



# Astellas Pharma Inc.

J.P. Morgan Healthcare Conference 2026

Naoki Okamura  
President and CEO  
January 12<sup>th</sup>, 2026

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On the forefront to  
healthcare change to turn  
innovative science into  
**VALUE** for patients

Outcomes  
that matter to patients

**VALUE =**



Cost  
to the healthcare system of  
delivering those outcomes

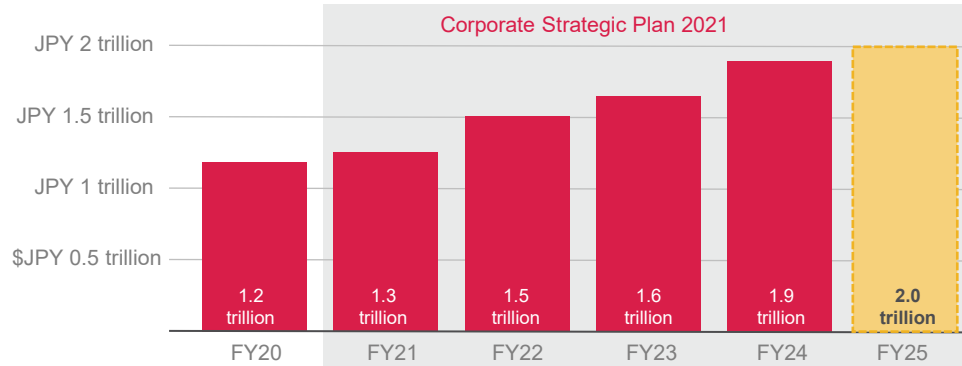


Numbers in red within each box represent the actual results for FY24 (FY3/25).  
In the chart, red bars represent actuals, and yellow bars represent forecast.

# Who we are: Astellas at a glance

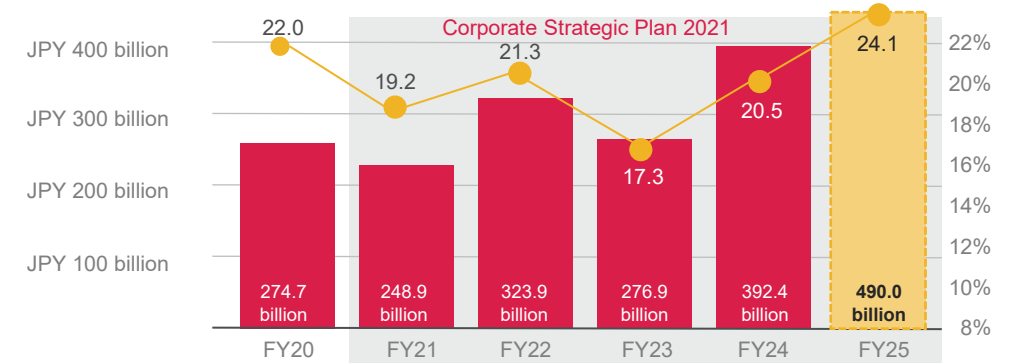
## SALES REVENUE

**¥1.9 trillion**  
**(\$13.1 billion)**

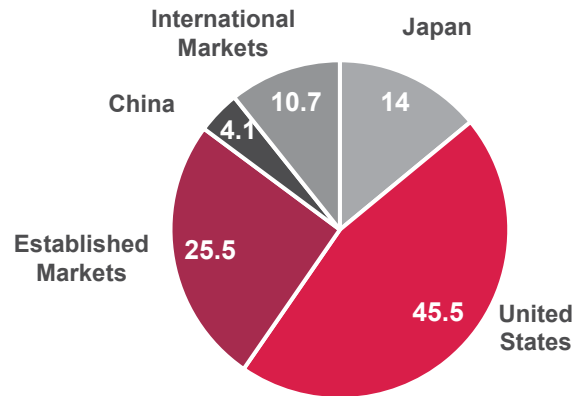


## CORE OPERATING PROFIT / MARGIN

**¥392.4 billion / 20.5%**  
**(\$2.7 billion)**



## SALES REVENUE BY REGION (%)



## R&D EXPENSES

**¥328 billion**  
**(\$2.26 billion)**

R&D expenses-to-revenue ratio of **17%**

## OPERATING COUNTRIES

**> 70** countries

## SHAREHOLDER RETURN (DIVIDEND)

**¥74 (\$0.51)**



## DEVELOPMENT AND SUPPLY OF GROUNDBREAKING NEW MEDICINES\*

Over **172M** patients in **103** countries

Converted at 1 USD = 145 JPY

Core OP definition changed from FY2024; excludes other income, other expenses, amortization of intangible assets, gains on disposal of intangible assets, and equity in earnings of affiliates from operating income on a full basis.

\*Cumulative number of patients (estimated) who have been prescribed Astellas products from 1994 to the end of September 2024.

# Xtandi® Track record of turning innovation into global success

#1 most prescribed branded ARPI for advanced prostate cancer across multiple indications



## Brand Maximization

We have maximized the value of XTANDI through **Life Cycle Management (LCM) activities globally**



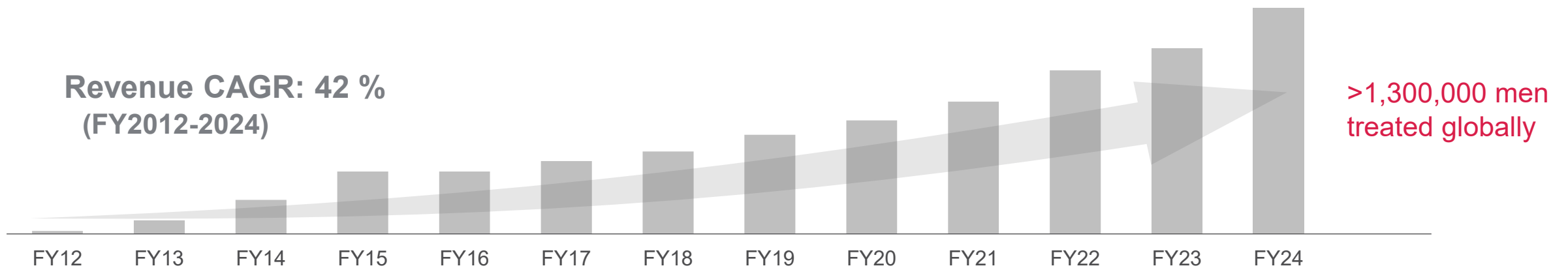
## Global Capability

We have built **end-to-end capabilities** in Oncology: clinical development, manufacturing, and commercial



## Market Access

We have delivered core value proposition to meet **payers needs** and integrated them into an **evidence generation plan**



ARPI: androgen receptor pathway inhibitor

# Strategic Brands with blockbuster potential will drive future growth



Oncology

Oncology

Oncology

Ophthalmology

Medical Specialty

Peak Sales:

**¥400-500<sub>B</sub>**  
**(\$2.8-3.5<sub>B</sub>)**

Helping patients with bladder cancer live twice as long compared to chemotherapy

Peak Sales:

**¥100-200<sub>B</sub>**  
**(\$0.7-1.4<sub>B</sub>)**

Adding nearly 3 extra months of life in gastric cancers when combined with chemo compared to chemotherapy alone

Peak Sales:

**¥100-200<sub>B</sub>**  
**(\$0.7-1.4<sub>B</sub>)**

Redefining the treatment of acute myeloid leukemia across various stages of disease

Peak Sales:

**¥200-400<sub>B</sub>**  
**(\$1.4-2.8<sub>B</sub>)**

Reducing vision loss progression within 6 months in geographic atrophy compared to placebo

Peak Sales:

**¥150-250<sub>B</sub>**  
**(\$1.0-1.7<sub>B</sub>)**

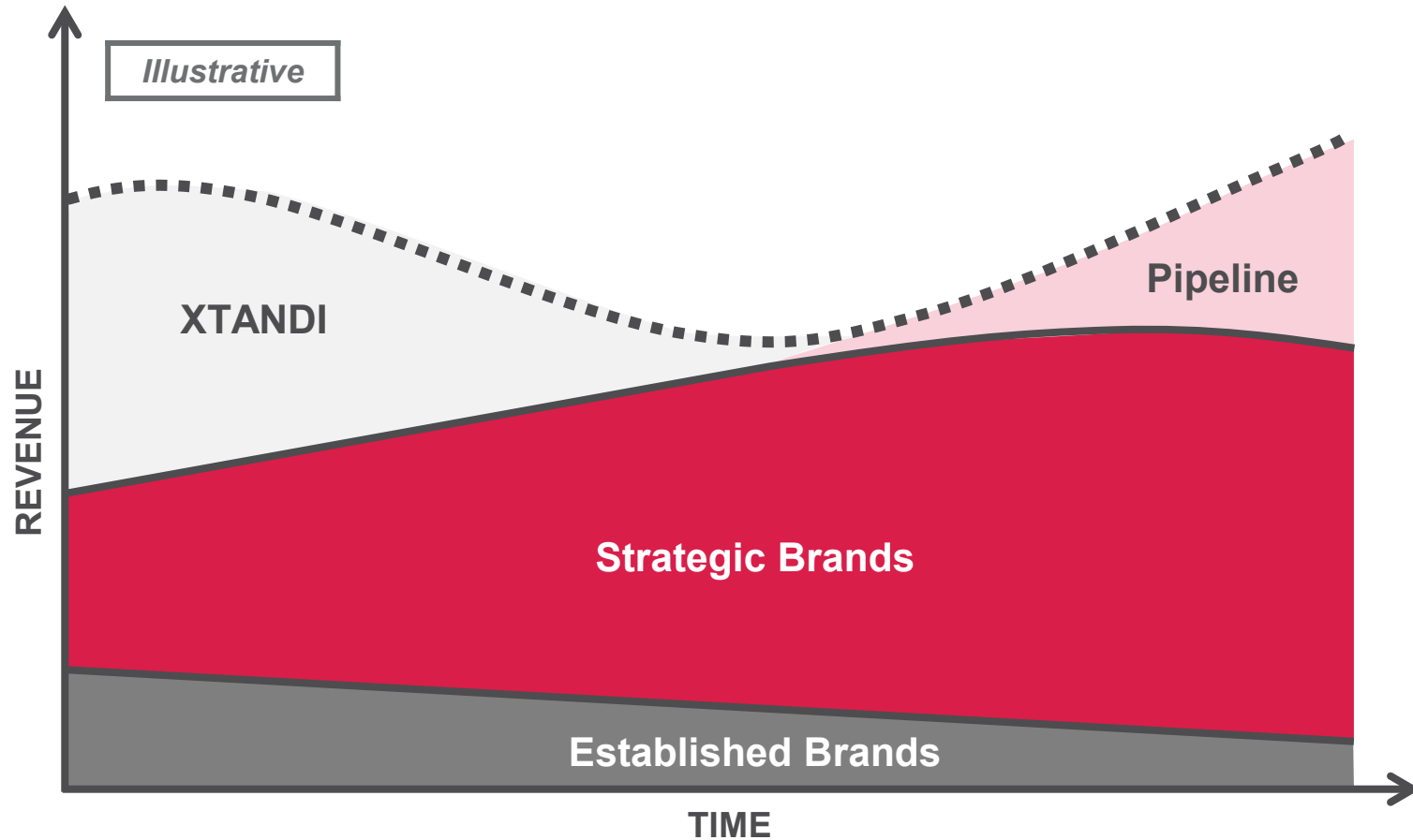
Revolutionizes treatment of VMS due to menopause as the non-hormonal choice, empowering women to feel like themselves again

Converted at 1 USD = 145 JPY. VMS: vasomotor symptoms

PADCEV peak sales are disclosed as "in-market sales," not Astellas revenue. Sales for the Americas are calculated based on sales booked by our partner.

# We are clear about near-term challenges and confident in our long-term trajectory

Astellas is managing its transition with focus and control



## Maximize Revenue

Elevate the peak and flatten the dip

## Accelerate Pipeline

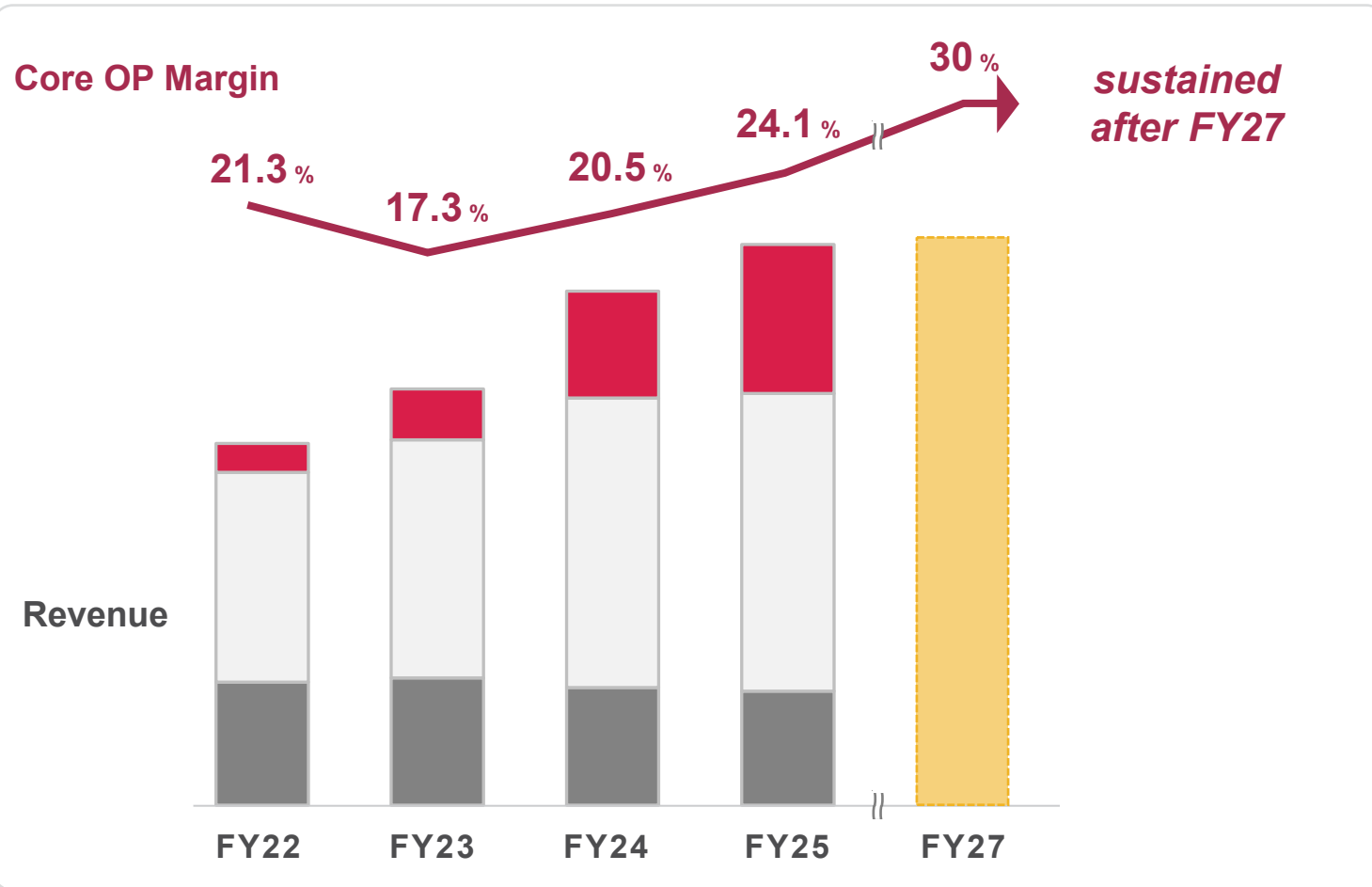
Expected sales contribution in 2030s

## Operational Efficiency

Elevate profitability and invest in Strategic Brands and pipeline

# We have a diversified and profitable Strategic Brand portfolio

Shift from XTANDI's co-promotion towards majority fully owned, higher margin brands, elevating core OP margin



## Strategic Brands\*



## XTANDI ...Co-promotion

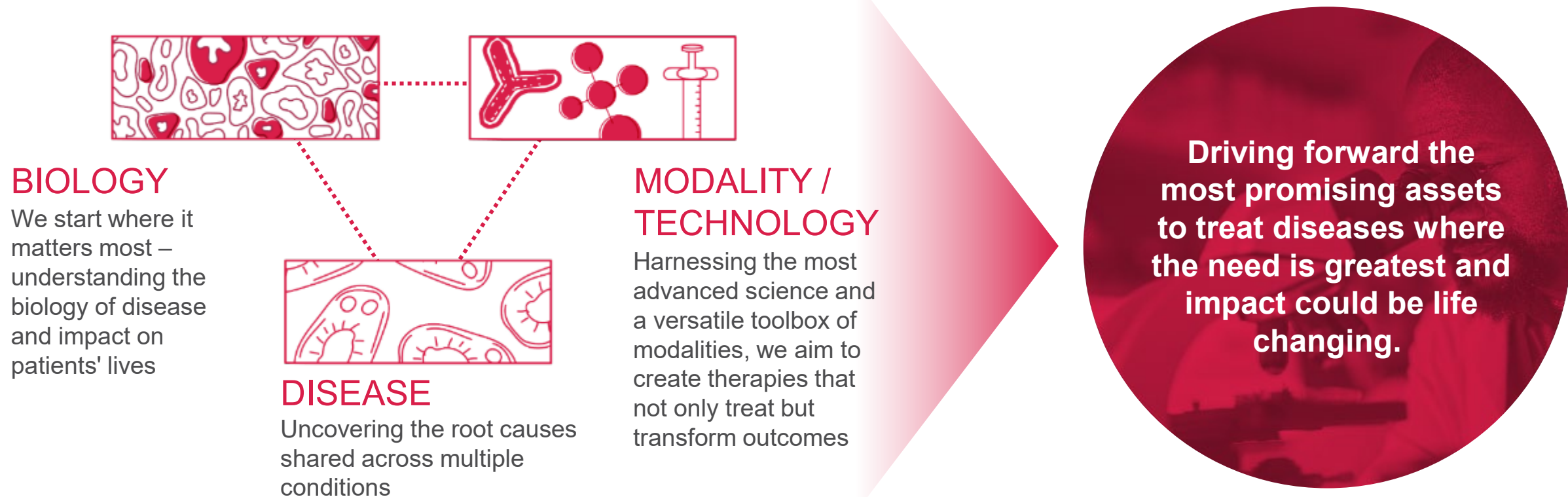


## Established Brands



\*PADCEV is a jointly-owned product that is subject to a profit share in certain major markets

# We pursue innovation through Focus Area Approach with one goal: delivering meaningful outcomes for patients



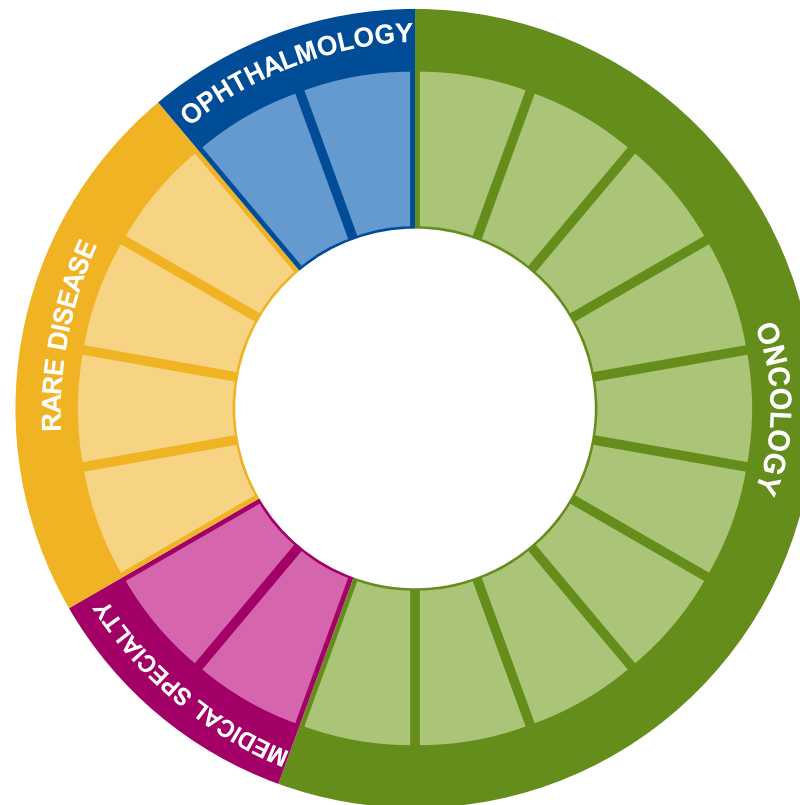
# We have made significant progress in building our pipeline

## Progressing R&D pipelines in synergy with Strategic Brands

		Phase
GA	<b>IZERVAY (avacincaptad pegol)</b> GA secondary to AMD	In market
	<b>ASP7317</b> GA secondary to AMD	1

		Phase
Rare disease	<b>AT132</b> X-linked myotubular myopathy	2
	<b>ASP2957</b> X-linked myotubular myopathy	IND cleared
	<b>AT845</b> Pompe disease	2
	<b>ASP5502</b> Primary Sjogren's syndrome	1

		Phase
Vasomotor symptoms (VMS)	<b>VEOZAH (fezolinetant)</b> VMS due to menopause	In market
	<b>fezolinetant</b> VMS due to menopause: China, Japan and VMS in breast cancer women	3
Urology	<b>Myrbetriq (mirabegron)</b> OAB and NDO	In market
	<b>mirabegron</b> Pediatric use in Europe	3



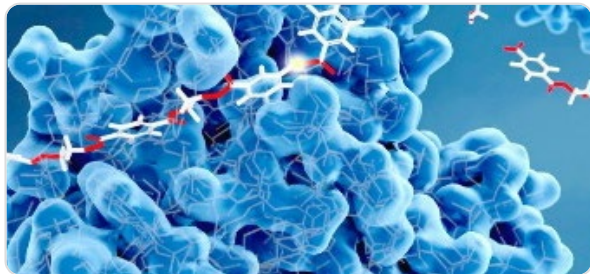
		Phase
Prostate cancer	<b>XTANDI (enzalutamide)</b> Prostate cancer	In market
	<b>ASP5541/PRL-02</b> Prostate cancer	2
Bladder and urothelial cancer	<b>PADCEV (enfortumab vedotin)</b> mUC, Cisplatin-ineligible MIBC	In market
	<b>enfortumab vedotin</b> Cisplatin-eligible MIBC	3
Upper GI, lung, pancreatic cancer	<b>VYLOY (zolbetuximab)</b> Gastric and GEJ cancer	In market
	<b>zolbetuximab</b> Gastric and GEJ cancer	3
	<b>ASP2138</b> Gastric and GEJ cancer, PDAC	1
	<b>ASP546C</b>	1
	<b>ASP3082</b> NSCLC and PDAC	3 (Planned)
	<b>ASP5834</b> <b>gilteritinib</b> ALK-positive NSCLC	1
Acute myeloid leukemia	<b>XOSPATA (gilteritinib)</b> AML	In market
	<b>gilteritinib</b> Earlier-stage AML, pediatric use	3
	<b>gilteritinib</b> ND AML, HIC-ineligible	2
Other cancers	<b>ASP1570, ASP1002</b>	1
	<b>ASP2998</b>	IND cleared

\*Not exhaustively listed

GA: geographic atrophy, AMD: age-related macular degeneration, IND: Investigational New Drug, VMS: vasomotor symptoms, OAB: overactive bladder, NDO: neurogenic detrusor overactivity, mUC: metastatic urothelial cancer MIBC: muscle-invasive bladder cancer, GEJ: gastroesophageal junction, PDAC: pancreatic ductal adenocarcinoma, NSCLC: non-small cell lung cancer, ALK: anaplastic lymphoma kinase, AML: acute myeloid leukemia, ND: newly diagnosed, HIC: high-intensity chemotherapy

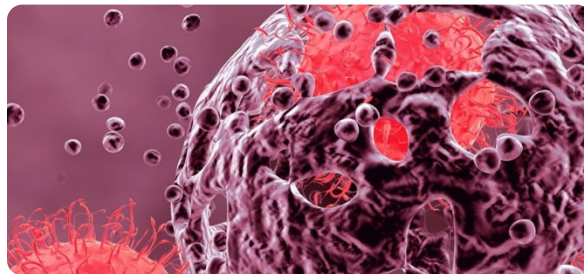
# We are prioritizing four high-potential flagship assets through our Primary Focuses

Four key PoCs provide visibility toward the inflection to growth



## TARGETED PROTEIN DEGRADATION

**ASP3082 (setidegrasib)** – a potential first-in-class targeted protein degrader for treating **solid tumors with KRAS G12D mutations, including pancreatic and lung cancer.**



## IMMUNO-ONCOLOGY

**ASP2138** – a bispecific immune cell engager with the potential to be a first-in-class therapy in notoriously hard-to-treat **gastric, gastroesophageal junction and pancreatic cancers.**



## BLINDNESS & REGENERATION

**ASP7317** – the **first ophthalmic cell therapy** derived from pluripotent stem cells to enter the clinic for a leading cause of blindness.



## GENETIC REGULATION

**AT845** – an AAV gene replacement therapy designed to address the underlying cause of Pompe disease, a **devastating rare neuromuscular disease.**

PoC: proof of concept, KRAS: Kirsten rat sarcoma viral oncogene homologue, AAV: adeno-associated virus

# Unlocking the potential of our Targeted Protein Degradation platform starting with KRAS

## Hard to treat cancers

- ~30% of NSCLC patients have a **KRAS mutation or are WT amplified**, ~4% have **KRAS G12D**; usually associated with poor response on current SoC<sup>1</sup>
- ~90% of pancreatic cancer patients have a **KRAS mutation or are WT amplified**, ~40% have **KRAS G12D**; associated with one of the lowest survival rates in cancer, rapid resistance and disease progression<sup>2</sup>



## Leading Pipeline

- **ASP3082 (setidegrasib)** KRAS G12D targeted VHL E3 ligase degrader
- **ASP5834** Pan-KRAS targeted Cereblon E3 ligase degrader
- **Additional programs** (undisclosed)



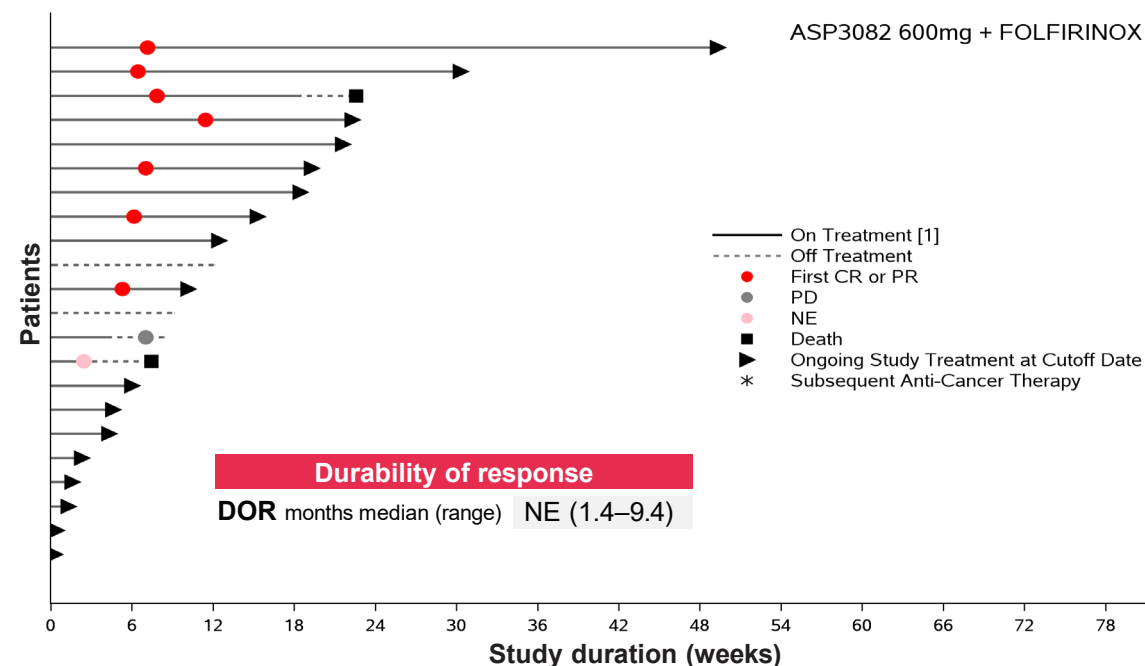
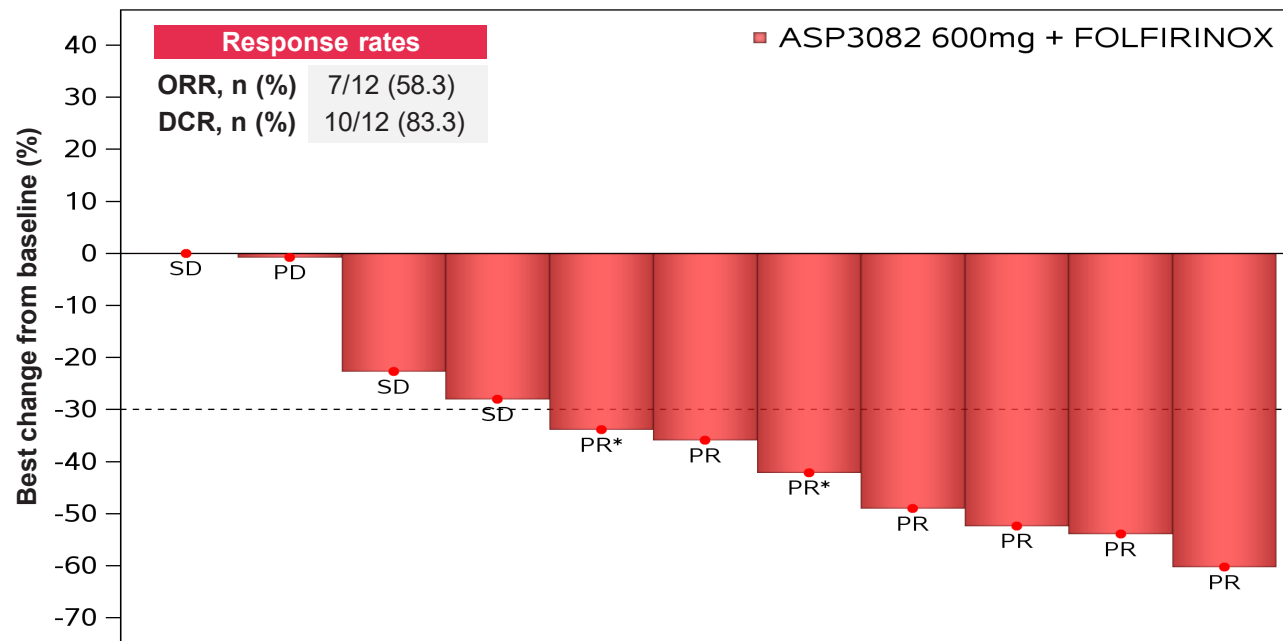
## Strong Capabilities

- **Manufacturing** chemically complex, middle-sized molecules with multiple chiral centers
- **Precision medicine** & companion diagnostics development and commercialization
- **Commercialization capabilities** by leveraging our robust global launch and market access expertise in Oncology



NSCLC: non-small cell lung cancer, KRAS: Kirsten rat sarcoma viral oncogene homologue, WT: wild type, SoC: standard of care  
<sup>1</sup>Cancers (Basel) 2022 Nov 4;14(21):5430, <sup>2</sup>Front. Med., 20 March 2024, Sec. Precision Medicine, Volume 11 – 2024.

# Objective responses observed in PDAC patients with KRAS G12D mutations with ASP3082 (setidegrasib) + mFOLFIRINOX



## ASP3082 (setidegrasib) + mFOLFIRINOX combination shows objective responses

- Current ORR = 7/12 (58.3%); DCR = 10/12 (83.3%)
- Duration of response data is maturing; early data demonstrates correlation with reduction of KRAS G12D protein and *KRAS G12D* VAF ctDNA

## Tolerable safety profile of combination regimen is allowing patients to continue on trial

- IRRs were low grade, occurred mostly during the first cycle and well managed
- Discontinuations related to TRAEs seen in 5/22 (22.7%) patients

## Advancing ASP3082 (setidegrasib) in PDAC and other solid tumors

Data presented at ASCO GI 2026 (data cutoff Oct 2025)

PDAC: pancreatic adenocarcinoma, mFOLFIRINOX: modified folinic acid, fluorouracil, irinotecan and oxaliplatin, ORR: objective response rate, DCR: disease control rate, PR: partial response, SD: stable disease, PD: progressive disease, NE: not evaluable, VAF: variant allele frequency, ctDNA: circulating tumor DNA, IRR: infusion-related reaction, TRAE: treatment-related adverse event. One patient was not included due to lack of a post-baseline scan (patients was off study on Day 2 due to non-compliance)

# Unlocking potential of our Immuno-Oncology pipeline starting with Claudin 18.2

## Hard to treat cancers

- **Gastric & GEJ cancers** ~80% express Claudin 18.2, ~35% at high levels<sup>1</sup>
- **Pancreatic cancers** >50% express Claudin 18.2, ~28% at high levels<sup>2</sup>
- **Other cancers** also express Claudin 18.2 (biliary tract, ovarian and lung are among them)



GEJ: gastroesophageal junction

<sup>1</sup>Gastric Cancer, Volume 27, pages 1058–1068, (2024); <sup>2</sup>Astellas data.

## Leading Pipeline

- **VYLOY brought the first Claudin 18.2 targeted therapy** in Gastric & GEJ cancer
- **ASP2138 has the potential to expand availability** of a Claudin 18.2 targeted therapy in gastric and pancreatic cancer
- **ASP546C has the potential to bring systemic chemotherapy free regimens** in gastric, pancreatic and other Claudin 18.2 positive cancers



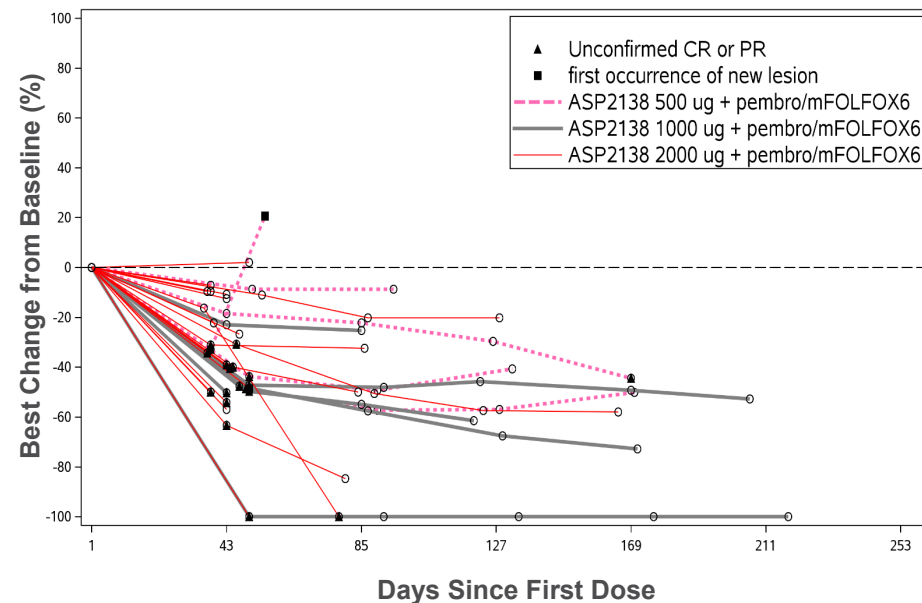
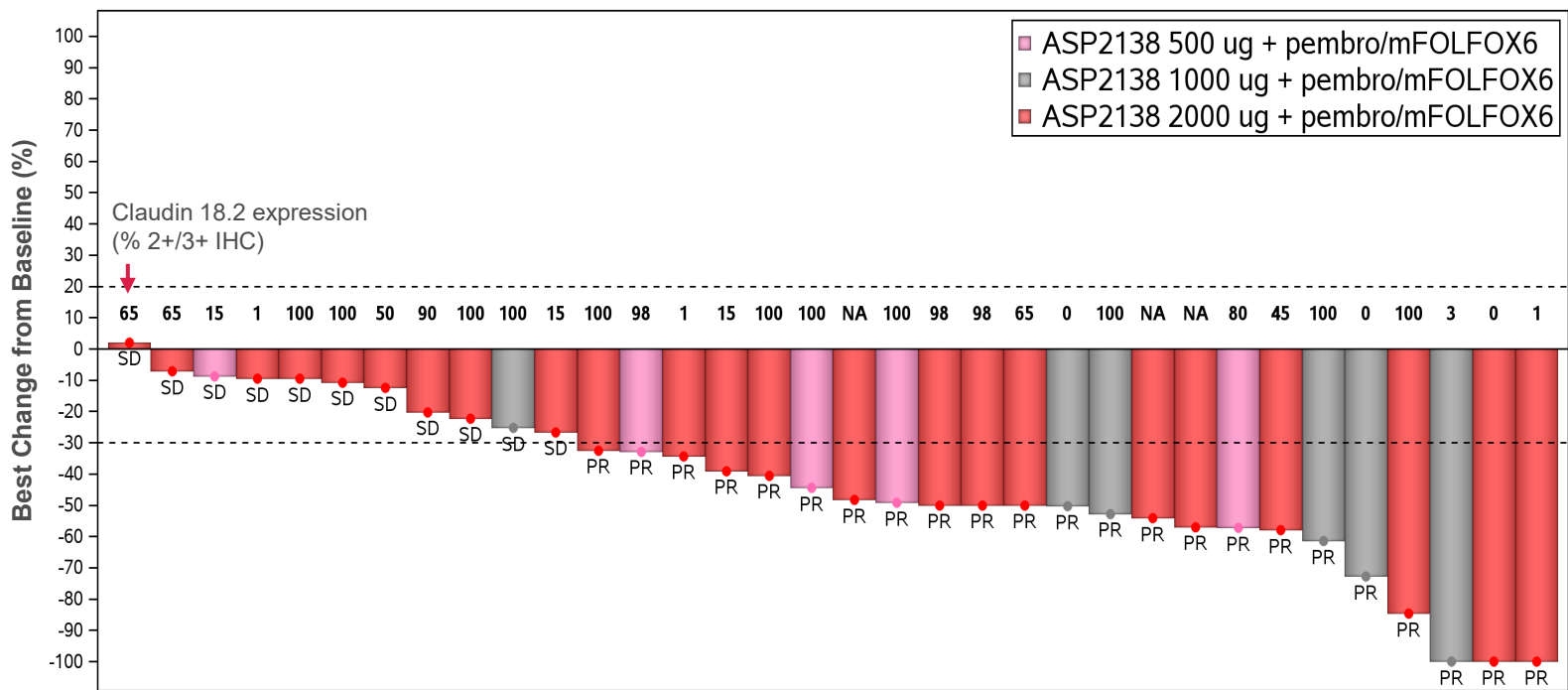
## Strong Capabilities

- **Precision medicine & companion diagnostics development and commercialization** established with VYLOY
- **Commercialization capabilities** across indications and in GI oncology in particular, with the global launch of VYLOY



# ASP2138 in combination with Standard of Care drives striking anti-tumor activity in Gastric/GEJ adenocarcinoma irrespective of Claudin 18.2 Expression

## 1L Gastric/GEJ – ASP2138 subcutaneous + pembro/mFOLFOX6 (n=34)



### Promising antitumor activity in 1L gastric/GEJ cancer patient population

- ORR = 62.5% (15/24); 12-week DCR = 100.0% (6/6) at data cutoff (21/09/2025)  
mDOR = not reached; mPFS = not estimable at data cutoff (Sept 21<sup>st</sup>, 2025)
- Data continues to mature

### Subcutaneous dosing results in low CRS rate

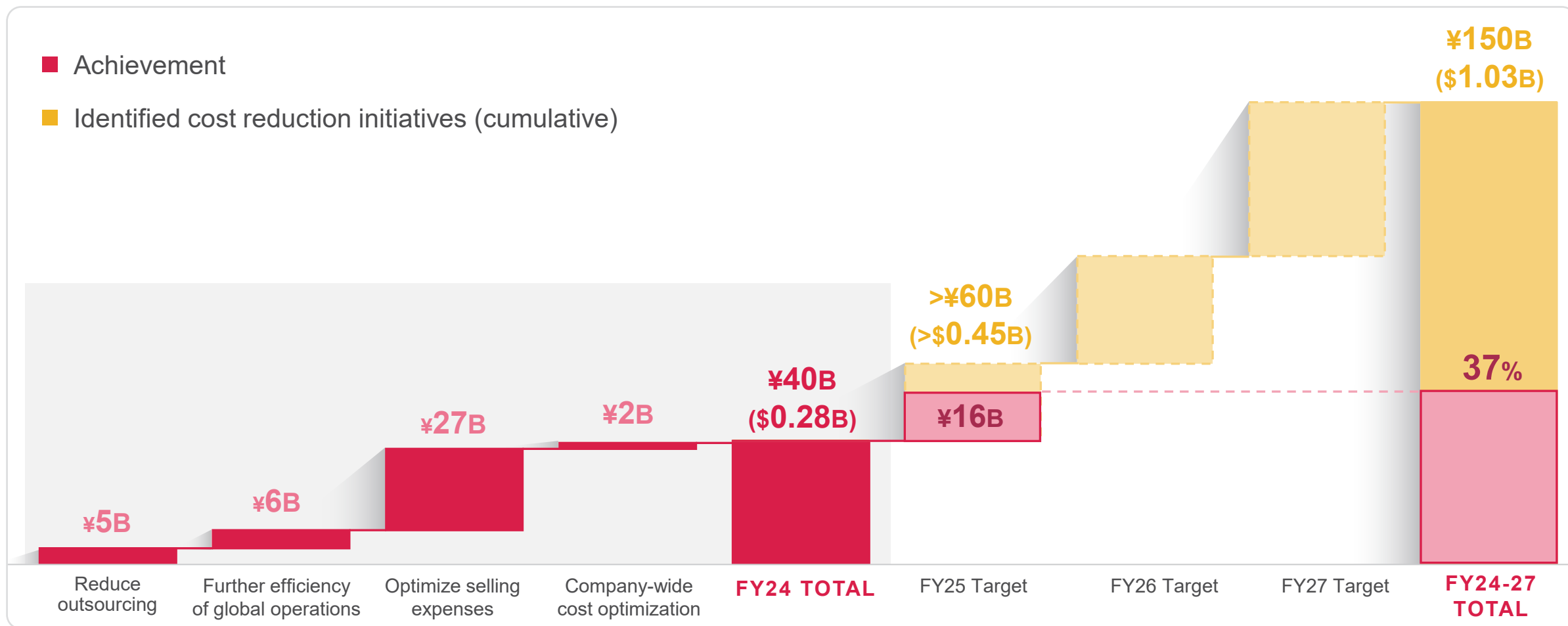
- Other safety events are primarily target related and manageable
- No treatment related adverse events leading to drug discontinuation

Data presented at ESMO 2025

GEJ: gastroesophageal junction, mFOLFOX6: modified folinic acid, fluorouracil and oxaliplatin, PR: partial response, SD: stable disease, 1L: first line, ORR: objective response rate, DCR: disease control rate, (m)DOR: (median) duration of response, PFS: progression-free survival, CRS: cytokine release syndrome

# Operational efficiency to elevate profitability and invest in growth drivers

Disciplined cost optimization of 150 billion yen (USD 1.03 billion) before XTANDI LOE is on track



LOE: loss of exclusivity  
 Converted at 1 USD = 145 JPY

# Our experienced leadership team is committed to strategic focus and Shareholder value

## TOP MANAGEMENT



**Naoki Okamura**

Representative Director,  
President and Chief Executive  
Officer (CEO)



**Katsuyoshi Sugita**

Representative Director,  
Executive Vice President,  
Chief People Officer (CPO)



**Tadaaki Taniguchi,  
M.D., Ph.D.**

Chief Research &  
Development Officer (CRDO)



**Rao Mantri, Ph.D.**

Chief Manufacturing Officer  
(CMfgO)



**Claus Zieler**

Chief Commercial & Medical  
Affairs Officer (CCMAO)



**Adam Pearson**

Chief Strategy Officer (CStO)



**Atsushi Kitamura**

Chief Financial Officer (CFO)



**Tatjana Dragovic**

General Counsel and Chief Ethics &  
Compliance Officer (GC & CECO)

## BOARD OF DIRECTORS



**Kenji Yasukawa,  
Ph.D.**

Representative Director,  
Chairman of the Board



**Naoki Okamura**

Representative Director,  
President and CEO



**Katsuyoshi Sugita**

Representative Director,  
Executive Vice President



**Takashi Tanaka**

Independent Outside  
Director



**Eriko Sakurai  
Ph.D.**

Independent Outside  
Director



**Masahiro Miyazaki**

Independent Outside  
Director



**Yoichi Ohno  
M.D., Ph.D.**

Independent Outside  
Director

NEW



**Andreas Busch  
Ph.D.**

Independent Outside Director

NEW



**Mark Enyedy**

Independent Outside Director



**Rika Hirota  
Ph.D.**

Director, Audit & Supervisory  
Committee Member



**Mika Nakayama**

Independent Outside Director,  
Audit & Supervisory  
Committee Member



**Rie Akiyama**

Independent Outside Director,  
Audit & Supervisory  
Committee Member



**Tomoko Aramaki**

Independent Outside Director,  
Audit & Supervisory  
Committee Member

# Strengthening our trajectory toward sustainable growth



## Maximize Revenue

- Strategic Brands
- XTANDI



## Accelerate Pipeline

- Prioritized Primary Focus assets
- Business Development



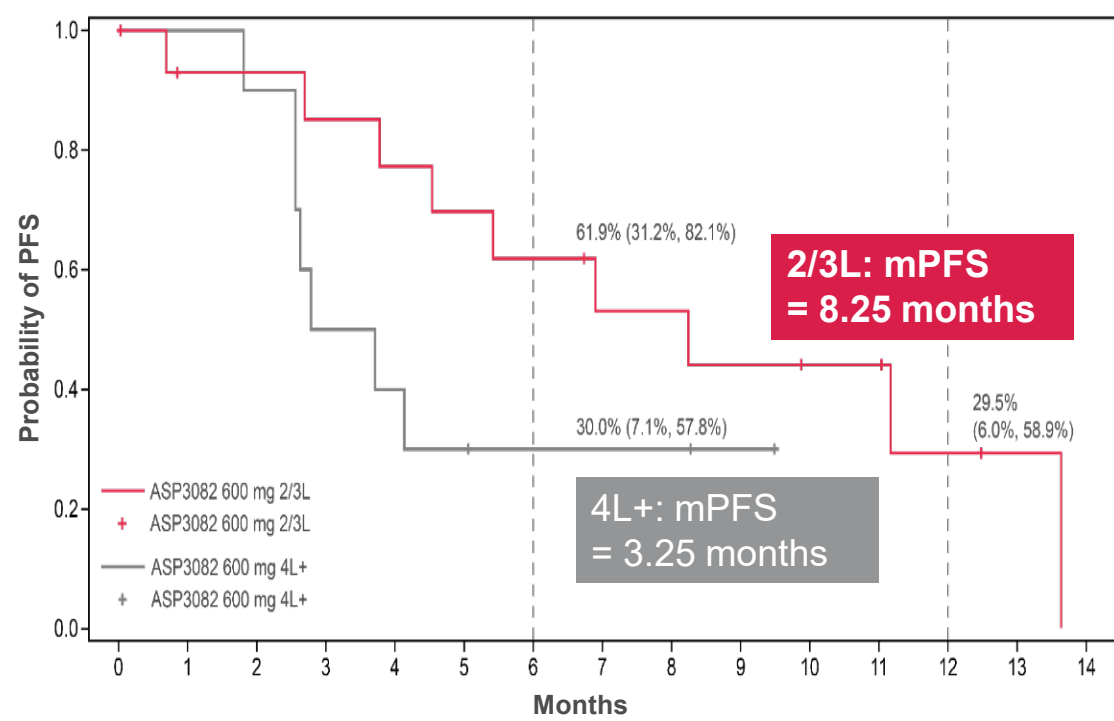
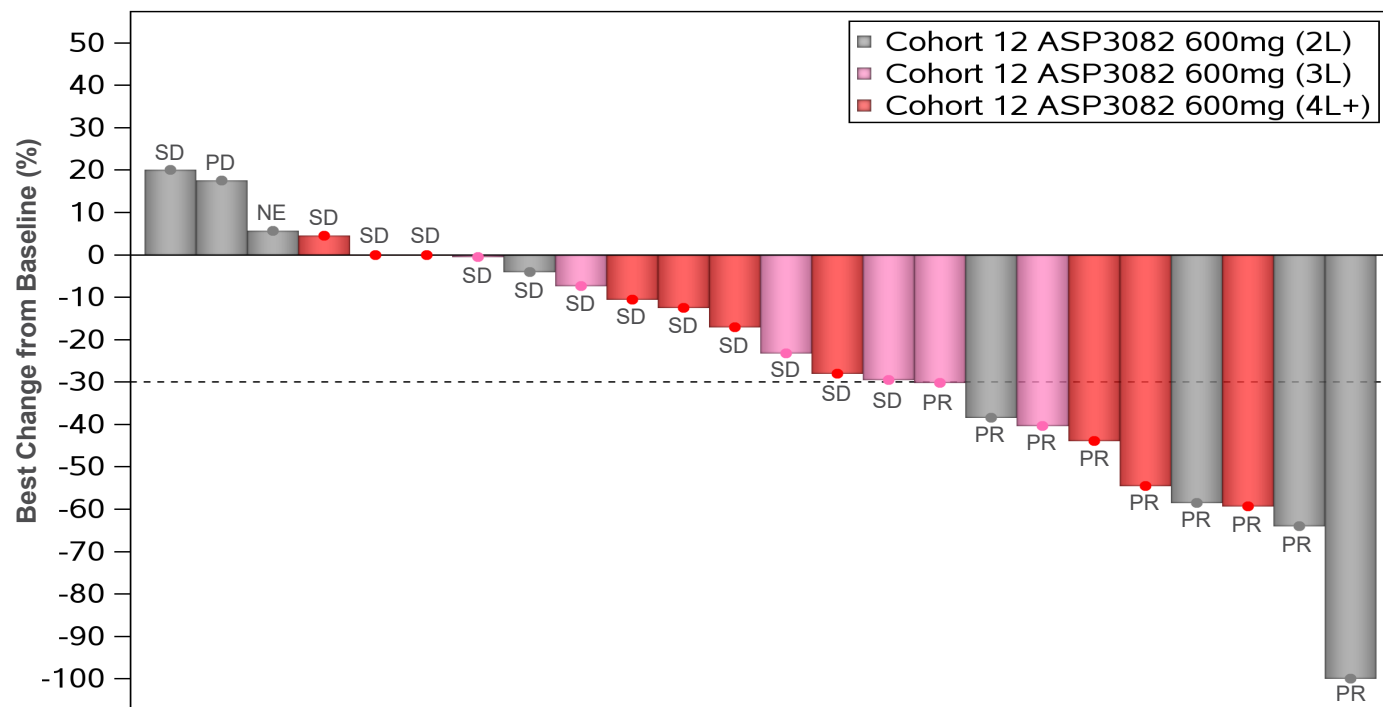
## Elevate Profitability

- Operational efficiency
- Shift towards majority fully owned Strategic Brands

**Turn innovative science into VALUE for patients**

# Appendix

# Deep and durable responses observed in 2/3L NSCLC with ASP3082 (setidegrasib) monotherapy holds potential to change treatment paradigm in 2L NSCLC



## Promising antitumor activity in an advanced NSCLC patient population as monotherapy

- ORR = 37.5% (9/24) overall and 42.9% (6/14) in 2/3L\*
- Current projected mPFS = 8.25 months in 2/3L (data cut off July 15<sup>th</sup>, 2025).
- Standard of Care mPFS = approx. 3 to 4 months<sup>1,2</sup>

## Safety events were generally manageable

- No treatment related adverse events leading to drug discontinuation (0/25)

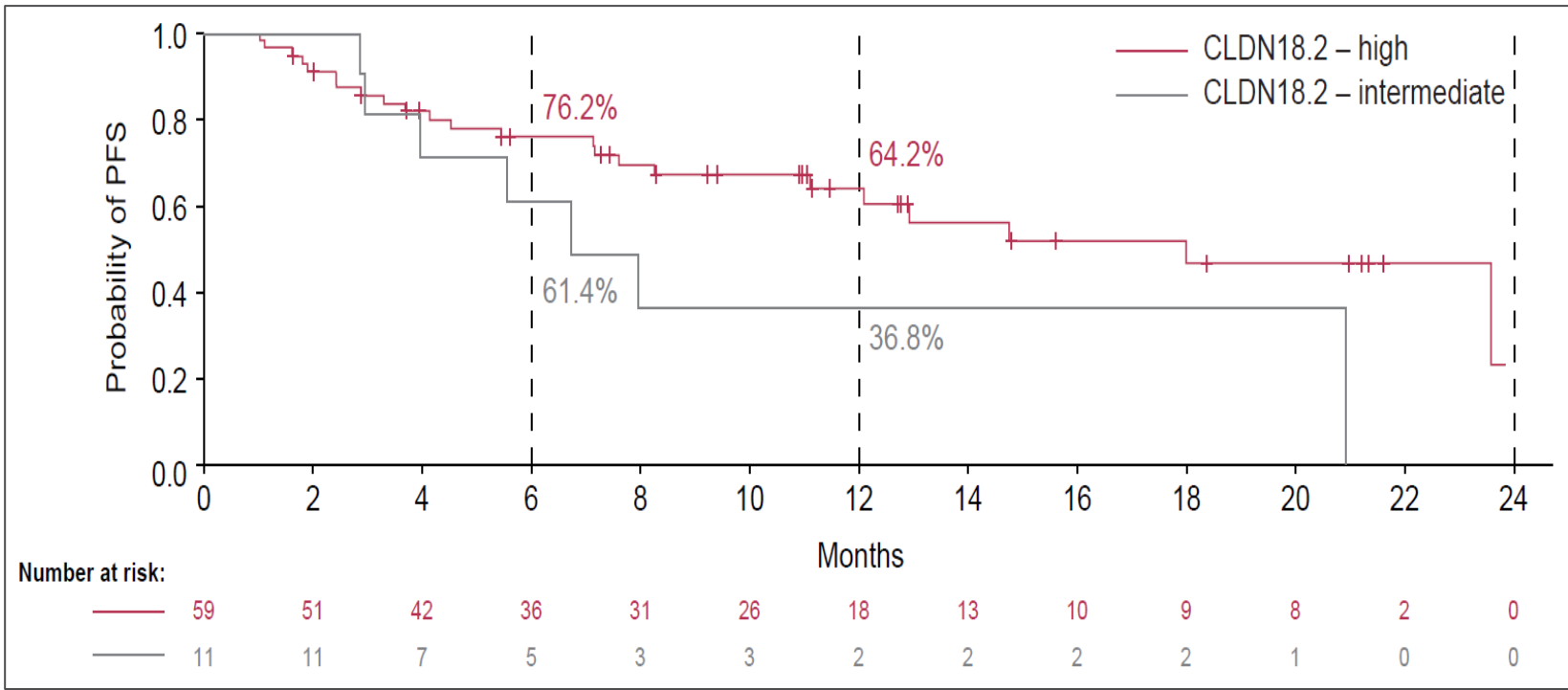
## Advancing ASP3082 in NSCLC, PDAC, and other solid tumors

Data presented at AACR-NCI-EORTC 2025

ORR: objective response rate, DCR: disease control rate, (m)PFS: (median) progression-free survival, 2/3L: second and third line, 4L+: fourth or later line, PD: progressive disease, PR: partial response, SD: stable disease  
 \*8 patients had confirmed PR and 1 patient unconfirmed PR as of data cutoff

<sup>1</sup>J Clin Oncol 43, 260-272(2025), Volume 43, Number 3, DOI: 10.1200/JCO-24-01544, <sup>2</sup>Journal of Thoracic Oncology, Volume 20, Issue 10, p1489-1504 October 2025

# Combination of zolbetuximab with a checkpoint inhibitor + chemo nearly doubles mPFS versus chemo combination in Claudin 18.2-high advanced gastric and/or GEJ cancer



**ILUSTRO cohort 4b**  
zolbetuximab + nivolumab + mFOLFOX6

Claudin 18.2	Events, n (%)	Median PFS, months (95% CI)
High	23/59 (39.0)	18.0 (11.1—NE)
Intermediate	7/11 (63.6)	6.7 (3.0—NE)

Note: Benchmark data for zolbetuximab + chemotherapy in this population (Shitara K et al. *N Engl J Med.* 2024;391:1159-62)

- mPFS: 9.2 months versus 8.2 months with chemo alone
- mOS: 16.4 months versus 13.7 months with chemo alone

- OS was immature at data cutoff but was favorable in the Claudin 18.2-high population, mOS (95% CI) NE (13.7-NE)
- Safety profile was manageable with no unexpected signals
- LUCERNA, a Phase 3 registrational trial of zolbetuximab + pembrolizumab + chemotherapy is currently enrolling

**Data presented at ASCO GI 2026**  
Data are shown for the safety analysis set. PFS was assessed by investigators per RECIST v1.1. Median (95% CI) follow-up times in Cohort 4B were 11.5 (9.4–15.6) months and 11.3 (3.9–NE) months for the high Claudin 18.2 expression and intermediate Claudin 18.2 expression subgroups, respectively.  
GEJ: gastroesophageal junction, (m)PFS: (median) progression-free survival, OS: overall survival, NE: not evaluable