

Novavax: Large study finds COVID-19 shot about 90% effective

June 14 2021, by Linda A. Johnson



In this Wednesday, Oct. 7, 2020, file photo, a vial of the Phase 3 Novavax coronavirus vaccine is seen ready for use in the trial at St. George's University hospital in London. Novavax says its vaccine appears effective against COVID-19 in a large study, including against variants. Results from the study in the U.S. and Mexico were released on Monday, June 14, 2021. Credit: AP Photo/Alastair Grant, File



Vaccine maker Novavax said Monday its COVID-19 shot was highly effective against the disease and also protected against variants in a large study in the U.S. and Mexico, potentially offering the world yet another weapon against the virus at a time when developing countries are desperate for doses.

The two-shot <u>vaccine</u> was about 90% effective overall, and preliminary data showed it was safe, the American biotechnology company said. That would put the vaccine about on par with Pfizer's and Moderna's.

While demand for COVID-19 shots in the U.S. has dropped off dramatically and the country has more than enough doses to go around, the need for more vaccines around the world remains critical. The Novavax vaccine, which is easy to store and transport, is expected to play an important role in boosting <u>vaccine supplies</u> in the developing world.

That help is still months away, however. The company says it plans to seek authorization for the shots in the U.S., Europe and elsewhere by the end of September and will be able to produce up to 100 million doses a month by then.

"Many of our first doses will go to ... low- and <u>middle-income countries</u>, and that was the goal to begin with," Novavax Chief Executive Stanley Erck said.

While more than half of the U.S. population has had at least one vaccine dose, less than 1 percent of people in the developing world have had one shot, according to <u>Our World In Data</u>.

The Pfizer, Moderna and Johnson & Johnson vaccines are already authorized for use in the U.S. and Europe. Europe also uses AstraZeneca's formula.



Novavax's study involved nearly 30,000 people ages 18 and up. Two-thirds received two doses of the vaccine, three weeks apart, and the rest got dummy shots.

There were 77 cases of COVID-19—14 in the group that got the vaccine, the rest in volunteers who received the dummy shots. None in the vaccine group had moderate or severe disease, compared with 14 in the placebo group.

The vaccine was similarly effective against several variants, including the one first detected in Britain that is dominant in the U.S., and in highrisk populations, including the elderly and people with other health problems.

Side effects were mostly mild—tenderness and pain at the injection site. There were no reports of unusual blood clots or heart problems, Erck said.

Novavax reported the results in a news release and plans to publish them in a <u>medical journal</u>, where they will be vetted by independent experts. The Gaithersburg, Maryland-based company previously released findings from smaller studies in Britain and South Africa.

COVID-19 vaccines train the body to recognize the coronavirus, especially the spike protein that coats it, and get ready to fight the virus off. The Novavax vaccine is made with lab-grown copies of that protein. That's different from some of the other vaccines now widely used, which include genetic instructions for the body to make its own spike protein.





In this Wednesday, Oct. 7, 2020, file photo, a Phase 3 Novavax coronavirus vaccine trial volunteer is given an injection at St George's University hospital in London. Novavax says its vaccine appears effective against COVID-19 in a large study, including against variants. Results from the study in the U.S. and Mexico were released on Monday, June 14, 2021. Credit: AP Photo/Alastair Grant, File

The Novavax vaccine can be stored in standard refrigerators, making it easier to distribute.

Novavax previously announced manufacturing delays because of supply shortages. The company now expects to reach production of 100 million doses a month by the end of September and 150 million doses a month by December.

The company has committed to supplying 110 million doses to the U.S.



over the next year and a total of 1.1 billion doses to developing countries.

In May, vaccines alliance Gavi, a leader of the U.N.-backed COVAX project to provide shots to poorer countries, announced it had signed an agreement to buy 350 million doses of Novavax's formula. COVAX is facing a critical shortage of vaccines after its biggest supplier in India suspended exports until the end of the year.

Novavax has been working on developing vaccines for more than three decades but hasn't brought one to market. Its coronavirus vaccine work is partly funded by the U.S. government.

Dr. Peter English, a vaccines expert previously with the British Medical Association, called the Novavax results "excellent news." English said that because vaccine production is complicated, it's crucial to have as many shots as possible.

"Any minor imperfection in the production plant can shut down the production for days or weeks," he said in a statement. "The more different manufacturers we have producing vaccine, the more likely it is we will have availability of vaccines."

He said it was encouraging news that Novavax would be able to adapt its vaccine to any potentially worrying variants in the future if necessary.

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Citation: Novavax: Large study finds COVID-19 shot about 90% effective (2021, June 14) retrieved 12 June 2024 from https://medicalxpress.com/news/2021-06-novavax-large-covid-shot-effective.html



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