# Drug Express

Synapse by patsnap

## Weekly New Drug Approvals

Jun. 3rd 2024

## mRNA-1345

**FDA Approval Date:** May 31th, 2024

**Brand name:** mRESVIA

**Indication:** Respiratory Syncytial Virus Infections

**Mechanism:** Respiratory syncytial virus F protein modulators

**Company:** Moderna

mRESVIA®is an RSV vaccine that consists of an mRNA sequence encoding a stabilized prefusion F glycoprotein. The vaccine uses the same lipid nanoparticles (LNPs) as the Moderna COVID-19 vaccines.

- The FDA's approval of mRESVIA is based on positive data from the Phase 3 clinical trial ConquerRSV, a global study conducted in approximately 37,000 adults ages 60 years or older in 22 countries. The primary analysis with 3.7 months of median follow-up found a vaccine efficacy against RSV lower respiratory tract disease (LRTD) of 83.7% (95.88% CI 66.0%, 92.2%).

- No serious safety concerns were identified in the Phase 3 trial. The most commonly reported solicited adverse reactions were injection site pain, fatigue, headache, myalgia and arthralgia.