FDA NEWS RELEASE

FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants

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Today, the U.S. Food and Drug Administration approved Abrysvo (Respiratory Syncytial Virus Vaccine), 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 for use at 32 through 36 weeks gestational age of pregnancy. Abrysvo is administered as a single dose injection into the muscle. The FDA approved Abrysvo in May for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

"RSV is a common cause of illness in children, and infants are among those at highest risk for severe disease, which can lead to hospitalization," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "This approval provides an option for healthcare providers and pregnant individuals to protect infants from this potentially life-threatening disease."

RSV is a highly contagious virus that causes respiratory infections in individuals of all age groups. It is the most frequent cause of lower respiratory tract illness in infants worldwide. In most parts of the U.S., RSV circulation is seasonal, typically starting during the fall and peaking in the winter. The virus is especially common in children, and most individuals can be expected to be infected with RSV by the time they reach two years of age. While RSV most often causes cold-like symptoms in infants and young children, it can also lead to serious LRTD such as pneumonia and bronchiolitis (swelling of the small airway passages in the lungs). In infants and children, the risk of RSV-associated LRTD is highest during the first year of life. According to the Centers for Disease Control and Prevention, RSV is the leading cause of infant hospitalization in the U.S.

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 was evaluated in ongoing, randomized, placebo-controlled international clinical studies.

A clinical study evaluated 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. In one study, approximately 3,600 pregnant individuals received a single dose of Abrysvo and approximately 3,600 pregnant individuals received a placebo. In the second study, approximately 100 pregnant individuals received Abrysvo and approximately 100 pregnant individuals received placebo.

The most commonly reported side effects by pregnant individuals who received Abrysvo were pain at the injection site, headache, muscle pain and nausea.

In addition, although not commonly reported, a dangerous hypertensive disorder, known as pre-eclampsia, occurred in 1.8% of pregnant individuals who received Abrysvo compared to 1.4% of pregnant individuals who received placebo. In the safety studies, low birth weight and jaundice in infants occurred at a higher rate in the pregnant Abrysvo recipients compared to pregnant placebo recipients.

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.

The application was granted Priority Review (/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review) status and Fast Track (/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track) and Breakthrough Therapy (/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy) designations.

The FDA granted approval of Abrysvo to Pfizer Inc.

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