NEWS RELEASE

Merck Receives Positive EU CHMP Opinion for ENFLONSIA™ (clesrovimab) for the Prevention of Respiratory Syncytial Virus (RSV) in Infants During Their First RSV Season

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If approved by the European Commission, ENFLONSIA will be the first and only RSV preventive option in Europe for administration to infants using the same dose regardless of weight

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended the approval of ENFLONSIA™ (clesrovimab) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates (newborns) and infants during their first RSV season. The CHMP recommendation will now be reviewed by the European Commission (EC) for marketing authorization in the European Union (EU), Iceland, Liechtenstein and Norway, and a final decision is expected before the end of the year.

“As one of the most pervasive seasonal respiratory infections and a leading cause of infant hospitalization globally, RSV continues to place a significant burden on families and health care systems,” said Dr. Macaya Douoguih, vice president, Therapeutic Area Head, Global Clinical Development, Merck Research Laboratories. “With strong clinical data paired with convenient dosing, this positive opinion recognizes ENFLONSIA as an important new potential option to help protect infants in Europe.”

ENFLONSIA is a preventive, long-acting monoclonal antibody (mAb) designed to provide direct, rapid and durable protection through 5 months, a typical RSV season, with the same dose regardless of infant weight. In most parts of

the Northern Hemisphere, including Europe, a typical RSV season usually spans autumn through spring of the next year.

ENFLONSIA should not be administered to infants with a history of serious hypersensitivity reactions, including anaphylaxis, to any component of ENFLONSIA. See additional Selected Safety Information below.

The CHMP recommendation is supported by results from the pivotal Phase 2b/3 CLEVER trial (MK-1654-004) (**NCT04767373**), which evaluated the safety and efficacy of ENFLONSIA administered to preterm and full-term infants (birth to 1 year of age), and the Phase 3 SMART trial (MK-1654-007) (**NCT04938830**), which evaluated the safety and efficacy of ENFLONSIA versus palivizumab in infants at increased risk for severe RSV disease. The data from these two pivotal clinical trials were recently published in the New England Journal of Medicine.

ENFLONSIA was approved in the **United States** and United Arab Emirates in June 2025 and is currently under review in several additional markets globally.

About ENFLONSIA™ (clesrovimab-cfor) in the U.S.

ENFLONSIA is Merck's **FDA-approved**, extended half-life monoclonal antibody (mAb) indicated for passive immunization for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants who are born during or entering their first RSV season. ENFLONSIA is administered using the same dose regardless of weight (105 mg/0.7 mL in a prefilled syringe) and is designed to provide direct, rapid and durable protection through 5 months, a typical RSV season. For infants born during the RSV season, ENFLONSIA is to be administered within the first week of life. For infants born outside of the RSV season, ENFLONSIA should be administered shortly before the RSV season begins. For infants undergoing cardiac surgery with cardiopulmonary bypass during or entering their first RSV season, an additional 105 mg dose is recommended as soon as the infant is stable after surgery. ENFLONSIA has a 30-month shelf life.

Selected Safety Information for ENFLONSIA™ (clesrovimab-cfor) in the U.S.

Do not administer ENFLONSIA to infants with a history of serious hypersensitivity reactions, including anaphylaxis, to any component of ENFLONSIA.

Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy.

The most common adverse reactions were injection-site erythema (3.8%), injection-site swelling (2.7%) and rash

(2.3%).

About RSV Globally

Respiratory syncytial virus (RSV) is a contagious virus that causes widespread seasonal infections and can lead to serious respiratory conditions such as bronchiolitis and pneumonia. As a leading cause of hospitalization among infants globally, there is persisting unmet need for RSV preventive options for both healthy and high-risk infants during their first RSV season. RSV season is the time of year when RSV infections are most common, usually occurring autumn through spring of the next year in temperate climates. Timing and severity in a given community or region can vary year to year.

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, 2024 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

Please see Prescribing Information for ENFLONSIA (clesrovimab-cfor) at **https://www.merck.com/product/usa/pi_circulars/e/enflonsia/enflonsia_pi.pdf** and Patient Information/Medication Guide for ENFLONSIA at **https://www.merck.com/product/usa/pi_circulars/e/enflonsia/enflonsia_ppi.pdf**.

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