Enflonsia™ (clesrovimab-cfor) – New drug approval

- On June 9, 2025, Merck announced the FDA approval of Enflonsia (clesrovimab-cfor), for the **prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season**.

- Enflonsia is a preventive, long-acting monoclonal antibody designed to provide protection through 5 months, a typical RSV season.

    - A typical RSV season usually spans from autumn to the following spring.

- The efficacy of Enflonsia was established in Trial 004, a randomized, double-blind, placebo-controlled study in early and moderate preterm infants (≥ 29 to < 35 weeks gestational age) and late preterm and full-term infants (≥ 35 weeks gestational age). Participants were randomized to a single dose of Enflonsia or placebo. The primary endpoint was the incidence 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, tachypnea, dehydration due to respiratory symptoms) through 150 days after dosing. RSV-associated hospitalization through 150 days after dosing was evaluated as a key secondary endpoint.

    - The incidence rate of MALRI was 0.026 and 0.065 with Enflonsia and placebo, respectively (efficacy 60.5%, 95% CI: 44.2, 72.0; $p < 0.001$).
    - The incidence rate of hospitalization was 0.004 and 0.024 with Enflonsia and placebo, respectively (efficacy 84.3%, 95% CI: 66.7, 92.6; $p < 0.001$).

- Warnings and precautions for Enflonsia include hypersensitivity including anaphylaxis and RSV diagnostic test interference.

- The most common adverse reactions with Enflonsia use were injection-site erythema, injection-site swelling, and rash.

- The recommended dose for neonates and infants born during or entering their first RSV season is **105 mg administered as a single intramuscular injection**.

    - For neonates and infants born during the RSV season, Enflonsia should be administered once starting from birth.
    - For infants born outside the RSV season, Enflonsia should be administered once prior to the start of their first RSV season considering the duration of protection provided by Enflonsia.

- Enflonsia must be administered by a healthcare provider.

- Merck is expected to make Enflonsia available for ordering beginning in July, with shipments delivered before the start of the 2025-2026 RSV season. Enflonsia will be available as a 105 mg/0.7 mL single-dose prefilled syringe.