FDA and CDC Give Green Light to Novavax COVID-19 Vaccine

The engineered protein vaccine was highly effective in a clinical trial but faced a long delay for authorization.

August 23, 2022 By Liz Highleyman

[UPDATE: On October 19, the Food and Drug Administration authorized the Novavax COVID-19 vaccine as a first booster, and the Centers for Disease Control and Prevention said that adults could receive the Novavax booster instead of the Moderna or Pfizer-BioNTech bivalent boosters if they are unwilling or unable to received mRNA vaccines.]

[UPDATE: On August 19, the Food and Drug Administration extended the emergency use authorization for the Novavax vaccine to include adolescents ages 12 to 17 years. The Centers for Disease Control and Prevention subsequently recommended the new vaccine as an additional option for this age group.]

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On July 13, the Food and Drug Administration (FDA) granted emergency use authorization for the Novavax COVID-19 vaccine. A week later, the Centers for Disease Control and Prevention (CDC) recommended that it be included as a fourth vaccine in the COVID prevention armamentarium.

“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 Robert Califf, MD, said in a press statement. “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 for safety, effectiveness and manufacturing quality needed to support emergency use authorization.”

The Novavax vaccine was authorized as an initial vaccine series for individuals ages 18 or older. It is given as two shots spaced three weeks apart. It has not yet been authorized for use as a booster for people who have already received other COVID vaccines.

Based on favorable safety and effectiveness data, an FDA advisory committee voted overwhelmingly in June that the vaccine’s benefits outweigh its risks. The CDC’s Advisory Committee on Immunization Practices voted unanimously to recommend the vaccine on June 19,

and CDC director Rochelle Walensky, MD, MPH, quickly signed off.

> Today, I endorsed ACIP's recommendation that Novavax's #COVID19 vaccine be used as another primary series option for adults 18 & older.
>
> For those waiting for a COVID-19 vaccine built on a different technology, now is the time to get vaccinated.
>
> More: https://t.co/M8YYIUFJ0f
>
> — Rochelle Walensky, MD, MPH (@CDCDirector) July 19, 2022

"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 media 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."

Safety and Effectiveness

The Novavax vaccine contains an engineered version of the SARS-CoV-2 coronavirus spike protein produced in insect cells plus an adjuvant to induce a stronger immune response. This vaccine employs more traditional technology that is already used in widely used influenza and hepatitis B vaccines. In contrast, the Pfizer-BioNTech and Moderna messenger RNA (mRNA) vaccines encode genetic instructions for producing the spike protein while the Johnson & Johnson and AstraZeneca/Oxford vaccines use a weakened adenovirus vector to deliver blueprints for the protein.

The authorization is supported by the results of the PREVENT-19 trial, which initially enrolled

nearly 30,000 adults in the United States and Mexico; it was later expanded to include adolescents ages 12 to 17. Participants were randomly assigned in a 2:1 ratio to receive two doses of the Novavax vaccine, spaced three weeks apart, or placebo injections.

In adults, the vaccine was 90% effective at preventing symptomatic COVID: 17 vaccine recipients came down with COVID versus 79 in the placebo group. No one who received the vaccine developed moderate or severe disease, was hospitalized or died from COVID-19. Vaccine effectiveness remained high, at 79%, among people over 65, who typically have weaker immune responses.

Importantly, however, the vaccine was tested when the SARS-CoV-2 alpha variant was the main circulating strain. All vaccines are less effective against the more recent—and more transmissible—omicron variants, which have been circulating in the United States since late 2021.

The Novavax vaccine is generally safe and well tolerated. Typical side effects are similar to those of other COVID vaccines, including pain, tenderness or swelling at the injection site and flu-like symptoms, including fatigue, fever, headache and muscle or joint aches.

More serious adverse events, including myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of tissue surrounding the heart), are rare. These are more likely to occur in young men but are very uncommon even in this group. Myocarditis and pericarditis also rarely occur in recipients of the Pfizer-BioNTech and Moderna mRNA vaccines.

Uncertain Demand

The new vaccine—one of six funded by the federal government's Operation Warp Speed—will be offered for free in the United States. More than 3.2 million doses have been shipped from the Serum Institute of India, the world's largest vaccine manufacturer, and are ready for distribution.

But it is unclear whether there will be much demand. Although the Novavax vaccine was previously authorized by the European Union and is endorsed by the World Health Organization, clinical trial delays and production difficulties allowed other vaccines to pull far ahead of it in the United States.

Because it uses more tried-and-true technology, the Novavax vaccine may be more acceptable to people who are hesitant to receive mRNA or adenovirus vector vaccines. Like the Johnson & Johnson vaccine, the new vaccine can be kept in a standard refrigerator and does not need super-cold storage like the mRNA vaccines, making it easier to store and transport.

Making the Novavax vaccine available as a booster option could increase demand among people who initially received other vaccines. Some research suggests that mixing and matching vaccines that work in different ways produces a stronger immune response.

"Patients and providers in the U.S. now have access to a protein-based COVID-19 vaccine backed by data that have demonstrated efficacy, safety, and tolerability," Karen Kotloff, MD, of

the University of Maryland School of Medicine, said in a Novavax press release. “Offering more vaccine technologies and options in our vaccination portfolio, including those built upon technologies that have been successfully used for years, will hopefully help to increase our country’s vaccination rate.”

Click here for the FDA’s Novavax vaccine fact sheet.

Click here for more news about COVID-19 vaccines.

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http://beta.docker.poz.com/article/fda-cdc-give-green-light-novavax-covid19-vaccine