



News Release

Merck & Co., Inc., Rahway, N.J., USA Announces Third-Quarter 2025 Financial Results

- Total Worldwide Sales Were \$17.3 Billion, an Increase of 4% From Third Quarter 2024; Excluding the Impact of Foreign Exchange, Sales Grew 3%
 - o KEYTRUDA Sales Grew 10% to \$8.1 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 8%
 - o WINREVAIR Sales Were \$360 Million; Growth of 141% Both Nominally and Excluding the Impact of Foreign Exchange
 - o CAPVAXIVE Sales Were \$244 Million
 - o GARDASIL/GARDASIL 9 Sales Declined 24% to \$1.7 Billion; Excluding the Impact of Foreign Exchange, Sales Declined 25%
 - o Animal Health Sales Grew 9% to \$1.6 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 7%
- GAAP EPS Was \$2.32; Non-GAAP EPS Was \$2.58; GAAP and Non-GAAP EPS Include a Charge of \$0.10 per Share for Milestone Payment to LaNova for Technology Transfer for MK-2010
- Received FDA Approval of KEYTRUDA QLEX Injection for Subcutaneous Use Across All Solid Tumor Indications for KEYTRUDA
- Presented New Research Across More Than 20 Types of Cancer and Multiple Treatment Settings at ESMO Congress 2025, Including Positive Survival Data From KEYNOTE-905 and KEYNOTE-B96
- Announced Positive Topline Results From Third Phase 3 CORALreef Lipids Trial of Enlicitide Decanoate for Treatment of Adults With Hypercholesterolemia
- Completed Acquisition of Verona Pharma and Its First-In-Class COPD Maintenance Treatment for Adults, OHTUVAYRE, in October
- Full-Year 2025 Financial Outlook
 - o Now Expects Worldwide Sales To Be Between \$64.5 Billion and \$65.0 Billion
 - o Raises and Narrows Expected Non-GAAP EPS Range To Be Between \$8.93 and \$8.98

RAHWAY, N.J., Oct. 30, 2025 – Merck & Co., Inc., Rahway, N.J., USA (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the third quarter of 2025.

“In the third quarter, we continued to execute on our strategy with important pipeline advancements, significant approvals and successful new product launches,” said Robert M. Davis, chairman and chief executive officer. “We’re delivering value to patients and customers through our innovative portfolio of medicines and vaccines, and we’re securing our future by

making important investments in our pipeline – including through compelling, strategic business development like our completed acquisition of Verona Pharma and expanded U.S. manufacturing and R&D spending. With each milestone we achieve, my conviction that we’re well-positioned to drive the next chapter of success for our Company increases.”

Financial Summary

	Third Quarter			
	2025	2024	Change	Change Ex-Exchange
\$ in millions, except EPS amounts				
Sales	\$17,276	\$16,657	4%	3%
GAAP net income ¹	5,785	3,157	83%	84%
Non-GAAP net income that excludes certain items ^{1,2*}	6,448	3,985	62%	62%
GAAP EPS	2.32	1.24	87%	88%
Non-GAAP EPS that excludes certain items ^{2*}	2.58	1.57	64%	65%

*Refer to table on page 7.

For the third quarter of 2025, Generally Accepted Accounting Principles (GAAP) earnings per share (EPS) assuming dilution was \$2.32 and non-GAAP EPS was \$2.58. GAAP and non-GAAP EPS in the third quarter of 2025 include a charge of \$0.10 per share for a milestone payment to LaNova Medicines Ltd. (LaNova, acquired by Sino Biopharmaceutical Limited) associated with the technology transfer for MK-2010. GAAP and non-GAAP EPS in the third quarter of 2024 include a net charge of \$0.79 per share in the aggregate for the acquisition of Eyebiotec Limited (EyeBio) and a related development milestone, the acquisition of 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 to include gocatamig (MK-6070).

Non-GAAP EPS in both periods excludes acquisition- and divestiture-related costs, costs related to restructuring programs, and income and losses from investments in equity securities. Non-GAAP EPS in the third quarter of 2025 also excludes tax expense relating to audit reserve adjustments.

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

¹ Net income attributable to the Company.

² 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 this release.

Third-Quarter Sales Performance

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

\$ in millions	Third Quarter				Commentary
	2025	2024	Change	Change Ex-Exchange	
Total Sales	\$17,276	\$16,657	4%	3%	
Pharmaceutical	15,611	14,943	4%	3%	Increase primarily driven by growth in oncology, cardiovascular and diabetes, partially offset by declines in vaccines, virology and immunology.
KEYTRUDA	8,142	7,429	10%	8%	Growth driven by continued strong global demand from metastatic indications, including urothelial, endometrial and gastric cancers, as well as robust global uptake in earlier-stage indications including triple-negative breast cancer, cervical cancer, renal cell carcinoma (RCC) and non-small cell lung cancer (NSCLC). Sales also benefitted from timing of wholesaler purchases in the U.S., partially offset by other channel movements.
GARDASIL/GARDASIL 9	1,749	2,306	-24%	-25%	Decline primarily due to lower demand in China. Excluding China, sales declined 2%, or 3% excluding impact of foreign exchange, reflecting lower demand in Japan following a national catch-up immunization program, partially offset by higher sales in the U.S. due to higher net pricing and favorable public-sector purchasing patterns.
PROQUAD, M-M-R II and VARIVAX	684	703	-3%	-3%	Decline primarily due to lower demand, partially offset by higher net pricing in the U.S.
JANUVIA/JANUMET	624	482	29%	29%	Growth driven by higher net pricing in the U.S., partially offset by lower demand in China as well as in most other international markets due to generic competition.
BRIDION	439	420	5%	4%	Growth primarily due to higher demand in the U.S., partially offset by lower demand in most international markets due to ongoing generic competition.
Lynparza*	379	337	12%	12%	Growth primarily due to higher demand in the U.S. and certain international markets.
WINREVAIR	360	149	141%	141%	Growth largely reflects continued uptake in the U.S., partially offset by timing of distributor purchases and lower net pricing in the U.S. largely due to Medicare Part D redesign.

PREVYMIS	266	208	28%	25%	Increase primarily due to higher demand in the U.S. and launch of new indications in certain international markets, partially offset by lower demand in China due to generic competition.
Lenvima*	258	251	3%	2%	Increase primarily due to higher sales in the U.S. reflecting higher demand, partially offset by lower net pricing.
CAPVAXIVE	244	47	N/M	N/M	Represents continued uptake since third-quarter 2024 launch in the U.S., as well as expected seasonal inventory build.
VAXNEUVANCE	226	239	-6%	-7%	Decline primarily due to lower demand in certain international markets, particularly in Japan due to competitive pressure, partially offset by higher demand in certain European markets.
WELIREG	196	139	42%	41%	Growth primarily driven by higher demand in the U.S. and continued launch uptake in certain European markets, partially offset by lower net pricing in the U.S.
LAGEVRIO	138	383	-64%	-65%	Decline primarily due to lower demand in the Asia Pacific region, particularly in Japan, as well as in the U.S.
SIMPONI	-	189	-100%	-100%	Marketing rights in former territories of the Company reverted to Johnson & Johnson on Oct. 1, 2024.
Animal Health	1,615	1,487	9%	7%	Growth primarily due to performance of livestock products.
Livestock	1,023	886	16%	14%	Growth primarily driven by higher demand across all species, as well as timing of sales.
Companion Animal	592	601	-2%	-3%	Decline primarily due to lower demand, reflecting a reduction in veterinary visits and competitive pressure for parasiticides, partially offset by higher pricing, improved supply and new product launches. Sales of BRAVECTO were \$262 million and \$266 million in current and prior-year quarters, respectively, which represents a decline of 1%, or 3% excluding impact of foreign exchange.
Other Revenues**	50	227	-78%	-27%	Decline primarily due to unfavorable impact of revenue-hedging activities and lower revenue from third-party manufacturing arrangements.

*Alliance revenue for this product represents the Company'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.
N/M- Not meaningful.

In addition, Koselugo alliance revenue was \$214 million in the third quarter of 2025 compared with \$39 million in the third quarter of 2024. The increase was due to an amendment to the collaboration agreement with AstraZeneca, which discontinued the provisions whereby the Company shared revenue and costs with AstraZeneca, and revised the payment structure, resulting in the Company's recognition of a \$150 million upfront payment and a \$50 million regulatory milestone.

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 2025					
Cost of sales	\$3,855	\$621	\$110	\$-	\$3,124
Selling, general and administrative	2,633	34	-	-	2,599
Research and development	4,234	4	233	-	3,997
Restructuring costs	47	-	47	-	-
Other (income) expense, net	(238)	-	-	(344)	106
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)

GAAP Expense, EPS and Related Information

Gross margin was 77.7% for the third quarter of 2025 compared with 75.5% for the third quarter of 2024. The increase was primarily due to the favorable impact of product mix and lower restructuring costs, partially offset by higher inventory write-offs and the unfavorable impact of foreign exchange.

Selling, general and administrative (SG&A) expenses were \$2.6 billion in the third quarter of 2025, a decrease of 4% compared with the third quarter of 2024. The decrease was primarily due to lower administrative, restructuring and selling costs, partially offset by the unfavorable impact of foreign exchange.

Research and development (R&D) expenses were \$4.2 billion in the third quarter of 2025, a decrease of 28% compared with the third quarter of 2024. The decrease was primarily due to lower charges for business development activity, including charges of \$2.2 billion in the aggregate related to the acquisitions of EyeBio and MK-1045 in the third quarter of 2024,

³ Reflects expenses related to business combinations, 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.

compared with a charge of \$300 million in the third quarter of 2025 related to a milestone payment to LaNova for the completion of the technology transfer for MK-2010. Excluding these charges, R&D expenses increased primarily due to higher restructuring costs and clinical development spending.

Other (income) expense, net, was \$238 million of income in the third quarter of 2025 compared with \$162 million of income in the third quarter of 2024. The favorability was primarily due to net income from investments in equity securities in 2025 compared with net losses from investments in equity securities in 2024, partially offset by \$170 million of income recognized in 2024 related to a payment received from Daiichi Sankyo associated with the expansion of an existing development and commercialization agreement to include gocatamig (MK-6070).

The effective tax rate was 14.2% for the third quarter of 2025.

GAAP EPS was \$2.32 for the third quarter of 2025 compared with \$1.24 for the third quarter of 2024. The increase was primarily driven by a net charge of \$0.79 per share in the aggregate in 2024 for the EyeBio, Curon and Daiichi Sankyo transactions, partially offset by a charge of \$0.10 per share in 2025 related to the LaNova technology transfer milestone payment.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 81.9% for the third quarter of 2025 compared with 80.5% for the third quarter of 2024. The increase was primarily due to the favorable impact of product mix, partially offset by higher inventory write-offs and the unfavorable impact of foreign exchange.

Non-GAAP SG&A expenses were \$2.6 billion in the third quarter of 2025, a decrease of 2% compared with the third quarter of 2024. The decrease was primarily due to lower administrative and selling costs, partially offset by the unfavorable impact of foreign exchange.

Non-GAAP R&D expenses were \$4.0 billion in the third quarter of 2025, a decrease of 32% compared with the third quarter of 2024. The decrease was primarily due to lower charges for business development activity, including charges of \$2.2 billion in the aggregate related to the acquisitions of EyeBio and MK-1045 in the third quarter of 2024, compared with a charge of \$300 million in the third quarter of 2025 related to a milestone payment to LaNova for the completion of the technology transfer for MK-2010. Excluding these charges, R&D expenses increased primarily due to higher clinical development spending.

Non-GAAP other (income) expense, net, was \$106 million of expense in the third quarter of 2025 compared with \$193 million of income in the third quarter of 2024. The unfavorability was primarily due to \$170 million of income recognized in 2024 related to a payment received from Daiichi Sankyo associated with the expansion of an existing development and commercialization agreement to include gocatamig (MK-6070).

The non-GAAP effective tax rate was 13.4% for the third quarter of 2025.

Non-GAAP EPS was \$2.58 for the third quarter of 2025 compared with \$1.57 for the third quarter of 2024. The increase was primarily driven by a net charge of \$0.79 per share in the aggregate in 2024 for the EyeBio, Curon and Daiichi Sankyo transactions, partially offset by a charge of \$0.10 per share in 2025 related to the LaNova technology transfer milestone payment.

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

\$ in millions, except EPS amounts	Third Quarter	
	2025	2024
EPS		
GAAP EPS	\$2.32	\$1.24
Difference	0.26	0.33
Non-GAAP EPS that excludes items listed below ²	\$2.58	\$1.57
Net Income		
GAAP net income ¹	\$5,785	\$3,157
Difference	663	828
Non-GAAP net income that excludes items listed below ^{1,2}	\$6,448	\$3,985
Excluded Items:		
Acquisition- and divestiture-related costs ³	\$659	\$679
Restructuring costs	390	279
(Income) loss from investments in equity securities	(344)	58
Decrease to net income before taxes	705	1,016
Estimated income tax (benefit) expense ⁴	(42)	(188)
Decrease to net income	\$663	\$828

⁴ Includes the estimated tax impacts on the reconciling items based on applying the statutory rate of the originating territory of the non-GAAP adjustments for both periods presented. Amount in the third quarter of 2025 also includes \$86 million of tax expense relating to audit reserve adjustments.

Pipeline and Portfolio Highlights

In the third quarter, the Company continued to demonstrate pipeline progress with the achievement of key regulatory and clinical milestones.

In oncology, in September 2025, the U.S. Food and Drug Administration (FDA) approved KEYTRUDA QLEX injection for subcutaneous (SC) administration for use in adults across most solid tumor indications for KEYTRUDA, based on results from the Phase 3 MK-3475A-D77 trial. In October 2025, the FDA subsequently approved KEYTRUDA QLEX for the treatment of certain adult patients with resectable locally advanced head and neck squamous cell carcinoma (LA-HNSCC), based on results from the Phase 3 KEYNOTE-689 trial. KEYTRUDA QLEX is now approved for use in adults across all solid tumor indications approved for KEYTRUDA and is the first and only subcutaneously administered immune checkpoint inhibitor that can be given by a health care provider in as little as one minute.

In addition, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending approval for SC administration of KEYTRUDA for all adult indications; a final decision is expected in the fourth quarter of 2025. The European Commission (EC) also approved KEYTRUDA as part of a perioperative regimen for the treatment of PD-L1+ resectable LA-HNSCC.

At the European Society for Medical Oncology (ESMO) Congress 2025, the Company announced new research from its broad and differentiated portfolio and pipeline, highlighting progress in new tumor types and earlier stages of disease. This included positive results from the Phase 3 KEYNOTE-905 trial (also known as EV-303) in cisplatin-ineligible patients with muscle-invasive bladder cancer (MIBC), the Phase 3 KEYNOTE-B96 trial in platinum-resistant recurrent ovarian cancer and the Phase 2/3 REJOICE-Ovarian01 trial in collaboration with Daiichi Sankyo in certain types of platinum-resistant ovarian cancer, long-term follow-up data from the Phase 3 KEYNOTE-775 trial in advanced endometrial cancer, as well as long-term data for KEYTRUDA in both earlier-stage and metastatic NSCLC.

In vaccines and infectious diseases, in August 2025, the Company received two approvals in Japan: its nine-valent HPV vaccine for use in males ages 9 and older that will be marketed under the trademark SILGARD 9, and CAPVAXIVE for use in the elderly or adults who are at an increased risk of pneumococcal disease.

At the European AIDS Clinical Society 2025 conference, the Company also presented new data from Phase 3 trials evaluating the once-daily, oral, two-drug regimen of doravirine/islatravir in adults with virologically suppressed HIV-1 infection, which showed minimal changes in weight and body composition and no clinically meaningful effect on fasting lipids and the homeostatic model assessment of insulin resistance across both clinical trials.

In cardiovascular disease, the Company announced positive topline results from the Phase 3 CORALreef Lipids trial evaluating the safety and efficacy of enlicitide decanoate, an investigational, once-daily oral proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

being evaluated for the treatment of adults with hypercholesterolemia. The trial met all primary and key secondary endpoints. Enlicitide has the potential to be the first approved oral PCSK9 inhibitor.

In addition, the FDA approved an update to the U.S. product label for WINREVAIR, based on results from the Phase 3 ZENITH trial, expanding the indication to include components of the clinical worsening events: hospitalization for pulmonary arterial hypertension (PAH), lung transplantation and death. Further, at the 2025 European Respiratory Society Congress, the Company presented positive results from the Phase 3 HYPERION trial evaluating WINREVAIR versus placebo (both in combination with background therapy) in adults recently diagnosed with PAH (Group 1 pulmonary hypertension) with World Health Organization (WHO) functional class II or III at intermediate or high risk of disease progression. Results showed that adding WINREVAIR within the first year after PAH diagnosis significantly reduced the risk of clinical worsening events compared to placebo.

The Company also completed its acquisition of Verona Pharma plc (Verona Pharma) in October 2025, strengthening its cardio-pulmonary portfolio with the addition of OHTUVAYRE, an FDA-approved, first-in-class maintenance treatment for chronic obstructive pulmonary disease (COPD) in adult patients.

Notable recent news releases on the Company's pipeline and portfolio are provided in the table that follows. Visit the News Releases section of the Company's website to read the releases.*

Oncology	FDA Approved KEYTRUDA QLEX Injection for SC Use in Adults Across Most Solid Tumor Indications for KEYTRUDA; Based on Results From Phase 3 MK-3475A-D77 Trial
	FDA Granted Breakthrough Therapy Designation for Raludotatug Deruxtecan (R-DXd) for Patients With CDH6 Expressing Platinum-Resistant Ovarian, Primary Peritoneal, or Fallopian Tube Cancers Previously Treated With Bevacizumab; Based on Results From Phase 1 Trial and REJOICE-Ovarian01 Phase 2/3 Trial
	FDA Granted Breakthrough Therapy Designation for Ifinatamab Deruxtecan (I-DXd) for Patients With Pretreated Extensive-Stage Small Cell Lung Cancer; Based on Results From Phase 2 IDEATE-Lung01 Trial
	FDA Granted Priority Review for KEYTRUDA and KEYTRUDA QLEX, Each in Combination With Padcev, for Certain Patients With MIBC; FDA Set Prescription Drug User Fee Act (PDUFA) Date of April 7, 2026
	EC Approved KEYTRUDA as Part of a Treatment Regimen for Adults With Resectable LA-HNSCC Expressing PD-L1 (CPS $\geq$ 1); Based on Results From Phase 3 KEYNOTE-689 Trial
	EU CHMP Adopted Two Positive Opinions for KEYTRUDA, for SC Administration and for New Indication for Earlier-Stage Head and Neck Cancer; Latter Based on Results From Phase 3 KEYNOTE-689 Trial
	KEYTRUDA Plus Padcev Reduced Risk of Event-Free Survival Events by 60% and Risk of Death by 50% for Certain Patients With MIBC When Given Before and After Surgery; Based on Results From Phase 3 KEYNOTE-905 Trial
	KEYTRUDA Plus Chemotherapy, With or Without Bevacizumab, Reduced Risk of Disease Progression or Death Versus Chemotherapy, With or Without Bevacizumab, in Certain Patients With Platinum-Resistant Recurrent Ovarian Cancer; Based on Results From Phase 3 KEYNOTE-B96 Trial; FDA Set PDUFA Date of Feb. 20, 2026
	Phase 3 KEYNOTE-B96 Trial Met Secondary Endpoint of Overall Survival in All Comers Population of Patients With Platinum-Resistant Recurrent Ovarian Cancer

	R-DXd Demonstrated Clinically Meaningful Response Rates in Patients With Recurrent Platinum-Resistant Ovarian, Primary Peritoneal or Fallopian Tube Cancer in Phase 2 Part of REJOICE-Ovarian01 Phase 2/3 Trial
	KEYTRUDA Demonstrated Long-Term Survival Benefit in Certain Patients With Earlier or Advanced Stages of NSCLC; Based on Exploratory Five-Year Analyses of Phase 3 KEYNOTE-671 Trial, Eight-Year Analyses of Phase 3 KEYNOTE-024 and KEYNOTE-042 Trials, and 10-Year Analyses of Phase 1b KEYNOTE-001 and Phase 2/3 KEYNOTE-010 Trials
	KEYTRUDA Plus Lenvima Demonstrated Durable Five-Year Survival Benefit Versus Chemotherapy for Patients With Advanced Endometrial Carcinoma Following One Prior Platinum-Based Regimen; Based on Results From Phase 3 KEYNOTE-775 Trial
	WELIREG Plus Lenvima Met Primary Endpoint of Progression-Free Survival in Certain Previously Treated Patients With Advanced RCC; Based on Results From Phase 3 LITESPARK-011 Trial
	KEYTRUDA Plus WELIREG Met Primary Endpoint of Disease-Free Survival in Certain Patients With Clear Cell RCC Following Nephrectomy; Based on Results From Phase 3 LITESPARK-022 Trial
	I-DXd Demonstrated Clinically Meaningful Response Rates in Patients With Extensive-Stage Small Cell Lung Cancer in IDEATE-LUNG01 Phase 2 Trial
	HERTHENA-Breast04 Phase 3 Trial of Patritumab Deruxtecan (HER3-DXd) Initiated in Patients With Metastatic Hormone Receptor-Positive, HER2-Negative Breast Cancer Previously Treated With Endocrine Therapy
Vaccines and Infectious Diseases	CAPVAXIVE Demonstrated Positive Immune Responses in Children and Adolescents at Increased Risk of Pneumococcal Disease; Based on Results From Phase 3 STRIDE-13 Trial
	The Company Announced New Data From Phase 3 Trials Evaluating the Investigational, Once-Daily, Oral, Two-Drug Regimen of Doravirine/Islatravir in Adults With Suppressed HIV-1 Infection; Based on Results From Phase 3 MK-8591A-051 and MK-8591A-052 Trials
	Systematic Review of 15 Studies Focused on Epidemiology and Antimicrobial Resistance of Pneumococcal Serotypes Covered by CAPVAXIVE in U.S. Adults
Cardiovascular	FDA Approved Updated Indication for WINREVAIR in Adults With PAH Based on Phase 3 ZENITH Study
	WINREVAIR Reduced the Risk of Clinical Worsening Events by 76% Compared to Placebo in Patients Recently Diagnosed With PAH on Background Therapy in Phase 3 HYPERION Trial
	Oral PCSK9 Inhibitor Enlicitide Decanoate Met All Primary and Key Secondary Endpoints in Adults With Hypercholesterolemia in Pivotal Phase 3 CORALreef Lipids Study
Immunology	The Company Expanded Tulisokibart Clinical Development Program With Initiation of Phase 2b Trials in Three Additional Immune-Mediated Inflammatory Diseases

*References to the Company's name in the above news release titles have been modified for the purpose of this announcement.

Manufacturing and R&D Investment

The Company continued to make long-term investments in its U.S. manufacturing and R&D capabilities and broke ground on a new \$3 billion Center of Excellence for Pharmaceutical Manufacturing at its Elkton, Virginia site. The 400,000-square-foot facility will include both active pharmaceutical ingredient and drug product investment to support small molecule manufacturing and testing, creating more than 500 full-time jobs. This investment is part of the Company's commitment to dedicate more than \$70 billion beginning in 2025 to expand domestic manufacturing and R&D — not including any future business development in R&D — to drive its long-term growth and strengthen the U.S. as a global leader in biopharmaceutical innovation.

Upcoming Investor Event

The Company also plans to present new data from its innovative cardiovascular pipeline and portfolio at the American Heart Association (AHA) Scientific Sessions 2025 from Nov. 7-10. The Company will host an Investor Event to coincide with the AHA Scientific Sessions 2025 on Sunday, Nov. 9 at 6 p.m. CT. The event will take place in New Orleans and will be accessible via live audio webcast at this [weblink](#).

Sustainability Highlights

The Company's 2024/2025 Purpose for Progress Impact Report provided a comprehensive view of how it is pursuing innovative science for the health of people and animals and ensuring its efforts drive significant and sustainable value. The report noted that the Company's medicines and vaccines reached more than 450 million people around the world in 2024.

Full-Year 2025 Financial Outlook

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

	Full Year 2025	
	Updated	Prior
Sales*	\$64.5 billion to \$65.0 billion	\$64.3 billion to \$65.3 billion
Non-GAAP Gross margin ²	Approximately 82%	Approximately 82%
Non-GAAP Operating expenses ^{2(a)}	\$25.9 billion to \$26.4 billion	\$25.6 billion to \$26.4 billion
Non-GAAP Other (income) expenses, net ²	\$400 million to \$500 million expense	\$300 million to \$400 million expense
Non-GAAP Effective tax rate ²	14.0% to 15.0%	15.0% to 16.0%
Non-GAAP EPS ^{2(b)(c)}	\$8.93 to \$8.98	\$8.87 to \$8.97
Share count (assuming dilution)	Approximately 2.51 billion	Approximately 2.51 billion

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

^(a)Includes one-time R&D charges of \$300 million for a milestone payment to LaNova associated with the technology transfer for MK-2010 and \$200 million for an upfront payment for a license agreement with Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma). Outlook does not assume any additional significant potential business development transactions.

^(b)Includes one-time charges totaling \$0.16 per share associated with the payment for the LaNova technology transfer for MK-2010 and the upfront payment to Hengrui Pharma.

^(c)Updated full-year 2025 outlook reflects a benefit of approximately \$0.09 per share resulting from an amendment to the collaboration agreement with AstraZeneca related to Koselugo, and an estimated negative impact of \$0.04 per share related to the acquisition of Verona Pharma.

The Company 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 income 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.

The Company now expects full-year 2025 sales to be between \$64.5 billion and \$65.0 billion, including a negative impact of foreign exchange of approximately 0.5% at mid-October 2025 exchange rates.

The Company now expects its full-year non-GAAP effective income tax rate to be between 14.0% and 15.0%.

The Company now expects its full-year non-GAAP EPS to be between \$8.93 and \$8.98, including a negative impact of foreign exchange of approximately \$0.15 per share. This revised

non-GAAP EPS outlook reflects several items not previously included, such as a benefit from an amended collaboration agreement with AstraZeneca related to Koselugo, and operational improvements, including a more favorable estimated tax rate and lower estimated costs related to the impact of tariffs, partially offset by an estimated negative impact related to the acquisition of Verona Pharma and an incremental negative impact from foreign exchange. The midpoint of this revised non-GAAP EPS range reflects a net improvement of \$0.04 per share compared to the midpoint of the Company's prior outlook.

As previously communicated, the revised estimated full-year 2025 non-GAAP EPS range reflects the impacts of the one-time charges in connection with a license agreement with Hengrui Pharma and the completion of the technology transfer with LaNova for MK-2010, which impact EPS by approximately \$0.16 in the aggregate. In 2024, non-GAAP EPS of \$7.65 was negatively impacted by a net charge of \$1.28 per share related to certain asset acquisitions, licensing agreements and collaborations.

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

Earnings Conference Call

Investors, journalists and the general public may access a live audio webcast of the call on Thursday, Oct. 30, at 9 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 on the Company's website.

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 Our Company

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

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, 2024 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 HCl*)

JANUVIA (*sitagliptin*)

KEYTRUDA (*pembrolizumab*)

KEYTRUDA QLEX (*pembrolizumab and berahyaluronidase alfa-pmph*)

Koselugo (*selumetinib*)

LAGEVRIO (*molnupiravir*)

Lenvima (*lenvatinib*)

Lynparza (*olaparib*)

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

OHTUVAYRE (*ensifentrine*)

PREVYMIS (*letermovir*)

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

SIMPONI (*golimumab*)

VARIVAX (*Varicella Virus Vaccine Live*)

VAXNEUVANCE (*Pneumococcal 15-valent Conjugate Vaccine*)

WELIREG (*belzutifan*)

WINREVAIR (*sotatercept-csrk*)

Animal Health

BRAVECTO (*fluralaner*)

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