



# Second-Quarter 2025 Sales and Earnings

Merck & Co., Inc., Rahway, N.J., USA

July 29, 2025



# Agenda



## Strategy and Business Update

Robert M. Davis  
Chairman and Chief Executive Officer



## Financial Results and Outlook

Caroline Litchfield  
Executive Vice President and Chief Financial Officer



## Research Update

Dr. Dean Y. Li  
Executive Vice President and President, Research Laboratories



## Question & Answer Session



# Forward-looking statement of Merck & Co., Inc., Rahway, N.J., USA

This presentation of Merck & Co., Inc., Rahway, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s Annual Report on Form 10-K for the year ended December 31, 2024 and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site ([www.sec.gov](http://www.sec.gov)).



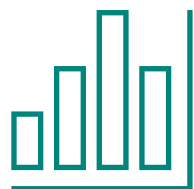


# Strategy and Business Update

Robert M. Davis  
Chairman and Chief Executive Officer

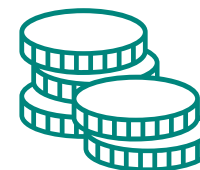


# Q2 performance in-line with expectations



Q2 Worldwide Sales

\$15.8B



Q2 Non-GAAP EPS<sup>1,2</sup>

\$2.13

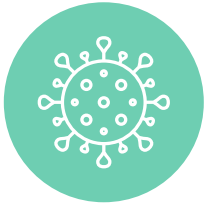
Results reflect strength in **Oncology**, **Animal Health**,  
and increasing contributions from **new launches**

# Driving value by progressing innovative pipeline



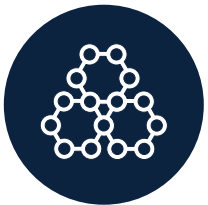
## Cardiopulmonary

- Positive topline results for **enlicitide** in hyperlipidemia in first two CORALreef studies
- Positive topline results for **WINREVAIR** in recently diagnosed PAH in HYPERION study
- Supplemental BLA accepted for **WINREVAIR** based on ZENITH study



## Infectious Disease

- FDA approved and ACIP recommended **ENFLONSIA** for prevention of RSV in infants younger than 8 months of age born during or entering their first RSV season
- FDA accepted NDA for **doravirine + islatravir** for HIV-1 treatment in adults with suppressed virus
- Presented Phase 2 data at IAS for **MK-8527** for PrEP



## Oncology

- Received 10<sup>th</sup> earlier stage approval for **KEYTRUDA**
- Presented data at **ASCO** from multiple novel candidates and broad oncology portfolio



# Continuing to advance science-led strategy through pending acquisition of Verona Pharma



- **Science-driven** business development that **strengthens and complements** cardiopulmonary portfolio
- Ohtuvayre® is the **first novel inhaled COPD maintenance treatment** in more than 20 years, a large disease area with **significant unmet medical need**
- **Multibillion dollar commercial opportunity** with potential to drive both near- and long-term **revenue growth**
- Significant potential to **positively impact patients** and **create shareholder value**

# Entering period of rapid transformation with expansive late-phase pipeline

## Recent launches

  
**WINREVAIR**<sup>™</sup>  
(sotatercept-csrk) for injection  
45 mg, 60 mg

  
**CAPVAXIVE**<sup>™</sup>  
Pneumococcal 21-valent  
Conjugate Vaccine

  
**ENFLONSIA**<sup>™</sup>  
(clesrovimab-cfor) 105 mg  
injection

## Broad late-phase pipeline

subQ pembrolizumab + berahyaluronidase alfa

intismeran autogene<sup>1</sup>

nemtabrutinib

bomedemstat

opevesostat

MK-1084<sup>2</sup>

sacituzumab tirumotecan<sup>3</sup>

zilovertamab vedotin

patritumab deruxtecan<sup>4</sup>

ifinatumab deruxtecan<sup>4</sup>

raludotatug deruxtecan<sup>4</sup>

doravirine + islatravir

islatravir + lenacapavir<sup>5</sup>

MK-8527

V181

enlicitide decanoate

tulisokibart

MK-3000

 Oncology  Vaccines & Infectious Disease  Other Pharma

Excludes ongoing Phase 3 studies for marketed products including KEYTRUDA, Lenvima, Lynparza, Verquvo, LAGEVRIO and WELIREG. Reflects select late-phase programs.

1. Collaboration with Moderna 2. Collaboration with Taiho and Astex 3. Collaboration with Kelun Biotech 4. Collaboration with Daiichi Sankyo 5. Collaboration with Gilead





# Delivering the next wave of innovation

**Well positioned to successfully navigate the KEYTRUDA LOE period**



## **Advancing Early- and Late-Phase Pipeline**

Tripled late-phase pipeline since 2021



## **Launching New Growth Drivers**

>\$50B commercial opportunity by mid-2030s from recent launches and late-phase pipeline



## **Executing Business Development**

Actively pursuing additional science-driven value-creating transactions



# Financial Results and Outlook

Caroline Litchfield  
Executive Vice President and  
Chief Financial Officer



# Q2 performance driven by robust demand for our innovative portfolio



**WORLDWIDE SALES<sup>1</sup>**

**\$15.8B**

-2% nominal & ex-FX  
+7% ex-GARDASIL China<sup>2</sup>, nominal & ex-FX



**Human Health**

**\$14.1B**

-2% nominal  
-3% ex-FX  
+7% ex-GARDASIL China<sup>2</sup>, nominal & ex-FX



**Animal Health**

**\$1.6B**

+11% nominal & ex-FX

1. Worldwide Sales includes Other Revenue 2. Excludes sales of GARDASIL in China of \$1.3 billion in 2Q24

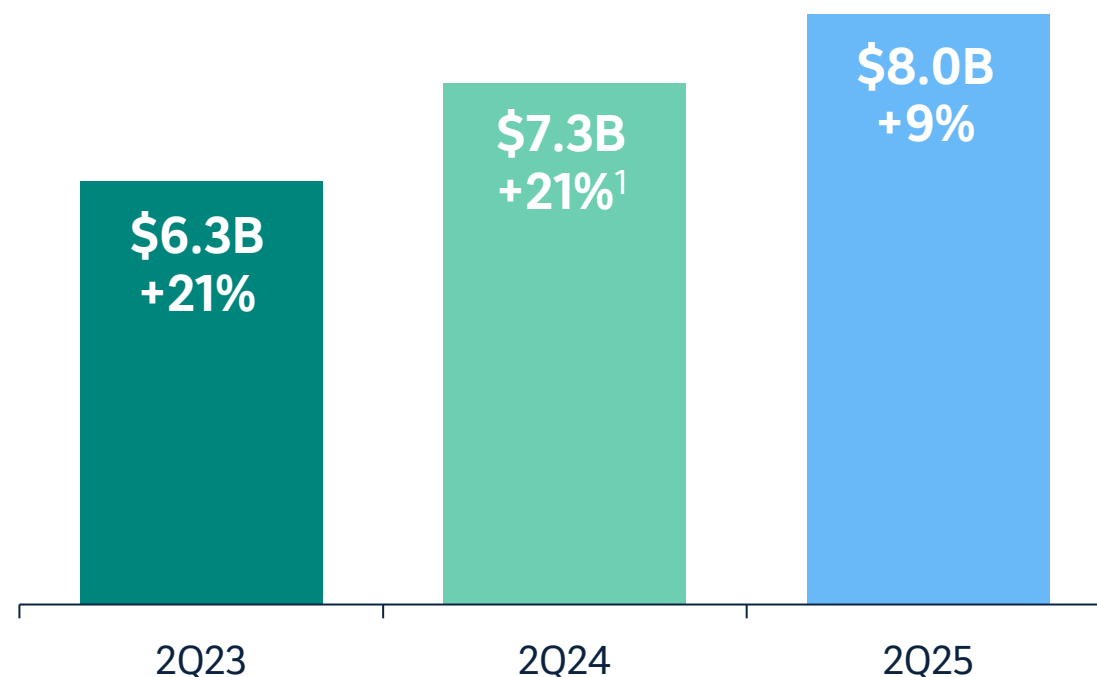


# Oncology: KEYTRUDA continues to benefit patients and drive growth

KEYTRUDA sales of \$8.0B increased 9%, driven by robust demand from metastatic indications and increased uptake in earlier-stage cancers

- Growth driven by usage in tumors predominantly affecting women, including those with certain breast, cervical and endometrial cancers
- Increased use of KEYTRUDA in combination with enfortumab vedotin in first-line, locally advanced urothelial cancer
- Positive feedback from HCPs following recent launch of KN-689 in certain patients with locally advanced head and neck cancer

**KEYTRUDA®**  
(pembrolizumab) Injection 100 mg



Growth rates exclude the impact of foreign exchange.

1. ~4 percentage points of negative impact of foreign exchange substantially all of which was due to devaluation of Argentine peso, which was largely offset by inflation-related price increases.

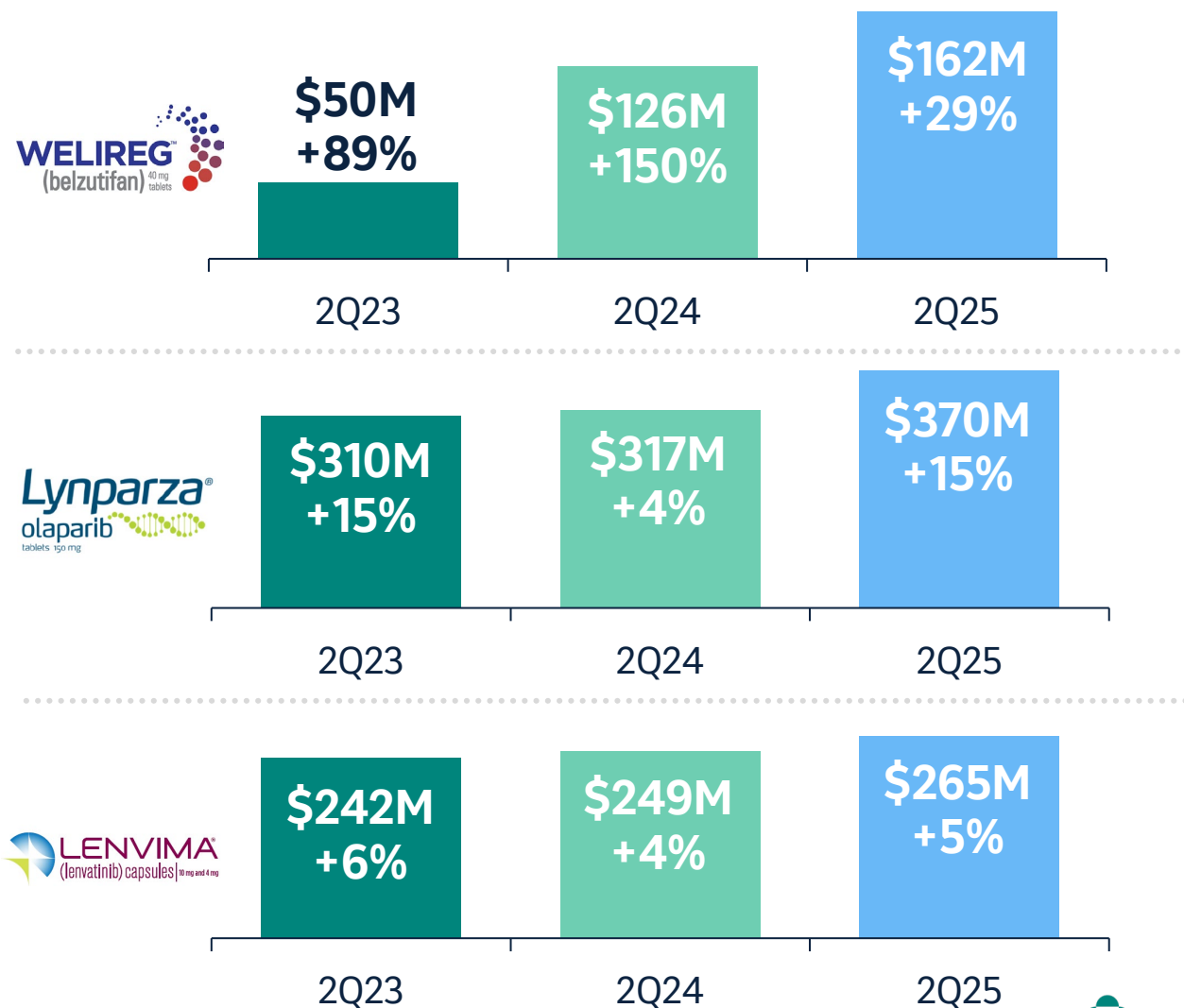


# Oncology: Strong growth across broad portfolio

WELIREG sales grew 29%, driven by increased uptake in certain adult patients with previously treated advanced RCC in the U.S.

Lynparza<sup>1</sup> sales grew 15%, primarily due to higher demand in the U.S. and certain international markets

Lenvima<sup>2</sup> sales grew 5%, primarily due to higher sales in the U.S. reflecting higher demand, partially offset by lower pricing



Growth rates exclude the impact of foreign exchange.

1. In collaboration with AstraZeneca 2. In collaboration with Eisai

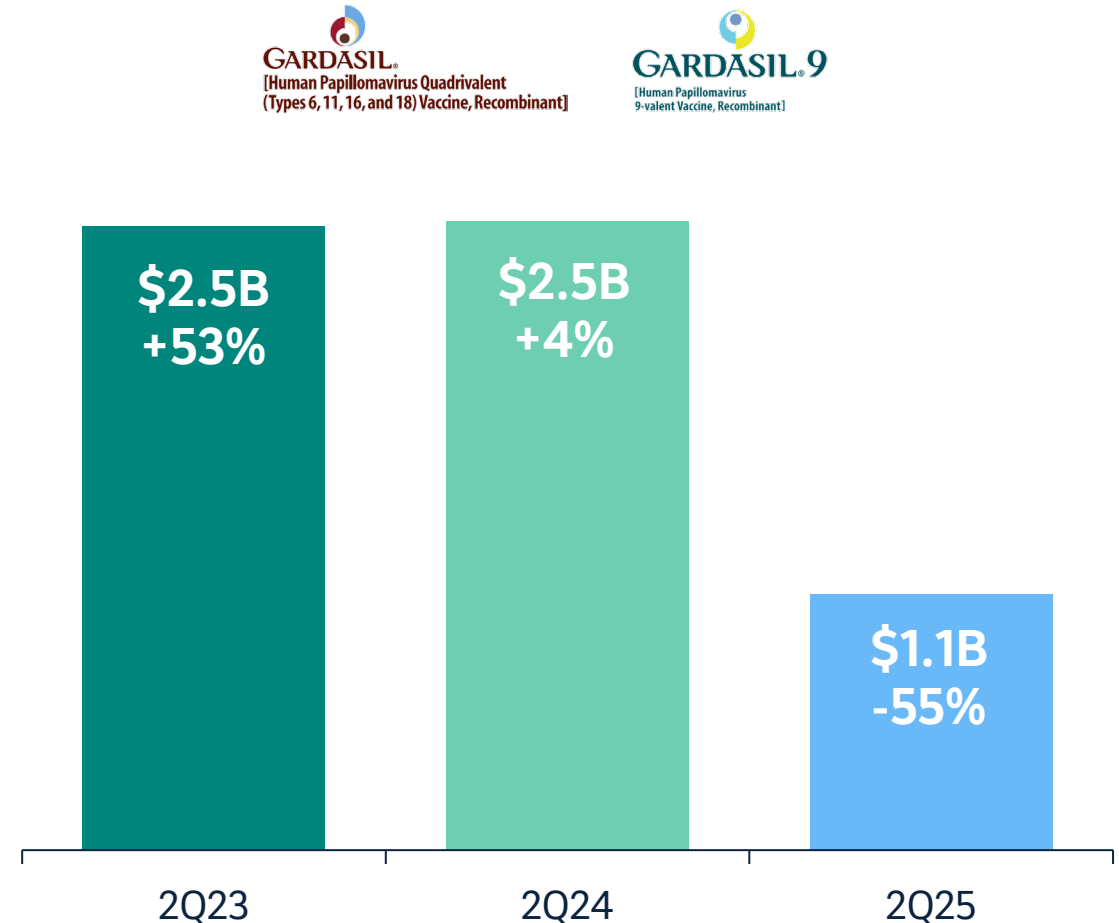




# Vaccines: GARDASIL protecting lives from HPV-related cancers

GARDASIL sales of \$1.1B decreased 55%, driven primarily by China

- Outside the U.S. and China, decline driven by lower sales in Japan reflecting expiration of reimbursement for catch-up cohort and timing of public sector purchases in certain international markets
- In the U.S., growth of 2% driven by price and higher demand, partially offset by CDC purchasing patterns

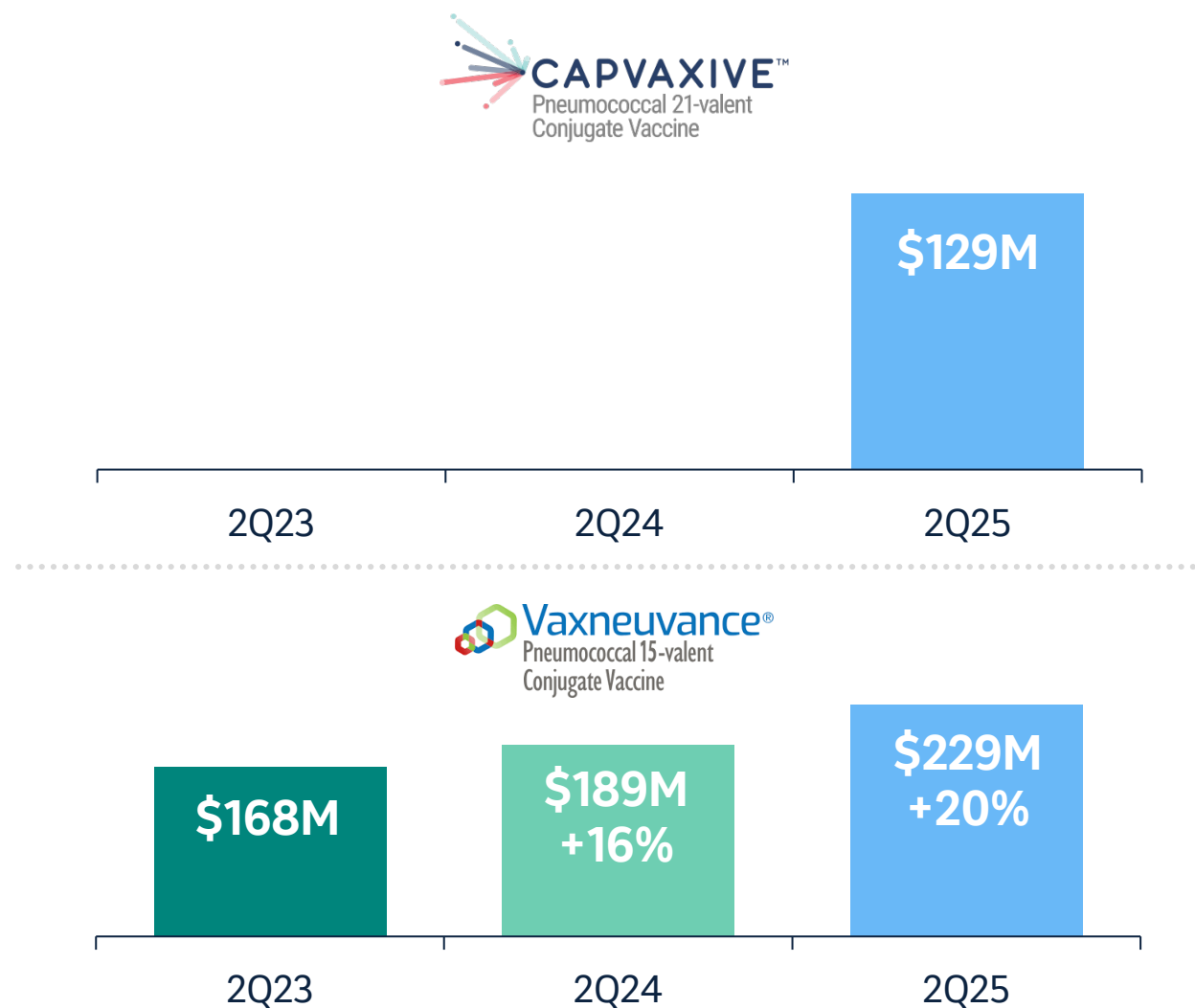


# Vaccines: Growth across pneumococcal vaccine portfolio

CAPVAXIVE<sup>1</sup> sales of \$129M driven by demand from retail pharmacies and non-retail customers

VAXNEUVANCE sales of \$229M increased 20%

- In the U.S., growth benefitted by ~\$60M from CDC stockpile activity<sup>2</sup>, partially offset by competitive pressures
- Outside the U.S., growth in certain international markets offset by competitor preferential recommendation in Japan



Growth rates exclude the impact of foreign exchange.

1. Launched in 3Q24 2. Benefit to VAXNEUVANCE was offset by a draw down of CDC stockpile inventory for ROTATEQ and VARIVAX resulting in a net neutral transaction



# ENFLONZIA: Excited to bring new option for RSV prevention in infants



First and only RSV preventive option for administration to infants using same dose regardless of weight

Compelling clinical data and operational simplicity make it an important option

Initial orders received in July

# WINREVAIR: Strong launch execution demonstrates ability to maximize value of pipeline

**WINREVAIR™**  
(sotatercept-csrk) for injection  
45 mg, 60 mg



**>\$1B cumulative net sales since launch**

## In the U.S., continued growth in new patient starts and TRx

- >1,600 new patients prescribed in the quarter
- >8,200 total patients prescribed since launch
- >6,500 patients with claims approved by payers started treatment since launch
- ~58,000 total prescriptions filled since launch

## Strong breadth and depth of prescribers

- >1,200 physicians have written at least one prescription since launch
- Steady increase in percentage of prescriptions for patients whose background PAH therapies do not include a prostacyclin

## Achieved coverage for >70% of lives since launch

## Ex-U.S., progressing with approvals and reimbursement

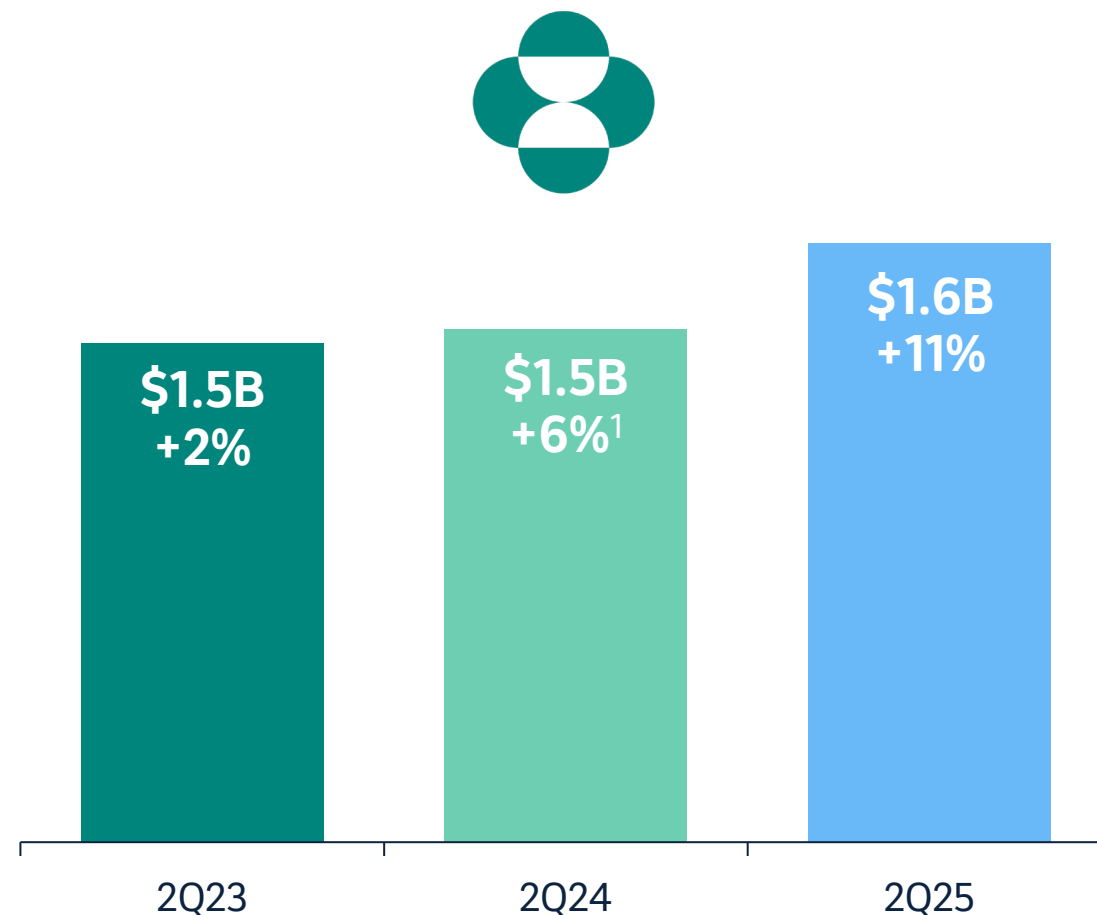
- Expect to launch later in 3Q25 in Japan



# Animal Health: Growth across livestock and companion animal

Animal Health sales increased 11% to \$1.6B

- Livestock sales grew 16%, driven by higher demand across all species, as well as inclusion of sales from recently expanded aqua portfolio
- Companion Animal sales growth of 6% reflects price
- Growth in both segments benefitted from improved supply



Growth rates exclude the impact of foreign exchange.

1. ~3 percentage points of negative impact of foreign exchange due to devaluation of Argentine peso, which was largely offset by inflation-related price increases.





# Q2 2025 non-GAAP financial results summary<sup>1</sup>

\$ in billions, except EPS amounts

	Q2 2025	Q2 2024	Change	Change Ex-FX
<b>Sales</b>	\$15.8	\$16.1	-2%	-2%
<b>Non-GAAP Gross Margin</b>	82.2%	80.9%	+1.3pts	+1.4pts
<b>Non-GAAP Operating Expenses</b>	\$6.6	\$6.2	+7%	+7%
<b>Non-GAAP Tax Rate</b>	15.0%	14.1%	+0.9pts	N/A
<b>Non-GAAP EPS<sup>2,3</sup></b>	\$2.13	\$2.28	-7%	-5%

1. The company is providing certain 2025 and 2024 non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of the company's results because management uses non-GAAP results to assess performance. Management uses non-GAAP measures internally for planning and forecasting purposes and to measure the performance of the company along with other metrics. In addition, annual employee compensation, including senior management's compensation, is derived in part using a non-GAAP pretax income metric. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP. For a description of the non-GAAP adjustments, see Table 2a attached to the earnings release. 2. Q2 2025 includes a charge of \$0.07 per share related to the closing of a license agreement with Hengrui Pharma. 3. Q2 2025 GAAP EPS of \$1.76



# Updated 2025 financial outlook

	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$64.1B to \$65.6B	\$64.3B to \$65.3B	<ul style="list-style-type: none"> <li>Now assumes ~0.5 percentage point FX headwind</li> <li>Implies +0% to +2% nominal (+1% to +2% ex-FX)</li> </ul>
Non-GAAP Gross Margin Rate	~82.0%	~82.0%	<ul style="list-style-type: none"> <li>Continues to assume ~\$200M of costs related to tariffs, pending the outcome of additional potential government actions</li> </ul>
Non-GAAP Operating Expenses <sup>1</sup>	\$25.6B to \$26.6B	\$25.6B to \$26.4B	<ul style="list-style-type: none"> <li>Continues to assume \$300M tech transfer milestone to LaNova, which was completed in July, and includes \$200M upfront payment related to license agreement with Hengrui Pharma</li> </ul>
Other (Income) / Expense	~\$300M to ~\$400M of expense	~\$300M to ~\$400M of expense	
Tax Rate	~15.5% to 16.5%	~15.0% to 16.0%	
Shares Outstanding	~2.51B	~2.51B	
Non-GAAP EPS <sup>1</sup>	\$8.82 to \$8.97	\$8.87 to \$8.97	<ul style="list-style-type: none"> <li>Continues to assume one-time charges related to tech transfer milestone to LaNova and upfront payment to Hengrui Pharma (now totaling ~\$0.16 per share)</li> <li>Now assumes ~\$0.15 FX headwind</li> </ul>

1. Guidance does not assume any additional significant potential business development transactions, and does not include anticipated impact of the announced acquisition of Verona Pharma.



# Key modeling considerations

## GARDASIL Family<sup>1</sup>

- In China, channel inventories remain elevated and demand continues to be soft, therefore will not resume shipments through at least the end of this year
- Japan will be a more significant headwind to growth in second half as we lap increased vaccinations from catch-up cohort

## Other Revenue

- Expect second half other revenue to be significantly lower due to negative impact from foreign exchange hedging program

## Operating Expenses

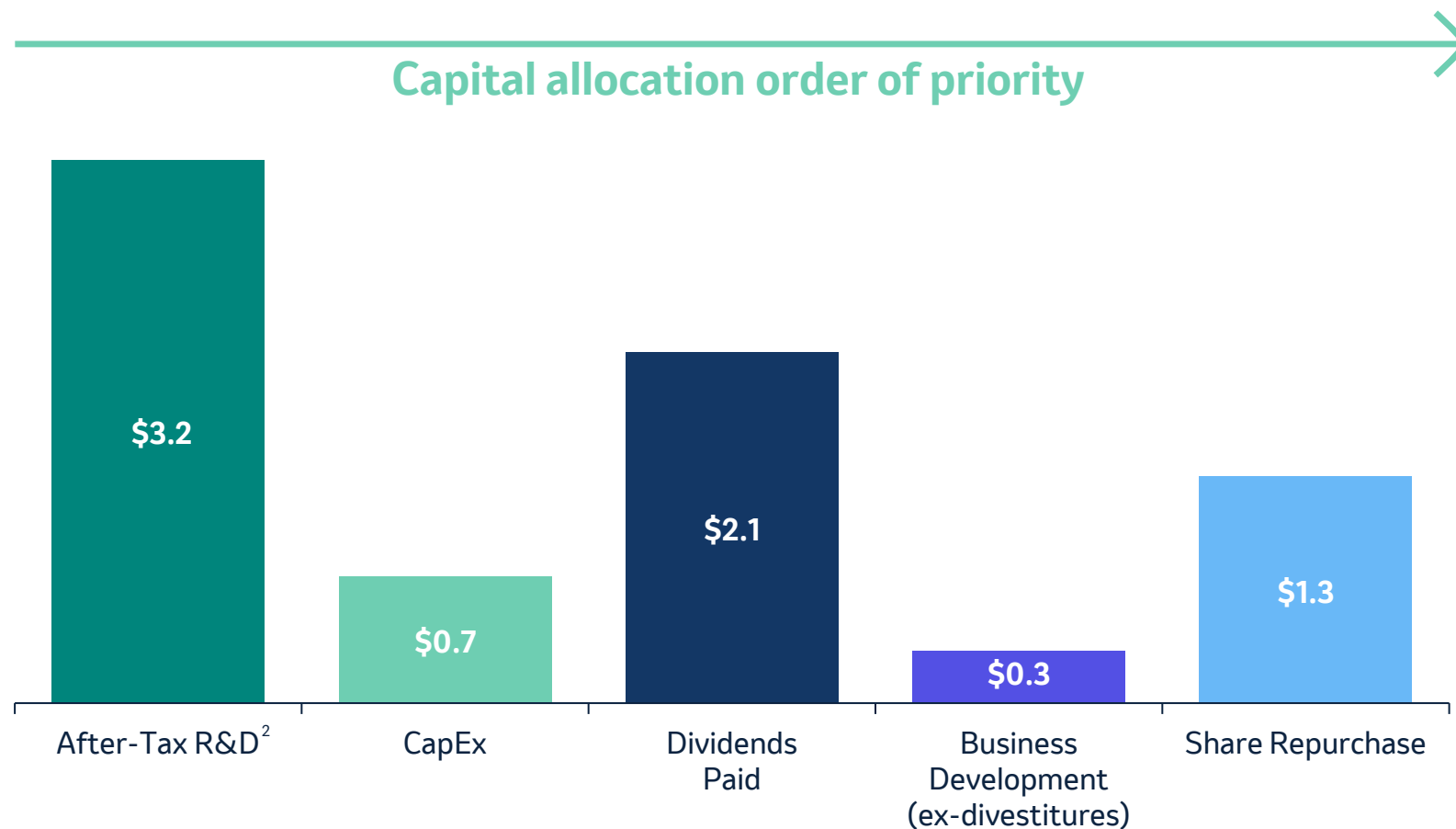
- Expect second half operating expenses to be roughly evenly split between 3Q and 4Q, excluding business development

1. GARDASIL Family includes GARDASIL and GARDASIL 9



# Remain committed to balanced capital allocation strategy

Q2 Spend (\$ in billions)<sup>1</sup>



Continue to invest in our **pipeline** and **business**, as well as augment our pipeline with value-enhancing **business development**, while returning **cash to shareholders**

1. Reflects quarter spend

2. Reflects R&D excluding Business Development



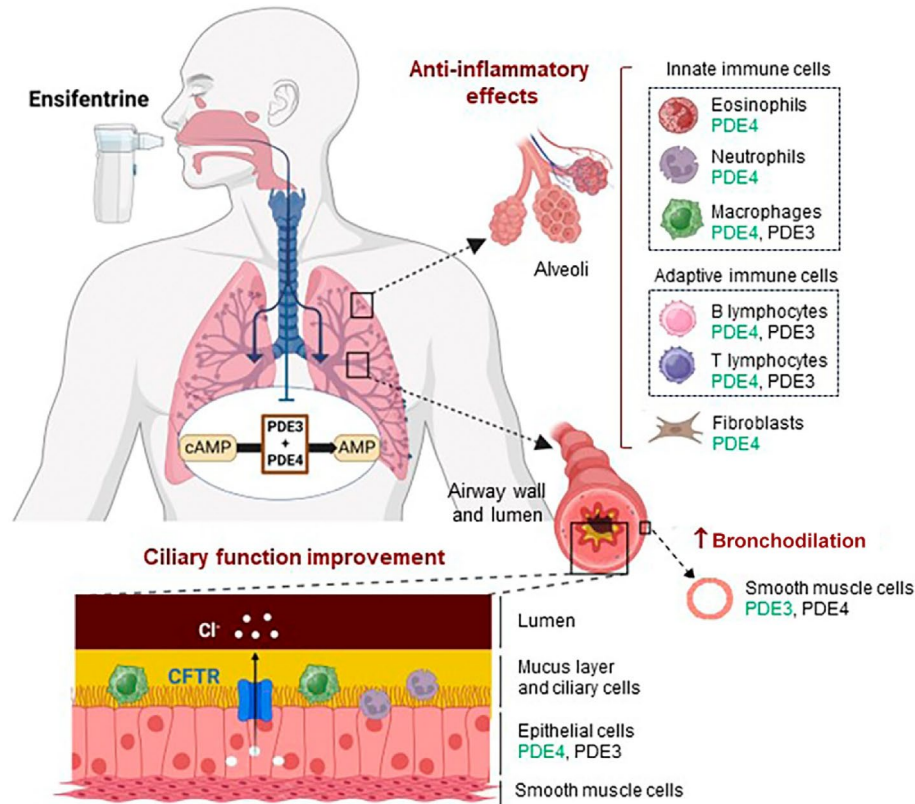
# Research Update

Dr. Dean Y. Li  
Executive Vice President and President,  
Research Laboratories





# Ohtuvayre is the first inhaled COPD maintenance treatment that combines bronchodilatory and non-steroidal anti-inflammatory activity



**First novel inhaled mechanism** for maintenance treatment of COPD **in more than two decades**

**Dual inhibitor** of phosphodiesterase 3 (PDE3) and phosphodiesterase 4 (PDE4)

**Improves symptoms** of COPD for better breathing and **to reduce number of flare-ups**

# Important updates across cardiopulmonary portfolio

## WINREVAIR

Topline results for Phase 3 **HYPERION** trial in adults **recently diagnosed with PAH** showed adding WINREVAIR on top of background PAH therapy significantly **reduced risk of clinical worsening events** compared to background therapy alone

- Detailed results to be presented later this year

FDA granted **priority review for sBLA** to update label for WINREVAIR based on **ZENITH** trial

- PDUFA date of October 25, 2025

**Received approval** from MHLW in **Japan**

## Enlicitide decanoate

Announced positive topline results from Phase 3 **CORALreef HeFH** and **CORALreef AddOn** trials

- Both trials met primary and all key secondary endpoints, demonstrating statistically significant and clinically meaningful reductions in LDL-C versus placebo (CORALreef HeFH) and versus other oral non-statin therapies (CORALreef AddOn)

Results from three Phase 3 trials, including **CORALreef Lipids** trial in broader hypercholesterolemia patient population, will be presented at future scientific congresses

Completed enrollment for Phase 3 **CORALreef Outcomes** trial



# Building on our progress in infectious diseases

## RSV

FDA approved **ENFLONSIA** for **prevention of RSV** lower respiratory tract disease in infants born during or entering first RSV season

- First and only option designed to protect infants with same dose regardless of weight
- ACIP recommended for use in infants younger than eight months of age, and inclusion in VFC<sup>1</sup> program

## Dengue

Initiated first Phase 3 trial to evaluate **V181**, investigational quadrivalent vaccine for **prevention of dengue disease** caused by any four dengue virus serotypes, regardless of prior dengue exposure

## HIV

Presented data at IAS<sup>2</sup> from Phase 2 trial evaluating **MK-8527** for **PrEP**

- Potential to enable rapid onset of protection within one hour of intake without need for loading dose
- Support imminent initiation of Phase 3 EXPrESSIVE program

Presented data at IAS<sup>2</sup> for combination of **islatravir and ulonivirine** for **once-weekly treatment** of adults living with HIV

FDA accepted NDA for combination of **doravirine and islatravir** for **once-daily treatment** of adults living with HIV-1 that is virologically suppressed on antiretroviral therapy

- PDUFA date of April 28, 2026

# Continuing to advance cancer care with a broad, differentiated portfolio and pipeline

## Notable recent updates

Showcased diverse pipeline at **ASCO** investor event

Three ongoing Phase 3 trials evaluating **ifinatamab deruxtecan**<sup>1</sup>

- **IDeate-Esophageal01** in unresectable advanced or metastatic esophageal squamous cell carcinoma
- **IDeate-Prostate01** in metastatic castration-resistant prostate cancer
- **IDeate-Lung02** in relapsed small cell lung cancer

**KEYNOTE-689:** Received FDA approval for KEYTRUDA as part of perioperative treatment regimen for adult patients with resectable, locally advanced HNSCC whose tumors express PD-L1 (CPS >1)

**KEYNOTE-B96:** Announced positive PFS and OS results for KEYTRUDA plus chemotherapy with or without bevacizumab in certain patients with platinum-resistant recurrent ovarian cancer

Received approval from MHLW in Japan for **WELIREG** for certain patients with **advanced RCC**

**KEYTRUDA**<sup>®</sup>  
(pembrolizumab)

**42** total approvals<sup>2</sup>

**10** earlier stage approvals<sup>2</sup>

1. In collaboration with Daiichi Sankyo 2. Represents approvals in the U.S.



# Key second half dates and milestones

## Oncology

### **Subcutaneous pembrolizumab with berahyaluronidase alfa**

- PDUFA date September 23<sup>rd</sup>

## Cardiopulmonary

### **WINREVAIR**

- PDUFA date October 25<sup>th</sup> for FDA label update based on ZENITH trial
- Presentation of detailed findings from HYPERION trial
- Primary completion date in September for CADENCE trial in Cpc-PH due to HFpEF

### **Enlicitide decanoate**

- Begin presenting detailed findings from CORALreef development program

## Business Development

### **Verona Pharma**

- Expect acquisition to close in 4Q25







# Q&A



**Robert M. Davis**  
Chairman and Chief Executive Officer



**Caroline Litchfield**  
Executive Vice President and Chief Financial Officer



**Dr. Dean Y. Li**  
Executive Vice President and President, Research Laboratories



**Peter Dannenbaum**  
Senior Vice President, Investor Relations



# Appendix

# Q2 2025 GAAP financial results summary

\$ in billions, EPS amounts

	Q2 2025	Q2 2024	Change	Change Ex-FX
<b>Sales</b>	\$15.8	\$16.1	-2%	-2%
<b>Operating Expenses (SG&amp;A and R&amp;D)<sup>1</sup></b>	\$6.7	\$6.2	+7%	+7%
<b>Tax Rate</b>	11.4%	9.1%	+2.3pts	N/A
<b>GAAP EPS<sup>1,2</sup></b>	\$1.76	\$2.14	-18%	-16%

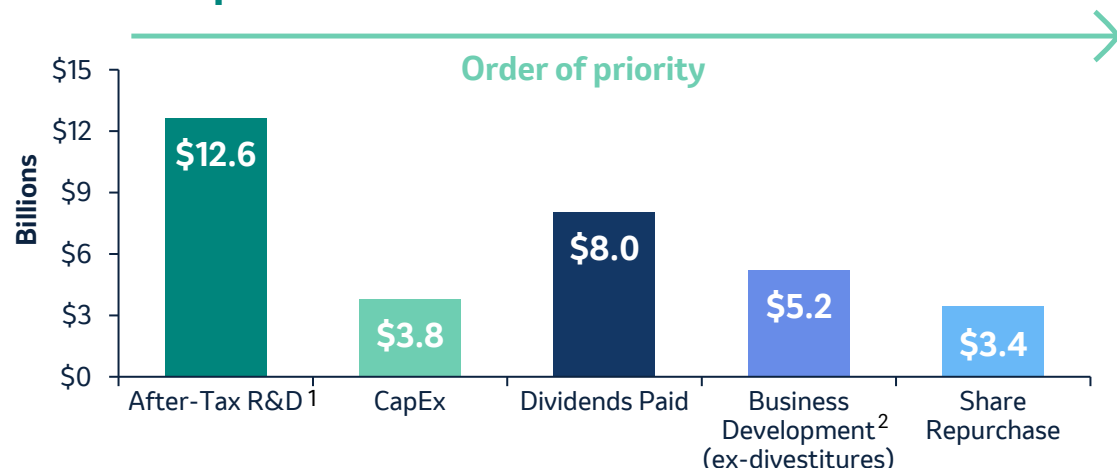
1. 2Q25 GAAP results include \$200 million charge, or \$0.07 negative EPS impact, related to the closing of a license agreement with Hengrui Pharma

2. 2Q25 GAAP results include \$779 million charge (\$649 million related to 2025 restructuring program), or \$0.25 negative EPS impact



# Capital allocation: Trailing twelve months

## Over the past 12 months



## Capital investments 2025 to 2029

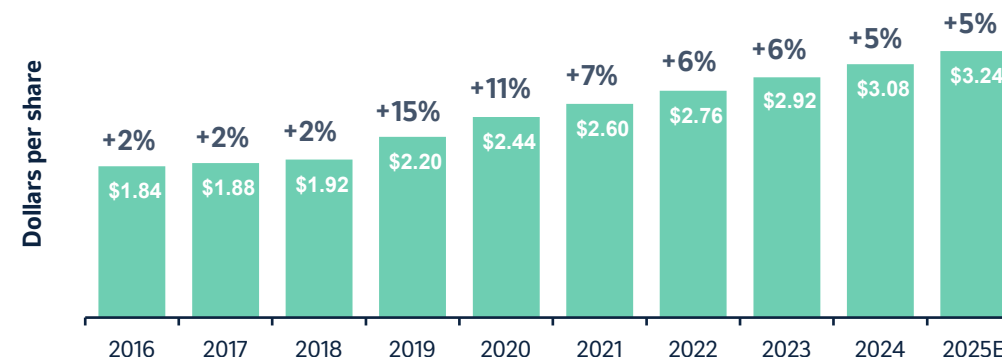
~\$21B

Over 5 years, including expanding manufacturing capacity for Oncology, Vaccines, and Animal Health. Includes >\$11B in the U.S.

1. Reflects R&D excluding Business Development  
2. Includes BD payments reflected in operating cash flow

Well-positioned balance sheet  
with capacity to fund  
**additional value-enhancing  
business development  
opportunities**

## Commitment to the dividend



# Driving value for patients and shareholders by progressing our pipeline

## Key regulatory milestones since the last earnings call:

### In the U.S.:

- FDA approved BRAVECTO QUANTUM as a once-yearly injectable product to treat and protect dogs from fleas and ticks
- FDA approved KEYTRUDA as part of a neoadjuvant/adjuvant treatment regimen for adult patients with resectable locally advanced HNSCC whose tumors express PD-L1 (CPS  $\geq 1$ ), based on KEYNOTE-689
- FDA approved WELIREG for the treatment of adults and pediatric patients 12 years and older with locally advanced, unresectable, or metastatic PPGL
- FDA accepted for review an NDA for doravirine/islatravir, an investigational, once-daily, oral, two-drug regimen for adults with HIV-1 infection that is virologically suppressed on antiretroviral therapy
- FDA accepted and granted priority review for a new sBLA to update the U.S. product label for WINREVAIR based on the Phase 3 ZENITH trial
- Following FDA approval, ACIP voted to recommend ENFLONIA as an option for the prevention of RSV lower respiratory tract disease in infants younger than 8 months of age who are born during or entering their first RSV season

### In the EU:

- EC approved NUMELVI for the treatment of pruritus associated with allergic dermatitis including atopic dermatitis and treatment of clinical manifestations of atopic dermatitis for dogs

### In China:

- NMPA approved KEYTRUDA in combination with LENVIMA plus TACE for the treatment of patients with unresectable non-metastatic HCC

### In Japan:

- MHLW approved AIRWIN (sotatercept) for the treatment of adults with PAH
- MHLW approved WELIREG as monotherapy for the treatment of adults with VHL disease-associated tumors, and for adults with unresectable or metastatic RCC that has progressed after chemotherapy
- MHLW approved KEYTRUDA for metastatic HER2+ gastric cancer based on KEYNOTE-811
- MHLW approved KEYTRUDA for 1L unresectable advanced or metastatic malignant pleural mesothelioma based on KEYNOTE-483

## Key data & clinical advancements since the last earnings call:

### Announced:

- Phase 3 HYPERION study evaluating WINREVAIR met primary endpoint in recently diagnosed adults with PAH FC II or III at intermediate or high risk of disease progression
- Phase 3 CORALreef HeFH and CORALreef AddOn trials evaluating enlicitide decanoate met primary and all key secondary endpoints for the treatment of adults with hyperlipidemia
- Phase 3 KEYNOTE-B96 trial evaluating KEYTRUDA met primary endpoint of PFS in patients with platinum-resistant recurrent ovarian cancer whose tumors expressed PD-L1 and in all comers, as well as secondary endpoint of OS for patients whose tumors express PD-L1

### Presented data for:

- MK-8527, an investigational novel NRTTI, once-monthly pill, in development for the prevention of HIV as pre-exposure prophylaxis (PrEP) at IAS
- Broad oncology portfolio at ASCO, including for KEYTRUDA (KN-D19, KN-564, KN-859, KN-A18, KN-689), WELIREG (LITESPARK-004), sac-TMT (TROPION-Lung02, OptiTROP-Lung03), MK-1084 (KANDLELIT-001), and zilovertamab vedotin (waveLINE-003)
- WINREVAIR at ATS, including new clinical and outcomes data

### Announced initiation of Phase 3 studies evaluating:

- MK-8527 (HIV PrEP), I-DXd (B7H3 ADC), V181 (Dengue), sac-TMT (TROP2 ADC), MK-1084 (KRAS G12Ci)



