MERCK

News Release

## Merck Announces Fourth-Quarter and Full-Year 2024 Financial Results

- Fourth-Quarter Worldwide Sales Were $15.6 Billion, an Increase of 7% From Fourth Quarter 2023; Excluding the Impact of Foreign Exchange, Growth Was 9%
- Fourth-Quarter GAAP EPS Was $1.48; Non-GAAP EPS Was $1.72; GAAP and Non-GAAP EPS Include a Charge of $0.23 per Share Related to Certain Business Development Transactions
- Full-Year Worldwide Sales Were $64.2 Billion, an Increase of 7% From Full Year 2023; Excluding the Impact of Foreign Exchange, Growth Was 10%
    - KEYTRUDA Sales Grew 18% to $29.5 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 22%
    - WINREVAIR Sales Were $419 Million
    - Animal Health Sales Grew 4% to $5.9 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 8%
    - GARDASIL/GARDASIL 9 Sales Declined 3% to $8.6 Billion; Excluding the Impact of Foreign Exchange, Sales Declined 2%
- Full-Year 2024 GAAP EPS Was $6.74; Non-GAAP EPS Was $7.65; GAAP and Non-GAAP EPS Include a Net Charge of $1.28 per Share Related to Certain Business Development Transactions
- In the Fourth Quarter:
    - Announced Positive Topline Results From Pivotal Phase 3 Trial of Subcutaneous Pembrolizumab With Berahyaluronidase Alfa
    - Received FDA Acceptance of Biologics License Application for Clesrovimab, an Investigational Long-Acting Monoclonal Antibody Designed to Protect Infants From RSV Disease During Their First RSV Season
    - Augmented Diverse Pipeline Through Exclusive Global Licenses With LaNova for MK-2010, an Investigational Anti-PD-1/VEGF Bispecific Antibody, and With Hansoh for MK-4082, an Investigational Oral GLP-1 Receptor Agonist
- Received Approval of GARDASIL for Males in China, in January 2025
- Full-Year 2025 Financial Outlook
    - Anticipates Worldwide Sales To Be Between $64.1 Billion and $65.6 Billion
    - Expects Non-GAAP EPS To Be Between $8.88 and $9.03; Outlook Reflects a One-Time Charge of Approximately $0.09 per Share Related to an Anticipated Milestone Payment to LaNova

RAHWAY, N.J., Feb. 4, 2025 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the fourth quarter of 2024.

"We delivered strong growth in 2024, reflecting demand for our innovative portfolio, including for KEYTRUDA, which continues to benefit more patients with cancer globally, the successful launch of WINREVAIR and strong performance of our Animal Health business," said Robert M. Davis, chairman and chief executive officer, Merck. "We're continuing to progress our pipeline, advance key clinical programs and augment our pipeline through promising business development. Our business remains well positioned thanks to the dedication of our talented global team, and I am more confident than ever in our long-term growth potential."

## Financial Summary

| $ in millions, except EPS amounts | Fourth Quarter | | | | Year Ended | | | |
|---|---|---|---|---|---|---|---|---|
| | 2024 | 2023 | Change | Change Ex-Exchange | Dec. 31, 2024 | Dec. 31, 2023 | Change | Change Ex-Exchange |
| Sales | $15,624 | $14,630 | 7% | 9% | $64,168 | $60,115 | 7% | 10% |
| GAAP net income (loss)[1] | 3,743 | (1,226) | N/M | N/M | 17,117 | 365 | N/M | N/M |
| Non-GAAP net income that excludes certain items[1,2*] | 4,372 | 66 | N/M | N/M | 19,444 | 3,837 | N/M | N/M |
| GAAP EPS | 1.48 | (0.48) | N/M | N/M | 6.74 | 0.14 | N/M | N/M |
| Non-GAAP EPS that excludes certain items[2*] | 1.72 | 0.03 | N/M | N/M | 7.65 | 1.51 | N/M | N/M |

*Refer to table on page 9.
N/M - not meaningful

Generally Accepted Accounting Principles (GAAP) earnings per share (EPS) assuming dilution was $1.48 for the fourth quarter and $6.74 for the full year of 2024. Non-GAAP EPS was $1.72 for the fourth quarter and $7.65 for the full year of 2024. GAAP and non-GAAP EPS in the fourth quarter of 2024 include a charge of $0.23 per share related to the execution of licensing agreements with LaNova Medicines Ltd. (LaNova) and Hansoh Pharma (Hansoh). GAAP loss per share and non-GAAP EPS in the fourth quarter of 2023 include a charge of $1.69 per share related to a collaboration with Daiichi Sankyo. GAAP and non-GAAP EPS for the full years of 2024 and 2023 include charges of $1.28 and $6.21 per share, respectively, related to certain collaborations, licensing agreements and asset acquisitions.

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

[1] Net income (loss) 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.

GAAP EPS in the fourth quarter and full year of 2024 also exclude a benefit due to a reduction in reserves for unrecognized income tax benefits resulting from the expiration of the statute of limitations for assessments related to certain federal tax return years. Non-GAAP EPS for the full year of 2023 also excludes a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation.

**Fourth-Quarter Sales Performance**

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

| | Fourth Quarter | | | | |
|---|---|---|---|---|---|
| $ in millions | 2024 | 2023 | Change | Change Ex-Exchange | Commentary |
| Total Sales | $15,624 | $14,630 | 7% | 9% | The negative impact of foreign exchange was primarily due to devaluation of Argentine peso, which was largely offset by inflation-related price increases, consistent with practice in that market. |
| Pharmaceutical | 14,042 | 13,141 | 7% | 8% | Increase driven by growth in oncology and cardiovascular, partially offset by declines in diabetes, vaccines, immunology and virology. |
| KEYTRUDA | 7,836 | 6,608 | 19% | 21% | Growth driven by continued strong global demand from metastatic indications, including increased uptake in bladder and endometrial cancers, as well as increased global uptake in earlier-stage indications, including triple-negative breast cancer and non-small cell lung cancer (NSCLC). The negative impact of foreign exchange was primarily due to devaluation of Argentine peso, which was largely offset by inflation-related price increases. |
| GARDASIL/GARDASIL 9 | 1,550 | 1,871 | -17% | -18% | Decline primarily due to lower demand in China, partially offset by higher demand in most international regions, particularly in Japan. |
| PROQUAD, M-M-R II and VARIVAX | 594 | 545 | 9% | 9% | Growth primarily due to higher pricing in the U.S. and higher tenders in certain international markets, partially offset by lower demand in the U.S. |
| JANUVIA/JANUMET | 487 | 787 | -38% | -36% | Decline primarily due to lower pricing in the U.S., as well as ongoing generic competition in many international markets and supply constraints in China. |
| BRIDION | 449 | 429 | 5% | 5% | Growth primarily due to higher demand in the U.S., partially offset by generic competition in certain international markets, particularly in Japan and Europe. |
| Lynparza* | 365 | 315 | 16% | 18% | Growth primarily due to higher global demand. |
| Lenvima* | 255 | 226 | 13% | 14% | Growth primarily due to timing of shipments in certain international markets. |
| PREVYMIS | 215 | 175 | 23% | 23% | Growth primarily due to higher demand in most markets, particularly in the U.S. |
| WINREVAIR | 200 | - | - | - | Represents continued uptake since second-quarter launch in the U.S. |

| | Fourth Quarter | | | | |
|---|---|---|---|---|---|
| $ in millions | **2024** | **2023** | **Change** | **Change Ex-Exchange** | **Commentary** |
| VAXNEUVANCE | 161 | 176 | -9% | -9% | Decline primarily driven by lower demand in the U.S. due to competition, partially offset by continued uptake from launches in Europe and the Asia Pacific region. |
| WELIREG | 160 | 72 | 122% | 123% | Growth primarily driven by higher demand in the U.S., largely attributable to ongoing uptake of a new indication. |
| SIMPONI | - | 171 | N/M | N/M | Marketing rights in former Merck territories reverted to Johnson & Johnson on Oct. 1, 2024. |
| Animal Health | 1,397 | 1,278 | 9% | 13% | Growth primarily driven by higher pricing for both Livestock and Companion Animal product portfolios, as well as sales related to July 2024 acquisition of Elanco aqua business and higher demand for Livestock products. Approximately 3 percentage points of the negative impact of foreign exchange were due to devaluation of Argentine peso, which were largely offset by inflation-related price increases. |
| Livestock | 889 | 808 | 10% | 14% | Growth primarily driven by higher demand for poultry products, sales related to acquisition of Elanco aqua business, as well as higher pricing across the portfolio. |
| Companion Animal | 508 | 470 | 8% | 10% | Growth primarily driven by higher pricing across the product portfolio. Sales of BRAVECTO were $209 million and $197 million in current and prior year quarters, respectively, which represented growth of 6%, or 10% excluding impact of foreign exchange. |
| Other Revenues** | 185 | 211 | -13% | 3% | Decline primarily due to impact of revenue-hedging activities and lower revenues from third-party manufacturing arrangements, partially offset by payments received for out-licensing arrangements and higher 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.

N/M – not meaningful

**Full-Year Sales Performance**

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

| | Year Ended | | | |
|---|---|---|---|---|
| $ in millions | Dec. 31, 2024 | Dec. 31, 2023 | Change | Change Ex-Exchange |
| Total Sales | $64,168 | $60,115 | 7% | 10% |
| Pharmaceutical | 57,400 | 53,583 | 7% | 10% |
| KEYTRUDA | 29,482 | 25,011 | 18% | 22% |
| GARDASIL/GARDASIL 9 | 8,583 | 8,886 | -3% | -2% |
| PROQUAD, M-M-R II and VARIVAX | 2,485 | 2,368 | 5% | 5% |
| JANUVIA/JANUMET | 2,268 | 3,366 | -33% | -29% |
| BRIDION | 1,764 | 1,842 | -4% | -3% |
| Lynparza* | 1,311 | 1,199 | 9% | 11% |
| Lenvima* | 1,010 | 960 | 5% | 6% |
| LAGEVRIO | 964 | 1,428 | -33% | -28% |
| VAXNEUVANCE | 808 | 665 | 22% | 23% |
| PREVYMIS | 785 | 605 | 30% | 33% |
| ROTATEQ | 711 | 769 | -8% | -7% |
| SIMPONI** | 543 | 710 | -24% | -23% |
| WELIREG | 509 | 218 | 133% | 133% |
| WINREVAIR | 419 | - | - | - |
| Animal Health | 5,877 | 5,625 | 4% | 8% |
| Livestock | 3,462 | 3,337 | 4% | 9% |
| Companion Animal | 2,415 | 2,288 | 6% | 7% |
| Other Revenues*** | 891 | 907 | -2% | 4% |

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

**Marketing rights in former Merck territories reverted to Johnson & Johnson on Oct. 1, 2024.

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

Full-year 2024 pharmaceutical sales grew 7% to $57.4 billion. Excluding the unfavorable impact of foreign exchange, pharmaceutical sales grew 10%. Approximately 2 percentage points of the negative impact of foreign exchange were due to devaluation of the Argentine peso, which were largely offset by inflation-related price increases, consistent with practice in that market. Pharmaceutical sales growth was primarily driven by higher sales in oncology, particularly KEYTRUDA and WELIREG, as well as increased alliance revenue from Reblozyl and Lynparza. Higher sales in the cardiovascular franchise, reflecting the successful launch of WINREVAIR, as well as higher sales of certain hospital acute care products, particularly PREVYMIS, also drove revenue growth in 2024. Pharmaceutical sales growth in 2024 was partially offset by lower sales of JANUVIA and JANUMET, primarily reflecting lower pricing in the U.S. and generic competition in many international markets, lower sales of the COVID-19 medication LAGEVRIO, lower sales of GARDASIL/GARDASIL 9 and lower sales of SIMPONI and REMICADE, reflecting the transfer of marketing rights in former Merck territories back to Johnson & Johnson.

Full-year 2024 Animal Health sales grew 4% to $5.9 billion. Excluding the unfavorable impact of foreign exchange, Animal Health sales grew 8%. Approximately 2 percentage points of the negative impact of foreign exchange were due to devaluation of the Argentine peso, which were largely offset by inflation-related price increases, consistent with practice in that

market. Full-year sales growth was primarily driven by higher pricing across both the Companion Animal and Livestock product portfolios, and higher demand for poultry and swine products, as well as sales related to the acquisition of the Elanco aqua business. Sales of BRAVECTO were $1.1 billion in 2024, which represented growth of 6%, or 8% excluding the impact of foreign exchange.

## Fourth-Quarter and Full-Year 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] |
|---|---|---|---|---|---|
| **Fourth Quarter 2024** | | | | | |
| Cost of sales | $3,828 | $701 | $121 | $- | $3,006 |
| Selling, general and administrative | 2,864 | 29 | 16 | - | 2,819 |
| Research and development | 4,585 | 12 | (1) | - | 4,574 |
| Restructuring costs | 51 | - | 51 | - | - |
| Other (income) expense, net | 126 | (31) | - | 152 | 5 |
| | | | | | |
| **Fourth Quarter 2023** | | | | | |
| Cost of sales | $3,911 | $454 | $117 | $- | $3,340 |
| Selling, general and administrative | 2,804 | 24 | 29 | - | 2,751 |
| Research and development | 9,628 | 790 | - | - | 8,838 |
| Restructuring costs | 255 | - | 255 | - | - |
| Other (income) expense, net | 78 | (35) | - | (61) | 174 |

| $ in millions | GAAP | Acquisition- and Divestiture-Related Costs[3] | Restructuring Costs | (Income) Loss From Investments in Equity Securities | Certain Other Items | Non-GAAP[2] |
|---|---|---|---|---|---|---|
| **Year Ended December 31, 2024** | | | | | | |
| Cost of sales | $15,193 | $2,409 | $495 | $- | $- | $12,289 |
| Selling, general and administrative | 10,816 | 117 | 83 | - | - | 10,616 |
| Research and development | 17,938 | 72 | 1 | - | - | 17,865 |
| Restructuring costs | 309 | - | 309 | - | - | - |
| Other (income) expense, net | (24) | (79) | - | 45 | - | 10 |
| | | | | | | |
| **Year Ended December 31, 2023** | | | | | | |
| Cost of sales | $16,126 | $2,018 | $211 | $- | $- | $13,897 |
| Selling, general and administrative | 10,504 | 86 | 122 | - | - | 10,296 |
| Research and development | 30,531 | 819 | 1 | - | - | 29,711 |
| Restructuring costs | 599 | - | 599 | - | - | - |
| Other (income) expense, net | 466 | (47) | - | (279) | 573 | 219 |

[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.

**GAAP Expense, EPS and Related Information**

Gross margin was 75.5% for the fourth quarter of 2024 compared with 73.3% for the fourth quarter of 2023. The increase was primarily due to the favorable effects of product mix (including lower royalty rates related to KEYTRUDA and GARDASIL/GARDASIL 9) and foreign exchange, partially offset by higher manufacturing-related costs (including inventory write-offs) and higher amortization of intangible assets. Gross margin was 76.3% for the full year of 2024 compared with 73.2% for the full year of 2023. The increase was primarily due to the favorable effects of product mix (including lower royalty rates related to KEYTRUDA and GARDASIL/GARDASIL 9) and foreign exchange, partially offset by higher amortization of intangible assets, as well as higher restructuring costs (primarily reflecting asset impairment charges) and higher manufacturing-related costs (including inventory write-offs).

Selling, general and administrative (SG&A) expenses were $2.9 billion in the fourth quarter of 2024, an increase of 2% compared with the fourth quarter of 2023. The increase was primarily due to higher promotional and selling costs, partially offset by the favorable impact of foreign exchange and lower restructuring costs. Full-year 2024 SG&A expenses were $10.8 billion, an increase of 3% compared with full-year 2023. The increase was primarily due to higher administrative, promotional, selling and acquisition-related costs, partially offset by the favorable impact of foreign exchange and lower restructuring costs.

Research and development (R&D) expenses were $4.6 billion in the fourth quarter of 2024, a decrease of 52% compared with the fourth quarter of 2023. R&D expenses were $17.9 billion for the full year of 2024, a decrease of 41% compared with the full year of 2023. The declines in both the fourth quarter and full year of 2024 were primarily due to lower charges for business development activity, lower intangible asset impairment charges, and the favorable impact of foreign exchange, partially offset by increased compensation and benefit costs and higher clinical development spending.

Other (income) expense, net, was $126 million of expense in the fourth quarter of 2024 compared with $78 million of expense in the fourth quarter of 2023. The unfavorability was primarily due to net losses from investments in equity securities compared with net income from investments in equity securities in the prior year quarter, partially offset by lower foreign exchange losses and lower net interest expense. Other (income) expense, net, was $24 million of income in the full year of 2024 compared with $466 million of expense in the full year of 2023, primarily due to a $572.5 million charge in 2023 related to settlements with certain plaintiffs in the Zetia antitrust litigation. The favorability was also due to $170 million of income related to the expansion of an existing development and commercialization agreement with Daiichi Sankyo, as well as lower foreign exchange losses in 2024. Other (income) expense, net, in the full year of 2024 was unfavorably affected by lower net income from investments in equity securities and higher net interest expense compared with 2023.

The effective tax rates of 10.2% and 14.1% for the fourth quarter and full year of 2024, respectively, include a 6.2 percentage point favorable impact and a 2.6 percentage point favorable impact, respectively, due to a reduction in reserves for unrecognized income tax

benefits, resulting from the expiration of the statute of limitations for assessments related to certain federal tax return years.

GAAP EPS was $1.48 for the fourth quarter of 2024 compared with a loss per share of $0.48 for the fourth quarter of 2023, primarily driven by lower charges for business development transactions, operational strength in the business, lower intangible asset impairment charges, and a benefit from the expiration of the statute of limitations for assessments related to the 2020 federal tax return year. GAAP EPS was $6.74 for the full year of 2024 compared with EPS of $0.14 for the full year of 2023. The increase was primarily driven by lower charges for business development transactions, operational strength in the business, lower intangible asset impairment charges, a benefit from the expiration of the statute of limitations for the 2020 and 2019 federal tax return years, and a charge in the prior year for settlements with certain plaintiffs in the Zetia antitrust litigation, partially offset by the unfavorable effect of foreign exchange.

**Non-GAAP Expense, EPS and Related Information**

Non-GAAP gross margin was 80.8% for the fourth quarter of 2024 compared with 77.2% for the fourth quarter of 2023. Non-GAAP gross margin was 80.8% for the full year of 2024 compared with 76.9% for the full year of 2023. The non-GAAP gross margin improvements in both the fourth quarter and full year of 2024 were primarily due to the favorable effects of product mix (including lower royalty rates related to KEYTRUDA and GARDASIL/GARDASIL 9) and foreign exchange, partially offset by higher manufacturing-related costs (including inventory write-offs).

Non-GAAP SG&A expenses were $2.8 billion in the fourth quarter of 2024, an increase of 2% compared with the fourth quarter of 2023. Non-GAAP SG&A expenses were $10.6 billion for the full year of 2024, an increase of 3% compared with the full year of 2023. The increases were primarily due to higher promotional and selling costs and, for the full year, higher administrative costs, partially offset by the favorable impact of foreign exchange.

Non-GAAP R&D expenses were $4.6 billion in the fourth quarter of 2024, a decrease of 48% compared with the fourth quarter of 2023. Non-GAAP R&D expenses were $17.9 billion for the full year of 2024, a decrease of 40% compared with the full year of 2023. The declines in both the fourth quarter and full year of 2024 were primarily due to lower charges for business development activity and the favorable impact of foreign exchange, partially offset by increased compensation and benefit costs and higher clinical development spending.

Non-GAAP other (income) expense, net, was $5 million of expense in the fourth quarter of 2024 compared with $174 million of expense in the fourth quarter of 2023. The favorability was primarily due to lower foreign exchange losses and lower net interest expense. Non-GAAP other (income) expense, net, was $10 million of expense in the full year of 2024 compared with $219 million of expense in the full year of 2023. The favorability was primarily due to $170 million of income related to the expansion of an existing development and commercialization agreement with Daiichi Sankyo, as well as lower foreign exchange losses in 2024, partially offset by higher net interest expense.

The non-GAAP effective tax rate was 16.2% for the fourth quarter and 16.8% for the full year of 2024.

Non-GAAP EPS was $1.72 for the fourth quarter of 2024 compared with $0.03 for the fourth quarter of 2023. Non-GAAP EPS was $7.65 for the full year of 2024 compared with EPS of $1.51 for the full year of 2023. The increase in both periods was primarily driven by lower charges for business development transactions and operational strength in the business. The unfavorable effect of foreign exchange partially offset the increase in the full year.

A reconciliation of GAAP to non-GAAP net income (loss) and earnings (loss) per share is provided in the table that follows.

| | Fourth Quarter | | Year Ended | |
|---|---|---|---|---|
| $ in millions, except EPS amounts | **2024** | **2023** | **Dec. 31, 2024** | **Dec. 31, 2023** |
| **EPS** | | | | |
| GAAP EPS | $1.48 | $(0.48) | $6.74 | $0.14 |
| Difference | 0.24 | 0.51 | 0.91 | 1.37 |
| Non-GAAP EPS that excludes items listed below[2] | $1.72 | $0.03 | $7.65 | $1.51 |
| | | | | |
| **Net Income (Loss)** | | | | |
| GAAP net income (loss)[1] | $3,743 | $(1,226) | $17,117 | $365 |
| Difference | 629 | 1,292 | 2,327 | 3,472 |
| Non-GAAP net income that excludes items listed below[1,2] | $4,372 | $66 | $19,444 | $3,837 |
| | | | | |
| **Excluded Items:** | | | | |
| Acquisition- and divestiture-related costs[3] | $711 | $1,233 | $2,519 | $2,876 |
| Restructuring costs | 187 | 401 | 888 | 933 |
| Loss (income) from investments in equity securities | 152 | (61) | 45 | (279) |
| Charge for Zetia antitrust litigation settlements | - | - | - | 573 |
| Decrease to net income/increase to net loss before taxes | 1,050 | 1,573 | 3,452 | 4,103 |
| Estimated income tax (benefit) expense[4] | (421) | (281) | (1,125) | (631) |
| Decrease to net income/increase to net loss | $629 | $1,292 | $2,327 | $3,472 |

## Pipeline and Portfolio Highlights

Merck made important advancements in its broad, diverse pipeline, meeting significant regulatory and clinical milestones throughout the fourth quarter.

In oncology, Merck announced positive topline results from the pivotal Phase 3 MK-3475A-D77 trial evaluating the noninferiority of subcutaneous pembrolizumab and berahyaluronidase alfa, in combination with chemotherapy, versus intravenous (IV) KEYTRUDA administered with chemotherapy, for the first-line treatment of adult patients with metastatic NSCLC. Subcutaneous pembrolizumab and berahyaluronidase alfa has the potential to improve

[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, as well as a $260 million benefit and a $519 million benefit in the fourth quarter and full year of 2024, respectively, due to reductions in reserves for unrecognized income tax benefits resulting from the expiration of the statute of limitations for assessments related to certain federal tax return years. The benefit recognized in the fourth quarter of 2024 relates to the 2020 federal tax return year and the benefit for the full year of 2024 relates to both the 2020 and 2019 federal tax return years.

the patient experience and increase access for patients and health care providers compared to IV administration.

Merck presented new data across multiple hematologic malignancies at the American Society of Hematology Annual Meeting and Exposition in December 2024, including promising Phase 2 data for its investigational antibody-drug conjugate zilovertamab vedotin for the treatment of patients with previously untreated diffuse large B-cell lymphoma. With more than 20 abstracts presented, the data showcased Merck's continued progress in advancing clinical research for its expanding and diverse hematology pipeline.

Merck also achieved several key regulatory milestones in the U.S., Europe, Japan and China. Highlights include the U.S. Food and Drug Administration (FDA) granting Breakthrough Therapy designation to sacituzumab tirumotecan (sac-TMT) for the treatment of certain patients with previously treated advanced or metastatic nonsquamous NSCLC with epidermal growth factor receptor (EGFR) mutations. Additionally, Merck received new approvals for KEYTRUDA-based regimens in Japan and China, as well as for WELIREG and Lynparza in China.

In vaccines and infectious diseases, the FDA accepted the Biologics License Application (BLA) for clesrovimab, an investigational prophylactic long-acting monoclonal antibody designed to protect infants from respiratory syncytial virus (RSV) disease during their first RSV season and set a Prescription Drug User Fee Act (PDUFA) date of June 10, 2025. This regulatory milestone marks important progress toward having clesrovimab available in time for the 2025-26 RSV season. The filing was based on results from the pivotal Phase 2b/3 study of clesrovimab in infants for the prevention of RSV that was presented at ID Week 2024. In addition, Merck announced topline results from two pivotal Phase 3 trials of the investigational, once-daily, oral, two-drug, single-tablet regimen of doravirine/islatravir (DOR/ISL) in adults with virologically suppressed HIV-1 infection, in line with Merck's commitment to help address the needs of people living with HIV.

In January 2025, Merck also received expanded approval in China for GARDASIL. It is now the first HPV vaccine approved in China for the prevention of certain HPV-related cancers and diseases in males 9-26 years of age. In addition, the European Union's (EU) Committee for Medicinal Products for Human Use (CHMP) recommended the approval of CAPVAXIVE for pneumococcal vaccination in adults, with a final decision for EU approval expected in the second quarter of 2025.

In cardiovascular disease, Merck announced positive topline results from the Phase 3 ZENITH study, evaluating WINREVAIR in adults with pulmonary arterial hypertension (PAH) with World Health Organization (WHO) Group 1 functional class (FC) III or IV at high risk of mortality. Based on the positive results of an interim analysis, an independent data monitoring committee recommended that the study be stopped early due to overwhelming efficacy. In addition, in January 2025, Merck announced the Phase 3 HYPERION study evaluating WINREVAIR in newly diagnosed adults with PAH with FC II or III at intermediate or high risk of disease progression was also stopped early based on the positive results from the interim

analysis of the ZENITH trial and a review of the totality of data from the WINREVAIR clinical program to date. All participants in both the ZENITH and HYPERION studies will be offered the opportunity to receive WINREVAIR as part of the open-label, long-term extension study, SOTERIA.

Merck continued to execute on its business development strategy. The company announced the closing of an exclusive global license for MK-2010, a novel investigational PD-1/VEGF bispecific antibody from LaNova. Merck also entered into an exclusive global license agreement with Hansoh to evaluate MK-4082, an investigational preclinical oral small molecule glucagon-like peptide (GLP-1) receptor agonist.

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

| | | |
|---|---|---|
| **Oncology** | FDA Granted Breakthrough Therapy Designation to sac-TMT for the Treatment of Certain Patients With Previously Treated Advanced or Metastatic Nonsquamous NSCLC With EGFR Mutations | (Read Announcement) |
| | FDA Granted Priority Review to Merck's Application for WELIREG for the Treatment of Patients With Advanced Pheochromocytoma and Paraganglioma | (Read Announcement) |
| | Merck Received Positive EU CHMP Opinion for WELIREG as Treatment for Adult Patients With Certain Types of Von Hippel-Lindau (VHL) Disease-Associated Tumors and for Certain Previously Treated Adult Patients With Advanced RCC, Based on Results From Phase 2 LITESPARK-004 and Phase 3 LITESPARK-005 Trials | (Read Announcement) |
| | Merck Received Positive EU CHMP Opinion for KEYTRUDA Plus Chemotherapy as First-Line Treatment for Adult Patients With Unresectable Non-Epithelioid Malignant Pleural Mesothelioma, Based on Results From Phase 2/3 IND.227/KEYNOTE-483 Trial | (Read Announcement) |
| | KEYTRUDA Approved in China in Combination With Chemotherapy as Neoadjuvant Treatment, Then Continued as Monotherapy After Surgery as Adjuvant Treatment for Patients With Resectable Stage II, IIIA or IIIB NSCLC, Based on Results From Phase 3 KEYNOTE-671 Trial | (Read Announcement) |
| | WELIREG Approved in China for Treatment of Adult Patients With Certain Types of VHL Disease-Associated Tumors, Based on Results From Phase 2 LITESPARK-004 Trial | (Read Announcement) |
| | Merck Announced Phase 3 MK-3475A-D77 Trial of Subcutaneous Pembrolizumab With Berahyaluronidase Alfa Met Primary Endpoints | (Read Announcement) |
| | Merck Announced Phase 3 KEYLYNK-001 Trial Met Primary Endpoint of Progression-Free Survival in Patients With Advanced Epithelial Ovarian Cancer | (Read Announcement) |
| | Lynparza Demonstrated Clinically Meaningful Prolonged Survival Benefit in Early Breast Cancer, Based on Results From Phase 3 OlympiA Trial | (Read Announcement) |
| | Investigational Zilovertamab Vedotin in Combination With R-CHP Demonstrated Complete Response Rate of 100% at 1.75 MG/KG Dose in Previously Untreated Patients With Diffuse Large B-Cell Lymphoma, Based on Results From Phase 2 WaveLINE-007 Trial | (Read Announcement) |

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|---|---|---|
| **Vaccines** | Merck Announced FDA Acceptance of BLA for Clesrovimab (MK-1654), an Investigational Long-Acting Monoclonal Antibody Designed to Protect Infants From RSV Disease During Their First RSV Season; FDA Set PDUFA Date of June 10, 2025 | (Read Announcement) |
| | Merck Received Expanded Approval of GARDASIL for Males in China | (Read Announcement) |
| | Merck Received Positive EU CHMP Opinion for CAPVAXIVE for Pneumococcal Vaccination in Adults | (Read Announcement) |
| | Merck Presented New Data From GARDASIL 9 Studies Reinforcing Importance of Gender-Neutral HPV Vaccination in Adults Up to Age 45 at International Papillomavirus Conference 2024 | (Read Announcement) |
| **Cardiovascular** | Merck Announced Pivotal Phase 3 ZENITH Trial Evaluating WINREVAIR Met Primary Endpoint at Interim Analysis | (Read Announcement) |
| | Merck Announced Decision to Stop Phase 3 HYPERION Trial Evaluating WINREVAIR Early and Move to Final Analysis | (Read Announcement) |
| **Infectious Diseases** | Merck Announced Topline Results From Pivotal Phase 3 Trials Evaluating Investigational, Once-Daily, Oral, Two-Drug, Single-Tablet Regimen of Doravirine/Islatravir (DOR/ISL) for the Treatment of Adults With Virologically Suppressed HIV-1 Infection | (Read Announcement) |

## Full-Year 2025 Financial Outlook

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

| | **Full Year 2025** |
|---|---|
| Sales* | $64.1 billion to $65.6 billion |
| Non-GAAP Gross margin[2] | Approximately 82.5% |
| Non-GAAP Operating expenses[2]** | $25.4 billion to $26.4 billion |
| Non-GAAP Other (income) expense, net[2] | $300 million to $400 million expense |
| Non-GAAP Effective tax rate[2] | 16.0% to 17.0% |
| Non-GAAP EPS[2]*** | $8.88 to $9.03 |
| Share count (assuming dilution) | Approximately 2.53 billion |

*The company does not have any non-GAAP adjustments to sales.
**Includes $300 million for an anticipated milestone payment to LaNova associated with the technology transfer for MK-2010 expected to be completed in 2025. Outlook does not assume any additional significant potential business development transactions.
***Includes expected one-time charge of approximately $0.09 per share related to the $300 million milestone payment to LaNova upon completion of the technology transfer for MK-2010.

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 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.

Merck anticipates full-year 2025 sales to be between $64.1 billion and $65.6 billion, including a negative impact of foreign exchange of approximately 2% at mid-January 2025 exchange rates. This sales range reflects a decision to temporarily pause shipments of GARDASIL/GARDASIL 9 into China beginning February 2025 through at least mid-year.

Merck's full-year non-GAAP effective income tax rate is expected to be between 16.0% and 17.0%.

Merck expects full-year 2025 non-GAAP EPS to be between $8.88 and $9.03, including a negative impact of foreign exchange of approximately $0.35 per share. This range includes an expected one-time charge of $300 million, or approximately $0.09 per share, related to a milestone payment to LaNova, which will be recognized upon completion of the technology transfer for MK-2010. 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 earnings conference call on Tuesday, Feb. 4, 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 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 HCl)*
**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)*
**Reblozyl** *(luspatercept)*
**REMICADE** *(infliximab)*
**ROTATEQ** *(Rotavirus Vaccine, Live, Oral, Pentavalent)*
**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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