Abrysvo® (respiratory syncytial virus vaccine) – New indication

- On October 22, 2024, Pfizer announced the FDA approval of Abrysvo (respiratory syncytial virus [RSV] vaccine), for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

- Abrysvo is also approved for active immunization:

    - Of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age
    - For the prevention of LRTD caused by RSV in individuals 60 years of age and older.

- Abrysvo is the first RSV vaccine approved for adults younger than 50.

- The approval of Abrysvo for the new indication was based on Study 4, a randomized, double-blind, placebo-controlled study assessing the safety and immunogenicity of Abrysvo in individuals 18 through 59 years of age considered to be at increased risk of LRTD caused by RSV due to chronic medical conditions. The study enrolled individuals who had chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic or metabolic disorders (including diabetes mellitus and hyper/hypothyroidism). Effectiveness was assessed by comparison of the RSV neutralizing geometric mean titers (GMTs) and seroresponse rates of the evaluable immunogenicity population in Study 4 who received Abrysvo (n = 437) to those of a subgroup of individuals in a separate study (Study 3) (n = 410). Participants in the Study 3 subgroup were 60 years of age or older; 44% had chronic medical conditions.

    - Non-inferiority was demonstrated for the ratio of neutralizing GMTs for RSV A and RSV B, and the percentage difference in neutralizing titer seroresponse rates for RSV A and RSV B.

- The most commonly reported solicited local and systemic adverse reactions (≥ 10%) with Abrysvo use in individuals 18 through 59 years of age were pain at the injection site, muscle pain, joint pain, and nausea.

- Abrysvo is administered as a single intramuscular dose.