Moderna reports positive results for COVID vaccine in younger children

October 25 2021

Credit: Pixabay/CC0 Public Domain

US biotech firm Moderna said Monday its COVID vaccine was safe and produced a strong immune response in children aged 6-11, adding it would submit trial data to global regulators soon.

The news comes as a panel of government advisors was preparing to meet Tuesday on the question of whether to authorize the Pfizer vaccine in kids aged 5-11, with top infectious disease expert Anthony Fauci predicting it would be available by mid-November.

"We are encouraged by the immunogenicity and safety profile of mRNA-1273 in children aged 6 to under 12 years and are pleased that the study met its primary immunogenicity endpoints," Moderna chief executive Stephane Bancel said in a statement.

An interim analysis from a mid-to-late stage clinical trial of 4,753 children showed that two doses of vaccine produced a high level of neutralizing antibodies—Y-shaped proteins that bind to the coronavirus and block it from entering human cells.

The vaccine was dosed at 50 micrograms, which is half of what is used among adults, but still produced on average 1.5 times as many antibodies in children as it did in young adults given the higher dose.

The majority of adverse events were mild or moderate, including fatigue, headache, fever, and injection site pain.

These early results, released via a press statement, do not yet include a vaccine efficacy estimate, which may be expected at a later time once cases have accrued.

FDA meeting on Pfizer

The Moderna news comes as the US Food and Drug Administration (FDA) is preparing to convene a panel of advisors to vote on whether to greenlight the Pfizer shot for younger children, paving the way for 28 million more Americans to be vaccinated.

A briefing document posted on the FDA's website indicated the agency believes benefits outweigh the most worrying side effect for this age group, namely myocarditis, or heart inflammation.

"The overall analysis predicted that the numbers of clinically significant COVID-19-related outcomes prevented would clearly outweigh the numbers of vaccine-associated excess myocarditis cases," the document said.

But it acknowledged the benefit-risk calculus would differ when community transmission is very low, as was the case in the United States in June 2021.

The FDA also uploaded Pfizer's efficacy analysis, with the company estimating a two-dose course of its vaccine at 10 micrograms was more than 90 percent effective in preventing symptomatic disease.

Overall, more than 150 children aged 5 to 11 have died from COVID in the United States since the start of the pandemic, according to official data.

"If all goes well, and we get the regulatory approval and the recommendation from the CDC, it's entirely possible, if not very likely, that vaccines will be available for children from 5 to 11 within the first week or two of November," Fauci told ABC News Sunday.