Advisory committee votes to recommend EUA for Moderna vaccine

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The Moderna COVID-19 vaccine received recommendation from a U.S.

Food and Drug Administration advisory committee on Thursday, clearing the way for it to become the second COVID-19 vaccine to be granted emergency use authorization.

After a day-long series of presentations on the vaccine data, the Vaccines and Related Biological Products Advisory Committee voted on the question, "Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine outweigh its risks for use in individuals 18 years of age and older?" The vote to recommend was nearly unanimous with 20 yes votes and one abstention.

The FDA is likely to authorize the vaccine Friday, the *Washington Post* reports. Gen. Gustave F. Perna, who is overseeing the federal vaccine distribution effort, said the government is preparing to ship nearly 6 million doses of the Moderna vaccine to 3,285 locations within the first week after approval.

"Following today's positive advisory committee meeting outcome regarding the Moderna COVID-19 vaccine, the U.S. Food and Drug Administration has informed the sponsor that it will rapidly work toward finalization and issuance of an emergency use authorization," FDA Commissioner Stephen M. Hahn, M.D., and Peter Marks, M.D., Ph.D., director of the FDA Center for Biologics Evaluation and Research, said in a statement. "The agency has also notified the U.S. Centers for Disease Control and Prevention and Operation Warp Speed, so they can execute their plans for timely vaccine distribution."

On Tuesday, the FDA released briefing documents with a data review showing that the Moderna vaccine, which is administered in two doses one month apart, was found to be 94 percent effective in a clinical trial and had no serious safety concerns. The Moderna vaccine was developed in partnership with the National Institute of Allergy and Infectious Diseases, with a government investment of $4.1 billion for research,

development, and advanced purchase of 200 million doses.

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