FDA panel to vote on first RSV vaccine given in pregnancy to protect infants

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The first RSV vaccine designed to protect infants is under consideration

by a panel of advisers to the U.S. Food and Drug Administration.

An independent committee of experts will vote Thursday on whether to recommend the shot for pregnant mothers at 24 to 36 weeks gestation.

"Before the pandemic, RSV was the No. 1 cause of infant hospitalization in the United States, so this is a big deal," Dr. Ofer Levy, director of the precision vaccines program at Boston Children's Hospital, told NBC News. Levy is a temporary voting member of the panel, but not one who will vote on this vaccine.

If the panel recommends the vaccine, the FDA would still need to approve it, a process that could take months. The agency is not obligated to follow its advisers' recommendations, but it usually does.

The Pfizer-made vaccine would only be the second one ever approved in the United States for RSV (respiratory syncytial virus). A vaccine made by pharmaceutical company GSK was approved for adults ages 60 and up earlier this month. However, 11 RSV vaccines for various age groups are being tested in ongoing clinical trials.

When a mother-to-be receives the vaccine, protective antibodies transfer to infants through the placenta.

Safety data for the infant vaccine is "generally favorable," according to the FDA.

Trial participants had a slightly elevated rate of preterm births compared to the control group, according to the news report. However, that rate was still lower than that seen in the general population. The rate of preterm births among the 7,400 trial participants was 5.7% for those who received the vaccine compared to 4.7% of those who received a placebo and 10% in the general population. A trial by GSK for an infant

vaccine was halted last year because of a higher preterm birth rate.

RSV generally causes mild, cold-like symptoms. It is a minor illness in healthy adults, but can be severe in more vulnerable groups, including babies and older adults.

Up to 300 children younger than 5 years die from RSV in the United States each year. Up to 10,000 people age 65 and older also die from the virus, according to the U.S. Centers for Disease Control and Prevention.

In a clinical trial for the vaccine, infants had an 82% lowered risk of severe disease in the first three months after birth, NBC News said. That dropped to 69% by six months. Infants also had 51% lowered risk of developing respiratory disease so severe that it required a doctor's visit.

"Maternal immunization looks like an important piece of the puzzle, but we're going to need more to shield into the second half of the first year [of infancy] and beyond," Levy said.

Vaccines given in pregnancy are always concerning, he said.

"There's always the background concern: Are you inducing some inflammation that could be a problem? Because the body reads inflammation as, 'The woman's no longer safe, let's get the baby out.' So you want a fairly bland vaccine," Levy said.

Pfizer also has a proposal for an RSV vaccine used by older adults before the FDA panel this month. That is for the same vaccine, but for use in people ages 60 and up.

Another option, a monoclonal antibody injection, has already been approved in Canada, Europe and the United Kingdom for infants. An application for that shot is also being reviewed by the FDA.

Vaccine side effects including fatigue, headache, muscle pain and injection site pain in pregnant women.

More information: The U.S. Centers for Disease Control and Prevention has more on RSV.