mRESVIA™ (respiratory syncytial virus vaccine) – Expanded indication

- On June 12, 2025, Moderna announced the FDA approval of mRESVIA (respiratory syncytial virus vaccine), for **active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV**.
    - mRESVIA is also approved for this indication in individuals 60 years of age and older.
- The approval of mRESVIA for the expanded indication was based on a safety and immunogenicity study in adults aged 18 to 59 with underlying health conditions. The immune responses against both RSV-A and RSV-B met prespecified non-inferiority immunobridging criteria when compared to those observed in adults aged 60 years and older in the pivotal placebo-controlled safety and efficacy study.
    - Comparable levels of neutralizing antibodies were observed across both the 18 to 49 and 50 to 59 age subgroups.
- The most commonly reported adverse reactions (≥ 10%) with mRESVIA use in individuals 18 through 59 years who are at increased risk for LRTD caused by RSV were injection site pain, fatigue, headache, myalgia, arthralgia, chills, axillary (underarm) swelling or tenderness, and nausea/vomiting.
- mRESVIA is administered intramuscularly as a single dose (0.5 mL).

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