

## mRESVIA<sup>™</sup> (respiratory syncytial virus vaccine) – New vaccine approval

- On May 31, 2024, <u>Moderna announced</u> the FDA approval of <u>mRESVIA</u> (<u>respiratory syncytial virus vaccine</u>), for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.
- mRESVIA is the third FDA approved RSV vaccine and a competitor to Pfizer's <u>Abrysvo®</u> and GSK's Arexvy.
- mRESVIA is an RSV vaccine that consists of an mRNA sequence encoding a stabilized prefusion
  F glycoprotein. The F glycoprotein is expressed on the surface of the virus and is required for
  infection by helping the virus to enter host cells.
  - The vaccine uses the same lipid nanoparticles as the Moderna COVID-19 vaccines.
- The efficacy of mRESVIA was established in a randomized, placebo-controlled, observer-blind, case-driven study in 35,064 individuals 60 years of age and older. Participants were randomized to a single dose of mRESVIA or placebo. The primary endpoints were the prevention of a first episode of RSV-LRTD with either ≥ 2 signs/symptoms or ≥ 3 signs/ symptoms starting 14 days after vaccination.
  - At 3.7 months of median follow-up, the vaccine efficacy of mRESVIA was 78.7% (95.04% CI: 62.8, 87.9) for prevention of a first episode of RSV-LRTD with ≥ 2 signs/symptoms and 80.9% (95.10% CI: 50.1, 92.7) for prevention of a first episode of RSV-LRTD with ≥ 3 signs/symptoms.
- Warnings and precautions for mRESVIA include management of acute allergic reactions, syncope, and altered immunocompetence.
- The most common adverse reactions (≥ 10%) with mRESVIA use were injection-site pain, fatigue, headache, myalgia, arthralgia, axillary swelling or tenderness, and chills.
- mRESVIA is administered as a single dose (0.5 mL) as an intramuscular injection.
- Moderna plans to launch mRESVIA by the 2024/2025 respiratory virus season. mRESVIA will be available as a 0.5 mL suspension in a pre-filled plastic syringe.



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