CLDN18.2: Claudin 18.2, GEJ: Gastroesophageal junction, mFOLFOX6: 5-FU, leucovorin and oxaliplatin, DB: Double-blind, CAPOX: Capecitabine and oxaliplatin, BLA: Biologics License Application, FLOT: Fluorouracil, leucovorin, oxaliplatin and docetaxel

astellas

FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

(Blue: 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

VMS associated with menopause

Japan	**P3: STARLIGHT 2**	NCT06206408	Mild to severe VMS associated with menopause; 12 weeks: DB, 2 doses vs. placebo (1:1:1)	n=390	FSFT: Mar 2024
Japan	**P3: STARLIGHT 3**	NCT06206421	VMS associated with menopause; 52 weeks: DB, vs. placebo (1:1)	n=260	FSFT: Feb 2024
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)
China	**P3: MOONLIGHT 3**	NCT04451226	VMS associated with menopause; open label, 30 mg for 52 weeks	n=150	Topline results obtained in Sep 2022

VMS in breast cancer women receiving adjuvant endocrine therapy

P3: HIGHLIGHT 1	NCT06440967	Moderate to severe VMS associated with adjuvant endocrine therapy for breast cancer; 52 weeks (efficacy endpoints at 4 and 12 weeks): DB, vs. placebo (1:1)	n=540	**FSFT: Aug 2024**

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, FSFT: First subject first treatment

astellas

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

(Blue: 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[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	sNDA for label update accepted in US in Mar 2024. **MAA withdrawn in Europe in Oct 2024**
	P3: GATHER2	NCT04435366	2 mg vs. Sham	n=448	
Stargardt disease	**P2b**	NCT03364153	vs. Sham	n=121	FSFT: Jan 2018

1. Retina. 2017;37:819-835, 2. IQVIA Medical Claims (DX) data Jan ’20-Dec ’21: 24 Months, 3. JAMA Ophthalmol. 2021;139:743-750
sNDA: Supplemental New Drug Application, MAA: Marketing Authorization Application, FSFT: First subject first treatment

astellas

ON THE FOREFRONT OF HEALTHCARE CHANGE