NEWS RELEASE

ACIP Recommends Use of Merck's ENFLONSIA™ (clesrovimab-cfor) for Prevention of Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease in Infants Younger than 8 Months of Age Born During or Entering Their First RSV Season

2025-06-26

ENFLONSIA is the first and only RSV preventive option for administration to infants using the same dose regardless of weight

Ordering will begin in July, with shipments delivered before the start of the 2025-2026 RSV season

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend ENFLONSIA™ (clesrovimab-cfor) as an option for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in infants younger than 8 months of age who are born during or entering their first RSV season. The ACIP also voted to include ENFLONSIA in the Vaccines for Children Program—an important step in ensuring broad access to this preventive option for infants.

ENFLONSIA Logo

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 weight. A typical RSV season usually spans autumn to 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.

“Ahead of the 2025-2026 RSV season, we are proud to offer ENFLONSIA as a new preventive option designed to protect healthy and at-risk infants from RSV disease across a spectrum of severity, including worsening disease requiring hospitalization,” said Dr. Richard M. Haupt, vice president, head of global medical & scientific affairs, vaccines and infectious diseases, Merck Research Laboratories. “The Committee’s recommendation is an important step forward in efforts to help reduce the significant burden RSV continues to place on infants, families and health care systems.”

The U.S. Food and Drug Administration (FDA) **approved** ENFLONSIA earlier this month based on clinical data from the Phase 2b/3 CLEVER and Phase 3 SMART trials. Merck plans to make ENFLONSIA available for ordering by physicians and health care administrators in July 2025, with shipments to be delivered before the start of the 2025-2026 RSV season.

The ACIP’s recommendation for ENFLONSIA is provisional and will be official once reviewed and finalized by the CDC Director or the Health and Human Services Secretary (in the absence of a CDC Director).

About ENFLONSIA™ (clesrovimab-cfor)

ENFLONSIA is Merck’s 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)

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

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. According to the CDC, two to three out of every 100 infants under 6 months of age are hospitalized with RSV annually. As the leading cause of hospitalization among infants in the U.S., there is persisting unmet need for RSV preventive options for both healthy and high-risk infants born during or entering their first RSV season. RSV season is the time of year when RSV infections are most common, usually occurring fall/autumn through spring of the next year. RSV typically peaks in the winter in most regions of the United States, but 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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Source: Merck & Co., Inc.