mRESVIA™ (respiratory syncytial virus vaccine) – New vaccine approval

- On May 31, 2024, 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 60 years of age and older.

- mRESVIA is the third FDA approved RSV vaccine and a competitor to Pfizer's Abrysvo® 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.