CDC backs COVID vaccine from Novavax

July 20 2022

The U.S. Centers for Disease Control and Prevention on Tuesday gave its blessing for the emergency use of Novavax's COVID-19 vaccine, the fourth coronavirus shot to be approved in the United States.

CDC Director Dr. Rochelle Walensky signed off on the recommendation from the agency vaccine advisory panel that unanimously endorsed the vaccine on Tuesday afternoon.

"Today, we have expanded the options available to adults in the U.S. by recommending another safe and effective COVID-19 vaccine," Walensky said in a statement. "If you have been waiting for a COVID-19 vaccine built on a different technology than those previously available, now is the time to join the millions of Americans who have been vaccinated. With COVID-19 cases on the rise again across parts of the country, vaccination is critical to help protect against the complications of severe COVID-19 disease."

The CDC approval follows last Wednesday's emergency use authorization from the U.S. Food and Drug Administration.

"Authorizing an additional COVID-19 vaccine expands the available vaccine options for the prevention of COVID-19, including the most severe outcomes that can occur such as hospitalization and death," FDA Commissioner Dr. Robert Califf said in a statement last week. "Today's authorization offers adults in the United States who have not yet received a COVID-19 vaccine another option that meets the FDA's rigorous standards... COVID-19 vaccines remain the best preventive measure against severe disease caused by COVID-19 and I encourage anyone who is eligible for, but has not yet received a COVID-19 vaccine, to consider doing so."

Right now, the Novavax shot is only authorized as an initial immunization series, so those who have gotten one of the three other COVID vaccines can't use it as a booster shot, *The New York Times* reported. The company has said it plans to apply for booster authorization soon.

Novavax hopes its shot will be seen an as an alternative to the most widely used shots from Pfizer and Moderna, which use messenger RNA (mRNA) technology. The third shot option in the United States is a vaccine from Johnson & Johnson.

"Today's FDA emergency use authorization of our COVID-19 vaccine provides the U.S. with access to the first protein-based COVID-19 vaccine," Novavax President and CEO Stanley Erck said in a company statement. "This authorization reflects the strength of our COVID-19 vaccine's efficacy and safety data, and it underscores the critical need to offer another vaccine option for the U.S. population while the pandemic continues."

While many Americans have already had their first or second booster shots, about 22% have not received any doses.

Novavax's vaccine is given in two shots, three weeks apart. The Biden administration plans to buy 3.2 million doses of the vaccine, enough for 1.6 million people.

The vaccine uses nanoparticles made of proteins from the surface of the coronavirus to stimulate an immune response, making it the latest in a long line of protein-based vaccines that have been used worldwide for many years.

Like the mRNA vaccines, Novavax's vaccine is linked to an elevated risk of myocarditis and pericarditis, with six cases of the heart inflammation found in about 40,000 trial volunteers. COVID-19 can also trigger these types of heart inflammation, experts note.

The vaccine took longer to get to this point than the other options because of manufacturing issues. The new doses will be released after quality testing is finished "in the next few weeks," the *Times* reported.

Not clear yet is how Americans will receive the news. Only about 10% of unvaccinated people surveyed in a Morning Consult poll said they would definitely or probably get a protein-based vaccine. Other wealthy countries have shown weak demand for the drug, including European countries where only 12.6 million doses were distributed between December and June 30, compared to more than a billion doses so far of mRNA vaccines.

Clinical trials have found Novavax highly protective against symptomatic infection, but it's not clear whether it will be as effective against the Omicron variant. The company is working to develop new versions of the vaccine that would target Omicron and its variants, the *Times* reported.

A booster targeted at Omicron's BA.1 variant showed strong immune response in preliminary data. Clinical trial results could be available in September and be ready the last quarter of the year, the company said in a statement. Novavax will also speed efforts to tailor shots specifically to the BA.4 and BA.5 variants.

Weill Cornell virologist John Moore told the *Times* he considered Novavax an excellent vaccine but was not yet convinced that an Omicron-based booster would provide much extra protection compared with the original version.

"There's too little information," Moore said.

Moore thinks that if Novavax receives authorization as a booster, it may appeal to some because it caused few aches, fatigue and other side effects in clinical trials, including for Moore, who volunteered in one.

"The only way I could tell the next day which arm I had the needle in was the Band-Aid," he said. "At some point in the fall, I'll have another

dose, and it would be Novavax."

More information: The U.S. Centers for Disease Control and Prevention has more on COVID-19 vaccines.