

## First-Quarter 2025 Sales and Earnings

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





**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

Agenda

## 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).

## Strategy and Business Update

Robert M. Davis Chairman and Chief Executive Officer



## Q12025 total company performance and pipeline progress

# Q1 Worldwide Sales

Strength in **Oncology** and **Animal Health** 

Meaningful contributions from **new launches** 







#### Cardiometabolic

Important results for **WINREVAIR** from Phase 3 ZENITH trial Licensed **HRS-5346**, oral Lp(a) inhibitor, from Hengrui Pharma



#### **Infectious Disease**

Results from two Phase 3 switch studies for **islatravir + doravirine** for HIV treatment in adults



## Oncology

Presentation of data and FDA acceptance of BLA for **subcutaneous pembrolizumab** with berahyaluronidase-alfa

FDA acceptance of sBLA for **KEYTRUDA** in earlier-stage HNSCC

## Delivering the next wave of innovation



# Well positioned to successfully navigate through the KEYTRUDA LOE period



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

"Confident in our strategic direction, our commitment to research and development as the source for sustainable value-creation, and our enduring promise to positively impact patients"



# Financial Results and Outlook

Caroline Litchfield Executive Vice President and Chief Financial Officer



## Q1 worldwide performance driven by demand for our innovative portfolio

# worldwide sales<sup>1</sup> \$15.5B

-2% decrease +1% ex-exchange +6% ex-GARDASIL China<sup>2</sup> +8% ex-GARDASIL China, ex-exchange

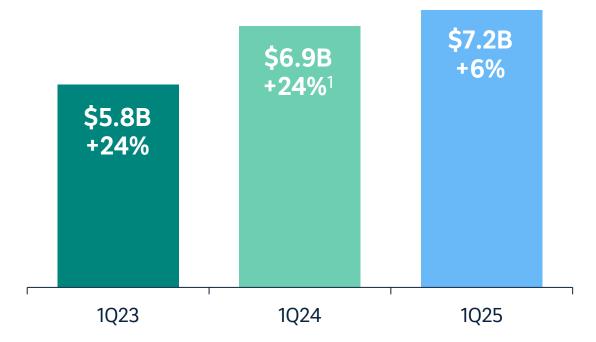


## Human Health \$13.6B

-3% decrease -1% ex-exchange +5% ex-GARDASIL China<sup>2</sup> +7% ex-GARDASIL China, ex-exchange Animal Health \$1.6B +5% growth +10% ex-exchange KEYTRUDA sales of \$7.2B increased 6%, driven by increased uptake from earlier-stage cancers and robust demand from metastatic indications

- In earlier-stage settings, growth driven by increased utilization in resectable TNBC, RCC and NSCLC
- In metastatic disease, growth driven by increased use of KEYTRUDA in combination with Padcev in first-line, locally advanced urothelial cancer, as well as KEYTRUDA in combination with chemotherapy in 1L endometrial cancer
- In the U.S., growth negatively impacted by ~\$250M due to timing of wholesaler purchases





Growth rates exclude the impact of foreign exchange.

1. Includes ~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.

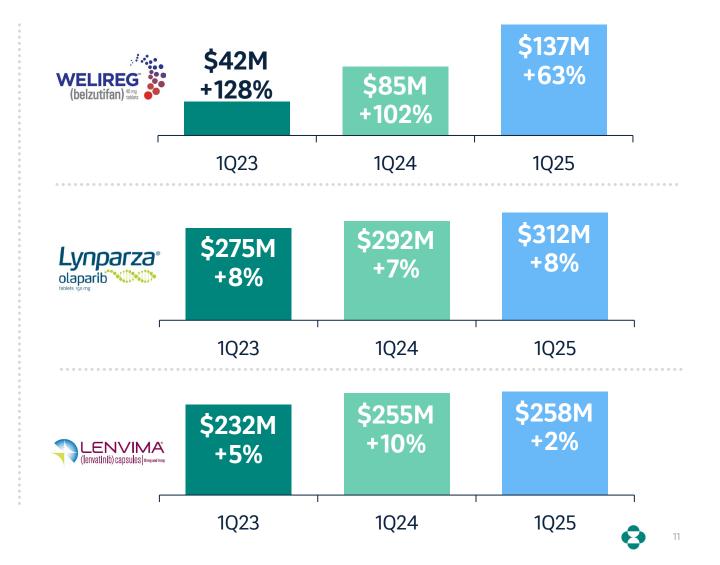
## Oncology: Important contributions across broad portfolio

WELIREG sales grew 63%, driven by increased uptake in certain adult patients with previously treated advanced RCC in the U.S

 Now market leader for treatment of adult patients with advanced RCC following indicated prior therapies

Lynparza<sup>1</sup> sales grew 8%, primarily due to higher demand in the U.S. and certain international markets

Lenvima<sup>2</sup> sales grew 2%, primarily due to higher demand in the U.S.



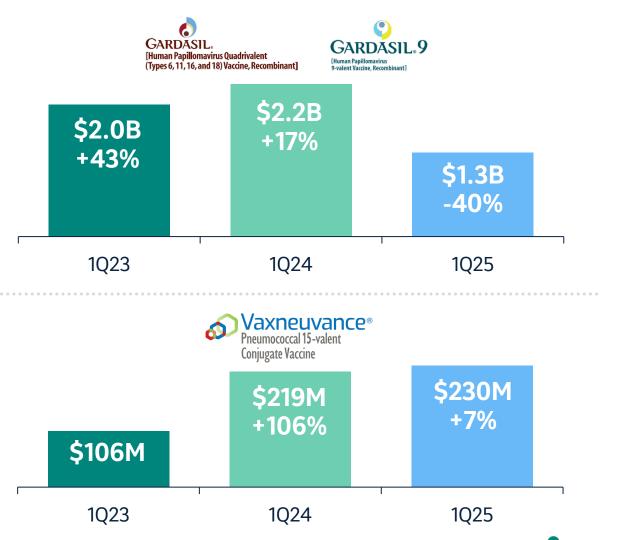
## Vaccines: Broad vaccines portfolio driving global impact

GARDASIL sales of \$1.3B decreased 40%, driven by continued soft demand in China where channel inventories remain elevated

- In the U.S., sales benefitted from price and demand
- Outside the U.S. and China, growth driven by higher overall demand including catch-up cohort in Japan

CAPVAXIVE sales of \$107M, driven primarily by demand from retail pharmacy segment

VAXNEUVANCE sales of \$230M increased 7%, driven by ongoing launches in international markets, partially offset by competitive pressures in the U.S.

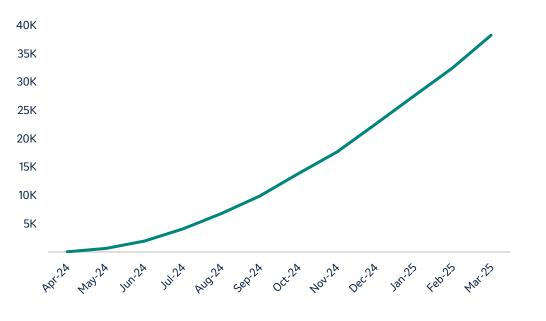


## Cardiovascular: Successful ongoing launch of WINREVAIR



**U.S. Launch Progress** 

Total Prescriptions (TRx)



## Global Q1 sales of \$280M

#### U.S.:

#### Continued growth in new patient starts and TRx

- >1,400 new patients prescribed in the quarter
- ~6,600 total patients prescribed since launch
- ~5,200 patients with claims approved by payers started treatment since launch
- >38,000 total prescriptions filled since launch

#### Strong breadth and depth of prescribers

- ~1,100 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.:

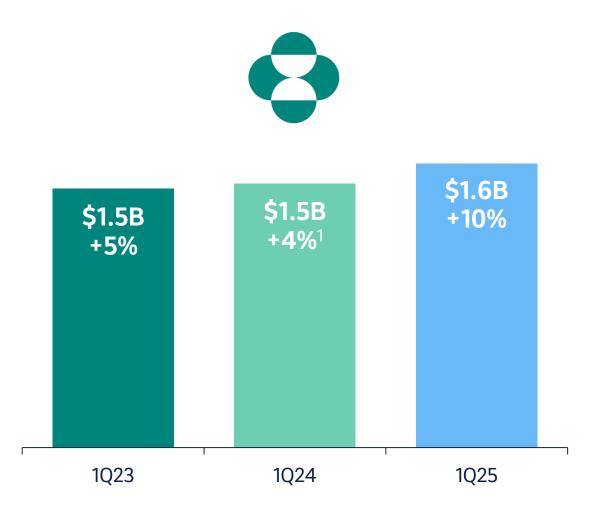
#### **Progressing with launches**

- Anticipate securing reimbursement in other European countries in 2H25

## Animal Health: Robust growth driven by demand for livestock products

## Animal Health sales increased 10% to \$1.6B

- Livestock sales grew 16%, driven by higher demand across all species, as well as benefit from timing of ruminant sales and inclusion of sales from recently expanded aqua portfolio
- Companion Animal sales growth of 3% reflects price



E

## Q12025 non-GAAP financial results summary<sup>1</sup>

	Q1 2025	Q12024	Change	Change Ex-FX
Sales	\$15.5	\$15.8	-2%	+1%
Non-GAAP Gross Margin	82.2%	81.2%	+1.0pts	+1.5pts
Non-GAAP Operating Expenses	\$6.1	\$6.4	-4%	-3%
Non-GAAP Tax Rate	14.2%	16.1%	-1.9pts	N/A
Non-GAAP EPS <sup>2,3</sup>	\$2.22	\$2.07	+7%	+12%

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. Q1 2024 includes a charge of \$0.26 per share for the acquisition of Harpoon. 3. Q1 2025 GAAP EPS of \$2.01

## Updated 2025 financial outlook

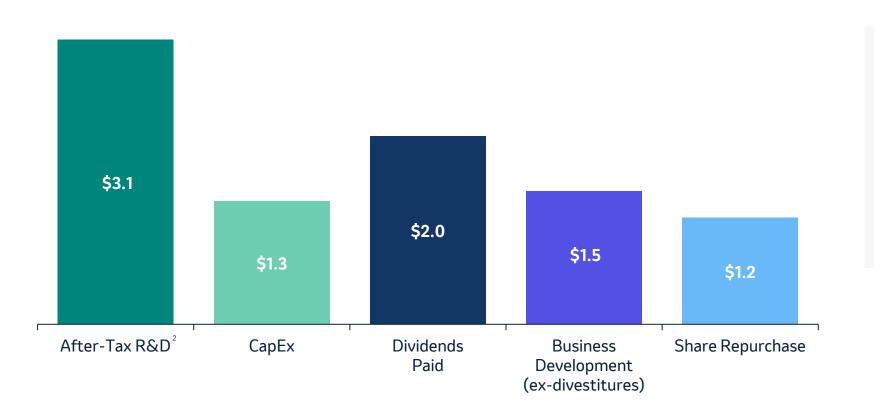
	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$64.1B to \$65.6B	\$64.1B to \$65.6B	<ul> <li>Now assumes ~1 percentage point FX headwind</li> <li>Implies +0% to +2% nominal (+1% to +3% ex-FX)</li> </ul>
Non-GAAP Gross Margin Rate	~82.5%	~82.0%	<ul> <li>Now includes ~\$200M of costs related to tariffs implemented to date</li> </ul>
Non-GAAP Operating Expenses <sup>1</sup>	\$25.4B to \$26.4B	\$25.6B to \$26.6B	<ul> <li>Now includes \$200M anticipated 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	~16.0% to 17.0%	~15.5% to 16.5%	
Shares Outstanding	~2.53B	~2.51B	
Non-GAAP EPS <sup>1</sup>	\$8.88 to \$9.03	\$8.82 to \$8.97	<ul> <li>Now includes ~\$0.06 charge related to license agreement with Hengrui Pharma</li> <li>Now assumes negative impact from FX of &gt;\$0.20</li> </ul>

1. Guidance does not assume any additional significant potential business development transactions.

## Key modeling considerations

GARDASIL Family <sup>1</sup>	<ul> <li>Following successful HPV catch-up vaccination program in Japan, expect uptake to moderate as future sales will predominantly reflect the primary age cohort</li> <li>Therefore, global GARDASIL growth ex-China, while still strong, is anticipated to slow going forward</li> </ul>
KEYTRUDA	<ul> <li>Timing of wholesaler purchases negatively impacted U.S. sales by ~\$250M in 1Q25, and will positively impact sales by roughly the same amount in 3Q25</li> </ul>
JANUVIA Family <sup>2</sup>	<ul> <li>Lowered U.S. list prices at the beginning of 2025 which will reduce rebate amount paid to Medicaid</li> <li>As a result, expect higher net sales in the U.S. in 2025</li> <li>1Q25 U.S. sales also benefitted by &gt;\$100M from favorable one-time true ups</li> </ul>

## Remain committed to balanced capital allocation strategy Q1 Spend (\$ in billions)<sup>1</sup>



**Capital allocation order of priority** 

Continue to invest in our **pipeline** and **business** while augmenting our pipeline with value-enhancing **business development** 

# Research Update

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



## Broadening our impact in cardiometabolic research

## WINREVAIR - ZENITH Study

- First study in PAH to use a primary endpoint comprised entirely of major morbidity and mortality events
- First Phase 3 study in PAH stopped early for 'overwhelming efficacy'
- Profound risk reduction of 76% on composite endpoint of all-cause death, PAH-worsening related hospitalization (≥24 hours), and lung transplantation in patients with advanced PAH at high risk of mortality despite maximally tolerated background therapy vs placebo
  - Early and sustained separation between treatment groups
- Loss of clinical equipoise in HYPERION: stopped early and moving to final analysis based on totality of data in WINREVAIR clinical program to date

## HRS-5346

- Entered exclusive license agreement with Hengrui Pharma to develop investigational oral small molecule Lp(a) formation inhibitor
- Hengrui recently initiated Phase 2 clinical trial in China for HRS-5346
- Planning robust global clinical development program

## Progress across vaccines and infectious disease programs

#### Vaccines

#### CAPVAXIVE

 EC granted approval for active immunization for prevention of invasive disease and pneumonia caused by streptococcus pneumoniae in adults

## GARDASIL

• NMPA of China approved GARDASIL 9 to help prevent certain HPV-related cancers and diseases in males 16 to 26 years old

## HIV

- Presented detailed results from two pivotal Phase 3 trials evaluating investigational, once-daily, oral fixed dose combination of doravirine and islatravir, an investigational NRTTI, in treatment-experienced adults with HIV-1 infection at CROI<sup>1</sup>
  - Both trials met primary efficacy success criteria for noninferiority to comparator antiretroviral therapies and primary safety objectives
  - Plan to submit applications for marketing authorization by mid-year

## Continuing to advance our broad oncology program

#### Subcutaneous pembrolizumab

Announced detailed findings from **3475A**-**D77 pivotal Phase 3 trial**, evaluating sixweek dosing regimen of the investigational **subcutaneous fixed dose combination of pembrolizumab and berahyaluronidase alfa**, with chemotherapy, versus intravenous KEYTRUDA with chemotherapy at ELCC<sup>1</sup>

- Study met dual primary endpoints, demonstrating non-inferior pharmacokinetics with a median injection time of ~2 minutes
- FDA set PDUFA date of September 23rd
- Seeking approval for six-week and threeweek dosing options
- EMA reviewing application for approval

### **KEYTRUDA** in Earlier Stage

**KEYNOTE-689:** FDA granted priority review for **KEYTRUDA as part of a perioperative treatment regimen** for patients newly diagnosed with resectable, **locally advanced HNSCC** 

- FDA set PDUFA date of June 23<sup>rd</sup>

If approved, would mark **10th indication** of a KEYTRUDA based regimen for treatment of certain **earlier stage cancers**:

- Lung: KEYNOTE-671, KEYNOTE-091
- Renal: KEYNOTE-564
- Skin: KEYNOTE-054, KEYNOTE-716, KEYNOTE-629
- Breast: KEYNOTE-522
- Cervical: KEYNOTE-A18
- Bladder: KEYNOTE-057

### WELIREG

**EC** conditionally approved **WELIREG** for treatment of adults with:

- vHL disease who require therapy for associated, localized RCC, CNS, hemangioblastomas, or pancreatic NET tumors, and for whom localized procedures are unsuitable based on LITESPARK-004
- Advanced clear cell RCC that progressed following two or more lines of therapy that included a PD-1 or PD-L1 inhibitor and at least two VEGF targeted therapies based on LITESPARK-005

## Key upcoming dates and milestones

## **Save the Date:** ASCO Investor Event in Chicago

JUNE 2

## **Upcoming Milestones:**

## Oncology

- KEYNOTE-689 in locally advanced HNSCC PDUFA date June 23rd
- Subcutaneous pembrolizumab PDUFA date September 23<sup>rd</sup>

## RSV

 Clesrovimab in RSV to help protect infants during their first RSV season - PDUFA date June 10<sup>th</sup>

## Cardiometabolic

- Enlicitide for treatment of hypercholesterolemia results from three Phase 3 registration-enabling studies
- WINREVAIR
  - Phase 2 CADENCE study PCD scheduled for Fall
  - Phase 3 HYPERION study final data readout

## HIV

- Islatravir/doravirine regimen regulatory filing in U.S
- MK-8527 Phase 2a study for PrEP data readout





Robert M. Davis Chairman and Chief Executive Officer



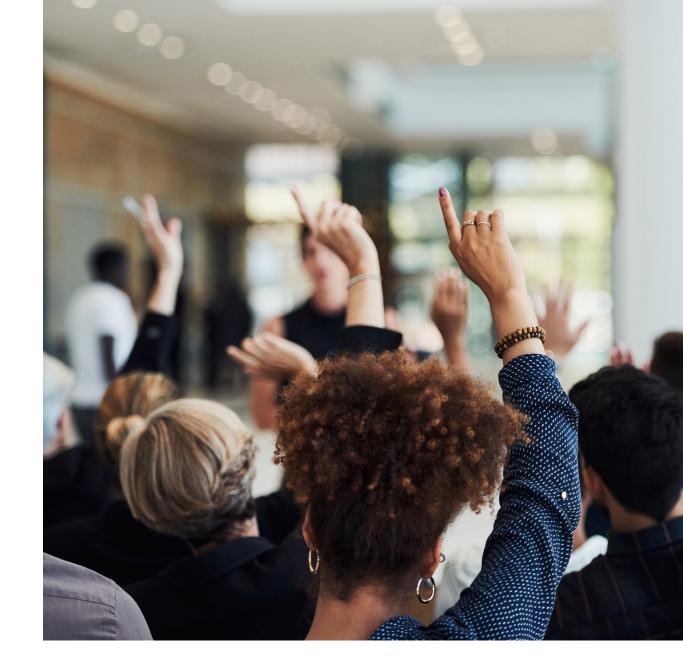
**Caroline Litchfield** Executive Vice President and Chief Financial Officer



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



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

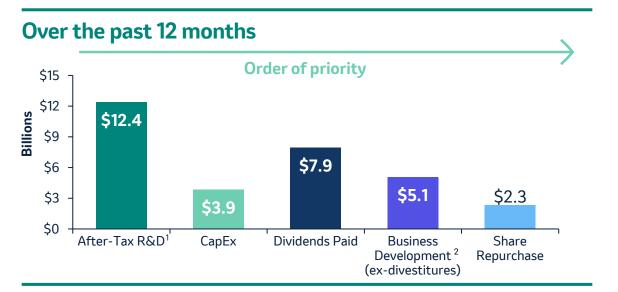


# Appendix

## Q12025 GAAP financial results summary \$ in billions, EPS amounts

	Q1 2025	Q12024	Change	Change Ex-FX
Sales	\$15.5	\$15.8	-2%	+1%
<b>Operating Expenses</b> <sup>1</sup>	\$6.2	\$6.5	-5%	-3%
Tax Rate	13.9%	15.9%	-2.0pts	N/A
GAAP EPS <sup>1</sup>	\$2.01	\$1.87	+7%	+13%

## Capital allocation: Trailing twelve months

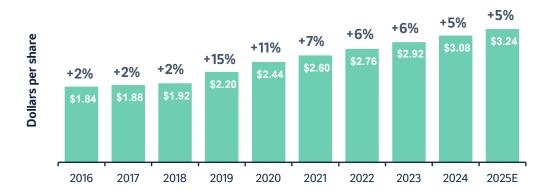


**Capital investments** 2024 to 2028

~\$20B

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

- Accepted for review a BLA for subcutaneous pembrolizumab with berahyaluronidase alfa across all previously approved solid tumor indications for KEYTRUDA based on 3475A-D77
- Accepted for priority review the sBLA for KEYTRUDA plus standard of care as perioperative treatment for resectable locally advanced head and neck squamous cell carcinoma based on KEYNOTE-689

#### In the EU, the European Commission:

- Approved CAPVAXIVE for active immunization for the prevention of invasive disease and pneumonia caused by certain types of streptococcus pneumoniae in adults
- Approved KEYTRUDA plus chemotherapy as first-line treatment for adult patients with unresectable non-epithelioid metastatic malignant pleural mesothelioma based on IND.227/KEYNOTE-483
- Conditionally approved WELIREG for the treatment of adult patients with VHL disease who require therapy for associated, localized RCC, CNS, hemangioblastomas, or pNET, and for whom localized procedures are unsuitable based on LITESPARK-004
- Conditionally approved WELIREG for the treatment of adult patients with advanced clear cell RCC that progressed following two or more lines of therapy that included a PD-1 or PD-L1 inhibitor and at least two VEGF-targeted therapies based on LITESPARK-005

#### In China, the NMPA:

• Approved GARDASIL-9 for the prevention of certain HPV-related cancers and diseases in males 16-26 years of age

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

#### Presented data for:

- Phase 3 ZENITH trial at the American College of Cardiology's Annual Scientific Session and Expo demonstrating WINREVAIR significantly reduced the risk of major morbidity and mortality events in adults with PAH WHO FC III or IV at high risk of mortality
- Pivotal 3475A-D77 Phase 3 trial at the European Lung Cancer Congress 2025 showing that pembrolizumab with berahyaluronidase alfa administered subcutaneously (subcutaneous pembrolizumab) was non-inferior to pembrolizumab IV with respect to PK endpoints, and results across reported safety and efficacy endpoints were consistent between the treatment arms
- Two pivotal Phase 3 trials at the 32nd Conference on Retroviruses and Opportunistic Infections evaluating the once-daily, oral, two-drug regimen of doravirine/islatravir demonstrating non-inferiority and a similar safety profile to comparator antiretroviral therapies in adults with virologically suppressed HIV-1

#### Initiated Phase 3 study evaluating:

• Zilovertamab vedotin, an investigational ROR1 antibody-drug conjugate, for the treatment of patients with previously untreated diffuse large B-cell lymphoma (waveLINE-010)

## Broad and innovative pipeline to address significant unmet medical needs

Phase 2		Phase 3		Under regulatory review	
Oncology		Cardiometabolic	Oncology		Oncology
AK-1022 (patritumab leruxtecan) <sup>1,3</sup> Billiary Bladder Breast Cervical RC indometrial Esophageal Dastric HCC HNSCC Alelanoma Dvarian Pancreas Prostate MK-1308 (quavonlimab pembrolizumab) <sup>2</sup> ISCLC MK-2400 (ifinatamab deruxtecan) <sup>1</sup> Billiary Bladder Breast Cervical RC Endometrial ICC HNSCC Alelanoma Dvarian Pancreas	MK-2870 (sacituzumab tirumotecan) <sup>1,3</sup> Biliary Bladder CRC Neoplasm Malignant Pancreatic KEYTRUDA (MK-3475) Advanced Solid Tumors Prostate MK-3475A (pembrolizumab + berahyaluronidase alfa) cSCC Hematological Malignancies MK-5909 (raludotatug deruxtecan) <sup>1</sup> Biliary Bladder Cervical CRC Endometrial Gastric Ovarian Pancreas RCC SCLC V940 (intismeran autogene) <sup>1,2</sup> Bladder RCC	MK-5475 PH-COPD MK-6024 (efinopegdutide) MASH WINREVAIR (MK-7962) Pulmonary Hypertension due to Left Heart Disease Vaccines V181 Dengue Fever Virus Infectious Disease MK-8527 HIV-1 PrEP MK-8591B (islatravir+MK-8507) HIV-1 Infection Immunology MK-6194 Lupus Vitiligo MK-7240 (tulisokibart) Systemic Sclerosis Neuroscience MK-1167 Alzheimer's	MK-1022 (patritumab deruxtecan) <sup>1</sup> NSCLC (EU) MK-1026 (nemtabrutinib) Hematological Malignancies MK-1084 <sup>2</sup> NSCLC MK-1308A (quavonlimab +pembrolizumab) RCC MK-2140 (zilovertamab vedotin) Hematological Malignancies MK-2400 (ifinatamab deruxtecan) <sup>1</sup> Esophageal SCLC MK-2870 (sacituzumab tirumotecan) <sup>1,3</sup> Breast Cervical Endometrial Gastric NSCLC Ovarian MK-3543 (bomedemstat) Myeloproliferative Disorders Infectious Disease MK-8591A (doravirine+islatravir) <sup>4</sup> HIV-1 Infection MK-8591D (islatravir+lenacapavir) <sup>1,4</sup> HIV-1 Infection LAGEVRIO (MK-4482) <sup>1,5</sup>	KEYTRUDA (MK-3475) Hepatocellular (EU) Ovarian SCLC MK-5684 (opevesostat) Prostate LYNPARZA (MK-7339) <sup>1,2</sup> NSCLC SCLC LENVIMA (MK-7902) <sup>1,2</sup> Esophageal V940 (intismeran autogene) <sup>1,2</sup> Melanoma NSCLC <b>Ophthalmology</b> MK-3000 <sup>6</sup> Diabetic Macular Edema <b>Immunology</b> MK-7240 (tulisokibart) Crohn's Disease Ulcerative Colitis <b>Cardiometabolic</b> MK-0616 (enlicitide decanoate) Hypercholesterolemia	KEYTRUDA (MK-3475) HNSCC (US, JPN) Mesothelioma (JPN) MK-3475A (pembrolizumab + berahyaluronidase alfa) Previously Approved Solid Tumors (U.S.) Previously Approved Tumors (EU) MK-1022 (patritumab deruxtecan) <sup>1,7</sup> NSCLC (US) WELIREG (MK-6482) Advanced RCC (JPN) Certain VHL Tumors (JPN) PPGL (US) Vaccines CAPVAXIVE (V116) Pneumococcal Vaccine Adult (JPN) Infectious Disease MK-1654 (clesrovimab) Respiratory Syncytial Virus (US, EU) Cardiometabolic WINREVAIR (MK-7962) Pulmonary Arterial Hypertension (JPN)

As of April 24, 2025