Moderna to ask FDA for COVID-19 vaccine authorization

Moderna plans to file for authorization of its COVID-19 vaccine today, after the final analysis of its clinical trial data confirmed that it is safe and 94 percent effective. It is the second company to submit COVID-19 vaccine data to the Food and Drug Administration, after Pfizer and BioNTech submitted their data earlier this month.

In a press release, Moderna said that there were 196 cases of symptomatic COVID-19 reported in the 30,000-person trial. Of those cases, 185 developed in people who received a placebo, and 11 cases developed in people who took the vaccine. There were 30 cases of severe disease in the trial, and all of them were in the placebo group – indicating that the vaccine can prevent the most dangerous forms of COVID-19.

"With evidence of high efficacy against disease and severe disease, the vaccine checks a lot of boxes," Natalie Dean, a statistician at the University of Florida, told *Stat News*.

The new analysis is consistent with the interim look at the data released earlier this month. That report included 11 cases of severe disease, all of which were in the placebo group. Moderna said that there continued to be no major safety concerns in the updated data. The most commonly reported side effects of vaccination included joint pain, fatigue, and headache.

Stéphane Bancel, Moderna's chief executive officer, told *The New York Times* that the FDA's vaccine advisory committee would

review the application on December 17th. If it's authorized as expected, he said the first people could get their first shots on December 21st. Like Pfizer's vaccine, each person would need two doses given a few weeks apart. The same advisory committee is meeting on December 10th to review the Pfizer and BioNTech vaccine, which is also expected to receive authorization.

However, Peter Marks, the head of the FDA's Center for Biologics Evaluation and Research, cautioned that there could be a longer lag between the advisory committee meetings and authorization of the vaccines. "It's possible that it could be within days, but our goal is to make sure it is certainly within a few weeks," he said in remarks reported by CNN.

Moderna said it could have up to 20 million doses of the vaccine, enough to vaccinate 10 million people, by the end of 2020. Pfizer could provide up to 25 million doses to the US this year, which would cover 12.5 million people.

Under the current plans, each state will get an allotment of vaccines based on its population. The Advisory Committee on Immunization Practices at the Centers for Disease Control and Prevention is meeting Tuesday to vote on which groups it will recommend get vaccinated first. Health care workers will likely be at the top of the list, but the committee will also consider adding residents in long-term care facilities to that first group. There are around 21 million health care workers and 3 million long-term care residents in the US.

If authorized, more doses of these vaccines will be available through January and February, and other people in high-risk groups — like those with underlying medical conditions and adults over the age of 65 — should start to get access to vaccines. "As you go down the line, you get to people who are essentially normal, have no co-morbidities and are not elderly," Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, told CNN. He expects that

anyone who wants a vaccine will be able to get one by April 2021.

https://www.theverge.com/2020/11/30/21726554/moderna-covid-vaccine-fda-pfizer-biontech