

# Merck Q3 2024 Earnings

October 31, 2024



# Agenda



**Strategy and Business Update** 

**Rob Davis**Chairman and Chief
Executive Officer



**Business/Financial Results and Outlook** 

Caroline Litchfield Chief Financial Officer



Research Update

**Dr. Dean Li**President, Merck
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, 2023 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

### **Rob Davis**

Chairman and Chief Executive Officer



## Delivered on our key strategic priorities in Q3 2024



Advanced the pipeline to meet patient unmet need



**Executed on strategic business development to augment pipeline** 



Achieved strong commercial and financial performance



**Created long-term value for patients and shareholders** 



# Strong Q3 underlying performance<sup>1</sup>



**Q3 Worldwide Sales** 

\$16.7B

+4%

+7% ex-Exchange

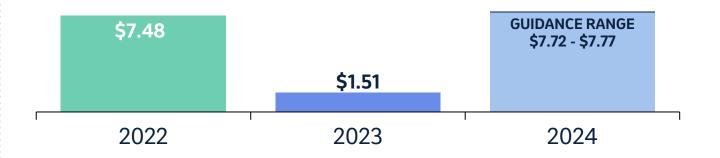


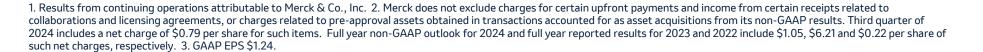
**Q3 Non-GAAP EPS**<sup>3</sup>

\$1.57



## **Full Year Non-GAAP EPS**<sup>2</sup>







## Advancing and broadening our diverse pipeline

## **Vaccines**

Presented positive Phase 2b/3 results for clesrovimab, & ACIP voted to expand recommendation for CAPVAXIVE to 50-64

## **Oncology**

Presented data for 10 investigational or approved medicines at FSMO

## **Infectious Disease**

Presented positive Phase 2 islatravir and lenacapavir combination data for HIV

## **Immunology**

Presented positive Phase 2 maintenance data for tulisokibart in UC and CD

## **Business Development**

Acquired CN201 (MK-1045) from Curon with potential applications in oncology and immunology



# Business/Financial Results and Outlook

**Caroline Litchfield**Chief Financial Officer



## Strong Q3 worldwide sales growth



Merck

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

\$16.7B

+4% growth +7% ex-exchange<sup>2</sup>



**Human Health** 

\$14.9B

+5% growth +8% ex-exchange<sup>2</sup>



**Animal Health** 

\$1.5B

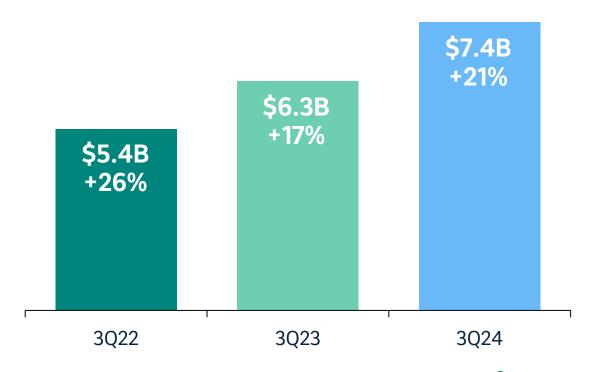
+6% growth +11% ex-exchange<sup>2</sup>



# Oncology: KEYTRUDA continues to drive exceptional growth

- KEYTRUDA sales of \$7.4B increased 21%<sup>1</sup>
  year-over-year, driven by uptake in earlier
  stage cancers and continued robust global
  demand from metastatic indications
  - In the U.S., growth reflects increased use in resectable NSCLC, as well as uptake from KN-A39 in advanced urothelial cancer
  - Ex-U.S. growth reflects continued uptake in earlier stage cancers, including high-risk, earlystage TNBC, as well as demand from metastatic indications

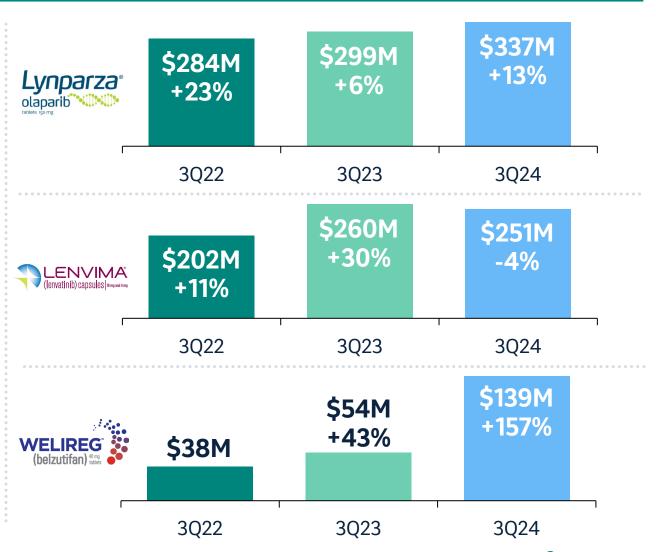






# Oncology: Updates across broad portfolio

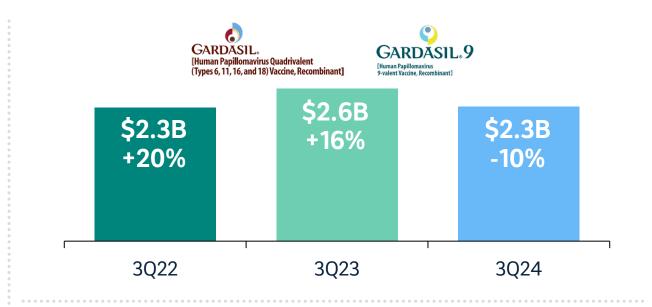
- Lynparza<sup>1</sup> sales grew 13%, driven primarily by increased global demand
- Lenvima<sup>2</sup> sales declined 4%, driven primarily by timing of shipments last year
- WELIREG sales more than doubled, driven by increased uptake in certain patients with previously treated advanced RCC

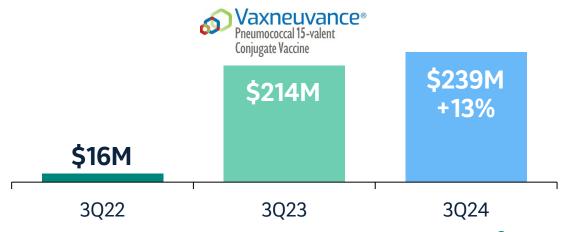




# Vaccines: Broad vaccines portfolio having significant patient impact

- GARDASIL sales of \$2.3B decreased 10% year-over-year, driven by a decline in China
  - In the U.S., sales benefitted from CDC purchasing patterns, as well as price and demand
  - Ex-U.S. sales increased by double digits in almost every region driven by robust demand
- VAXNEUVANCE sales of \$239M grew 13%, driven by ongoing launches in ex-U.S. markets
- Recent launch of CAPVAXIVE off to an encouraging start







## Cardiovascular: Continued successful launch of WINREVAIR



**Q3** sales of \$149M

**Patients** 

- ~1,700 new patients prescribed in the quarter
- >3,700 total patients prescribed since launch
- ~80% of prescribed patients receive commercial product
- >2,600 commercial patients started treatment since launch
- ~10,000 total prescriptions written since launch

Prescribers

- Nearly 800 physicians have written at least one prescription since launch
- Most prescribers are from large academic centers or larger private practices
- Physicians continue to **prioritize the sickest PAH patients**

Pavors

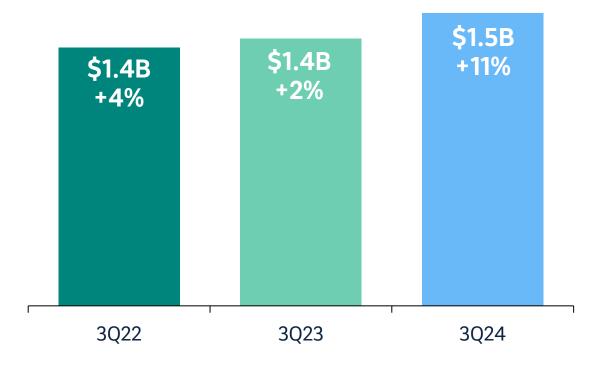
- Achieved coverage for ~60% of lives since launch
- Many payors established coverage policies consistent with the label or STELLAR criteria

Positive initial feedback following recent EU approval

# Animal Health: Strong growth across companion animal and livestock

- Animal Health sales increased 11%<sup>1</sup> to \$1.5B
  - Companion Animal grew 17%, driven by uptake from new product launches and price
  - Livestock sales grew 7%, driven by higher demand for poultry and swine products, the inclusion of sales from the recently expanded aqua portfolio, and price







# Q3 2024 non-GAAP financial results summary<sup>1</sup>

## \$ in billions, except EPS amounts

	Q3 2024	Q3 2023	Change	Change Ex-FX
Sales	\$16.7	\$16.0	+4%	+7%
Non-GAAP Gross Margin	80.5%	77.0%	+3.5pts	+3.4pts
Non-GAAP Operating Expenses	\$8.5	\$5.8	+48%	+49%
Non-GAAP Tax Rate	21.9%	15.0%	+6.9pts	N/A
Non-GAAP EPS <sup>2,3</sup>	\$1.57	\$2.13	-26%	-23%

<sup>1.</sup> Merck is providing certain 2024 and 2023 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. Q3 2024 includes a net charge of \$0.79 per share for the EyeBio (including milestone), Curon and Daiichi Sankyo transactions. 3. Q3 2024 GAAP EPS of \$1.24

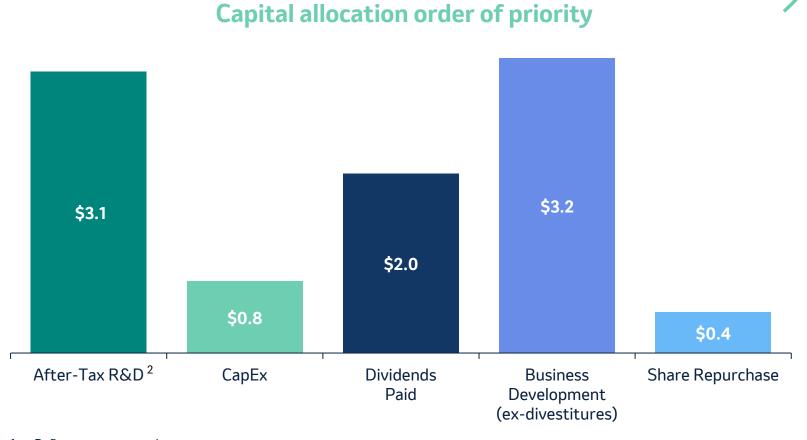


# Updated 2024 financial outlook

	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$63.4B to \$64.4B	\$63.6B to \$64.1B	<ul> <li>Assumes ~3 percentage point FX headwind (no change)</li> <li>Implies growth of 6% to 7%</li> </ul>
Non-GAAP Gross Margin Rate	~81.0%	~81.0%	
Non-GAAP Operating Expenses <sup>1</sup>	\$26.8B to \$27.6B	\$27.8B to \$28.3B	Now includes \$750 million one-time charge related to the asset acquisition from Curon
Other (Income) / Expense	~\$350M of expense	~\$100M of expense	Now includes \$170 million payment from Daiichi Sankyo
Tax Rate	~15.5% to 16.5%	~16.0% to 17.0%	Now includes unfavorable impact related to the Curon transaction
Shares Outstanding	~2.54B	~2.54B	Assumes modest share repurchase (no change)
Non-GAAP EPS	\$7.94 to \$8.04	\$7.72 to \$7.77	<ul> <li>Now includes one-time \$0.29 charge related to the Curon transaction, and \$0.05 benefit related to payment from Daiichi Sankyo</li> <li>Assumes ~\$0.30 FX headwind in 2024 (no change)</li> </ul>

## Remain committed to balanced capital allocation strategy

Q3 Spend (\$ in billions)<sup>1</sup>



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

<sup>1.</sup> Reflects quarter spend

<sup>2.</sup> Reflects R&D excluding Business Development



# Research Update

**Dr. Dean Li**President, Merck Research Laboratories



# Important updates across our vaccines, immunization and infectious disease programs

#### **Pneumococcal**

- CDC's ACIP voted in favor of expanding the age-based recommendation for CAPVAXIVE to individuals 50-64 years of age
  - Decision expands on initial ACIP recommendation for individuals age 65+

#### **RSV**

- Presented results at IDWeek from Phase 2b/3 trial evaluating clesrovimab, an investigational RSV preventative monoclonal antibody for infants entering their first RSV season
  - Clesrovimab significantly reduced incidence of RSV through 5 months, the primary endpoint, and hospitalizations associated with RSV infection through 5 months, the secondary endpoint
- If approved, clesrovimab would be the first and only immunization designed to provide infants with protection for full 6-month RSV season with convenience of one dose, regardless of weight

#### HIV

- Presented results at IDWeek from Phase 2 trial evaluating combination of islatravir and lenacapavir<sup>1</sup> as once-weekly oral treatment option for people living with HIV
  - 48-Week results build on positive 24-Week data previously presented

# Extensive ongoing, Phase 3 clinical development program for KEYTRUDA-based regimens in earlier stages of cancer<sup>1</sup>

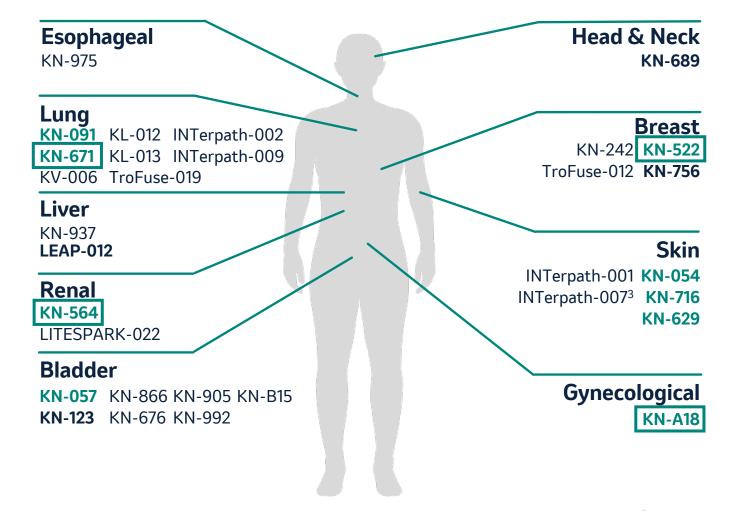
FDA approved indications

Demonstrated OS benefit<sup>2</sup>

Announced positive data for:

KN-756

**LEAP-012** 



1. Operable and/or no/limited spread to other parts of the body

KN-689

KN-123

- 2. Achieved OS in cancer type (not all currently labeled)
- 3. INTerpath-007 in csCC Ph 2/3 development

Europe

## Broadening the impact of KEYTRUDA

### **Recent Approvals**

U.S.

- KEYNOTE-483: FDA approved KEYTRUDA in combination with pemetrexed and platinum chemotherapy for 1L treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma
- **KEYNOTE-A39:** EC approved KEYTRUDA in combination with Padcev for 1L treatment of adult patients with unresectable or metastatic **urothelial carcinoma**
- **KEYNOTE-868:** EC approved KEYTRUDA in combination with carboplatin and paclitaxel for 1L treatment of certain patients with primary advanced or recurrent **endometrial carcinoma**
- **KEYNOTE-A18:** EC approved KEYTRUDA in combination with chemoradiotherapy for treatment of certain patients with FIGO 2014 Stage III-IVA locally advanced **cervical cancer**
- KEYNOTE-052: MHLW approved KEYTRUDA for treatment of patients with radically unresectable urothelial carcinoma not eligible for any platinum-containing chemotherapy
- KEYNOTE-671: MHLW approved KEYTRUDA for neoadjuvant and adjuvant treatment of certain patients with resectable NSCLC
- KEYNOTE-A39: MHLW approved KEYTRUDA in combination with Padcev for 1L treatment of patients with radically unresectable urothelial carcinoma

#### **ESMO**

- Three presentations for KEYTRUDA showcased during Presidential Symposium sessions:
  - OS data from KEYNOTE-522 in patients with high-risk early-stage triple-negative breast cancer
  - OS data from KEYNOTE-A18 in patients with newly diagnosed, highrisk, locally advanced cervical cancer
  - 10-year follow-up OS data from KEYNOTE-006 showing long-term benefit over ipilimumab in patients with advanced melanoma

## Continuing to advance our broader oncology program with BD

#### **Exelixis**

- Announced clinical development collaboration with Exelixis to evaluate investigational tyrosine kinase inhibitor, zanzalintinib in combination with:
  - **KEYTRUDA** for treatment of patients with **HNSCC**
  - WELIREG for treatment of patients with RCC

## **Daiichi Sankyo**

- Initiated Phase 3 IDeate-Lung02 trial evaluating I-DXd, a B7-H3 directed antibody drug conjugate, for treatment of patients with relapsed SCLC
- Expanded collaboration agreement to evaluate combination of I-DXd with MK-6070, an investigational DLL3 targeting T-cell engager

## Executing on our broader pipeline

### **Cardiometabolic**

 Received EC approval for WINREVAIR which has potential to transform the treatment journey for patients with PAH

### **Immunology**

- Presented 50-week efficacy and safety data for tulisokibart, a TL1A inhibitor, from Phase 2 ARTEMIS-UC and APOLLO-CD studies in ulcerative colitis and Crohn's disease at UEG Week Congress
  - Results reinforce potential to help patients achieve long-term clinical remission

### **Ophthalmology**

 Initiated Phase 2b/3 BRUNELLO trial for MK-3000, an investigational tetravalent trispecific Wnt antibody, for treatment of diabetic macular edema



# Q&A



**Rob Davis** Chairman & Chief Executive Officer



**Caroline Litchfield**Chief Financial Officer



**Dr. Dean Li**President, Merck Research Laboratories



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



# Appendix

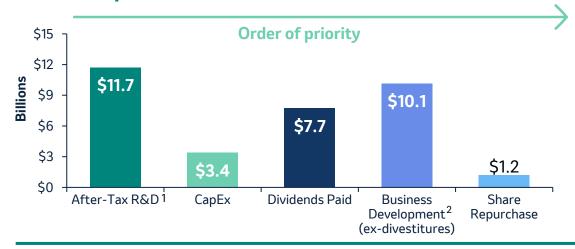
## Q3 2024 GAAP financial results summary

## \$ in billions, EPS amounts

	Q3 2024	Q3 2023	Change	Change Ex-FX
Sales	\$16.7	\$16.0	+4%	+7%
Operating Expenses	\$8.6	\$5.8	+47%	+49%
Tax Rate	22.7%	15.5%	+7.2pts	N/A
GAAP EPS <sup>1</sup>	\$1.24	\$1.86	-33%	-30%

## Capital allocation: Trailing twelve months

### Over the past 12 months



### **Capital investments**

2024 to 2028

~\$20B<sup>3</sup>

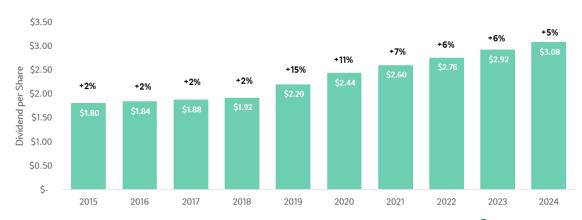
Over 5 years, including expanding manufacturing capacity for Oncology, Vaccines, and Animal Health. Includes >\$11B in the U.S.

. Reflects R&D excluding Business Development

- 2. Includes BD payments reflected in operating cash flow
- 3. Previous values presented at 2024 earnings corrected by the company

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 approved:

 KEYTRUDA in combination with pemetrexed and platinum chemotherapy for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma based on IND.227/KN-483

#### In the EU, the EC approved:

- KEYTRUDA in combination with carboplatin and paclitaxel followed by KEYTRUDA as a single agent, for the first-line treatment of adult patients with primary advanced or recurrent endometrial carcinoma who are candidates for systemic therapy based on NRG-GY018/KN-868
- KEYTRUDA in combination with chemoradiotherapy for the treatment of FIGO 2014 stage III-IVA locally advanced cervical cancer in adults who have not received prior definitive therapy based on KN-A18
- KEYTRUDA in combination with Padcev for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma based on KN-A39/EV-302<sup>1</sup>
- WINREVAIR in combination with other PAH therapies for the treatment of PAH in adult patients with WHO FC II to III to increase exercise capacity based on STELLAR

#### • In Japan, the MHLW approved:

- KEYTRUDA in combination with chemotherapy as a neoadjuvant treatment, then continued as monotherapy as an adjuvant treatment, for patients with NSCLC based on KN-671
- KEYTRUDA in combination with Padcev for the first-line treatment of patients with radically unresectable urothelial carcinoma based on KN-A39/EV-302<sup>1</sup>
- KEYTRUDA monotherapy in patients with radically unresectable urothelial carcinoma who are not eligible for any platinum-containing chemotherapy based on KN-052

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

#### Announced:

- Phase 3 KN-689 trial evaluating KEYTRUDA met its primary endpoint of event-free survival as perioperative treatment regimen in patients with resected, LA-HNSCC
- Phase 3 HERTHENA-Lung02 trial evaluating patritumab deruxtecan (HER3 ADC)<sup>2</sup> met its primary endpoint and demonstrated statistically significant improvement in progression-free survival in patients with locally advanced or metastatic EGFRmutated NSCLC

#### Presented data from:

- Diverse vaccines and infectious disease portfolio at IDWeek, including positive results from the Phase 2b/3 study evaluating clesrovimab, data from the Phase 3 STRIDE-8 trial evaluating CAPVAXIVE in adults 18-64 years of age at increased risk of pneumococcal disease, and data from the Phase 2 study evaluating a once-weekly oral combination regimen of islatravir and lenacapavir for treatment of people with HIV-1 infection
- Phase 2 studies evaluating tulisokibart, an investigational humanized monoclonal antibody directed to TL1A, in ulcerative colitis and Crohn's disease at UEG Week
- Broad oncology portfolio at ESMO, including for KEYTRUDA, WELIREG, Lenvima, Lynparza, patritumab deruxtecan (HER3 ADC)<sup>2</sup>, ifinatamab deruxtecan (B7-H3 ADC)<sup>2</sup>, sacituzumab tirumotecan (TROP2 ADC)<sup>3</sup>, and opevsostat (CYP11A1 inhibitor)<sup>4</sup>
- Phase 2 IDeate-Lung01 study at the World Conference on Lung Cancer showing ifinatamab deruxtecan (B7-H3 ADC)<sup>2</sup> in SCLC

#### **Initiated Phase 3 trials evaluating:**

 V940<sup>5</sup>, ifinatamab deruxtecan (B7-H3 ADC)<sup>2</sup>, bomedemstat (LSD1 inhibitor), zilovertamab vedotin (ROR1 ADC), MK-3000 (Wnt agonist), and the fixed-dose combination of islatravir and lenacapavir (HIV1)<sup>6,7</sup>



# Broad and innovative pipeline to address significant unmet medical needs

Phase 2		Phase 3		Under regulatory review		
Oncology				Oncology		Oncology
deruxtecan)4 Bladder Cervical Endometrial Esophageal Gastric HNSCC Melanoma Ovarian Pancreas Prostate MK-1308 (quavonlimab) NSCLC MK-1308A (quavonlimab +pembrolizumab) CRC MK-3475A (pembrolizumab + hyaluronidase) cSCC Heme  Vaccines V181 Dengue Virus  Infectious disease MK-8527 HIV-1 Pre-Exposure Prophylax MK-8591B (islatravir+MK-850 HIV-1 infection	07) <sup>1</sup> Pulmonary Hype to Left Heart Di	pegdutide)  K-7962) ertension due sease		MK-1022 (patritumab deruxtecan) <sup>4</sup> NSCLC (EU)  MK-1026 (nemtabrutinib) Hematological Malignancies  MK-1084 NSCLC  MK-1308A (quavonlimab +pembrolizumab) RCC  MK-2140 (zilovertamab vedotin) Hematological Malignancies  MK-2400 (ifinatamab deruxtecan) <sup>4</sup> SCLC  MK-2870 (sacituzumab tirumotecan) <sup>5</sup> Breast Cervical Endometrial Gastric NSCLC  MK-3543 (bomedemstat) Myeloproliferative Disorders  Immunization  MK-1654 (clesrovimab) Respiratory Syncytial Virus (RSV)  Infectious disease  MK-8591A (doravirine+islatravir) <sup>2</sup> HIV-1 Infection  MK-8591D (islatravir+lenacapavir) <sup>2,8</sup> HIV-1 infection	KEYTRUDA (MK-3475) Hepatocellular (EU) Ovarian SCLC  MK-3475A (pembrolizumab +hyaluronidase) NSCLC  MK-4280A (favezelimab +pembrolizumab) Hematological Malignancies  MK-5684 (opevesostat) <sup>10</sup> Prostate  LYNPARZA (MK-7339) <sup>6</sup> NSCLC SCLC  LENVIMA (MK-7902) <sup>11</sup> Esophageal Gastric  MK-7684A (vibostolimab +pembrolizumab) NSCLC  V940 <sup>7</sup> Melanoma NSCLC  Ophthalmology  MK-3000 <sup>12</sup> Diabetic macular edema  Immunology  MK-7240 (tulisokibart) Ulcerative Colitis  Cardiometabolic	KEYTRUDA (MK-3475) Endometrial Carcinoma (JPN) Cervical (JPN) Mesothelioma (EU, JPN) MK-1022 (patritumab deruxtecan) <sup>4,13</sup> NSCLC (US) WELIREG (MK-6482) Advanced RCC (EU, JPN) Certain VHL tumors (EU, JPN)  Vaccines  CAPVAXIVE (V116) Pneumococcal conjugate vaccine, adult (EU, JPN)
<sup>1</sup> On FDA clinical hold <sup>2</sup> On FDA partial cli <sup>3</sup> Available in the US under EUA <sup>4</sup> In collal <sup>7</sup> In collaboration with Moderna <sup>8</sup> In collab <sup>11</sup> In collaboration with Eisai <sup>12</sup> Program is	linical hold for higher doses than those aboration with Daiichi Sankyo <sup>5</sup> In collal boration with Gilead <sup>9</sup> Developed unde s in Phase 2/3 study <sup>13</sup> FDA issued CRL	e used in current clinical trials boration with Kelun-Biotech <sup>6</sup> In collabor r an agreement with Ridgeback Bio <sup>10</sup> In in June 2024	ration with AstraZeneca collaboration with Orion	LAGEVRIO (MK-4482) <sup>3,9</sup> COVID-19 antiviral	Cardiometabolic  MK-0616 (enlicitide decanoate) Hypercholesterolemia	As of October 31, 20