

# US FDA approves Merck's RSV antibody for infants

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Bengaluru: The U.S. Food and Drug Administration on Monday approved Merck's preventive antibody shot to protect infants up to one year of age from respiratory syncytial virus during their first RSV season, the company said.

Merck's monoclonal antibody, called clesrovimab and branded as Enflonsia, is the first and only preventive shot that can be administered as a single dose regardless of birth weight in healthy pre-term, full-term and at-risk infants to protect them against mild, moderate and severe RSV. The company told Reuters the therapy will be priced at \$556 per dose.

RSV is a common respiratory virus that causes seasonal infections such as the flu, but is a leading cause of pneumonia and death in infants and older adults.

The approval was based on results from a late-stage trial in which Enflonsia had a comparable safety profile to Swedish Orphan Biovitrum's Synagis, a monthly injection.

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The U.S. saw limited supply of antibody Beyfortus up to the 2023 RSV season, but the companies have since tripled production capacity and doubled the number of manufacturing sites.

A Sanofi spokesperson said "current supply ... matches the total amount distributed during the entire last season ... We are continuing to manufacture more doses, which will result in a larger overall supply than was available last year."

In the U.S., an estimated 58,000-80,000 children younger than five years are hospitalized due to RSV each year, according to the U.S. Centers for Disease Control and Prevention.

The CDC currently recommends two immunization options for babies to be protected from severe RSV - an RSV vaccine given to the mother during pregnancy or an RSV antibody given to the baby.

Merck expects the drug's shipments to arrive in time for the 2025-2026 RSV season.

Merck had earlier on Monday said the CDC's Advisory Committee on Immunization Practices was expected to meet later this month to discuss and make recommendations for the use of Enflonsia in infants. However, Health Secretary Robert F. Kennedy Jr. has fired all members sitting on the CDC panel.

Merck was immediately not available for a comment on clarification regarding the meeting.

**News Source:**

[https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/us-fda-approves-mercks-rsv-antibody-for-infants/121740373?utm\\_source=whatsapp\\_web&utm\\_medium=social&utm\\_campaign=socialsharebuttons](https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/us-fda-approves-mercks-rsv-antibody-for-infants/121740373?utm_source=whatsapp_web&utm_medium=social&utm_campaign=socialsharebuttons)