Indian Health Service
National Pharmacy and Therapeutics Committee
Medication Update

August 22, 2023

FDA Approves First Vaccine for Pregnant Individuals to Prevent Respiratory Syncytial Virus (RSV) in Infants

On August 21st, 2023, the U.S. Food and Drug Administration (FDA) approved Abrysvo®, the first vaccine approved for use in pregnant individuals to prevent 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 approved as a single dose for use at 32 through 36 weeks gestational age of pregnancy.**

Background:[1]

RSV is a highly contagious virus that causes infections of the lungs and breathing passages in individuals of all age groups. RSV circulation is seasonal, typically starting during the fall and peaking in the winter. RSV is especially common in children and can lead to serious lower respiratory tract disease (LRTD), which affects the lungs and can cause life-threatening pneumonia and bronchiolitis. In infants and children, the risk of RSV-associated LRTD is highest during the first year of life. According to the U.S. Centers for Disease Control and Prevention, RSV is the leading cause of infant hospitalization in the United States.

Safety and Efficacy Data:[1,2,3]

The safety and effectiveness of Abrysvo® for immunization of pregnant individuals to prevent LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age is based on the FDA's analysis of data from ongoing, randomized, placebo-controlled international clinical studies.

The main clinical study was designed to evaluate the effectiveness of Abrysvo® to prevent LRTD and severe LRTD caused by RSV in infants born to individuals who were vaccinated during pregnancy. Among approximately 3,500 pregnant individuals who received Abrysvo®, compared to approximately 3,500 pregnant individuals who received placebo, 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, of whom approximately 1,500 received Abrysvo® and 1,500 received placebo, 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 safety of Abrysvo® was evaluated in two studies with a total of 3,700 pregnant individuals receiving Abrysvo® compared to an equal number receiving placebo. The most commonly reported side effects by pregnant individuals who received Abrysvo® were pain at the injection site, headache, muscle pain and nausea.

The Prescribing Information for Abrysvo® includes a warning to inform that a numerical imbalance in preterm births in Abrysvo® recipients (5.7%) occurred compared to those who received placebo (4.7%). The available data are insufficient to establish or exclude a causal relationship between preterm birth and Abrysvo®. Specifically, the warning informs healthcare providers that to avoid the potential risk of preterm birth with use of Abrysvo before 32 weeks of gestation, administer Abrysvo® as indicated in pregnant individuals at 32 through 36 weeks gestational age. Pregnant individuals who were at increased risk of preterm birth were generally excluded from clinical studies of Abrysvo®.

The FDA is requiring the company to conduct postmarketing studies to assess the signal of serious risk of preterm birth and to assess hypertensive disorders of pregnancy, including pre-eclampsia.

Agency Considerations:

At the Summer 2023 quarterly meeting earlier this month, the Indian Health Service National Pharmacy and Therapeutics Committee reviewed “Prevention of RSV”, including Abrysvo® for the prevention of LRTD caused by RSV in individuals 60 years of age and older (FDA approved in May 2023). Clinical guidance from the Committee’s review will be disseminated to the field.

References:

1. U.S. Food and Drug Administration, FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants. Published Aug 21, 2023
2. Kampmann B, Madhi S, et al. Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants. N Engl J Med, 2023; 20;388(16):1451-64.
3. U.S. Food and Drug Administration, Package Insert - ABRYSVO (STN 125768). Published online Aug 21, 2023.