

# **News Release**

#### Merck Announces First-Quarter 2023 Financial Results

- First Quarter 2023 Reflected Continued Strong Underlying Performance Across Key Growth Drivers, Particularly in Oncology and Vaccines
- Total Worldwide Sales Were \$14.5 Billion, a Decrease of 9% From First Quarter 2022;
   Excluding LAGEVRIO, Growth Was 11%; Excluding LAGEVRIO and the Impact of Foreign Exchange, Growth Was 15%
  - KEYTRUDA Sales Grew 20% to \$5.8 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 24%
  - GARDASIL/GARDASIL 9 Sales Grew 35% to \$2.0 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 43%
  - LAGEVRIO Sales Declined 88% to \$392 Million; Excluding the Impact of Foreign Exchange, Sales Declined 87%
- GAAP EPS Was \$1.11; Non-GAAP EPS Was \$1.40; GAAP and Non-GAAP EPS Include \$0.52 of Charges Related to Acquisition of Imago and Collaboration and Licensing Agreement With Kelun-Biotech
- Announced Proposed Acquisition of Prometheus Biosciences to Strengthen Immunology Pipeline
- Presented Compelling Data From Innovative Cardiovascular Pipeline With:
  - Positive Phase 3 Results for Sotatercept
  - Positive Phase 2b Results for MK-0616; Plans to Start Phase 3 Studies in 2023
- Advanced Oncology Research Efforts, Sharing Notable Progress for Earlier Stages of Disease in Certain Tumor Types, Including:
  - o Positive Topline Results From Phase 3 KEYNOTE-671 Trial
  - Positive Detailed Results in Collaboration With Moderna From Phase 2b KEYNOTE-942/mRNA-4157-P201 Trial
- 2023 Financial Outlook
  - Raises and Narrows Expected Full-Year 2023 Worldwide Sales Range To Be Between \$57.7 Billion and \$58.9 Billion, Including Negative Impact of Foreign Exchange of Approximately 2 Percentage Points; Outlook Includes Approximately \$1.0 Billion of LAGEVRIO Sales
  - Lowers and Narrows Expected Full-Year 2023 GAAP EPS Range To Be Between \$5.85 and \$5.97, Reflecting Zetia Antitrust Litigation Settlement
  - Raises and Narrows Expected Full-Year 2023 Non-GAAP EPS Range To Be Between \$6.88 and \$7.00, Including Negative Impact of Foreign Exchange of Approximately 4 Percentage Points
  - Outlook Does Not Reflect Any Impact From Proposed Acquisition of Prometheus Biosciences, Which Is Expected to Close in Third Quarter 2023, and Would Result in a One-Time Charge to Both GAAP and Non-GAAP Results of Approximately \$10.3 Billion or Approximately \$4.00 per Share

RAHWAY, N.J., April 27, 2023 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the first quarter of 2023.

"Inspired by our commitment to bring bold science forward to address critical unmet patient needs, we began 2023 with significant advancements across our innovative pipeline," said Robert M. Davis, chairman and chief executive officer, Merck. "Our first-quarter results are a reflection of the focused execution of our science-led strategy, strong performance across our key growth drivers, continued momentum commercially and operationally, and – most importantly – the collective and dedicated efforts of our colleagues around the world. I'm proud of the progress we've made, and we will continue to move with speed and agility to deliver value for patients and shareholders, now and well into the future."

## **Financial Summary**

	First Quarter			
\$ in millions, except EPS amounts	2023	2022	Change	Change Ex- Exchange
Sales	\$14,487	\$15,901	-9%	-5%
GAAP net income <sup>1</sup>	2,821	4,310	-35%	-29%
Non-GAAP net income that excludes certain items <sup>1,2*</sup>	3,564	5,429	-34%	-30%
GAAP EPS	1.11	1.70	-35%	-30%
Non-GAAP EPS that excludes certain items <sup>2*</sup>	1.40	2.14	-35%	-30%

\*Refer to table on page 10.

Generally Accepted Accounting Principles (GAAP) earnings per share (EPS) assuming dilution was \$1.11 for the first quarter of 2023. Non-GAAP EPS was \$1.40 for the first quarter of 2023. The declines in GAAP and non-GAAP EPS in the first quarter versus the prior year were primarily due to \$0.52 of charges related to the acquisition of Imago BioSciences, Inc. (Imago) and the collaboration and licensing agreement with Kelun-Biotech (a holding subsidiary of Sichuan Kelun Pharmaceutical Co., Ltd). The declines in GAAP and non-GAAP EPS were also due to lower sales of COVID-19 medicine LAGEVRIO (molnupiravir) and the unfavorable impact of foreign exchange. Additionally, the GAAP EPS decline reflects a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation. The GAAP EPS decline was partially offset by the favorable impact of net gains from investments in equity securities compared with net losses in the prior year.

Non-GAAP EPS excludes acquisition- and divestiture-related costs and costs related to restructuring programs, as well as income and losses from investments in equity securities and a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation.

<sup>&</sup>lt;sup>1</sup> Net income attributable to Merck & Co., Inc.

<sup>&</sup>lt;sup>2</sup> Merck is providing certain 2023 and 2022 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, senior management's annual compensation is derived in part using a non-GAAP pre-tax 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 this release.

## Proposed Acquisition of Prometheus Biosciences Strengthens Immunology Pipeline

On April 16, 2023, Merck <u>announced</u> a definitive agreement to acquire Prometheus Biosciences, Inc. (Prometheus) through a subsidiary for \$200 per share in cash for a total equity value of approximately \$10.8 billion. The agreement accelerates Merck's growing presence in immunology and adds diversity to Merck's overall portfolio with PRA023, a novel, late-stage candidate for ulcerative colitis, Crohn's disease and other autoimmune conditions, as well as Prometheus' comprehensive data set that enables its target discovery and precision medicine approach in inflammation and immunology. The transaction is expected to close in the third quarter of 2023, subject to Prometheus shareholder approval and certain conditions.

## **Cardiovascular Program Highlights**

- The following data were presented at the American College of Cardiology's 72<sup>nd</sup> Annual Scientific Session together with World Heart Federation's World Congress of Cardiology:
  - Results from the Phase 3 STELLAR trial, which evaluated sotatercept, Merck's novel investigational activin signaling inhibitor, in combination with stable background therapy for the treatment of adult patients with pulmonary arterial hypertension (PAH) (World Health Organization Group 1). These landmark data included a significant improvement in exercise capacity for patients receiving sotatercept compared to placebo, increasing 6-minute walk distance (6MWD) by 40.8 meters from baseline at week 24, the study's primary endpoint. In addition, sotatercept demonstrated statistically significant improvements in eight of nine secondary measures, including reduction in risk of clinical worsening or death. These data were simultaneously published in *The New England Journal of Medicine (NEJM)*.
  - Results from the Phase 2b clinical trial evaluating MK-0616, an investigational once-daily oral proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor in adults with hypercholesterolemia. MK-0616 significantly reduced low-density lipoprotein cholesterol (LDL-C) across all dose levels compared to placebo and was generally well tolerated. These data were simultaneously published in the *Journal of The American College of Cardiology*.

#### **Oncology Program Highlights**

- Merck announced the following regulatory and clinical milestones for KEYTRUDA (pembrolizumab):
  - Positive topline <u>results</u> from the Phase 3 KEYNOTE-671 trial investigating KEYTRUDA as a perioperative treatment regimen for patients with resectable stage II, IIIA or IIIB non-small cell lung cancer (NSCLC). The U.S. Food and Drug Administration (FDA) accepted Merck's supplemental Biologics License Application (sBLA) based on these data and has set a Prescription Drug User Fee Act (PDUFA), or target action, date of Oct. 16, 2023.
  - In collaboration with Moderna, Inc., first presentation of detailed <u>results</u> from the Phase 2b KEYNOTE-942/mRNA-4157-P201 trial at the American Association for Cancer Research Annual Meeting. Data showed that KEYTRUDA in combination with mRNA-4157/V940, an investigational individualized neoantigen therapy,

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demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of recurrence-free survival versus KEYTRUDA alone for the adjuvant treatment of patients with stage III/IV melanoma following complete resection.

- In addition, the combination of KEYTRUDA and mRNA-4157/V940
   received Breakthrough Therapy Designation by the FDA and was granted
   Priority Medicines (PRIME) scheme designation by the European
   Medicines Agency.
- Accelerated <u>approval</u> of KEYTRUDA by the FDA in combination with Padcev®<sup>3</sup>
   (enfortumab vedotin-ejfv) for the treatment of adult patients with locally advanced
   or metastatic urothelial carcinoma who are not eligible for cisplatin-containing
   chemotherapy, based on data from the KEYNOTE-869 trial.
- Results from the Phase 3 NRG-GY018 trial investigating KEYTRUDA in combination with chemotherapy, then continued as a single agent, for the first-line treatment of patients with stage III-IV or recurrent endometrial carcinoma, presented at the 2023 Society of Gynecologic Oncology Annual Meeting on Women's Cancer, with simultaneous publication in NEJM. Results showed KEYTRUDA plus chemotherapy significantly improved progression-free survival compared to chemotherapy alone in these patients, regardless of tumor DNA mismatch repair status.
- Results from the pivotal Phase 3 KEYNOTE-859 trial, investigating KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with human epidermal growth factor receptor 2 (HER2)-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, presented at a European Society for Medical Oncology Virtual Plenary. Study showed KEYTRUDA in combination with chemotherapy significantly improved overall survival (OS) versus chemotherapy alone in these patients, regardless of PD-L1 expression.
  - In addition, the FDA <u>accepted</u> Merck's sBLA based on these data and has set a PDUFA date of Dec. 16, 2023.
- Positive topline <u>results</u> from the Phase 2/3 Canadian Cancer Trials Group IND.227/KEYNOTE-483 trial evaluating KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with unresectable advanced or metastatic malignant pleural mesothelioma.
- Merck <u>announced</u> that the FDA will convene a meeting of the Oncologic Drugs Advisory Committee on April 28, 2023, to discuss the supplemental New Drug Application (sNDA) for use of Lynparza (olaparib) in combination with abiraterone and prednisone or prednisolone (abi/pred), for the treatment of adult patients with metastatic castration-resistant prostate cancer. The sNDA is based on the results of the Phase 3 PROpel trial, including the primary endpoint of radiographic progression-free survival. Merck also <u>announced</u> results from the final analysis of the key secondary endpoint of OS from PROpel.
- Merck will host an Oncology Investor Event to coincide with the American Society for Clinical Oncology Annual Meeting on Monday, June 5, 2023, 6:00 p.m. CT, at which senior management will provide an update on the company's oncology strategy and

<sup>&</sup>lt;sup>3</sup> Registered trademark of Seagen and Agensys.

program. The event will take place in Chicago, III., and will be accessible via webcast. Further details, including the webcast link, will be announced at a later date.

# <u>Infectious Diseases Program Highlights</u>

- Merck <u>opened</u> enrollment in new Phase 3 clinical trials evaluating the investigational once-daily combination of doravirine, 100 mg, and islatravir, 0.25 mg (DOR/ISL) for the treatment of people with HIV-1 infection, as part of the company's ongoing commitment to HIV.
- Merck and Gilead Sciences have resumed under an amended protocol a Phase 2 clinical <u>study</u> evaluating an investigational once-weekly oral combination treatment regimen of islatravir and lenacapavir, for people living with HIV who are virologically suppressed on antiretroviral therapy.

## **Environmental, Social and Governance (ESG) Updates**

• Merck was <u>named</u> one of Barron's Top 100 Most Sustainable U.S. Companies for the third consecutive year, ranking No. 1 in the pharmaceutical industry and No. 29 overall.

## **First-Quarter Revenue Performance**

The following table reflects sales of the company's top Pharmaceutical products, as well as sales of Animal Health products.

	First Quarter			
				Change Ex-
\$ in millions	2023	2022	Change	Exchange
Total Sales	\$14,487	\$15,901	-9%	-5%
Pharmaceutical	12,721	14,107	-10%	-6%
KEYTRUDA	5,795	4,809	20%	24%
GARDASIL / GARDASIL 9	1,972	1,460	35%	43%
JANUVIA / JANUMET	880	1,233	-29%	-25%
PROQUAD, M-M-R II and	528	470	12%	14%
VARIVAX				
BRIDION	487	395	23%	27%
LAGEVRIO	392	3,247	-88%	-87%
ROTATEQ	297	216	38%	42%
Lynparza*	275	266	3%	8%
Lenvima*	232	227	2%	5%
SIMPONI	180	186	-3%	2%
Animal Health	1,491	1,482	1%	5%
Livestock	849	832	2%	8%
Companion Animals	642	650	-1%	2%
Other Revenues**	275	312	-12%	-22%

<sup>\*</sup>Alliance revenue for this product represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.

### **Pharmaceutical Revenue**

First-quarter Pharmaceutical sales declined 10% to \$12.7 billion, primarily due to lower sales in virology, largely attributable to LAGEVRIO, and diabetes, partially offset by growth in oncology, vaccines and hospital acute care. Excluding LAGEVRIO, Pharmaceutical sales grew 14%, and excluding LAGEVRIO and the unfavorable impact of foreign exchange, Pharmaceutical sales grew 18%.

The decline in virology was primarily due to lower sales of LAGEVRIO, which decreased 88% to \$392 million, largely attributable to sales in the U.S. and U.K. markets in the first quarter of 2022 that did not recur in the first quarter of 2023. The LAGEVRIO sales decline was also attributable to lower sales in Japan and Australia.

The sales decline within diabetes primarily reflects lower combined sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCI), which declined 29% to \$880 million, primarily due to generic competition in several international markets, particularly in Europe, and lower demand and pricing in the U.S.

Growth in oncology was largely driven by higher sales of KEYTRUDA, which rose 20% to \$5.8 billion in the quarter. Global sales growth of KEYTRUDA reflects continued strong momentum from metastatic indications, including certain types of NSCLC, renal cell carcinoma, head and neck squamous cell carcinoma, triple-negative breast cancer (TNBC) and

<sup>\*\*</sup>Other revenues are comprised primarily of revenues from third-party manufacturing arrangements and miscellaneous corporate revenues, including revenue-hedging activities.

microsatellite instability-high (MSI-H) cancers, and increased uptake across recent earlier-stage launches, including certain types of neoadjuvant/adjuvant TNBC in the U.S.

Growth in vaccines reflects higher combined sales of GARDASIL (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant) and GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), which grew 35% to \$2.0 billion, reflecting strong demand outside of the U.S., particularly in China, which also benefited from the timing of shipments and increased supply. Growth in vaccines also reflects higher sales of VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine), which increased to \$106 million, primarily due to continued uptake in the pediatric indication following launch in the U.S. In addition, vaccines sales performance reflects higher sales of ROTATEQ (Rotavirus Vaccine, Live Oral, Pentavalent), which grew 38% to \$297 million, primarily due to inventory stocking in China. Growth in vaccines was partially offset by lower sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent), which declined 44% to \$96 million, primarily reflecting lower U.S. demand as the market continues to shift toward newer adult pneumococcal conjugate vaccines.

Growth in hospital acute care reflects higher sales of BRIDION (sugammadex) injection 100 mg/ML, which grew 23% to \$487 million, primarily due to increased demand, particularly in the U.S., reflecting an increase in its share among neuromuscular blockade reversal agents.

#### **Animal Health Revenue**

Animal Health sales totaled \$1.5 billion for the first quarter of 2023, a 1% increase compared with the first quarter of 2022. Excluding the impact of foreign exchange, Animal Health sales increased 5%. Growth in livestock products reflects strong demand notably in the ruminant and poultry product portfolio, which includes technology solution products, as well as higher pricing. Excluding the unfavorable impact of foreign exchange, growth in companion animal products reflects the impact of higher pricing. The BRAVECTO (fluralaner) parasiticide line of products had sales of \$314 million in the quarter.

#### First-Quarter Expense, EPS and Related Information

The tables below present selected expense information.

\$ in millions	GAAP	Acquisition- and Divestiture- Related Costs <sup>4</sup>	Restructuring Costs	(Income) Loss From Investments in Equity Securities	Certain Other Items	Non- GAAP <sup>2</sup>
First Quarter 2023						
Cost of sales	\$3,926	\$545	\$29	\$-	\$-	\$3,352
Selling, general and administrative	2,479	20	1	-	-	2,458
Research and development	4,276	10	-	-	-	4,266
Restructuring costs	67	-	67	-	-	-
Other (income) expense, net	89	15	-	(429)	573	(70)
First Quarter 2022						
Cost of sales	\$5,380	\$680	\$46	\$-	\$-	\$4,654
Selling, general and administrative	2,323	50	21	-	-	2,252
Research and development	2,576	22	7	-	-	2,547
Restructuring costs	53	-	53	-	-	-
Other (income) expense, net	708	(115)	•	684	-	139

## **GAAP Expense, EPS and Related Information**

Gross margin was 72.9% for the first quarter of 2023 compared with 66.2% for the first quarter of 2022. The increase primarily reflects lower LAGEVRIO sales, which have a low gross margin, as well as the favorable impacts of product mix and lower amortization of intangible assets.

Selling, general and administrative (SG&A) expenses were \$2.5 billion in the first quarter of 2023, an increase of 7% compared with the first quarter of 2022. The increase primarily reflects higher administrative costs and higher promotional spending, partially offset by the favorable impact of foreign exchange.

R&D expenses were \$4.3 billion in the first quarter of 2023, an increase of 66% compared with the first quarter of 2022. The increase was primarily driven by a \$1.2 billion charge for the acquisition of Imago and a \$175 million charge related to a collaboration and licensing agreement with Kelun-Biotech. In addition, the increase was driven by higher compensation and benefit costs, reflecting in part increased headcount to support expanded clinical development activity, higher investments in discovery research and early drug development, and higher clinical development spending.

Other (income) expense, net, was \$89 million of expense in the first quarter of 2023 compared with \$708 million of expense in the first quarter of 2022. The change is primarily due to net gains from investments in equity securities in the first quarter of 2023 compared with net losses from investments in equity securities in the first quarter of 2022, as well as higher interest income in the first quarter of 2023. The favorability was partially offset by a \$573 million charge

<sup>4</sup> Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories recognized as a result of acquisitions, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also includes integration, transaction and certain other costs related to acquisitions and divestitures.

in the first quarter of 2023 related to settlements with certain plaintiffs in the Zetia antitrust litigation.

The effective tax rate of 22.6% for the first quarter of 2023 reflects the unfavorable discrete impact of a charge for the acquisition of Imago for which no tax benefit was recognized, as well as the unfavorable effects of higher foreign taxes, the R&D capitalization provision of the Tax Cuts and Jobs Act of 2017, and net unrealized gains from investments in equity securities, which were taxed at the U.S. tax rate.

GAAP EPS was \$1.11 for the first quarter of 2023 compared with \$1.70 for the first quarter of 2022.

## Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 76.9% for the first quarter of 2023 compared with 70.7% for the first quarter of 2022. The increase primarily reflects lower LAGEVRIO sales, which have a low gross margin, as well as the favorable impact of product mix.

Non-GAAP SG&A expenses were \$2.5 billion in the first quarter of 2023, an increase of 9% compared with the first quarter of 2022. The increase primarily reflects higher administrative costs and higher promotional spending, partially offset by the favorable impact of foreign exchange.

Non-GAAP R&D expenses were \$4.3 billion in the first quarter of 2023, an increase of 67% compared with the first quarter of 2022. The increase was primarily driven by a \$1.2 billion charge for the acquisition of Imago and a \$175 million charge related to a collaboration and licensing agreement with Kelun-Biotech. In addition, the increase was driven by higher compensation and benefit costs, reflecting in part increased headcount to support expanded clinical development activity, higher investments in discovery research and early drug development, and higher clinical development spending.

Non-GAAP other (income) expense, net, was \$70 million of income in the first quarter of 2023 compared with \$139 million of expense in the first quarter of 2022, primarily reflecting higher interest income in the first quarter of 2023.

The non-GAAP effective tax rate of 20.4% for the first quarter of 2023 reflects the unfavorable discrete impact of a charge for the acquisition of Imago for which no tax benefit was recognized, as well as the unfavorable effects of higher foreign taxes and the R&D capitalization provision of the Tax Cuts and Jobs Act of 2017.

Non-GAAP EPS was \$1.40 for the first quarter of 2023 compared with \$2.14 for the first quarter of 2022.

A reconciliation of GAAP to non-GAAP net income and EPS is provided in the table that follows.

	First Qua	First Quarter	
\$ in millions, except EPS amounts	2023	2022	
EPS			
GAAP EPS	\$1.11	\$1.70	
Difference	0.29	0.44	
Non-GAAP EPS that excludes items listed below <sup>2</sup>	\$1.40	\$2.14	
Net Income			
GAAP net income <sup>1</sup>	\$2,821	\$4,310	
Difference	743	1,119	
Non-GAAP net income that excludes items listed below <sup>1,2</sup>	\$3,564	\$5,429	
Decrease (Increase) in Net Income Due to Excluded Items:			
Acquisition- and divestiture-related costs <sup>4</sup>	\$590	\$637	
Restructuring costs	97	127	
(Income) loss from investments in equity securities	(429)	684	
Charge for Zetia antitrust litigation settlements	573	-	
Net decrease (increase) in income before taxes	831	1,448	
Estimated income tax (benefit) expense	(88)	(329)	
Decrease (increase) in net income	\$743	\$1,119	

#### **Financial Outlook**

The following table summarizes the company's full-year 2023 financial outlook.

	GAAP	Non-GAAP <sup>2</sup>
Sales*	\$57.7 to \$58.9 billion	\$57.7 to \$58.9 billion
Gross margin	Approximately 73%	Approximately 77%
Operating expenses**	\$23.5 to \$24.3 billion	\$23.3 to \$24.1 billion
Effective tax rate	17% to 18%	17% to 18%
EPS***	\$5.85 to \$5.97	\$6.88 to \$7.00

<sup>\*</sup>Includes approximately \$1.0 billion of LAGEVRIO sales. The company does not have any non-GAAP adjustments to sales.

\*\*Includes an aggregate \$1.4 billion of R&D expenses related to the Imago acquisition and upfront payment for the license and collaboration agreement with Kelun-Biotech. Outlook does not assume the proposed acquisition of Prometheus or any additional significant potential business development transactions.

Merck continues to experience strong global underlying demand across its key pillars of growth. Consequently, Merck is raising and narrowing its full-year outlook ranges for sales and non-GAAP EPS. For GAAP EPS, Merck is lowering and narrowing its full-year outlook, attributable to a GAAP-only charge related to settlements with certain plaintiffs in the Zetia antitrust litigation.

Merck now expects full-year 2023 sales to be between \$57.7 billion and \$58.9 billion, including a negative impact of foreign exchange of approximately 2 percentage points, at mid-April 2023 exchange rates. This full-year outlook includes expected sales of LAGEVRIO of approximately \$1.0 billion.

Merck's full-year effective income tax rate is expected to be between 17% and 18%.

<sup>\*\*\*</sup>Includes \$0.52 of charges related to the Imago acquisition and upfront payment to Kelun-Biotech.

Assumes a share count (assuming dilution) of approximately 2.55 billion shares.

Merck is lowering and narrowing its full-year 2023 GAAP EPS range to be between \$5.85 and \$5.97.

Merck is raising and narrowing its full-year 2023 non-GAAP EPS range to be between \$6.88 and \$7.00, including a negative impact of foreign exchange of approximately 4 percentage points, at mid-April 2023 exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs and costs related to restructuring programs, as well as income and losses from investments in equity securities and a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation.

A reconciliation of anticipated 2023 GAAP EPS to non-GAAP EPS and the items excluded from non-GAAP EPS are provided in the table below.

\$ in millions, except EPS amounts	Full Year 2023
GAAP EPS	\$5.85 to \$5.97
Difference	\$1.03
Non-GAAP EPS that excludes items listed below <sup>2</sup>	\$6.88 to \$7.00
Acquisition- and divestiture-related costs	\$2,500
Restructuring costs	400
(Income) loss from investments in equity securities	(375)
Charge for Zetia antitrust litigation settlements	573
Net decrease (increase) in income before taxes	\$3,098
Estimated income tax (benefit) expense	(470)
Decrease (increase) in net income	\$2,628

In April, Merck announced it has agreed to acquire Prometheus; the acquisition is expected to close in the third quarter of 2023. Merck's outlook does not reflect this transaction, which is expected to be accounted for as an asset acquisition, and would result in a one-time charge of approximately \$10.3 billion recorded to both GAAP and non-GAAP R&D expenses in 2023, or approximately \$4.00 per share. In addition, taking into consideration operational investment to advance the pipeline assets as well as the cost of financing, Merck also anticipates EPS will be negatively impacted by approximately \$0.25 in the first 12 months following close. Once the transaction closes, Merck will incorporate the anticipated impacts of this acquisition in both its GAAP and non-GAAP financial outlook.

#### **Earnings Conference Call**

Investors, journalists and the general public may access a live audio webcast of the earnings conference call on Thursday, April 27, at 9:00 a.m. ET via this weblink. A replay of the webcast, along with the sales and earnings news release, supplemental financial disclosures, and slides highlighting the results, will be available at www.merck.com.

All participants may join the call by dialing (888) 769-8514 (U.S. and Canada Toll-Free) or (517) 308-9208 and using the access code 8206435.

#### **About Merck**

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit <a href="www.merck.com">www.merck.com</a> and connect with us on <a href="Twitter">Twitter</a>, <a href="Facebook">Facebook</a>, <a href="Instagram">Instagram</a>, <a href="YouTube">YouTube</a> and <a href="LinkedIn">LinkedIn</a>.

## Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release 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 the global outbreak of novel coronavirus disease (COVID-19); 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, 2022, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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