FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted

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Español (https://www.fda.gov/news-events/press-announcements/actualizacion-sobre-el-coronavirus-covid-19-la-fda-autoriza-el-uso-de-emergencia-de-la-vacuna-contra)

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the Novavax COVID-19 Vaccine, Adjuvanted for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

"Authorizing an additional COVID-19 vaccine expands the available vaccine options for the prevention of COVID-19, including the most severe outcomes that can occur such as hospitalization and death," said FDA Commissioner Robert M. Califf, M.D. "Today's authorization offers adults in the United States who have not yet received a COVID-19 vaccine another option that meets the FDA's rigorous standards for safety, effectiveness and manufacturing quality needed to support emergency use authorization. COVID-19 vaccines remain the best preventive measure against severe disease caused by COVID-19 and I encourage anyone who is eligible for, but has not yet received a COVID-19 vaccine, to consider doing so."

The FDA has determined that the Novavax COVID-19 Vaccine, Adjuvanted has met the statutory criteria for issuance of an EUA. The data support that the known and potential benefits of the vaccine outweigh its known and potential risks in people 18 years of age and older, and that this vaccine may be effective in preventing COVID-19. In making this determination, the FDA can assure the public and medical community that a thorough analysis and evaluation of the available safety and effectiveness data and manufacturing information have been conducted.

The Novavax COVID-19 Vaccine, Adjuvanted is administered as a two-dose primary series, three weeks apart. The vaccine contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual. The spike protein in this vaccine is produced in insect cells; the Matrix M-adjuvant contains saponin extracts from the bark of the Soapbark tree that is native to Chile.

"After a comprehensive analysis and evaluation of the data, and assessment of the manufacturing processes and information, as well as input from the FDA's committee of external independent advisors, the FDA's medical and scientific experts have determined that the vaccine meets the FDA's high standards for safety and effectiveness for emergency use authorization," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "Novavax COVID-19 Vaccine, Adjuvanted provides another alternative for adults and adds another vaccine to the COVID-19 vaccine supply for the United States. The American public can trust that this vaccine, like all vaccines that are used in the United States, has undergone the FDA's rigorous and comprehensive scientific and regulatory review."

FDA Evaluation of Available Effectiveness Data

The vaccine was assessed in an ongoing randomized, blinded, placebo-controlled study conducted in the United States and Mexico. The effectiveness of the vaccine was assessed in clinical trial participants 18 years of age and older who did not have evidence of SARS-CoV-2 infection through 6 days after receiving the second vaccine dose. Among these participants, approximately 17,200 received the vaccine and approximately 8,300 received saline placebo. Overall, the vaccine was 90.4% effective in preventing mild, moderate or severe COVID-19, with 17 cases of COVID-19 occurring in the vaccine group and 79 cases in the placebo group. No cases of moderate or severe COVID-19 were reported in participants who received the vaccine, compared with 9 cases of moderate COVID-19 and 4 cases of severe COVID-19 reported in placebo recipients. In the subset of participants 65 years of age and older, the vaccine was 78.6% effective. The clinical trial was conducted prior to the emergence of delta and omicron variants.

FDA Evaluation of Available Safety Data

The safety of the vaccine was assessed in approximately 26,000 clinical trial participants who received the vaccine and approximately 25,000 who received placebo. The most commonly reported side effects by vaccine recipients included pain/tenderness, redness and swelling at the injection site, fatigue, muscle pain, headache, joint pain, nausea/vomiting and fever. Approximately 21,000 vaccine recipients had at least two months of safety follow-up after their second dose.

The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) includes a warning that clinical trial data provide evidence for increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of tissue surrounding the heart) following administration of Novavax COVID-19 Vaccine, Adjuvanted. The Fact Sheet for Recipients and Caregivers informs that in most people who have had myocarditis or pericarditis after receiving the vaccine, symptoms began within 10 days following vaccination and that vaccine recipients should seek medical attention right away if they experience any of the following symptoms after vaccination: chest pain, shortness of breath, feelings of having a fast-beating, fluttering or pounding heart.

As part of this authorization, it is mandatory for the company, Novavax Inc., and vaccination providers to report the following to the Vaccine Adverse Event Reporting System (VAERS): serious adverse events, cases of Multisystem Inflammatory Syndrome and cases of COVID-19 that result in hospitalization or death.

It is also mandatory for vaccination providers to report all vaccine administration errors to VAERS for which they become aware and for Novavax Inc. to include a summary and analysis of all identified vaccine administration errors in monthly safety reports submitted to the FDA.

The FDA has evaluated the pharmacovigilance plan submitted by the company to monitor the safety of Novavax COVID-19 Vaccine, Adjuvanted as it will be used under EUA to ensure that any safety concerns are identified and evaluated in a timely manner. As a condition of authorization, the company will conduct studies to further assess its safety, including studies to further assess the risks of myocarditis and pericarditis.

In addition, the FDA and the Centers for Disease Control and Prevention have several systems in place to continually monitor COVID-19 vaccine safety and allow for the timely detection and investigation of potential safety concerns.

The FDA also expects Novavax Inc. to continue their clinical trials to obtain additional safety and effectiveness data and pursue approval (licensure). The EUA was issued to Novavax Inc. The authorization will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19 is terminated. The EUA may be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance.

Related Information

- Novavax COVID-19 Vaccine, Adjuvanted (http://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine)
- COVID-19 Vaccines (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines)
- Emergency Use Authorization for Vaccines Explained (https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)
- Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19)
- Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19)

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