Johnson & Johnson's one-dose COVID vaccine promising in early trial

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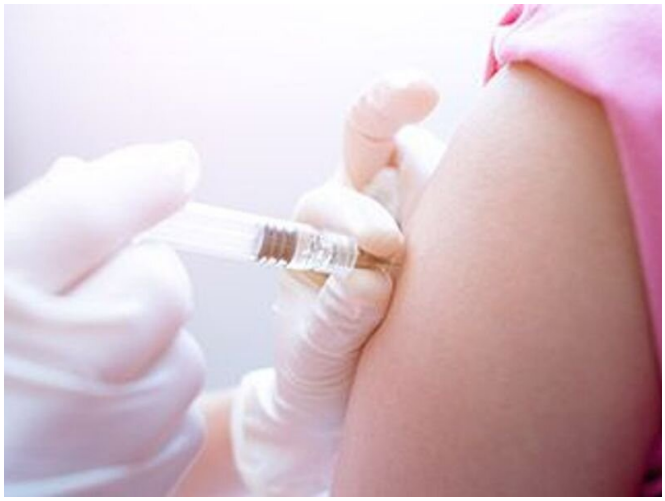

A single-shot COVID-19 vaccine from Johnson & Johnson has shown very strong results in early clinical trials, potentially providing a significant boost to U.S. vaccination efforts.

The vaccine produced an immune response of all 805 clinical trial participants within two months of inoculation, according to results published Jan. 13 in the *New England Journal of Medicine*.

The data "are encouraging in that they show robust generation of neutralizing antibody after a single dose in a younger population and in a population older than 65 years old, and because these responses persisted for at least 71 days," said Dr. Andrew Badley, director of the Mayo Clinic's HIV Immunology Laboratory in Rochester, Minn.

Efforts to distribute the two currently approved vaccines from Pfizer and Moderna have run into logjams, partially because the vaccines require extreme refrigeration and people have to receive two doses to achieve immunity.

"It certainly would be very helpful, having one dose instead of two," said Dr. Aaron Glatt, chair of the department of medicine and a hospital epidemiologist at Mount Sinai South Nassau Hospital in Oceanside, N.Y. "A lot of the logistical problems is getting that second dose, plus it takes a dose away from someone else. If you only have to give one dose, that would be great."

The Johnson & Johnson vaccine also would be hardier than either of the already approved vaccines because it relies on DNA technology rather than messenger RNA to prompt an immune system response.

The new vaccine is made up of a deactivated cold virus into which scientists cut-and-paste a genetic version of the "spike" protein used by the coronavirus to infect cells. The immune system recognizes the incomplete and harmless coronavirus protein as an invader and mounts a response, learning how to ward off any future infections from the actual coronavirus.

The Pfizer and Moderna vaccines rely on mRNA technology that works in much the same way, but delivers the genetic coding in an oily bubble that requires freezing temperatures and delicate handling.

The new vaccine remains stable for a time in the refrigerator. "Longer-term, this can be stored in just a regular freezer like you have in your kitchen, at that temperature," Dr. Thaddeus Stappenbeck, chair of the Department of Inflammation and Immunity at the Cleveland Clinic's Lerner Research Institute, said of the experimental vaccine. "But it's actually fine for several days, for extended periods of time, refrigerated."

The latest results from phase 1-2a trials of the Johnson & Johnson vaccine involved 805 participants in two groups, one featuring folks aged 18 to 55 and the other 65 and older.

More than 90% of participants mounted an immune response within a month, and all had levels of neutralizing antibodies by day 57.

A second dose of the vaccine more than doubled the amounts of neutralizing antibodies, the results showed.

It will be results from phase 3 clinical trials involving 45,000 participants that determine whether a single dose or two doses actually create lasting immune protection against COVID-19.

"It's very possible that the single dose will work, but it's not uncommon for vaccinations to require a booster," Stappenbeck said. "If this is slightly better with a booster, it would be worth getting the second shot."

Early results from the phase 3 trials are expected by the end of January, Johnson & Johnson has said.

"It will be essential to confirm these findings in phase 3 clinical trials, where efficacy of the vaccine against the virus can be determined," said Dr. Amesh Adalja, a senior scholar with the Johns Hopkins Center for Health Security in Baltimore.

Stappenbeck expects if the phase 3 results "are as strong as the data they saw with the mRNA vaccines, then the goal would be to wrap it up quickly and apply for emergency use authorization. It could happen by the end of January. That's what I've heard."

The phase 1-2a results also showed a similar safety profile to the existing vaccines, researchers reported. Fever was the most frequent adverse response, as well as fatigue, headache and body aches.

"The safety looks great. It's very much in line with what's been seen with the mRNA vaccine," Stappenbeck said.

Johnson & Johnson briefly paused its vaccine trial in October after a volunteer developed an unexplained neurological illness. A safety investigation determined that the illness was not related to the vaccine.

A similar COVID vaccine developed by AstraZeneca and Oxford University that relies on coronavirus DNA delivered through an inactivated cold virus also suffered delays based on safety concerns. Britain and India have authorized the vaccine for use, according to *The New York Times*.

Although the Johnson & Johnson vaccine would provide a needed third option, it's not yet clear how quickly the company will be able to get doses into arms.

The pharmaceutical giant pledged in its $1 billion contract with the U.S. federal government to have 12 million doses of its vaccine ready by the end of February and ramp up to a total 100 million doses by the end of June, the *Times* reported Wednesday.

However, federal officials have been told the company is as far as two months behind its original production schedule, the *Times* added. It's not expected to catch up until the end of April, by when it was to have delivered more than 60 million doses.

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

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