NEWS RELEASE

Merck Announces Positive New Data for ENFLONSIA™ (clesrovimab) for Infants and Children Under 2 Years of Age at Increased Risk for Severe Respiratory Syncytial Virus (RSV) Disease Over Two RSV Seasons

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Second season results from the Phase 3 SMART trial were presented at the 9th RSVVW Conference and will be shared with the U.S. FDA and other regulatory authorities

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced positive second RSV season findings from the Phase 3 SMART trial (MK-1654-007) (**NCT04938830**) evaluating the safety, efficacy and pharmacokinetics of ENFLONSIA™ (clesrovimab) in infants and children at increased risk for severe respiratory syncytial virus (RSV) disease over two RSV seasons. The data were presented during an oral session (Abstract #P455) at RSVVW'26, the 9th conference of the Respiratory Syncytial Virus Foundation (ReSViNET) in Rome, Italy.

New data from the SMART trial in children under 2 years of age who remained at increased risk for severe RSV disease through their second RSV season and received ENFLONSIA at the start of RSV season 2 showed that safety was generally consistent with safety observed in MK-1654-007 infants who received ENFLONSIA during RSV season 1. Additional safety data can be found below. Additionally, the monoclonal antibody (mAb) serum concentrations achieved in children under 2 years of age at increased risk for severe RSV disease through their second RSV season (secondary endpoint) were similar to those in healthy infants in the pivotal Phase 2b/3 CLEVER trial (MK-1654-004) (**NCT04767373**). Results from the SMART study support extrapolation of efficacy to children under 2 years of age at increased risk for severe RSV disease through RSV season 2.

“All children who received ENFLONSIA in their second RSV season were at increased risk for severe RSV disease, and nearly all had chronic lung disease or congenital heart disease,” said Dr. Paolo Manzoni, Head of Maternal–Infant Medicine, University of Torino Hospital Degli Infermi, Ponderano, Italy, and an investigator for the SMART clinical trial. “These new findings from SMART demonstrate the potential of ENFLONSIA to help protect these vulnerable children, who may require an additional dose for their second RSV season.”

Interim data from RSV season 1 of the Phase 3 SMART trial — alongside data from the pivotal Phase 2b/3 CLEVER trial—supported the **FDA approval** of ENFLONSIA in June 2025 and subsequent global regulatory approvals. Interim data from RSV season 1 of the SMART trial were also presented at **IDWeek 2024** and published in the **New England Journal of Medicine**. The SMART trial enrolled infants at increased risk of severe RSV disease due to prematurity (<29 weeks through ≤35 weeks gestational age), chronic lung disease of prematurity or hemodynamically significant congenital heart disease entering their first RSV season.

“RSV is among the leading causes of infant hospitalization globally and is especially serious for children under 2 years of age at high risk for severe disease,” said Dr. Macaya Douoguih, vice president, Therapeutic Area Head, Global Clinical Development, Merck Research Laboratories. “These new data from the SMART study further position ENFLONSIA as an important potential new option to help protect young children who remain at high risk entering their second RSV season. We aspire to bring ENFLONSIA to all eligible infants and high-risk children under 2 years of age around the world and look forward to sharing these encouraging data with global regulatory authorities to help achieve this goal.”

The second season results will be shared with the FDA and global regulatory authorities for evaluation for an expanded indication in children at increased risk for severe RSV disease through their second RSV season. ENFLONSIA is currently approved in the United States, Canada and several other countries for use in infants during their first RSV season, and regulatory filings are underway in additional markets globally.

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

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.

ENFLONSIA may interfere with some immunologically-based RSV diagnostic assays (i.e., rapid antigen tests) as observed in laboratory studies. Confirmation using a reverse transcriptase polymerase chain reaction (RT-PCR) assay is recommended when rapid antigen assay results are negative and clinical observations are consistent with RSV infection.

The most common adverse reactions were injection-site erythema (3.8%), injection-site swelling (2.7%) and rash (2.3%).

About the Phase 3 SMART Trial Findings Evaluating ENFLONSIA™ (clesrovimab) Presented at RSVVW'26

The SMART trial (MK-1654-007) (**NCT04938830**) was a Phase 3, randomized, partially-blind, palivizumab-controlled, multicenter study to evaluate the safety, efficacy and pharmacokinetics of ENFLONSIA in infants and children at increased risk for severe RSV disease over two RSV seasons. The trial enrolled early (<29 weeks gestational age [GA]) or moderate preterm infants (≥29 to ≤35 weeks GA) and infants with chronic lung disease (CLD) of prematurity or congenital heart disease (CHD) of any GA.

In RSV season 1, participants were randomized 1:1 to receive either a 105 mg dose of ENFLONSIA (n=502) or monthly palivizumab (n=501) by intramuscular (IM) injection. In RSV season 2, eligible participants (children under 2 years of age with CLD, CHD or early or moderate preterm birth with certain risk conditions) received an additional open-label 210 mg dose of ENFLONSIA by IM injection administered as two 105 mg injections (n=276, of whom 138 received ENFLONSIA and 138 received palivizumab in RSV season 1). Nearly all participants (99%) who received ENFLONSIA in RSV season 2 had CLD (n=229) or CHD (n=43).

RSV Season 1 Findings

Data from the completed SMART trial demonstrate that, among infants at increased risk for severe RSV disease entering their first RSV season, the safety profile of ENFLONSIA was similar to palivizumab and consistent with the safety profile of ENFLONSIA in infants in the pivotal Phase 2b/3 CLEVER trial (MK-1654-004) (**NCT04767373**).

The proportions of participants with adverse events (AEs) were generally comparable between study groups. The solicited AEs reported days 1-5 following any dose included irritability (28.8% ENFLONSIA arm; 33.7% palivizumab arm); somnolence (18.9%; 22.0%); decreased appetite (13.5%; 13.2%); injection site pain (7.8%; 10.8%); injection site erythema (6.2%; 6.4%); injection site swelling (6.2%; 5.6%); and fever (0.8%; 1.2%). No drug-related serious AEs (SAEs) were reported for ENFLONSIA.

The efficacy of ENFLONSIA in infants at increased risk for severe RSV disease entering their first RSV season was established by extrapolation of efficacy of ENFLONSIA from the CLEVER trial to the SMART trial based on pharmacokinetic exposure, a secondary endpoint. The incidence rates of RSV-associated medically attended lower respiratory infection (MALRI)—characterized as cough or difficulty breathing and requiring ≥1 indicator of LRI (wheezing, rales/crackles) or severity (chest wall in-drawing/retractions, hypoxemia, tachypnoea, dehydration due to respiratory symptoms)—and RSV-associated hospitalization were generally comparable between ENFLONSIA (3.2%, 95% CI: 1.8, 5.2 and 1.0%, 95% CI: 0.3, 2.4, respectively) and palivizumab (3.4%, 95% CI: 2.0, 5.6 and 1.7%, 95% CI: 0.7, 3.3, respectively) through Day 150 (5 months).

RSV Season 2 Findings

All participants in RSV season 2 received open-label ENFLONSIA. The proportions of participants experiencing AEs during RSV season 2 were generally comparable between those who had received either ENFLONSIA (105 mg) or palivizumab in season 1. In children under 2 years of age who remained at increased risk for severe RSV disease through their second RSV season and received ENFLONSIA at the start of RSV season 2, safety was generally consistent with safety observed in MK-1654-007 infants who received ENFLONSIA during RSV season 1. The solicited AEs reported days 1-5 post-dose included irritability (13.0%); somnolence (8.7%); decreased appetite (6.9%); injection site pain (4.3%); injection site erythema (1.8%); injection site swelling (1.8%); and fever (1.1%). No drug-related SAEs were reported.

The monoclonal antibody serum concentrations achieved in children under 2 years of age at increased risk for severe RSV disease through their second RSV season (secondary endpoint) were similar to those in healthy infants in the CLEVER trial. Results from SMART support extrapolation of efficacy to children under 2 years of age at increased risk for severe RSV disease through RSV season 2. Among children who received ENFLONSIA in RSV season 2, the incidence rates of RSV-associated MALRI ≥1 indicator of LRI or severity and RSV-associated hospitalization were 7.3% (95% CI: 4.4, 11.4) and 3.0% (95% CI: 1.3, 5.9), respectively, through Day 180 (6 months), reflecting these children's higher baseline risk as well as the RSV disease burden post-COVID pandemic.

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 as well as for children at increased risk for severe RSV disease through their second 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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