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FDA advisers support RSV vaccine for pregnant women

May 18, 2023

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Article type: News

Topics: Fetus/Newborn Infant, Maternal and Fetal Medicine, Obstetrics, RSV, Vaccine/Immunization

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A new vaccine that would be given to pregnant women to protect their infants from respiratory syncytial virus (RSV) received the endorsement of vaccine experts Thursday amid concerns about preterm births.

“If the vaccine actually lives up to data we’ve seen today, I can guarantee that many infants and their parents will breathe easier in the coming years,” said Jay M. Portnoy, M.D., a member of the Food and Drug Administration’s (FDA’s) Vaccines and Related Biological Products Advisory Committee (VRBPAC).

All 14 voting members agreed data are adequate to support efficacy of the vaccine, while 10 felt the safety data are adequate. The FDA is expected to decide whether to approve the vaccine in the next few months.

The vaccine from Pfizer is made up of RSV recombinant stabilized prefusion F proteins and is referred to as an RSVpreF vaccine (Abrysvo). If approved by the FDA and Centers for Disease Control and Prevention (CDC), it would be given to pregnant people at 24-36 weeks’ gestation to protect their infants up to 6 months after birth.

RSV can cause severe lower respiratory tract disease such as bronchiolitis or pneumonia and is the leading cause of hospitalization in U.S. infants. There are about 58,000 to 80,000 hospitalizations and 100 to 300 deaths per year in children under 5 years, according to data presented by the CDC. The virus wreaked havoc on the health care system last fall as patients with RSV, influenza, COVID and mental health issues filled clinics and hospitals.

There are no vaccines to protect infants from RSV, although the FDA is reviewing a monoclonal antibody from AstraZeneca and Sanofi that would be given to this age group. An FDA committee meets June 8 to

discuss that product. Another monoclonal antibody, palivizumab, is available to protect high-risk infants and toddlers, but only about 5% of infants are eligible.

Clinical trial data presented Thursday show RSVpreF is about 82% effective in preventing severe lower respiratory tract infection at 3 months of age and 69% effective at 6 months. Effectiveness against medically attended infections of any severity was 57% at 3 months and 51% at 6 months. Pfizer leaders estimate the vaccine could prevent 20,000 RSV hospitalizations and 322,000 medically attended RSV illnesses annually in infants under 6 months.

VRBPAC member Amanda Cohn, M.D., director of the CDC's Division of Birth Defects and Infant Disorders, called it a "very exciting and a really important tool for prevention."

The phase 3 randomized, double-blinded, placebo-controlled clinical trial spanned 18 countries and included safety data in about 3,700 pregnant women who received RSVpreF and their infants. Most reactions in women were mild to moderate. The most common were fatigue, headache and muscle pain. About 2.6% of those receiving the vaccine reported a fever.

The main safety concern for infants is preterm birth. The study found a preterm birth rate of 5.7% in the vaccine group compared to 4.7% in the placebo group. Pfizer representatives said these differences were driven largely by data from South Africa and are not statistically significant.

VRBPAC Chair Hana El Sahly, M.D., professor of molecular virology and microbiology at the Baylor College of Medicine, voted against the adequacy of the safety data, saying, a "20% increased risk of premature delivery is not trivial even if it is late preterm delivery."

VRBPAC member Henry H. Bernstein, D.O., M.H.C.M., FAAP, professor of pediatrics at the Zucker School of Medicine at Hofstra/Northwell, also expressed concerns about preterm births, saying, "Although it wasn't statistically significant, I'm concerned it might be a clinically significant signal."

Many who voted in favor also expressed some reservations about the preterm birth issue. However, several questioned whether it is related to vaccination.

"When I put all the evidence together, I'm not convinced that there's a clear causal relationship between this vaccine and preterm birth," said Daniel Feikin, M.D., M.S.P.H., a scientific adviser and respiratory diseases consultant in Switzerland.

Others said benefits outweigh risks and they would be watching data on real-world use closely if the vaccine is approved.

"If I compare the very small risk of earlier birth with the almost certain risk of getting RSV and a very high risk of ending up in the hospital, I have to on balance say the risk is much greater if we don't give the vaccine than if we do," said Dr. Portnoy, professor of pediatrics at the University of Missouri-Kansas City School of Medicine.

Some committee members also expressed reservations due to the potential for RSVpreF vaccination to interfere with the effectiveness of the tetanus, diphtheria, pertussis (Tdap) vaccine pregnant women also receive to protect their infants. Members said research on this is needed, but the impact may be mitigated if vaccines are spaced out during pregnancy.

"Is a reasonable alternative not to have this vaccine available or to administer it separately?" said VRBPAC member Saad B. Omer, M.B.B.S., M.P.H., Ph.D., FIDSA, director of the Yale Institute for Global Health. "To

my mind, even if that signal turns out to be clinically meaningful, there is a solution, which is suboptimal from a programmatic perspective but still better than not having this vaccine available."

Resources

- AAP policy *Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection*
- Information from the AAP *Red Book* on RSV
- Information for clinicians from the CDC on RSV
- Information for parents from HealthyChildren.org on RSV symptoms and when to call a doctor