Novavax COVID-19 Vaccine 90% Effective in U.S. Trial

The protein subunit vaccine provides 100% protection against moderate or severe disease, hospitalization and death.

June 15, 2021 By Liz Highleyman

An experimental COVID-19 vaccine from Novavax proved highly effective in a large trial in North America, offering a potential new tool for combatting the coronavirus pandemic. While authorization of the vaccine will come too late for it to play much of a role in the United States, it is expected to make an important contribution to global vaccine access.

The vaccine, dubbed NVX-CoV2373, demonstrated 90% efficacy for preventing symptomatic COVID-19. Effectiveness rose to 100% for prevention of moderate or severe disease, hospitalization and death. What's more, the vaccine offered very good protection against common coronavirus variants.

> NEW DATA RELEASE: Novavax #COVID19 Vaccine Demonstrates 90% Overall Efficacy and 100% Protection Against Moderate and Severe Disease in PREVENT-19 Phase 3 Trial https://t.co/llOiQXxDtD pic.twitter.com/4ePHxDpziZ
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> — Novavax (@Novavax) June 14, 2021

"Today, Novavax is one step closer to addressing the critical and persistent global public health need for additional COVID-19 vaccines. These clinical results reinforce that NVX-CoV2373 is extremely effective and offers complete protection against both moderate and severe COVID-19 infection," Novavax president and CEO Stanley Erck said in a press release. "Novavax continues to work with a sense of urgency to complete our regulatory submissions and deliver this vaccine,

built on a well understood and proven platform, to a world that is still in great need of vaccines."

NVX-CoV2373 is a protein subunit vaccine that contains an engineered version of the SARS-CoV-2 spike protein, which is produced in moth cells and encased in nanoparticles. In contrast, the Pfizer-BioNTech and Moderna vaccines contain messenger RNA (mRNA) that encodes genetic instructions for producing the spike protein, while the Johnson & Johnson vaccine and AstraZeneca and University of Oxford vaccines use a weakened adenovirus vector to deliver blueprints for the protein. While mRNA and adenovirus vectors are newer technologies, Novavax uses a tried and true approach that is already used for successful hepatitis B and human papillomavirus (HPV) vaccines.

All of these vaccines teach the immune system to recognize the spike protein and produce antibodies and T-cell responses against the virus. None of them contain intact SARS-CoV-2, and they cannot cause COVID-19.

North American Trial Results

The Phase III PREVENT-19 trial, which started in late December 2020, enrolled nearly 30,000 adults at more than 100 study sites in the United States and Mexico. About 20% of the participants were Latino or Latin American, 12% were Black, 7% were Native American and 5% were Asian. In May 2021, the study was expanded to include adolescents ages 12 to 17, and enrollment was recently completed.

The adult trial took place while more transmissible SARS-CoV-2 variants were circulating widely. Variants accounted for 82% of sequenced virus, mainly the alpha (B.1.1.7) variant first identified in the United Kingdom. (The Pfizer-BioNTech and Moderna vaccines were tested when the less transmissible original virus was predominant, but they have since been shown to be effective against viral variants as well.)

The participants were randomly assigned in a 2:1 ratio to receive two doses of the Novavax vaccine, spaced three weeks apart, or placebo injections.

Overall, the vaccine was 90% effective at preventing symptomatic COVID-19 seven or more days after the second dose, Novavax announced. Of the 77 reported cases, 14 occurred among vaccine recipients and 63 among placebo recipients—even though there were twice as many participants in the vaccine group. The efficacy against symptomatic disease was similar, at 91%, for "high-risk" individuals over age 65 and those with underlying health conditions—the groups most likely to have serious COVID-19 complications—and people with frequent coronavirus exposure. What's more, efficacy remained high, at 93%, against SARS-CoV-2 variants.

All vaccine recipients who came down with COVID-19 had mild illness. No one who received the vaccine developed moderate or severe disease, was hospitalized or died of COVID-19. In contrast, 10 placebo recipients developed moderate disease, four had severe cases, six were hospitalized and one died, the company reported. These results have not yet been published in a medical

journal.

Novavax previously reported findings from an earlier trial of more than 15,000 adults in the United Kingdom, showing that the vaccine was 90% effective overall at preventing symptomatic COVID-19. Effectiveness rose to 96% against the original SARS-CoV-2 strain but fell to 86% against the alpha variant.

Results were less impressive in a trial in South Africa, where a majority of COVID-19 cases were attributable to the beta (B.1.351) variant. In that study, the overall effectiveness was just 49%. When the analysis was limited to HIV-negative participants, efficacy rose to 55%, indicating that the response rate was substantially lower for people living with HIV. The beta variant accounted for less than 5% of cases in the United States while the North American trial was underway. Novavax is testing a new vaccine that targets the beta variant and recently reported promising data from animal studies.

So far, there have been no reports on how well the Novavax vaccine protects against the delta (B.1.617.2) variant first identified in India, which appears to partially evade immune responses. A recent analysis showed that a double dose of the Pfizer-BioNTech or AstraZeneca vaccine remains more than 90% effective against hospitalization due to the delta variant, but a single dose provides less protection that it does against the alpha variant.

The Novavax vaccine was safe and well tolerated in all studies to date. Typical side effects were similar to those seen with the other authorized vaccines, including injection site pain, fatigue and flu-like symptoms, though they appear to be somewhat less frequent and milder compared with the mRNA vaccines. To date, there have been no reports of anaphylactic reactions or unusual blood clotting problems, but these rare adverse events were not seen with other vaccines until many more people had received them.

Meeting Global Demand

Unlike the more fragile Pfizer-BioNTech and Moderna mRNA vaccines, the Novavax vaccine does not require ultra-cold temperatures. Like the Johnson & Johnson vaccine, it can be kept in a standard refrigerator, making it easier to store and transport. However, it is not as convenient as the J&J vaccine, which requires only a single shot.

Novavax, based in Gaithersburg, Maryland, indicated that it plans to apply for emergency use authorization from the Food and Drug Administration in the third quarter of this year. The company opted not to request earlier authorization based on the U.K. data, putting it far behind the Pfizer-BioNTech, Moderna and J&J vaccines.

Novavax’s big US-Mexico trial confirmed their protein vaccine works well, with 90 percent efficacy. It’s late for

the US, but not for the world. And it might prove a good booster too. Here is my story for @nytimes https://t.co/YGvfB5QZd7

— Carl Zimmer (@carlzimmer) June 14, 2021

As of mid-June, 53% of people in the United States have received at least one vaccine dose, and 44% are fully vaccinated, according to the Centers for Disease Control and Prevention's COVID-19 vaccine tracker. The country has an adequate supply of the three currently authorized vaccines—and a substantial portion of unvaccinated Americans say they don't plan to get one—so U.S. demand for the Novavax vaccine will be limited.

But it's a different story worldwide. According to Bloomberg's vaccine tracker, just 16% of the global population has been vaccinated, a large proportion of whom live in wealthy countries that have bought up the lion's share of the existing vaccine supply. This leaves a large unmet need that the Novavax vaccine could help fill. The company said it expects to be able to produce 150 million doses per month by the end of 2021, and it has agreed to provide more than 1 billion does to the COVAX global vaccination effort.

Click here for more news about COVID-19 vaccines.

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