News Release

Merck Announces Fourth-Quarter and Full-Year 2023 Financial Results

- Fourth-Quarter and Full-Year Sales Reflect Sustained Growth Across Oncology and Vaccines
- Fourth-Quarter Worldwide Sales Were $14.6 Billion, an Increase of 6% From Fourth Quarter 2022; Excluding LAGEVRIO, Growth Was 11%; Excluding LAGEVRIO and the Impact of Foreign Exchange, Growth Was 13%
- Fourth-Quarter GAAP Loss per Share Was $0.48; Non-GAAP EPS Was $0.03; GAAP Loss per Share and Non-GAAP EPS Include a Charge of $1.69 per Share for a Collaboration With Daiichi Sankyo
- Full-Year Worldwide Sales Were $60.1 Billion, an Increase of 1% From Full-Year 2022; Excluding LAGEVRIO, Growth Was 9%; Excluding LAGEVRIO and the Impact of Foreign Exchange, Growth Was 12%
    - KEYTRUDA Sales Grew 19% to $25.0 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 21%
    - GARDASIL/GARDASIL 9 Sales Grew 29% to $8.9 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 33%
    - LAGEVRIO Sales Declined 75% to $1.4 Billion; Excluding the Impact of Foreign Exchange, Sales Declined 74%
- Full-Year 2023 GAAP EPS Was $0.14; Non-GAAP EPS Was $1.51; GAAP and Non-GAAP EPS Include Charges of $6.21 per Share for Certain Business Development Transactions
- Obtained FDA Priority Review of Biologics License Applications for V116, an Investigational Pneumococcal Conjugate Vaccine, as Well as Merck and Daiichi Sankyo's Patritumab Deruxtecan, in the Fourth Quarter
- Received Multiple FDA Approvals Across Oncology Portfolio in 2023
- Initiated More Than 20 Phase 3 Study Starts, Including the Progression of Eight Novel Assets Into Phase 3 in 2023
- Augmented Pipeline Through Acquisitions of Prometheus and Imago, and Collaboration Agreements With Daiichi Sankyo and Kelun-Biotech in 2023
- Full-Year 2024 Financial Outlook
    - Anticipates Worldwide Sales To Be Between $62.7 Billion and $64.2 Billion
    - Expects Non-GAAP EPS To Be Between $8.44 and $8.59

RAHWAY, N.J., Feb. 1, 2024 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the fourth quarter and full year of 2023.

"2023 was another very strong year for Merck. I am extremely pleased by the progress we've made to develop and deliver transformative therapies and vaccines that will help save

and improve lives around the world. We reached more than 500 million people with our medicines last year alone, over half of which were donations, including through our program to treat river blindness," said Robert M. Davis, chairman and chief executive officer, Merck. "We also made investments of approximately $30 billion in research and development in our ongoing effort to discover, develop and collaborate to propel the next generation of impactful innovations. As we move forward, I'm confident that our strong momentum will continue, underpinned by the unwavering dedication of our talented global team."

Financial Summary

$ in millions, except EPS amounts	Fourth Quarter				Year Ended			
	2023	2022	Change	Change Ex-Exchange	Dec. 31, 2023	Dec. 31, 2022	Change	Change Ex-Exchange
Sales	$14,630	$13,830	6%	7%	$60,115	$59,283	1%	4%
GAAP net (loss) income[1]	(1,226)	3,017	N/M	N/M	365	14,519	-97%	-95%
Non-GAAP net income that excludes certain items[1,2*]	66	4,129	-98%	N/M	3,837	19,005	-80%	-75%
GAAP EPS	(0.48)	1.18	N/M	N/M	0.14	5.71	-98%	-95%
Non-GAAP EPS that excludes certain items[2*]	0.03	1.62	-98%	N/M	1.51	7.48	-80%	-75%

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

Generally Accepted Accounting Principles (GAAP) loss/earnings per share (EPS) assuming dilution was a loss per share of $0.48 for the fourth quarter and EPS of $0.14 for the full year of 2023. Non-GAAP EPS was $0.03 for the fourth quarter and $1.51 for the full year of 2023. GAAP loss per share and non-GAAP EPS in the fourth quarter of 2023 include a charge of $1.69 per share related to the collaboration with Daiichi Sankyo. GAAP and non-GAAP EPS for the full years of 2023 and 2022 include charges of $6.21 and $0.22 per share, respectively, related to certain collaborations, licensing agreements and asset acquisitions.

Non-GAAP EPS excludes acquisition- and divestiture-related costs, including pretax intangible asset impairment research and development (R&D) charges of $779 million in the fourth quarter and full year of 2023 related to gefapixant, and $780 million and $1.7 billion in the

[1] Net (loss) income attributable to Merck & Co., Inc.

[2] Merck is providing certain 2023 and 2022 non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of the company's results because management uses non-GAAP results to assess performance. Management uses non-GAAP measures internally for planning and forecasting purposes and to measure the performance of the company along with other metrics. In addition, senior management's annual compensation is derived in part using a non-GAAP pre-tax income metric. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP. For a description of the non-GAAP adjustments, see Table 2a attached to this release.

fourth quarter and full year of 2022, respectively, primarily related to nemtabrutinib. Non-GAAP EPS also excludes restructuring costs, including costs for the recently approved 2024 Restructuring Program, as well as income and losses from investments in equity securities.

Fourth-Quarter Sales Performance

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

	Fourth Quarter				
$ in millions	2023	2022	Change	Change Ex-Exchange	Commentary
Total Sales	$14,630	$13,830	6%	7%	
Pharmaceutical	13,141	12,180	8%	8%	Increase driven by growth in oncology, vaccines and hospital acute care, partially offset by a decline in virology, due to LAGEVRIO, and diabetes. Excluding LAGEVRIO and impact of foreign exchange, growth of 14%.
KEYTRUDA	6,608	5,450	21%	22%	Growth driven by increased global uptake in earlier-stage indications, including triple-negative breast cancer and renal cell carcinoma (RCC), and continued strong global demand from metastatic indications.
GARDASIL/ GARDASIL 9	1,871	1,470	27%	27%	Growth due to strong global demand, particularly in China, and public-sector buying patterns in the U.S.
JANUVIA/JANUMET	787	913	-14%	-13%	Decline primarily due to generic competition in several international markets, particularly in Europe, and lower demand in the U.S.
PROQUAD, M-M-R II and VARIVAX	545	526	4%	3%	Growth largely due to higher pricing in the U.S.
BRIDION	429	441	-3%	-3%	Decline primarily due to generic competition in certain ex-U.S. markets, particularly in Europe, partially offset by higher demand in the U.S.
Lynparza*	315	292	8%	8%	Growth driven primarily by higher pricing in the U.S.
Lenvima*	226	216	5%	5%	Growth primarily due to higher demand in the U.S., partially offset by timing of shipments in China.
LAGEVRIO	193	825	-77%	-76%	Decline due to nonrecurrence of sales in the U.K. and lower demand in Japan and Australia.
ROTATEQ	185	139	34%	33%	Growth primarily due to public-sector buying patterns in the U.S. and timing of shipments in China.
VAXNEUVANCE	176	138	28%	26%	Growth largely driven by launches in Europe and continued uptake for the pediatric indication in the U.S. Prior-year quarter benefited from inventory stocking in the U.S. in preparation for pediatric launch.
Animal Health	1,278	1,230	4%	4%	Growth primarily driven by higher demand for Companion Animal products.
Livestock	808	814	-1%	0%	Decline primarily due to timing of shipments for ruminant products, largely offset by higher pricing across the product portfolio and higher demand for swine products.

$ in millions	Fourth Quarter 2023	2022	Change	Change Ex-Exchange	Commentary
Companion Animal	470	416	13%	12%	Growth primarily due to higher demand and timing of shipments for BRAVECTO line of products, as well as higher pricing. Sales of BRAVECTO were $197 million and $168 million in the current and prior-year quarters, respectively, which represented growth of 18%, or 19% excluding the impact of foreign exchange.
Other Revenues**	211	420	-50%	-1%	Decline primarily due to impact of revenue hedging activities.

*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.

Full-Year Revenue Performance

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

$ in millions	Year Ended Dec. 31, 2023	Dec. 31, 2022	Change	Change Ex-Exchange
Total Sales	$60,115	$59,283	1%	4%
Pharmaceutical	53,583	52,005	3%	5%
KEYTRUDA	25,011	20,937	19%	21%
GARDASIL/GARDASIL 9	8,886	6,897	29%	33%
JANUVIA/JANUMET	3,366	4,513	-25%	-23%
PROQUAD, M-M-R II and VARIVAX	2,368	2,241	6%	6%
BRIDION	1,842	1,685	9%	11%
LAGEVRIO	1,428	5,684	-75%	-74%
Lynparza*	1,199	1,116	7%	9%
Lenvima*	960	876	10%	11%
ROTATEQ	769	783	-2%	-1%
VAXNEUVANCE	665	170	N/M	N/M
Animal Health	5,625	5,550	1%	3%
Livestock	3,337	3,300	1%	4%
Companion Animal	2,288	2,250	2%	3%
Other Revenues**	907	1,728	-48%	-15%

*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 2023 pharmaceutical sales grew 3% to $53.6 billion. Pharmaceutical sales growth was primarily driven by higher sales in oncology, particularly KEYTRUDA, higher sales of vaccines, reflecting strong growth of combined sales of GARDASIL/GARDASIL 9 and VAXNEUVANCE, as well as growth in hospital acute care products, including PREVYMIS and BRIDION. Pharmaceutical sales growth in 2023 was partially offset by lower sales of the COVID-19 medication LAGEVRIO, as well as lower sales of JANUVIA and JANUMET, primarily reflecting generic competition in many ex-U.S. markets and lower demand in the U.S., and lower sales of PNEUMOVAX 23 as the market continues to shift toward newer adult

pneumococcal conjugate vaccines. Pharmaceutical sales growth for the full year of 2023 was 14% excluding LAGEVRIO and the unfavorable impact of foreign exchange.

Full-year 2023 Animal Health sales grew 1% to $5.6 billion. Excluding the unfavorable impact of foreign exchange, Animal Health sales grew 3%, primarily due to higher pricing. Full-year sales growth was also driven by higher demand for livestock products, led by poultry and swine products, partially offset by lower demand for ruminant products. Sales of BRAVECTO were $1.1 billion in 2023, which represented growth of 4%, or 5% excluding the impact of foreign exchange, primarily reflecting higher pricing.

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 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
Fourth Quarter 2022					
Cost of sales	$3,881	$482	$38	$-	$3,361
Selling, general and administrative	2,687	39	20	-	2,628
Research and development	3,775	740	-	-	3,035
Restructuring costs	49	-	49	-	-
Other (income) expense, net	(75)	(69)	-	80	(86)

[3] Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories recognized as a result of acquisitions of businesses, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. R&D expenses include intangible asset impairment charges of $779 million in both the fourth quarter and full year of 2023 related to gefapixant and $780 million and $1.7 billion in the fourth quarter and full year of 2022, respectively, largely related to nemtabrutinib. 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.

$ 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 Dec. 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
Year Ended Dec. 31, 2022						
Cost of sales	$17,411	$2,059	$205	$-	$-	$15,147
Selling, general and administrative	10,042	176	94	-	-	9,772
Research and development	13,548	1,676	30	-	-	11,842
Restructuring costs	337	-	337	-	-	-
Other (income) expense, net	1,501	(207)	-	1,348	-	360

GAAP Expense, EPS and Related Information

Gross margin was 73.3% for the fourth quarter of 2023 compared with 71.9% for the fourth quarter of 2022. The increase was primarily due to the favorable impacts of lower LAGEVRIO sales, which have a low gross margin, lower manufacturing facilities costs and product mix, partially offset by the unfavorable impacts of foreign exchange and higher restructuring costs. Gross margin was 73.2% for the full year of 2023 compared with 70.6% for the full year of 2022. The increase was primarily due to the favorable impacts of lower LAGEVRIO sales, product mix, lower manufacturing facilities costs, and lower revenue from third-party manufacturing arrangements, partially offset by the unfavorable impact of foreign exchange.

Selling, general and administrative (SG&A) expenses were $2.8 billion in the fourth quarter of 2023, an increase of 4% compared with the fourth quarter of 2022. The increase was primarily due to higher administrative costs, including higher compensation and benefit costs, partially offset by lower promotional spending. Full-year 2023 SG&A expenses were $10.5 billion, an increase of 5% compared with the full year of 2022. The increase was primarily due to higher administrative costs, including higher compensation and benefit costs, and higher promotional spending, partially offset by the favorable impact of foreign exchange and lower acquisition- and divestiture-related costs.

R&D expenses were $9.6 billion in the fourth quarter of 2023 compared with $3.8 billion in the fourth quarter of 2022. R&D expenses were $30.5 billion for the full year of 2023 compared with $13.5 billion for the full year of 2022. The increase in the fourth quarter and full year of 2023 reflects a $5.5 billion charge for the collaboration with Daiichi Sankyo, and higher development costs due to spending on clinical programs, including newly acquired programs, as well as higher compensation and benefit costs (reflecting in part increased headcount). The

increase in R&D expenses for the full year was also due to charges of $11.4 billion in the aggregate for the acquisitions of Prometheus Biosciences, Inc. (Prometheus) and Imago BioSciences, Inc. (Imago). The increase in R&D expenses for the full year was partially offset by lower intangible asset impairment charges in 2023 and charges of $690 million in the aggregate in 2022 for collaboration and licensing agreements with Moderna, Inc. (Moderna), Orna Therapeutics (Orna) and Orion Corporation (Orion).

Other (income) expense, net, was $78 million of expense in the fourth quarter of 2023 compared with $75 million of income in the fourth quarter of 2022, primarily due to higher exchange losses and higher net interest expense, partially offset by net gains from investments in equity securities for the fourth quarter of 2023 compared with net losses from investments in equity securities for the fourth quarter of 2022, and lower pension settlement costs. Other (income) expense, net, was $466 million of expense in the full year of 2023 compared with $1.5 billion of expense in the full year of 2022, primarily due to net gains from investments in equity securities in 2023 compared with net losses from investments in equity securities in 2022, and lower pension settlement costs, partially offset by a $572.5 million charge in 2023 related to settlements with certain plaintiffs in the Zetia antitrust litigation.

The effective tax rate was 40.1% for the fourth quarter of 2023 compared with 14.1% in the fourth quarter of 2022. The effective tax rate for the fourth quarter of 2023 includes a 29.2 percentage point impact resulting from the charge for the Daiichi Sankyo collaboration. The effective tax rate was 80.0% for the full year of 2023 compared with 11.7% for the full year of 2022. The full-year 2023 effective tax rate reflects an aggregate 65.6 percentage point unfavorable impact, resulting from charges for asset acquisitions (for which no tax benefits were recognized) as well as the charge for the Daiichi Sankyo collaboration.

GAAP loss per share was $0.48 for the fourth quarter of 2023 compared with EPS of $1.18 for the fourth quarter of 2022, primarily driven by the charge in 2023 related to the collaboration with Daiichi Sankyo, the unfavorable impact of foreign exchange and higher restructuring costs, partially offset by a beneficial impact from the tax rate and operational strength in the business. GAAP EPS was $0.14 for the full year of 2023 compared with EPS of $5.71 for the full year of 2022. The EPS decline in 2023 was primarily due to higher charges for certain business development transactions, the unfavorable impact of foreign exchange and the tax rate, as well as a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation, partially offset by the beneficial impacts of operational strength in the business, better performance from equity investments and lower intangible asset impairment charges.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 77.2% for the fourth quarter of 2023 compared with 75.7% for the fourth quarter of 2022. Non-GAAP gross margin was 76.9% for the full year of 2023 compared with 74.4% for the full year of 2022. The non-GAAP gross margin improvement in the fourth quarter and full year of 2023 was primarily due to the favorable impacts of lower LAGEVRIO sales, which have a low gross margin, product mix, and lower manufacturing facilities costs. The increase in non-GAAP gross margin for the full year was also due to lower

revenue from third-party manufacturing arrangements. The non-GAAP gross margin improvement in the fourth quarter and full year of 2023 was partially offset by the unfavorable impact of foreign exchange.

Non-GAAP SG&A expenses were $2.8 billion for the fourth quarter of 2023 compared with $2.6 billion for the fourth quarter of 2022. The increase was primarily due to higher administrative costs, including higher compensation and benefit costs, partially offset by lower promotional spending. Full-year 2023 non-GAAP SG&A expenses were $10.3 billion, an increase of 5% compared with the full year of 2022. The increase was primarily due to higher administrative costs, including higher compensation and benefit costs, and higher promotional spending, partially offset by the favorable impact of foreign exchange.

Non-GAAP R&D expenses were $8.8 billion in the fourth quarter of 2023 compared with $3.0 billion in the fourth quarter of 2022. Non-GAAP R&D expenses were $29.7 billion for the full year of 2023 compared with $11.8 billion for the full year of 2022. The increase in the fourth quarter and full year of 2023 reflects a $5.5 billion charge for the collaboration with Daiichi Sankyo, and higher development costs due to spending on clinical programs, including newly acquired programs, as well as higher compensation and benefit costs (reflecting in part increased headcount). The increase in non-GAAP R&D expenses for the full year was also due to charges of $11.4 billion in the aggregate for the acquisitions of Prometheus and Imago. The increase in R&D expenses for the full year was partially offset by charges of $690 million in the aggregate in 2022 for collaboration and licensing agreements with Moderna, Orna and Orion.

Non-GAAP other (income) expense, net, was $174 million of expense in the fourth quarter of 2023 compared with $86 million of income in the fourth quarter of 2022, primarily due to higher exchange losses and higher net interest expense, partially offset by lower pension settlement costs. Non-GAAP other (income) expense, net, was $219 million of expense in the full year of 2023 compared with $360 million of expense in the full year of 2022, primarily due to lower pension settlement costs.

The non-GAAP effective tax rate was 114.2% for the fourth quarter of 2023 compared with 15.6% in the fourth quarter of 2022. The non-GAAP effective tax rate for the fourth quarter of 2023 includes a 101.1 percentage point unfavorable impact resulting from the charge for the Daiichi Sankyo collaboration. The non-GAAP effective tax rate was 35.8% for the full year of 2023 compared with 14.2% for the full year of 2022. The full-year 2023 non-GAAP effective tax rate reflects an aggregate 21.2 percentage point unfavorable impact, resulting from charges for asset acquisitions (for which no benefits were recognized) as well as the charge for the Daiichi Sankyo collaboration.

Non-GAAP EPS was $0.03 for the fourth quarter of 2023 compared with $1.62 for the fourth quarter of 2022. The non-GAAP EPS decline in the fourth quarter was primarily due to the charge in 2023 related to the collaboration with Daiichi Sankyo and the unfavorable impact of foreign exchange, partially offset by a beneficial impact from the tax rate and operational strength in the business. Non-GAAP EPS was $1.51 for the full year of 2023 compared with

$7.48 for the full year of 2022. The non-GAAP EPS decline for the full year was primarily due to higher charges for certain business development transactions, the unfavorable impact of foreign exchange and the tax rate, partially offset by operational strength in the business.

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

	Fourth Quarter		Year Ended	
$ in millions, except EPS amounts	2023	2022	Dec. 31, 2023	Dec. 31, 2022
EPS				
GAAP EPS	$(0.48)	$1.18	$0.14	$5.71
Difference	0.51	0.44	1.37	1.77
Non-GAAP EPS that excludes items listed below[2]	$0.03	$1.62	$1.51	$7.48
Net (Loss) Income				
GAAP net (loss) income[1]	$(1,226)	$3,017	$365	$14,519
Difference	1,292	1,112	3,472	4,486
Non-GAAP net income that excludes items listed below[1,2]	$66	$4,129	$3,837	$19,005
Excluded Items:				
Acquisition- and divestiture-related costs[3]	$1,233	$1,192	$2,876	$3,704
Restructuring costs	401	107	933	666
(Income) loss from investments in equity securities	(61)	80	(279)	1,348
Charge for Zetia antitrust litigation settlements	-	-	573	-
Increase to net loss/decrease to net income before taxes	1,573	1,379	4,103	5,718
Estimated income tax (benefit) expense	(281)	(267)	(631)	(1,232)
Increase to net loss/decrease to net income	$1,292	$1,112	$3,472	$4,486

2024 Restructuring Program

Merck recently approved a new restructuring program (2024 Restructuring Program) intended to continue the optimization of the company's Human Health global manufacturing network as the future pipeline shifts to new modalities, and also to optimize the Animal Health global manufacturing network to improve supply reliability and increase efficiency. The company recorded charges in its GAAP results of $190 million related to the 2024 Restructuring Program for the fourth quarter and full year of 2023.

Pipeline and Portfolio Highlights

In the fourth quarter, Merck continued to make significant progress advancing its broad portfolio and pipeline across key therapeutic areas, representing continued momentum toward addressing patient needs.

In oncology, Merck received multiple U.S. Food and Drug Administration (FDA) approvals, including KEYTRUDA plus Padcev for the first-line treatment of adult patients with locally advanced or metastatic urothelial cancer and WELIREG for the treatment of certain patients with previously treated advanced RCC, among other approvals. The FDA also accepted and granted Priority Review to Merck and Daiichi Sankyo's Biologics License Application (BLA) for patritumab deruxtecan for the treatment of certain patients with previously treated locally advanced or metastatic EGFR-mutated non-small cell lung cancer (NSCLC). The

FDA set a Prescription Drug User Fee Act (PDUFA), or target action, date of June 26, 2024. In addition, Merck showed meaningful progress in its robust oncology pipeline, initiating Phase 3 trials for four investigational medicines, including bomedemstat (LSD1 inhibitor), nemtabrutinib (BTK inhibitor), MK-2870 (anti-TROP2 antibody-drug conjugate) and MK-5684 (CYP11A1 inhibitor).

In vaccines, Merck received Priority Review from the FDA for a BLA for V116, the company's investigational, 21-valent pneumococcal conjugate vaccine specifically designed to protect adults, based on results from multiple Phase 3 trials. The FDA set a PDUFA date of June 17, 2024. If approved, V116 would be the first pneumococcal conjugate vaccine to include serotypes responsible for approximately 83 percent of adult invasive pneumococcal disease in individuals 65 and older, according to U.S. Centers for Disease Control and Prevention data from 2018-2021.

In hospital acute care, the European Commission (EC) approved PREVYMIS for prevention of cytomegalovirus (CMV) disease in high-risk adult kidney transplant recipients and extended 200-day dosing in adult hematopoietic stem cell transplant (HSCT) recipients who are at high risk for late CMV infection and disease.

Merck continued to augment its pipeline through business development, and in January 2024, entered into a definitive agreement to acquire Harpoon Therapeutics, Inc. (Harpoon), for an approximate total equity value of $680 million, further diversifying its oncology pipeline.

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

Oncology	FDA Approved Expanded Indication for KEYTRUDA Plus Padcev as First-Line Treatment for Adult Patients With Locally Advanced or Metastatic Urothelial Cancer, Based on Results From Phase 3 KEYNOTE-A39 Trial	(Read Announcement)
	FDA Approved Merck's WELIREG as Treatment for Patients With Advanced RCC Following a PD-1 or PD-L1 Inhibitor and a VEGF-TKI, Based on Results From LITESPARK-005 Trial	(Read Announcement)
	FDA Approved Merck's KEYTRUDA Plus Chemoradiotherapy as Treatment for Patients With FIGO 2014 Stage III-IVA Cervical Cancer, Based on Results From Phase 3 KEYNOTE-A18 Trial	(Read Announcement)
	FDA Approved Merck's KEYTRUDA Plus Chemotherapy as First-Line Treatment for Locally Advanced Unresectable or Metastatic HER2-Negative Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma, Based on Results From Phase 3 KEYNOTE-859 Trial	(Read Announcement)
	FDA Approved Merck's KEYTRUDA Plus Gemcitabine and Cisplatin as Treatment for Patients With Locally Advanced Unresectable or Metastatic Biliary Tract Cancer, Based on Results From Phase 3 KEYNOTE-966 Trial	(Read Announcement)
	EC Approved KEYTRUDA Plus Chemotherapy for New First-Line Indications in Advanced HER2-Negative Gastric or GEJ Adenocarcinoma in Tumors Expressing PD-L1 (CPS ≥1) and Advanced Biliary Tract Cancer, Based on Results From Phase 3 KEYNOTE-859 and KEYNOTE-966 Trials	(Read Announcement)
	FDA Granted Priority Review to Merck and Daiichi Sankyo's BLA for Patritumab Deruxtecan for the Treatment of Certain Patients With Previously Treated Locally Advanced or Metastatic EGFR-Mutated NSCLC, Based on Results From Phase 2 HERTHENA-Lung01 Trial; FDA Set PDUFA Date of June 26, 2024	(Read announcement)

	Merck Announced Phase 3 Trial Initiations for Bomedemstat, Nemtabrutinib, MK-2870 and MK-5684, Four Investigational Candidates From Promising Hematology and Oncology Pipeline	(Read announcement)
	Merck and Moderna Initiated INTerpath-002, a Phase 3 Study Evaluating V940 (mRNA-4157) in Combination With KEYTRUDA for Adjuvant Treatment of Patients With Certain Types of Resected NSCLC	(Read Announcement)
	KEYTRUDA Reduced the Risk of Death by 38% Versus Placebo as Adjuvant Therapy for Patients With RCC at an Increased Risk of Recurrence Following Nephrectomy, Based on Results From Phase 3 KEYNOTE-564 Trial	(Read Announcement)
	KEYTRUDA Significantly Improved Disease-Free Survival as Adjuvant Therapy Versus Observation in High-Risk Patients With Localized Muscle-Invasive and Locally Advanced Urothelial Carcinoma After Surgery, Based on Results From Phase 3 AMBASSADOR/KEYNOTE-123 Trial	(Read Announcement)
	Moderna and Merck Announced V940 (mRNA-4157) in Combination With KEYTRUDA Demonstrated Continued Improvement in Recurrence-Free Survival and Distant Metastasis-Free Survival in Patients With High-Risk Stage III/IV Melanoma Following Complete Resection Versus KEYTRUDA at Three Years, Based on Results From Phase 2b Randomized KEYNOTE-942/mRNA-4157-P201 Study	(Read Announcement)
Vaccines	FDA Granted Priority Review to Merck's New BLA for V116, an Investigational, 21-valent Pneumococcal Conjugate Vaccine Specifically Designed to Protect Adults, Based on Results From Multiple Phase 3 Trials; FDA Set PDUFA Date of June 17, 2024	(Read Announcement)
	Merck's V116, an Investigational, 21-valent Pneumococcal Conjugate Vaccine Specifically Designed to Protect Adults, Demonstrated Superior Immunogenicity for 10 of 11 Unique Serotypes Compared to PCV20 in Adults 50 Years of Age and Older, Based on Results From Phase 3 STRIDE-3 Trial	(Read Announcement)

Full-Year 2024 Financial Outlook

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

	Full Year 2024
Sales*	$62.7 to $64.2 billion
Non-GAAP gross margin[2]	Approximately 80.5%
Non-GAAP operating expenses[2]**	$25.1 to $26.1 billion
Non-GAAP other (income) expense, net[2]	Approximately $200 million expense
Non-GAAP effective tax rate[2]	14.5% to 15.5%
Non-GAAP EPS[2]***	$8.44 to $8.59
Share count (assuming dilution)	Approximately 2.54 billion

*The company does not have any non-GAAP adjustments to sales.
**Includes approximately $650 million of R&D expense related to the recently announced Harpoon acquisition, which is expected to close in the first half of 2024. Outlook does not assume any additional significant potential business development transactions.
***Includes a one-time charge of approximately $0.26 per share related to the Harpoon acquisition.

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 2024 sales to be between $62.7 billion and $64.2 billion, including a negative impact of foreign exchange of approximately 2% at mid-January 2024 exchange rates. The negative impact is primarily due to the devaluation of the Argentine peso, which the company expects will largely be offset by inflation-related price increases, consistent with market practice.

The outlook for operating expenses reflects incremental R&D spending expected to be incurred to advance the development of promising programs related to the acquisitions of Prometheus, Imago and Harpoon, as well as the collaborations with Daiichi Sankyo and Kelun-Biotech.

Merck's full-year non-GAAP effective income tax rate is expected to be between 14.5% and 15.5%.

Merck expects full-year 2024 non-GAAP EPS to be between $8.44 and $8.59, including a negative impact of foreign exchange of approximately $0.25 per share. In 2023, non-GAAP EPS of $1.51 was negatively impacted by charges of $6.21 per share related to certain acquisitions and collaboration agreements.

In early January 2024, Merck announced the acquisition of Harpoon, which is expected to close in the first half of 2024, and result in a non-tax deductible charge of approximately $650 million of R&D expense included in non-GAAP results. The impact of the transaction on expected full-year non-GAAP EPS is approximately $0.26 per share, which is included in the 2024 outlook.

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 Thursday, Feb. 1, at 9 a.m. ET via this weblink. A replay of the webcast, along with the sales and earnings news release, supplemental financial disclosures, prepared remarks and slides highlighting the results, will be available at www.merck.com.

All participants may join the call by dialing (800) 779-6561 (U.S. and Canada Toll-Free) or (773) 756-4619 and using the access code 5958465.

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 the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2022, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

Appendix

Generic product names are provided below.

Pharmaceutical

BRIDION *(sugammadex)*
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)*
PNEUMOVAX 23 *(Pneumococcal Vaccine Polyvalent)*
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*)
WELIREG (*belzutifan*)

Animal Health

BRAVECTO *(fluralaner)*

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