TuSalud

Three Countries Authorize Pfizer COVID-19 Vaccine

In the United States, an FDA expert advisory panel voted on December 10 to recommend emergency use authorization.

December 10, 2020 By Liz Highleyman

Update: On December 10, an expert advisory panel voted 17 to 4, with one abstention, in favor of FDA emergency use authorization of the Pfizer/BioNTech COVID-19 vaccine for people age 16 or older. The dissenters expressed concerned about authorization for teens under 18. The FDA usually follows advisory committee recommendations.

The same day, detailed data from the Phase III trial of the vaccine were published in The New England Journal of Medicine.

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This article was originally published on December 9, 2020.

The United Kingdom, Bahrain and Canada have granted emergency use authorization for Pfizer and BioNTech's COVID-19 vaccine, and rollout is currently underway in the United Kingdom. In the United States, the Food and Drug Administration (FDA) released detailed data ahead of a December 10 hearing, and regulators could authorize the vaccine by the end of the week.

This is the moment that 90-year-old grandmother Margaret Keenan returned to the ward at her local hospital in Coventry, after she became the first person in the world to receive the clinically-approved #COVIDVaccine this morning ??????????????????????

pic.twitter.com/80yRjJLRhM

— NHS Midlands (@NHSMidlands) December 8, 2020

On December 2, the Medicines and Healthcare Products Regulatory Agency (MHRA)—the FDA's U.K. counterpart—granted emergency authorization for the Pfizer/BioNTech vaccine. The United Kingdom has prioritized elderly people and certain health care workers. The first recipients—among them a 90-year-old grandmother and an 81-year-old man named William Shakespeare—were vaccinated on December 8.

Bahrain announced its authorization of the same vaccine on December 4; the country previously authorized another vaccine from the Chinese company Sinopharm for use by front-line workers. Canada followed suit, authorizing the Pfizer/BioNTech vaccine on December 9.

After a thorough and rigorous review process, Health Canada has approved Pfizer-BioNTech's COVID-19 vaccine. The first shipment of doses is tracking for delivery soon. This is all good news - but it doesn't mean we can let our guards down. https://t.co/Tl7uTBPWsR

— Justin Trudeau (@JustinTrudeau) December 9, 2020

Detailed Data Released

On December 10, the FDA will hold a hearing with a panel of outside experts to discuss emergency use authorization of the Pfizer/BioNTech vaccine, code-named BNT162b2. Members of the public can watch the proceedings online. In advance of the meeting, the agency released two detailed briefing documents describing clinical trial results:

- FDA briefing document
- Pfizer briefing document.

Pfizer previously announced top-line study findings showing that the two-dose vaccine—which uses novel mRNA technology to present the SARS-CoV-2 coronavirus spike protein to the immune system—is 95% effective at reducing the risk of COVID-19.

The Phase III trial enrolled a diverse population of more than 40,000 volunteers, three quarters of them in the United States. Men and women were equally represented, and 42% were over age 55. More than a quarter identified as Latino, and about 10% were Black. Nearly half had comorbidities, or underlying health conditions, linked to higher COVID-19 risk, including obesity (more than a third), hypertension and diabetes. A small number of people living with HIV (120) and adolescents ages 12 to 17 were enrolled later in the study and therefore were not included in the efficacy or safety analyses.

Study participants were randomly assigned to receive two doses of the vaccine or placebo injections spaced three weeks apart.

A total of 170 cases of symptomatic COVID-19 were observed, with 162 in the placebo group and just eight in the vaccine group. The risk of symptomatic disease fell by about half after the first dose and by 95% after the second dose. A protective effect was evident starting about 10 days after the first dose. Of the 10 observed cases of severe COVID-19, nine were in the placebo group. The single vaccine recipient classified as having severe COVID-19 based on low blood oxygen levels was not hospitalized and did not require advanced care. The vaccine was effective across all demographic groups, including people over age 65 and those with obesity or other comorbidities.

> This graph speaks volumes; @matthewherper fleshes out the rest in this story setting up Thursday's all-important meeting of @US_FDA's advisory committee, VRBPAC, on the Pfizer/BioNTech #Covid19 vaccine. https://t.co/jQhHVGGnz6 pic.twitter.com/aoDCjAv1n1
>
> — Helen Branswell (@HelenBranswell) December 8, 2020

It is not yet known whether the vaccine will prevent asymptomatic SARS-CoV-2 infection or transmission of the virus; so far, it has only been shown to prevent symptomatic illness. Trial volunteers were not tested regularly to see whether they had been infected; they were only tested if they developed symptoms. Most experts expect that the vaccine will offer some protection against infection, but this remains to be proved in further studies. It is also not yet known how long vaccine-induced immunity will last.

Turning to safety, about half of the study participants had at least two months of follow-up after

the second vaccine dose (an FDA requirement), and more than 90% had at least one month of follow-up.

Side effects were common, especially after the second dose, but most were mild to moderate. More than 80% of vaccine recipients experienced injection site reactions such as soreness. Other common symptoms included fatigue (63%), headache (55%), muscle pain (38%), chills (32%), joint pain (24%) and fever (14%); these were more common in people under age 55. These flu-like symptoms are not unusual after receiving vaccines and are an indication that the immune system is working.

About 5% of vaccine recipients over age 55 and 3% of younger volunteers had severe reactions. About half a percent experienced serious adverse events, which occurred at a similar rate in the vaccine and placebo groups. Four vaccine recipients—but no one in the placebo group—developed Bell's palsy, a sudden and usually temporary weakness or paralysis of facial muscles. The FDA recommended ongoing surveillance for this condition. There were two deaths in the vaccine group and four in the placebo group, most of them due to cardiovascular disease.

After the briefing documents were released, U.K. regulatory authorities announced that two National Health Service workers who were among the early vaccine recipients had experienced allergic reactions; both had a history of prior reactions, and both have recovered. The MHRA advised that people with a history of allergic or anaphylactic reactions to a vaccine, medicine or food and those who carry adrenaline autoinjectors (EpiPens) should not receive the vaccine, and vaccination should only be done in facilities prepared for emergency resuscitation.

The FDA reviewers concluded that the Pfizer/BioNTech vaccine is "highly effective" at preventing symptomatic COVID-19 and has a "favorable safety profile." This suggests that the expert panel is likely to vote that the vaccine's benefits outweigh its risks, and the agency is likely to grant emergency authorization soon after the meeting. While the FDA is not required to follow advisory panel recommendations, it usually does so.

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