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Novavax COVID-19 vaccine – FDA advisors discuss emergency use authorization request

- On June 7, 2022, the Food and Drug Administration (FDA) convened a Vaccine and Biologic Products Advisory Committee (VRBPAC) to discuss an Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older.

- The Novavax COVID-19 vaccine (NVX-CoV2373) is a recombinant protein that is adjuvanted (Matrix-M) and given as 2 doses 21 days apart. Matrix-M increases the magnitude and breadth of immune response.

- In the PREVENT-19 study (randomized, observer-blinded, placebo-controlled) conducted in the U.S. and Mexico, 29,945 participants were enrolled. The study was conducted when the Omicron variant was not circulating.

    — Vaccine efficacy was 90.4% against all disease (14 cases in vaccine arm; 63 cases in placebo arm), and 100% against moderate to severe disease (10 moderate cases and 4 severe cases in the placebo arm).

- There was discussion about the safety of the Novavax COVID-19 vaccine because of a potential safety signal for myocarditis/pericarditis, a reaction that has been observed with the mRNA COVID-19 vaccines (Comirnaty® and Spikevax®), as well as with COVID-19 infection alone.

    — In a safety database in about 40,000 vaccinated individuals, six recipients reported myocarditis and/or pericarditis.
    — Additionally, in post-marketing safety data of 744,235 Novavax doses administered in other countries, there were 36 reports of myocarditis and pericarditis.

- The Committee also discussed that the efficacy and safety data is similar to the mRNA vaccines, but there was disappointment that no data was presented on efficacy against the Omicron variant.

    — The Committee was asked to consider the totality of the available data supporting the vaccine for a potential EUA approval.
    — Twenty-one of the 22 members with 1 abstention voted that the benefits of the Novavax COVID-19 vaccine when administered as a 2-dose series outweigh its risks for use in individuals 18 years of age and older.

- If authorized by the FDA, the Novavax COVID-19 vaccine would offer a different mechanism compared with the mRNA vaccines, and this new, non-replicating, mechanism may be more attractive to individuals who have been reluctant to receive the currently available COVID-19 vaccines. Approximately 1/3 of Americans are not fully vaccinated against COVID-19.

What's Next?

- The FDA will review the EUA request and the recommendations of the VRBPAC. Then the FDA will either approve or deny the EUA request for the Novavax COVID-19 vaccine.

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- If the FDA approves the EUA for the Novavax COVID-19 vaccine, then the Centers for Disease Control and Prevention will convene its Advisory Committee for Immunization Practices (ACIP) to review and make recommendations for who should receive this vaccine. The next ACIP meeting is scheduled for June 17 and 18.

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