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Moderna's COVID-19 vaccine wins EUA recommendation from FDA vaccine committee

by Melissa Jenco, News Content Editor

Editor's note: *The FDA granted an EUA on Dec. 18. On Dec. 19, the CDC's vaccine committee voted 11-0 to recommend use of the vaccine.For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

A national group of vaccine experts recommended emergency use authorization (EUA) of a second COVID-19 vaccine on Thursday, Dec. 17.

The Food and Drug Administration's (FDA's) Vaccines and Related Biological Products Advisory Committee (VRBPAC), a group of independent science and public health experts, voted 20-0 in favor of Moderna's messenger RNA (mRNA) vaccine for adults. One member abstained. The FDA commissioner said he is working to quickly finalize an EUA.

"I would say the evidence that has been studied in great detail on this vaccine highly outweighs any of the issues that we've seen," said VRBPAC member Hayley A. Gans, M.D., FAAP, a pediatric infectious diseases expert at Lucile Packard Children's Hospital. "I think it really supports us being able to put the pandemic in our background, really move forward and finally provide a safe and effective way to get to herd immunity."

Member Michael G. Kurilla, M.D., Ph.D., director of clinical innovation at the National Center for Advancing Translational Sciences, abstained, saying he would prefer an EUA target use in specific high-risk groups instead of everyone 18 and older.

If an EUA is issued, it would mean more doses soon would be available to health care workers who were deemed a priority group. Some began receiving a vaccine from Pfizer/BioNTech on Monday, just days after that vaccine received an EUA.

The Moderna and Pfizer vaccines both are mRNA vaccines with similar efficacy and safety profiles. Moderna's has less challenging shipping and storage requirements and does not require dilution. Moderna's two doses are given 28 days apart, while the Pfizer/BioNTech vaccine doses are given 21 days apart.

Hospitalizations and deaths from COVID-19 have been surging. At the time of the vote, more than 17.1 million people in the U.S. had been infected and more than 309,000 had died, according to Johns Hopkins University.

Vaccine efficacy

Moderna company conducted randomized, placebo-controlled trials with just over 30,000 adults.

Data showed 196 people were infected with COVID-19 during the trials, only 11 of whom had received the vaccine. Efficacy was determined to be 94% and was similar across subgroups.

Thirty cases of COVID-19 were severe, and all were in the placebo group.

Vaccine safety

Reactions after receiving the Moderna vaccine typically were mild to moderate and resolved quickly. The most common were pain at the injection site, fatigue, headache, myalgia, arthralgia, nausea/vomiting, chills and fever. These reactions were more common after the second dose and in people under age 65.

Serious adverse events possibly related to vaccination included a case of intractable nausea/vomiting and two

cases of facial swelling in people who had dermal fillers.

There were three cases of Bell's palsy among people who received the vaccine, but FDA experts said there was no clear basis to conclude the vaccine caused the reaction. Four cases also were reported in vaccine recipients in the Pfizer/BioNTech trial, and the FDA will be looking at the issue more closely. Lymphadenopathy also was reported more frequently in the vaccine group than the placebo group.

Severe allergic reactions have become a focus after they occurred twice in the United Kingdom and twice this week in Alaska among people who had received the Pfizer/BioNTech vaccine.

The Pfizer/BioNTech vaccine is contraindicated for people who have had a severe allergic reaction to any of the vaccine's components. The Centers for Disease Control and Prevention (CDC) also recommends health care providers conduct a risk assessment for people with a history of severe allergic reaction to another vaccine or to an injectable medication when deciding whether to vaccinate. Medical treatment to manage an anaphylactic reaction must be available immediately for all patients.

While there were no reports of severe allergic reactions in Moderna's trial, similar guidance likely will be issued, and the FDA and CDC will continue to investigate reports of allergic reactions, according to Doran Fink, M.D., Ph.D., deputy director of the FDA's Division of Vaccines and Related Products Applications.

"While the totality of data at this time continue to support vaccinations under the Pfizer EUA without new restrictions, these cases underscore the need to remain vigilant during the early phase of the vaccination campaign," Dr. Fink said.

Melissa J. Moore, Ph.D., chief scientific officer, platform research, for Moderna also addressed the vaccine's components and noted it does not contain preservatives, antibiotics or adjuvants. It is cleared from the body quickly and does not have the ability to alter DNA.

Vaccines for children

While the Pfizer/BioNTech vaccine received an EUA down to age 16, Moderna's vaccine has been tested only in people 18 years and older. Moderna has said it intends to start enrolling children as young as 12 years in trials.

AAP President Sara "Sally" H. Goza, M.D., FAAP, submitted a letter to VRBPAC this week stressing the importance of children being included in trials. More than 1.6 million children have been infected and at least 162 have died, according to data from the AAP and Children's Hospital Association. Their education and their social and emotional well-being also have suffered.

"As such, it is counter to the ethical principle of distributive justice to allow children to take on great burdens during this pandemic but not have the opportunity to benefit from a vaccine, or to delay that benefit for an extended period of time, because they have not been included in vaccine trials," Dr. Goza wrote. "Children must be included so we can best understand any potential unique immune responses and unique safety concerns."

Next steps

The FDA commissioner could finalize an EUA within the next day or two.

The CDC's Advisory Committee on Immunization Practices will meet Saturday to discuss whether to recommend the Moderna vaccine. On Sunday, the committee will discuss priority groups for vaccination after health care workers and residents of long-term care facilities.

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Resources

- FDA briefing document on Moderna's COVID-19 vaccine
- CDC guidance on COVID-19 vaccines for health care providers
- CDC toolkit for communicating with patients about the COVID-19 vaccine
- AAP FAQ on COVID-19 vaccines
- AAP interim guidance on COVID-19