

News Release

Merck Announces Third-Quarter 2024 Financial Results

- Total Worldwide Sales Were \$16.7 Billion, an Increase of 4% From Third Quarter 2023;
 Excluding the Impact of Foreign Exchange, Growth Was 7%
 - KEYTRUDA Sales Grew 17% to \$7.4 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 21%
 - WINREVAIR Sales Were \$149 Million; U.S. Launch of WINREVAIR Gaining Momentum; Received Approval in the EU
 - Animal Health Sales Grew 6% to \$1.5 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 11%
- GAAP EPS Was \$1.24; Non-GAAP EPS Was \$1.57; GAAP and Non-GAAP EPS Include a Net Charge of \$0.79 per Share Related to Certain Business Development Transactions
- Achieved Significant Milestones in Vaccine Programs
 - CAPVAXIVE Recommended by the CDC's ACIP for Pneumococcal Vaccination in Adults 50 Years of Age and Older
 - Presented Positive Results From Clinical Studies Evaluating Clesrovimab (MK-1654), an Investigational RSV Preventative Monoclonal Antibody for Infants Entering Their First RSV Season
- Data Presented for Four Approved Medicines and Six Pipeline Candidates in More Than 20 Types of Cancer at ESMO Congress 2024, Including Overall Survival Data From KEYNOTE-522 and KEYNOTE-A18
- Completed Acquisition of Investigational B-Cell Depletion Therapy, CN201 (MK-1045),
 From Curon Biopharmaceutical
- Full-Year 2024 Financial Outlook
 - Narrows Expected Worldwide Sales Range To Be Between \$63.6 Billion and \$64.1 Billion
 - Now Expects Non-GAAP EPS To Be Between \$7.72 and \$7.77; Outlook Reflects a Net Negative Impact of \$0.24 per Share Related to Business Development Transactions With Curon Biopharmaceutical and Daiichi Sankyo

RAHWAY, N.J., Oct. 31, 2024 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the third quarter of 2024.

"Our third-quarter results were strong, as we continue to make progress heading into 2025 and beyond," said Robert M. Davis, chairman and chief executive officer, Merck. "Our pipeline is advancing and expanding, demonstrating our success in creating a sustainable innovation engine, and positioning Merck with a more diversified portfolio to drive growth. I continue to remain confident in the strength of our business and our ability to execute, and I

want to thank our colleagues across the globe for their focus and commitment as we work to create lasting value for patients, shareholders and all our stakeholders."

Financial Summary

	Third Quarter				
\$ in millions, except EPS amounts	2024	2023	Change	Change Ex- Exchange	
Sales	\$16,657	\$15,962	4%	7%	
GAAP net income ¹	3,157	4,745	-33%	-30%	
Non-GAAP net income that excludes certain items ^{1,2*}	3,985	5,427	-27%	-23%	
GAAP EPS	1.24	1.86	-33%	-30%	
Non-GAAP EPS that excludes certain items ^{2*}	1.57	2.13	-26%	-23%	

*Refer to table on page 7.

In the third quarter of 2024, total worldwide sales were \$16.7 billion, an increase of 4% compared with the third quarter of 2023; excluding the impact of foreign exchange, growth was 7%. Sales growth in the third quarter of 2024 was primarily due to increased usage of KEYTRUDA globally, contributions from new launches, including WINREVAIR and CAPVAXIVE, and strong growth in Merck's Animal Health business. Revenue growth in the third quarter of 2024 was partially offset by lower sales of JANUVIA and JANUMET, lower combined sales of GARDASIL/GARDASIL 9 and lower sales of LAGEVRIO. Third-quarter GARDASIL/GARDASIL 9 sales declined year-over-year due to reduced demand in China; outside of China, the company achieved double-digit sales growth for GARDASIL/GARDASIL 9 in almost every major region globally.

For the third quarter of 2024, Generally Accepted Accounting Principles (GAAP) earnings per share (EPS) assuming dilution was \$1.24 and non-GAAP EPS was \$1.57. The declines in GAAP and Non-GAAP EPS in the third quarter of 2024 versus the prior year were largely due to a net charge of \$0.79 per share in the aggregate for the acquisition of Eyebiotech Limited (EyeBio) and a related development milestone, the acquisition of CN201 (now known as MK-1045) from Curon Biopharmaceutical (Curon), as well as a payment received from Daiichi Sankyo related to the expansion of the existing development and commercialization agreement. There were no significant business development transaction charges in the third quarter of 2023.

Non-GAAP EPS in both periods excludes acquisition- and divestiture-related costs, costs related to restructuring programs, as well as income and losses from investments in equity securities.

¹ Net income attributable to Merck & Co., Inc.

² 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 this release.

Year-to-date results can be found in the attached tables.

<u>Third-Quarter Sales Performance</u>

The following table reflects sales of the company's top products and significant performance drivers.

	Third Quarter				
				Change	
				Ex-	_
\$ in millions	2024	2023	Change	Exchange	Commentary
					Approximately 2 percentage points of the
					negative impact of foreign exchange was due
					to devaluation of Argentine peso, which was largely offset by inflation-related price
					increases, consistent with practice in that
Total Sales	\$16,657	\$15,962	4%	7%	market.
					Increase driven by growth in oncology and
					cardiovascular, partially offset by declines in
Pharmaceutical	14,943	14,263	5%	8%	diabetes, vaccines and virology.
					Growth driven by increased global uptake in
					earlier-stage indications, including triple- negative breast cancer (TNBC), renal cell
					carcinoma (RCC) and non-small cell lung
					cancer (NSCLC), as well as continued strong
					global demand from metastatic indications.
					Approximately 3 percentage points of the
					negative impact of foreign exchange was due
					to devaluation of Argentine peso, which was
KEYTRUDA	7,429	6,338	17%	21%	largely offset by inflation-related price increases.
RETIRODA	7,429	0,330	1770	2170	Decline primarily due to lower demand in
					China compared with prior year, partially offset
					by higher sales in the U.S., driven by public-
					sector buying patterns, higher pricing and
GARDASIL/					demand, as well as higher demand in most
GARDASIL 9	2,306	2,585	-11%	-10%	international regions.
					Decline primarily due to timing of shipments
PROQUAD, M-M-R II					and lower tenders in Latin America, largely offset by higher demand in certain international
and VARIVAX	703	713	-1%	-1%	markets.
and vittiviot	700	710	170	170	Decline primarily due to lower pricing in the
					U.S., as well as ongoing generic competition in
JANUVIA/JANUMET	482	835	-42%	-38%	many international markets.
					Relatively flat compared with prior year due to
					generic competition in certain international
					markets, particularly in Europe and Japan, largely offset by higher demand and pricing in
BRIDION	420	424	-1%	0%	the U.S.
22.0	120	1=1	1,75	3,0	Decline primarily due to lower demand in
					Japan, partially offset by uptake from
LAGEVRIO	383	640	-40%	-36%	commercial launch in the U.S.
Lynparza*	337	299	13%	13%	Growth primarily due to higher global demand.
					Decline primarily due to timing of shipments in
Lonvimo*	254	260	20/	40/	China in the prior year, partially offset by
Lenvima*	251	260	-3%	-4%	higher demand in the U.S.

					Growth largely driven by continued uptake
					from launches in Europe and Japan, partially
\/A\/A\E\\\\	000	0.1.1	4007	400/	offset by lower demand in the U.S. due to
VAXNEUVANCE	239	214	12%	13%	competition.
					Growth primarily due to higher global demand,
PREVYMIS	208	157	32%	36%	particularly in the U.S.
					Growth primarily due to public-sector buying
					patterns in the U.S. and timing of shipments in
ROTATEQ	193	156	24%	25%	China.
					Represents continued uptake since launch in
WINREVAIR	149	-	-	•	the U.S. in the second quarter.
					Growth primarily driven by higher demand in
					the U.S., largely attributable to ongoing uptake
WELIREG	139	54	156%	157%	of a new indication.
					Growth primarily driven by higher demand and
					pricing for both Companion Animal and
					Livestock product portfolios, as well as sales
					related to July 2024 acquisition of Elanco aqua
					business. Approximately 2 percentage points
					of the negative impact of foreign exchange
					was due to devaluation of Argentine peso,
					which was largely offset by inflation-related
Animal Health	1,487	1,400	6%	11%	price increases.
					Growth primarily driven by higher pricing and
					higher demand for poultry and swine products,
					as well as sales related to acquisition of
Livestock	886	874	1%	7%	Elanco aqua business.
					Growth primarily driven by uptake from new
					product launches, including the injectable
					formulation of BRAVECTO in certain
					international markets, as well as higher pricing
					across product portfolio. Sales of BRAVECTO
					were \$266 million and \$235 million in current
					and prior year quarters, respectively, which
					represented growth of 13%, or 16% excluding
Companion Animal	601	526	14%	17%	impact of foreign exchange.
					Decline primarily due to lower payments
					received for out-licensing arrangements and
Other Revenues**	227	299	-24%	-22%	lower royalty income.

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

^{**}Other revenues are comprised primarily of revenues from third-party manufacturing arrangements and miscellaneous corporate revenues, including revenue-hedging activities.

Third-Quarter Expense, EPS and Related Information

The table below presents selected expense information.

\$ in millions	GAAP	Acquisition- and Divestiture- Related Costs ³	Restructuring Costs	(Income) Loss From Investments in Equity Securities	Non- GAAP ²
Third Quarter 2024					
Cost of sales	\$4,080	\$639	\$192	\$-	\$3,249
Selling, general and administrative	2,731	43	31	-	2,657
Research and development	5,862	24	-	-	5,838
Restructuring costs	56	-	56	-	-
Other (income) expense, net	(162)	(27)	-	58	(193)
Third Quarter 2023					
Cost of sales	\$4,264	\$552	\$33	\$-	\$3,679
Selling, general and administrative	2,519	17	40	-	2,462
Research and development	3,307	10	-	-	3,297
Restructuring costs	126	-	126	-	-
Other (income) expense, net	126	(24)	-	17	133

GAAP Expense, EPS and Related Information

Gross margin was 75.5% for the third quarter of 2024 compared with 73.3% for the third quarter of 2023. The increase was primarily due to the favorable impact of product mix (including lower royalty rates related to KEYTRUDA and GARDASIL/GARDASIL 9), partially offset by higher restructuring costs (primarily reflecting asset impairment charges), as well as higher amortization of intangible assets.

Selling, general and administrative (SG&A) expenses were \$2.7 billion in the third quarter of 2024, an increase of 8% compared with the third quarter of 2023. The increase was primarily due to higher administrative, promotional, selling, and acquisition-related costs, partially offset by the favorable impact of foreign exchange.

Research and development (R&D) expenses were \$5.9 billion in the third quarter of 2024, an increase of 77% compared with the third quarter of 2023. The increase was primarily due to a charge of \$1.35 billion for the acquisition of EyeBio and a \$100 million charge for a related development milestone, as well as a charge of \$750 million to acquire CN201 (MK-1045) from Curon. The increase in R&D expenses was also driven by higher compensation and benefit costs, as well as higher clinical development spending. The increase in R&D expenses was partially offset by the favorable impact of foreign exchange.

Other (income) expense, net, was \$162 million of income in the third quarter of 2024 compared with \$126 million of expense in the third quarter of 2023. The favorability was primarily due to a \$170 million payment received from Daiichi Sankyo related to the expansion

³ Reflects expenses related to acquisitions of businesses, including the amortization of intangible assets, 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 associated with acquisitions and divestitures, as well as amortization of intangible assets related to collaborations and licensing arrangements.

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of the existing development and commercialization agreement, lower exchange losses and lower net interest expense.

The effective tax rate of 22.7% for the third quarter of 2024 includes a 7.2 percentage point combined unfavorable impact related to the EyeBio and Curon transactions.

GAAP EPS was \$1.24 for the third quarter of 2024 compared with \$1.86 for the third quarter of 2023. GAAP EPS in the third quarter of 2024 includes a net charge of \$0.79 per share in the aggregate for the EyeBio, Curon and Daiichi Sankyo transactions. There were no significant business development transaction charges in the third quarter of 2023.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 80.5% for the third quarter of 2024 compared with 77.0% for the third quarter of 2023. The increase was primarily due to the favorable impact of product mix (including lower royalty rates related to KEYTRUDA and GARDASIL/GARDASIL 9).

Non-GAAP SG&A expenses were \$2.7 billion in the third quarter of 2024, an increase of 8% compared with the third quarter of 2023. The increase was primarily due to higher administrative, promotional and selling costs, partially offset by the favorable impact of foreign exchange.

Non-GAAP R&D expenses were \$5.8 billion in the third quarter of 2024, an increase of 77% compared with the third quarter of 2023. The increase was primarily due to a charge of \$1.35 billion for the acquisition of EyeBio and a \$100 million charge for a related development milestone, as well as a charge of \$750 million to acquire CN201 (MK-1045) from Curon. The increase in R&D expenses was also driven by higher compensation and benefit costs, as well as higher clinical development spending. The increase in R&D expenses was partially offset by the favorable impact of foreign exchange.

Non-GAAP other (income) expense, net, was \$193 million of income in the third quarter of 2024 compared with \$133 million of expense in the third quarter of 2023. The favorability was primarily due to a \$170 million payment received from Daiichi Sankyo related to the expansion of the existing development and commercialization agreement, lower exchange losses and lower net interest expense.

The non-GAAP effective tax rate of 21.9% for the third quarter of 2024 includes a 6.0 percentage point combined unfavorable impact related to the EyeBio and Curon transactions.

Non-GAAP EPS was \$1.57 for the third quarter of 2024 compared with \$2.13 for the third quarter of 2023. Non-GAAP EPS in the third quarter of 2024 includes a net charge of \$0.79 per share in the aggregate for the EyeBio, Curon and Daiichi Sankyo transactions. There were no significant business development transaction charges in the third quarter of 2023.

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

	Third Quarter		
\$ in millions, except EPS amounts	2024	2023	
EPS			
GAAP EPS	\$1.24	\$1.86	
Difference	0.33	0.27	
Non-GAAP EPS that excludes items listed below ²	\$1.57	\$2.13	
Net Income			
GAAP net income ¹	\$3,157	\$4,745	
Difference	828	682	
Non-GAAP net income that excludes items listed below ^{1,2}	\$3,985	\$5,427	
Excluded Items:			
Acquisition- and divestiture-related costs ³	\$679	\$555	
Restructuring costs	279	199	
Loss from investments in equity securities	58	17	
Decrease to net income	1,016	771	
Estimated income tax (benefit) expense	(188)	(89)	
Decrease to net income	\$828	\$682	

Pipeline and Portfolio Highlights

In the third quarter, Merck continued to develop and augment its strong, diverse pipeline and achieve key regulatory and clinical milestones.

In cardiovascular disease, Merck continued to build on positive momentum in its U.S. launch of WINREVAIR. As of the end of September 2024, more than 3,700 patients have been prescribed WINREVAIR. The company also received the European Commission's (EC) approval of WINREVAIR, in combination with other pulmonary arterial hypertension (PAH) therapies, for the treatment of adult patients with PAH with World Health Organization (WHO) functional Class II to III. WINREVAIR is the first activin signaling inhibitor approved for the treatment of PAH in Europe. WINREVAIR has launched in Germany and Merck is working to obtain reimbursement for WINREVAIR in other countries in the EU, which should occur in most other major European markets in the second half of 2025.

In oncology, Merck continued to reinforce its leadership in women's and earlier stages of cancers and demonstrate progress in its research pipeline. At the European Society for Medical Oncology (ESMO) Congress 2024, three of the company's data presentations were highlighted during Presidential Symposium sessions. These included overall survival (OS) data from the Phase 3 KEYNOTE-522 trial in high-risk, early-stage TNBC and from the Phase 3 KEYNOTE-A18 trial (also known as ENGOT-cx11/GOG-3047) in high-risk, locally advanced cervical cancer. In addition, new positive data on investigational candidates from Merck's pipeline were presented, including for patritumab deruxtecan (HER3-DXd), an antibody-drug conjugate (ADC) being developed in collaboration with Daiichi Sankyo, and for sacituzumab tirumotecan (sac-TMT), an anti-TROP2 ADC being developed in collaboration with Kelun-Biotech.

The company also achieved several regulatory milestones, including new approvals for KEYTRUDA-based regimens in the U.S., Europe and Japan. In addition, Merck recently

announced top-line results from the KEYNOTE-689 trial, which marks the first positive trial in two decades for patients with resected, locally advanced head and neck squamous cell carcinoma (LA-HNSCC).

In vaccines, the CDC's Advisory Committee on Immunization Practices (ACIP) voted in October 2024 to recommend CAPVAXIVE for individuals 50 to 64 years of age. This decision expanded upon the initial unanimous recommendation in June 2024 for use of CAPVAXIVE in adults age 65 and older, among other cohorts.

At IDWeek 2024, Merck presented positive results from the Phase 2b/3 trial of clesrovimab (MK-1654), an investigational respiratory syncytial virus (RSV) preventative monoclonal antibody for infants. These results support the potential for clesrovimab to become the first and only single-dose immunization designed to protect infants with the same dose, regardless of weight, for the duration of their first RSV season (six months).

In immunology, long-term efficacy and safety data for tulisokibart (MK-7240), an investigational humanized monoclonal antibody directed to a novel target, tumor necrosis factor (TNF)-like cytokine 1A (TL1A), from the Phase 2 ARTEMIS-UC and APOLLO-CD studies in ulcerative colitis (UC) and Crohn's disease (CD), were presented at the United European Gastroenterology (UEG) Week 2024 Congress. Both studies showed that, at week 50, maintenance of treatment efficacy was generally observed in 12-week induction responders. Phase 3 studies in UC and CD are ongoing.

In addition, Merck continued to expand and diversify its pipeline by securing strategic business development opportunities. Merck <u>completed</u> its acquisition of CN201 (MK-1045), a next-generation CD3xCD19 bispecific antibody with potential applications in B-cell malignancies and autoimmune diseases, from Curon. Merck also <u>announced</u> the expansion of the global development and commercialization agreement with Daiichi Sankyo to include MK-6070, an investigational delta-like ligand 3 (DLL3) targeting T-cell engager. The companies are planning to evaluate MK-6070 in combination with ifinatamab deruxtecan (I-DXd) in certain patients with small cell lung cancer (SCLC), as well as other potential combinations.

Notable recent news releases on Merck's pipeline and portfolio are provided in the table that follows.

	FDA Approved KEYTRUDA Plus Pemetrexed and Platinum Chemotherapy as First-Line Treatment for Adult Patients With Unresectable Advanced or Metastatic Malignant Pleural Mesothelioma, Based on Results From Phase 3 KEYNOTE-483/CCTG IND.227 Trial	(Read Announcement)
	EC Approved KEYTRUDA Plus Padcev as First-Line Treatment of Unresectable or Metastatic Urothelial Carcinoma in Adults, Based on Results From Phase 3 KEYNOTE-A39/EV-302 Trial	(Read Announcement)
	KEYTRUDA Received 30th Approval From EC With Two New Indications in Gynecologic Cancers, Based on Results From Phase 3 KEYNOTE-868/NRG-GY018 and KEYNOTE-A18 Trials	(Read Announcement)
	KEYTRUDA Received New Approvals in Japan for Certain Patients With NSCLC, Based on Results From Phase 3 KEYNOTE-671 Trial, and for Radically Unresectable Urothelial Carcinoma, Based on Results From Phase 3 KEYNOTE-A39/EV-302 and Phase 2 KEYNOTE-052 Trials	(Read Announcement)
	KEYTRUDA Plus Chemotherapy Before Surgery and Continued as Single Agent After Surgery Reduced Risk of Death by More Than One-Third (34%) Versus Neoadjuvant Chemotherapy in High-Risk, Early-Stage TNBC, Based on Results From Phase 3 KEYNOTE-522	(Read Announcement)
	KEYTRUDA Plus Chemoradiotherapy (CRT) Reduced Risk of Death by 33% Versus CRT Alone in Patients With Newly Diagnosed, High-Risk, Locally Advanced Cervical Cancer, Based on Results From Phase 3 KEYNOTE-A18/ENGOT-cx11/GOG- 3047 Trial	(Read Announcement)
Oncology	KEYTRUDA Ten-Year Data Demonstrated Sustained OS Benefit Versus Ipilimumab in Advanced Melanoma, Based on Results From Phase 3 KEYNOTE-006 Trial	(Read Announcement)
	KEYTRUDA Plus Lenvima in Combination With Transarterial Chemoembolization (TACE) Significantly Improved Progression-Free Survival Compared to TACE Alone in Patients With Unresectable, Non-Metastatic Hepatocellular Carcinoma, Based on Results From Phase 3 LEAP-012 Trial	(Read Announcement)
	KEYTRUDA Plus Trastuzumab and Chemotherapy Significantly Improved OS Versus Trastuzumab and Chemotherapy Alone in First-Line Treatment of Patients With HER2-Positive Advanced Gastric or GEJ Adenocarcinoma, Based on Results From Phase 3 KEYNOTE-811 Trial	(Read Announcement)
	KEYTRUDA Met Primary Endpoint of Event-Free Survival as Perioperative Treatment Regimen in Patients With Resected, LA-HNSCC, Based on Results From Phase 3 KEYNOTE-689 Trial	(Read Announcement)
	Patritumab Deruxtecan (HER3-DXd) Demonstrated Statistically Significant Improvement in Progression-Free Survival Versus Doublet Chemotherapy in Patients With Locally Advanced or Metastatic EGFR-Mutated NSCLC, Based on Results From Phase 3 HERTHENA-Lung02 Trial	(Read Announcement)
	Ifinatamab Deruxtecan Continued to Demonstrate Promising Objective Response Rates in Patients With Extensive-Stage SCLC, Based on Results From Phase 2 IDeate-Lung01 Trial	(Read Announcement)
	Merck and Moderna Initiated Phase 3 Trial Evaluating Adjuvant V940 (mRNA-4157) in Combination With KEYTRUDA After Neoadjuvant KEYTRUDA and Chemotherapy in Patients With Certain Types of NSCLC	(Read Announcement)
	Merck Initiated Phase 3 Shorespan-007 Trial for Bomedemstat, an Investigational Candidate for the Treatment of Certain Patients With Essential Thrombocythemia	(Read Announcement)

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Merck Announced Positive Top-line Results From Phase 3 Trial	(Read
Evaluating Efficacy and Safety of GARDASIL 9 in Japanese	Announcement)
Males	<u>Announcement)</u>
EC Approved WINREVAIR in Combination With Other PAH	
Therapies for the Treatment of PAH in Adult Patients With	(Read
Functional Class II-III, Based on Results From Phase 3	Announcement)
STELLAR Trial	
Merck Presented New Long-Term Data for Tulisokibart (MK-	(Read
7240), an Investigational Anti-TL1A Monoclonal Antibody, in	
Inflammatory Bowel Disease at UEG Week 2024	Announcement)
Merck and Gilead Announced Phase 2 Data Showing a	
Treatment Switch to an Investigational Oral Once-Weekly	(Read
Combination Regimen of Islatravir and Lenacapavir (MK-8591D)	Announcement)
Merck and EyeBio Initiated Phase 2b/3 Clinical Trial for MK-3000	(Read
for the Treatment of Diabetic Macular Edema	Announcement)
	Males EC Approved WINREVAIR in Combination With Other PAH Therapies for the Treatment of PAH in Adult Patients With Functional Class II-III, Based on Results From Phase 3 STELLAR Trial Merck Presented New Long-Term Data for Tulisokibart (MK- 7240), an Investigational Anti-TL1A Monoclonal Antibody, in Inflammatory Bowel Disease at UEG Week 2024 Merck and Gilead Announced Phase 2 Data Showing a Treatment Switch to an Investigational Oral Once-Weekly Combination Regimen of Islatravir and Lenacapavir (MK-8591D) Maintained Viral Suppression in Adults at Week 48 Merck and EyeBio Initiated Phase 2b/3 Clinical Trial for MK-3000

Sustainability Highlights

Merck <u>issued</u> its 2023/2024 Impact Report, reaffirming its commitment to operating responsibly and enabling broad access to its products. The report noted how the company reached more than 550 million people around the world with its medicines and vaccines through commercial channels, clinical trials, voluntary licensing and product donations.

Full-Year 2024 Financial Outlook

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

	Full Year 2024		
	Updated	Prior	
Sales [*]	\$63.6 to \$64.1 billion	\$63.4 to \$64.4 billion	
Non-GAAP Gross margin ²	Approximately 81%	Approximately 81%	
Non-GAAP Operating expenses ^{2**}	\$27.8 to \$28.3 billion	\$26.8 to \$27.6 billion	
Non-GAAP Other (income) expense, net ²	Approximately \$100 million expense	Approximately \$350 million expense	
Non-GAAP Effective tax rate ²	16.0% to 17.0%	15.5% to 16.5%	
Non-GAAP EPS ^{2***}	\$7.72 to \$7.77	\$7.94 to \$8.04	
Share count (assuming dilution)	Approximately 2.54 billion	Approximately 2.54 billion	

*The company does not have any non-GAAP adjustments to sales.

^{**}Includes one-time R&D charges of \$656 million for Harpoon Therapeutics, Inc. (Harpoon) acquisition, \$1.45 billion for EyeBio acquisition and related development milestone payment, and \$750 million for acquisition of CN201 (MK-1045) from Curon. Outlook does not assume any additional significant potential business development transactions.

^{***}Includes net one-time charge of \$1.05 per share in aggregate for the Harpoon, EyeBio and Curon transactions, and the cash payment received from Daiichi Sankyo.

Merck has not provided a reconciliation of forward-looking non-GAAP gross margin, non-GAAP operating expenses, non-GAAP other (income) expense, net, non-GAAP effective tax rate and non-GAAP EPS to the most directly comparable GAAP measures, given it cannot predict with reasonable certainty the amounts necessary for such a reconciliation, including intangible asset impairment charges, legal settlements, and gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds, without unreasonable effort. These items are inherently difficult to forecast and could have a significant impact on the company's future GAAP results.

Merck continues to experience strong growth, including from KEYTRUDA, new product launches and Animal Health. As a result, Merck is narrowing the range of its full-year sales outlook.

Merck now expects its full-year sales to be between \$63.6 billion and \$64.1 billion, including a negative impact of foreign exchange of approximately 3 percentage points, at mid-October 2024 exchange rates. Approximately 2 percentage points of the negative impact of foreign exchange is due to the devaluation of the Argentine peso, which is being largely offset by inflation-related price increases, consistent with practice in that market.

Merck now expects its full-year non-GAAP effective income tax rate to be between 16.0% and 17.0%, which includes an unfavorable impact related to the one-time charge associated with the acquisition of CN201 (MK-1045) from Curon.

Merck now expects its full-year non-GAAP EPS to be between \$7.72 and \$7.77. The outlook includes a negative impact of foreign exchange of approximately \$0.30 per share. The negative impact of foreign exchange is primarily due to the devaluation of the Argentine peso, which is being largely offset by inflation-related price increases, consistent with practice in that market. This revised non-GAAP EPS range reflects a net charge of \$0.24 per share for the following items not previously included in the outlook:

- The acquisition of CN201 (MK-1045) from Curon.
- Payment received from Daiichi Sankyo related to the expansion of the existing development and commercialization agreement.

Consistent with past practice, the financial outlook does not assume additional significant potential business development transactions.

Non-GAAP EPS excludes acquisition- and divestiture-related costs, costs related to restructuring programs, income and losses from investments in equity securities, as well as a tax benefit in 2024 due to a reduction in reserves for unrecognized income tax benefits, resulting from the expiration of the statute of limitations for assessments related to the 2019 federal tax return year.

Earnings Conference Call

Investors, journalists and the general public may access a live audio webcast of the earnings conference call on Thursday, October 31, at 9 a.m. ET via this <u>weblink</u>. 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 (800) 369-3351 (U.S. and Canada Toll-Free) or (517) 308-9448 and using the access code 9818590.

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 www.merck.com and connect with us on X (formerly Twitter), Facebook, Instagram, YouTube and LinkedIn.

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 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).

Appendix

Generic product names are provided below.

Pharmaceutical

BRIDION (sugammadex)

CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine)

GARDASIL (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine,

Recombinant)

GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

JANUMET (sitagliptin and metformin HCI)

JANUVIA (sitagliptin)

KEYTRUDA (pembrolizumab)

LAGEVRIO (molnupiravir)

Lenvima (lenvatinib)

Lynparza (olaparib)

M-M-R II (Measles, Mumps and Rubella Virus Vaccine Live)

PREVYMIS (letermovir)

PROQUAD (Measles, Mumps, Rubella and Varicella Virus Vaccine Live)

ROTATEQ (Rotavirus Vaccine, Live, Oral, Pentavalent)

VARIVAX (Varicella Virus Vaccine Live)

VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine)

VERQUVO (vericiquat)

WELIREG (belzutifan)

WINREVAIR (sotatercept-csrk)

Animal Health

BRAVECTO (fluralaner)

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