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FDA Authorizes Single-Shot COVID-19 Vaccine

The J&J vaccine, which is easier to store and deliver, will help speed up the coronavirus vaccine rollout.

February 27, 2021 By Liz Highleyman

On February 27, the Food and Drug Administration (FDA) granted emergency use authorization for Johnson & Johnson's COVID-19 vaccine for people ages 18 and older. Although it appears to be a bit less effective than the previously authorized Pfizer/BioNTech and Moderna mRNA vaccines, it only requires one dose, is easier to store and transport and is expected to have a major public health impact.

"The emergency use authorization of a third vaccine against COVID-19 in the United States today, just over a year since the virus was identified, demonstrates extraordinary scientific commitment and progress," Infectious Diseases Society of America president Barbara Alexander, MD, MHS, said in a statement. "The availability of another safe and effective vaccine that requires only one dose and that can be stored with only basic refrigeration opens new opportunities for delivery and expanded access for millions of people."

Today, FDA issued an emergency use authorization (EUA) for the third vaccine for the prevention of #COVID19 caused by SARS-CoV-2. The EUA allows the vaccine to be distributed in the U.S for use in individuals 18 years and older. https://t.co/QooSCJWSX0 pic.twitter.com/MWcCdt5n9U

— U.S. FDA (@US_FDA) February 27, 2021

The emergency authorization comes a day after an expert advisory panel voted unanimously that that the benefits of the vaccine outweigh its risks. Emergency use authorization is not the same as full approval, and it is typically granted after a simplified review. But given the political controversy around COVID-19 and skepticism about vaccines, the FDA undertook an extensive review process that included an outside expert review and public comment.

Rollout of the vaccine is expected to begin next week. The new one-shot option, along with expanded production of the two-shot Pfizer/BioNTech and Moderna products, will ease the current supply shortage and allow many more people to be vaccinated. At the end of February, more than 48 million Americans have received their first dose and more than 23 million are fully vaccinated, according to the Centers for Disease Control and Prevention COVID vaccine tracker.

The new vaccine, dubbed Ad26.COV2.S, was developed by Belgium-based Janssen Pharmaceuticals, which is owned by Johnson & Johnson (J&J). It uses an inactivated version of adenovirus type 26—a common cold virus—that cannot replicate and cause illness itself. The same AdVac platform is used for the company's Ebola virus vaccine and for the experimental HIV vaccine (Ad26.Mos.HIV) being evaluated in the ongoing Imbokodo and Mosaico trials.

The weakened adenovirus vector is used to deliver genetic blueprints for the SARS-CoV-2 spike protein—the red protuberances in the iconic image. The viral vector enters cells and releases the SARS-CoV-2 DNA, which instructs the cell to make spike proteins that trigger an immune response (click here for a graphical description from the New York Times).

via @NYTimes https://t.co/TOPXK9h4dv

— Chris Heaney (@heaneycd) February 28, 2021

Phase III Study Results

Authorization of the new vaccine was based on results from the Phase III ENSEMBLE trial, which enrolled more than 43,000 adults in the United States, Central and South America and South Africa. The study was designed to test how well the vaccine prevents moderate COVID-19 (any two symptoms plus a positive SARS-CoV-2 PCR test) or severe COVID-19 (severe systemic illness, respiratory failure, shock, organ failure, intensive care unit admission or death). The study participants were randomly assigned to receive a single injection of the vaccine or a placebo.

The trial included a diverse population. Just over half were men, and about a third were age 60 or older. About 40% had underlying health conditions associated with a higher risk of severe COVID-19, including obesity (29%), hypertension (10%) and diabetes (7%). The study enrolled 1,218 people living with HIV (3%). Across the U.S. sites, 74% of the participants were white, 15% were Latino, 13% were Black, 6% were Asian and 1% were Native American.

As described in an FDA briefing document and another document from J&J, a single dose of the

vaccine was 66% effective overall against moderate to severe COVID-19 at least 28 days after administration. A total of 66 cases of moderate or severe COVID-19 occurred in the vaccine group a month after vaccination versus 193 in the placebo group. Moreover, there was evidence that immunity improved over time.

But the overall number hides some notable regional differences. Effectiveness rose to 72% for trial participants in the United States, but fell to 64% in South Africa and 68% in Brazil, where more transmissible SARS-CoV-2 variant are circulating widely.

However, across all regions, the vaccine was 85% effective at preventing severe or critical COVID-19. No one in the vaccine group was hospitalized with COVD-19 after 28 days post-vaccination versus 16 in the placebo group. No COVID-19 deaths occurred in the vaccine group while seven were reported in the placebo group.

In general, the vaccine was effective regardless of demographics and underlying health conditions. Vaccine effectiveness was similar for people ages 60 or older and those ages 18 to 59, but it was lower, at 42%, for people over age 60 with comorbidities (who made up 17% of the study population). But even in this high-risk group, there were no COVID-19 hospitalizations or deaths 28 days or more after vaccination.

Two people with HIV in the vaccine group and four in the placebo group developed moderate or severe COVID-19 a month or more after vaccination (48% vaccine effectiveness); however, these numbers are too small to draw firm conclusions.

Although pregnant people were excluded from the trial, four participants in each group became pregnant during the study. These numbers are also too small to draw conclusions, but a study of the vaccine in rabbits did not see any adverse effects on fetal or postnatal development.

The J&J vaccine was well tolerated with no notable safety concerns. The most common adverse events were soreness at the injection site (49%) and flu-like symptoms, such as headache, fatigue and muscle aches, most of which were mild or moderate. One case of anaphylaxis (severe allergic reaction) was reported. Six people in the vaccine group, but none in the placebo group, reported tinnitus (ringing in the ears); this remains under investigation. Fifteen people in the vaccine group and 10 in the placebo group developed blood clots, and the FDA recommended ongoing monitoring. Eight vaccine recipients and three placebo recipients developed hives.

“[T]he vaccine was 100% effective in protecting against death from the disease everywhere it was tested,” National Institutes of Allergy and Infectious Diseases director Anthony Fauci, MD, said in a statement. “In addition to meeting the expectations of safety and effectiveness to support emergency use authorization, the Janssen vaccine has the advantage of requiring only a single injection and can be easily transported and stored without special refrigeration requirements.”

The FDA briefing document noted that the study was not able to show the duration of vaccine protection (this will require longer follow-up), effectiveness in people who previously had COVID-19 or effectiveness against long-term COVID. A study of the vaccine in pregnant people in underway and a trial of adolescents is expected to start soon, followed by studies of younger children and immunocompromised people.

So far, there are only limited data about whether the vaccine reduces asymptomatic infection and transmission. Among a subset of 2,650 people without symptoms who were tested for SARS-CoV-2 antibodies, 18 vaccine recipients and 50 placebo recipients tested positive—a 66% reduction.

“Demonstrated high efficacy against symptomatic COVID-19 may translate to overall prevention of transmission in populations with high enough vaccine uptake, though it is possible that if efficacy against asymptomatic infection were lower than efficacy against symptomatic infection, asymptomatic cases in combination with reduced mask-wearing and social distancing could result in significant continued transmission,” the document states. “Additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection.”

The results from this trial are not directly comparable with those of the Pfizer/BioNTech and Moderna studies, which had as their endpoint the prevention of symptomatic COVID-19 of any severity, including mild disease. And these vaccines completed their Phase III trials before resistant coronavirus variants were widespread.

The J&J vaccine requires only a single injection, doubling the number of people who can be vaccinated with a given supply. It can be stored in a standard refrigerator (36-46°F) and is easier to transport and distribute than the more fragile mRNA vaccines, which must be kept at super-cold temperatures. J&J said it would ship the vaccine using the same cold-chain procedures already in place for other medical products.

J&J indicated that it expects to provide enough doses to vaccinate 20 million people by the end of March, and 100 million by the end of June.

As expected -- FDA clears J&J vaccine

A new tool in the fight against horrible pandemic

With 20M doses available in March, getting closer to day where every American who wants a vaccine can get one

So pleased this superb vaccine will now be available https://t.co/eTO4SgIk3h

— Ashish K. Jha, MD, MPH (@ashishkjha) February 27, 2021

J&J requested FDA authorization only for the single-shot regimen but it is also testing a two-dose regimen that could prove more effective; those results are expected in a few months. The Pfizer/BioNTech and Moderna vaccines, which are 95% and 94% effective after two doses, are around 80% to 90% effective after a single dose. Authorization is based on the tested regimen, which is rather haphazard: Pfizer/BioNTech and Moderna could have just as easily tested a single dose regimen, which still would have looked very good, and J&J could have just as easily tested two doses initially, which might have looked better than the single shot. If two doses are ultimately found to be more effective, the FDA could amend its authorization and recipients could be given a second booster dose.

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