STAT

Pfizer Covid-19 vaccine generates robust antibody response in children, without serious safety issues, company says

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By Matthew Herper Sept. 20, 2021

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Pfizer and its partner BioNTech said Monday that they would file for authorization of their Covid-19 vaccine for use in children after clinical trial results showed encouraging antibody levels in volunteers and side effects similar to those in teens and young adults.

The pediatric study, in children ages 5 to 11, is the first to disclose results in young children.

It used a lower dose of the vaccine than the one currently being administered, because earlier studies showed that the adult dose could cause more side effects. Adults receive two 30 microgram doses of the vaccine three weeks apart. In school-aged children, this was lowered to 10 micrograms.

Antibody responses and common side effects were compared between 2,268 children and a separate group of volunteers ages 16 to 25 who received the adult dose. The children were also compared to a placebo group of similar age to determine safety. One volunteer received the placebo for every two who received the vaccine.

The antibody response in children was roughly comparable to the response in participants ages 16 to 25. The companies said that side effects were also "generally comparable" between the two groups.

William Gruber, a senior vice president of vaccine clinical research and development at Pfizer, said the company hopes to submit the data to the Food and Drug Administration by the end of the month. He said specific side effects such as fevers and chills were similar to those in the 16- to 25-year-old group.

Pfizer and BioNTech provided only an average antibody level. That could mean that some kids would have lower levels — and less protection. However, Gruber said antibody levels were high throughout the group.

Outside experts viewed the data as positive, but limited.

“It’s not a lot to go on, but what we do have to go on looks great,” said Kathleen Neuzil, director of the Center for Vaccine Development and Global Health at the University of Maryland School of Medicine. “A lower dose of this vaccine in children appears as good as the higher dose in older children and adults.”

Pfizer’s press release did not include any data on the extent to which the vaccine reduced the chances that children would become sick. Gruber said that there were not enough cases of illness to tell. But outside experts said it was reasonable to assume that similar levels of antibodies would mean similar protection from disease.

John Moore, a professor of microbiology and immunology at Weill Cornell Medical College, emphasized that the FDA will be able to analyze both safety and efficacy data from the vaccine. “The bigger dimension is what they’re going to have available for safety assessments because of course that’s going to matter,” Moore said.

One worry could be cases of myocarditis, an inflammation of the heart, that have been seen, albeit rarely, in adults. These have occurred only once in every tens or hundreds of thousands of vaccine administrations. But no clinical trial is going to be big enough to give an accurate study of such a rare risk.

“It appears that children in the five to 11 year old age group are the least likely to have severe outcomes of Covid,” said Neuzil, citing recent data from the Centers for Disease Control and Prevention. “So not that it’s not important and not that it’s not a disease worth preventing, but if your severe outcomes are lower, then you’re going to have a higher bar for the vaccine performance. You’re going to want to be very careful about safety issues.”

But that has to be balanced against the risk of Covid-19, experts said. Recent data show more infected children are being hospitalized, and more are ending up in intensive care units. It is no longer just children who have other ailments that are becoming sick, they said.

Neuzel said that she believed that risks could best be dealt with by making sure that parents understand them, and are making an informed choice for their children.

“If this misperception that children do not get affected persists, some people could think it’s not necessary to vaccinate children or this smaller risk of side effects could be enough to not vaccinate children,” said Flor M. Munoz, an associate professor of pediatrics at Baylor College of Medicine and an investigator in the trial. “We have a different pandemic now than the pandemic we had in 2020.”

That means a decision has to be made on more limited data than regulators might like.

“We’re stuck between an urgent need for a vaccine and the uncertainty that comes about with making decisions on modest studies,” said Andrew T. Pavia, the chief of the division of pediatric infectious disease at the University of Utah. Assuming that the safety and efficacy data hold up when closely examined, Pavia said he thinks the best option is to go ahead and to continue to track rare side effects among people who choose to receive the vaccine.

Gruber, the Pfizer executive, emphasized that public health authorities will have to be the ones to judge whether Pfizer’s data are enough to authorize its lower dose vaccine for children.

But Gruber argued that it is important to think of the benefits of the vaccine beyond just preventing severe illness.

“Until we actually get control of the pandemic and children are felt to be protected, there are still going to be significant restrictions in terms of masking, after-school activities, all the things that allow children to be children,” said Gruber. “You know, I’m a pediatrician. I see the vaccine as liberating. To allow people to get back to their normal lives, that particular aspect can’t be lost in all of this.”

Pavia said that, if the vaccine is authorized by the FDA, it will probably be received in the same fashion it has been among adults.

“There’s going to be a subset of people who are going to be lined up on the morning that it’s available, including doctors and their kids and nurses and their kids,” said Pavia. “I think there will be a group of people who are just going to be really against it because they’re convinced that children are not at risk. And a large number of people [will be] in the middle: ‘We need to understand what we know and what we don’t know.’ Every academic pediatrician in the country with kids 5 to 11 is probably already in line.”

Data readouts in children 2 to 5 and 6 months to 2 are expected as early as the fourth quarter of this year, the companies said.

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