# RSV vaccine given in pregnancy to help shield newborns receives full US approval

September 25 2023, by Cara Murez

Women may soon have a vaccine they can take during a pregnancy to

help protect their newborn from respiratory syncytial virus (RSV).

Following approval one month ago by the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention on Friday also approved the shot, called Abrysvo. That marks the last hurdle needed for the vaccine to become widely available.

"This is another new tool we can use this fall and winter to help protect lives," CDC Director Dr. Mandy Cohen said in an agency press release. "I encourage parents to talk to their doctors about how to protect their little ones against serious RSV illness, using either a vaccine given during pregnancy, or an RSV immunization given to your baby after birth."

The agency added that Abrysvo is already "available in some locations in the U.S. and availability is expected to increase in the coming weeks."

The vaccine is designed to be given to pregnant women between 32 and 36 weeks of pregnancy as a way to protect infants from birth through 6 months from the sometimes severe respiratory illness. Approval from the U.S. Centers for Disease Control and Prevention is still required before the vaccine is fully authorized for use.

"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," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said in a statement his agency issued at the time it approved the vaccine. "This approval provides an option for health care providers and pregnant individuals to protect infants from this potentially life-threatening disease."

While RSV poses a real threat to infants, it can infect people at any age. According to the FDA, it's the most frequent cause of lower respiratory tract illness in infants worldwide, typically circulating in fall and winter.

RSV is especially common in children, most of whom are infected with RSV by the time they reach 2 years of age.

Often RSV causes only cold-like symptoms, but can lead to serious lower respiratory illness, including pneumonia and bronchiolitis. The risk is highest in the first year of life, according to the FDA.

It is the leading cause of infant hospitalization in the United States, according to the CDC.

Currently the only other protection against RSV for infants is a lab-made antibody shot called Beyfortus. The first one-dose version was approved recently for infants younger than 8 months, to be given before the beginning of the first RSV season after their birth. Beyfortus should be available this fall.

Abrysvo's maker, Pfizer, predicts that the new vaccine could prevent 320,000 infant doctor visits and 20,000 hospitalizations each year if enough women receive it, the *Associated Press* reported.

The vaccine would be administered as a single-dose injection into the muscle. It is the same medication approved by the FDA and CDC in May to prevent RSV-caused illness in people ages 60 and older.

Clinical trials evaluated the vaccine's safety and effectiveness.

Among about 3,500 pregnant women who received Abrysvo and 3,500 who received a placebo, the vaccine reduced the risk of severe illness by almost 82% within three months after birth and by about 69% by the time a baby reaches 6 months of age.

In a subgroup of pregnant people, in which 1,500 received Abrysvo and 1,500 received placebo, the trial found that Abrysvo reduced the risk of

respiratory illness by about 35%, and reduced the risk of severe lower respiratory disease by just over 91% within three months after birth when compared to placebo.

By the time a baby is 6 months old, Abrysvo reduced the risk of RSV respiratory illness by about 57% and by 76.5% for severe illness, when compared to placebo, the FDA noted.

Safety was evaluated in two studies, one in about 7,200 women, half of whom received Abrysvo, and the other in about 200 pregnant women, half of whom also received Abrysvo. Side effects included pain at the injection site, headache, muscle pain and nausea.

A dangerous hypertensive disorder of pregnancy, known as pre-eclampsia, occurred in 1.8% of pregnant individuals who received Abrysvo compared to 1.4% of pregnant individuals who received a placebo, the FDA said.

Low birth weight and jaundice also occurred at a higher rate in infants of pregnant recipients of Abrysvo.

Prescribing information will include a warning about a "numerical imbalance" in preterm births in Abrysvo recipients—5.7%, versus 4.7% in those who received a placebo, the FDA noted. The data is not sufficient to establish that the vaccine can cause preterm births, but provides a warning to health care providers, the FDA said.

Pfizer will be required to conduct more studies to assess risks for preterm birth and pre-eclampsia.

**More information:** The American Lung Association has more on RSV

.