Abrysvo™ (respiratory syncytial virus vaccine) – New indication

- On August 21, 2023, the FDA announced the approval of Pfizer's Abrysvo (respiratory syncytial virus vaccine), for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age

- Abrysvo is also approved for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

- Abrysvo is the first maternal vaccine approved to help protect infants from LRTD due to RSV infection.

- The approval of Abrysvo for the new indication was based on a randomized study that assessed the efficacy of Abrysvo in the prevention of RSV-associated LRTD in infants born to individuals vaccinated during pregnancy. Maternal participants were randomized to receive a single dose of Abrysvo or placebo. The evaluable efficacy population included 6,975 patients. Vaccine efficacy was defined as the relative risk reduction of the endpoints of severe LRTD caused by RSV and LRTD caused by RSV in infants born to individuals who received Abrysvo compared to infants born to individuals who received placebo.

    — Overall, Abrysvo reduced the risk of severe LRTD by 81.8% within 90 days after birth, and 69.4% within 180 days after birth.
    — In a subgroup of pregnant individuals who were 32 through 36 weeks gestational age, Abrysvo reduced the risk of LRTD by 34.7%, and reduced the risk of severe LRTD by 91.1% within 90 days after birth when compared to placebo. Within 180 days after birth, Abrysvo reduced the risk of LRTD by 57.3% and by 76.5% for severe LRTD, when compared to placebo.

- The most commonly reported solicited local and systemic adverse reactions (≥ 10%) with Abrysvo use in pregnant individuals were pain at the injection site, headache, muscle pain, and nausea.

- For both indications, Abrysvo is administered as a single dose (approximately 0.5 mL) intramuscularly.