U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

CDC/DDID/NCIRD
August 19, 2022

DECISION REQUESTED

Recommendations:
The Centers for Disease Control and Prevention (CDC) recommends the following within the parameters of the Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA):

- A two-dose Novavax COVID-19 Vaccine, Adjuvanted primary series for persons ages 12-17 years

Status Quo Ante:

- ACIP has issued recommendations for COVID-19 vaccination for everyone ages 6 months and older for the prevention of COVID-19 in the United States.
- On July 19, 2022, ACIP and CDC recommended the Novavax COVID-19 Vaccine, Adjuvanted as a two-dose primary vaccine series for persons ages 18 years and older.
- On August 19, 2022, FDA issued an EUA for the Novavax COVID-19 vaccine to authorize the use of a two-dose primary vaccine series for persons ages 12 and older.
- The Novavax COVID-19 vaccine will be the third COVID-19 vaccine authorized for use in persons ages 12-17 years in the United States.

Key Issues:

- COVID-19 continues to pose a significant public health problem in the United States and COVID-19 vaccines continue to mitigate cases, hospitalizations, and deaths.
- As of August 3, 2022, over 604 million doses of COVID-19 vaccine have been administered in the United States.
- Not all people in the U.S. have received the benefits that COVID-19 vaccines provide. About 8 million U.S. adolescents ages 12-17 years have not yet received a single dose of COVID-19 vaccine and would benefit from starting a primary series.
- Vaccination of unvaccinated individuals remains the top priority of the U.S. COVID-19 vaccination program.
- Novavax COVID-19 vaccine had high efficacy among persons ages 12-17 years against symptomatic COVID-19 disease in the setting of the Delta variant predominance. This is consistent with other authorized COVID-19 vaccines at that time. However, efficacy with recent SARS-CoV-2 variants is unknown.
- Reactogenicity reported after Novavax COVID-19 vaccine is similar to what has been reported for other COVID-19 vaccine primary series.

- In the adolescent expansion of the U.S.-based Novavax COVID-19 clinical trial, there was one report of a single myocarditis case after Novavax COVID-19 vaccine in a 16-year-old male in the post-crossover phase.
- Based on available data, the vaccine effectiveness and myocarditis rates for Novavax and mRNA COVID-19 vaccines cannot be directly compared. Therefore, post-authorization monitoring for both vaccine effectiveness and safety will be important.
- The Novavax COVID-19 vaccine has been administered to more than seven thousand adults in the United States as of August 3, 2022.
- Vaccination remains the best way to protect against SARS-CoV-2 and rare cardiac risks of COVID-19 disease.
- An additional COVID-19 vaccine, manufactured with traditional vaccine technology that has been used in development of a number of other routinely used vaccines, will provide an additional option for unvaccinated individuals.

Pros:

- (b)(5)

Cons:

(b)(5)

Next Steps:

- If this recommendation is adopted by the CDC Director, CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States," clinical education materials, and related webpages will be updated.

Approved: ____X_____ **Not Approved:** _____ **Would like briefing:** _____

Rochelle P. Walensky, MD, MPH
Director, CDC

Drafted by: Melinda Wharton, MD, MPH, ACIP Executive Secretary
Approved by: José Romero, MD, Director, CDC/DDID/NCIRD
Attachment: Letter from ACIP Chair