Novavax COVID-19 vaccine, adjuvanted – New emergency use authorization

- On July 13, 2022, the FDA announced the emergency use authorization (EUA) of Novavax's COVID-19 vaccine, adjuvanted, for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

- The Novavax COVID-19 vaccine, adjuvanted 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.

- The efficacy of Novavax COVID-19 vaccine, adjuvanted was established in a randomized, observer-blinded, placebo-controlled study in 29,945 participants who were 18 years of age or older and did not have evidence of SARS-CoV-2 infection. Participants received two doses of the Novavax COVID-19 vaccine, adjuvanted (0.5 mL) or placebo three weeks apart.

    — Vaccine efficacy of the Novavax COVID-19 vaccine, adjuvanted to prevent symptomatic mild, moderate or severe COVID-19 from 7 days after dose 2 was 90.4% (95% CI: 83.8, 94.3).
    — There were no cases of moderate or severe COVID-19 reported in participants who had received the Novavax COVID-19 vaccine, adjuvanted, vs. nine cases of moderate COVID-19 and four cases of severe COVID-19 reported in participants who had received placebo.
    — The circulating variants during the study were predominantly alpha, beta, P.1 (gamma), B.1.427 and B.1.429 (epsilon), and B.1.526 (iota).

- Warnings and precautions for Novavax COVID-19 vaccine, adjuvanted include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitations of vaccine effectiveness.

- The most common adverse reactions with Novavax COVID-19 vaccine, adjuvanted use were pain/tenderness, redness and swelling at the injection site, fatigue, muscle pain, headache, joint pain, nausea/vomiting and fever.

- The recommended dose of Novavax COVID-19 vaccine, adjuvanted is given intramuscularly as a primary series of two doses (0.5 mL each) 3 weeks apart.

- The U.S. government has purchased 3.2 million doses of the Novavax COVID-19 vaccine, adjuvanted. The vaccine will be distributed by the government and available for free to appropriate individuals like the mRNA vaccines, Comirnaty® and Spikevax™.

- The Novavax COVID-19 vaccine, adjuvanted is supplied as a multi-dose vial containing 10 doses of 0.5 mL each. The NDCs are 80631-100-10 and 80631-100-01

What's Next?

- The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is scheduled to meet on July 19, 2022 to make recommendations for the use of the Novavax COVID-19 vaccine, adjuvanted.

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- After the ACIP makes its recommendations, the CDC director must sign off on the recommendations prior to implementation.