Creating tomorrow's vaccines today.

November 17, 2022

Oliver Triebel
Germany

Dear Mr. Triebel,

Thank you for your recent inquiry about NVX-CoV2540 (Omicron BA.5 SARS-CoV-2 rS/Matrix M adjuvant). You requested information regarding:

- NVX-CoV2540 – General Overview

Information pertaining to the above topic is included.

NVX-CoV2540 is an investigational candidate that has not been granted regulatory/health authority authorization or approval. Hence efficacy and safety has not been established.

Novavax is providing this material as an information service and professional courtesy. Providing this information does not constitute any recommendation for use.

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If you have questions regarding any of the information we have provided, please contact your healthcare provider. We hope this information will be helpful to you.

Sincerely,

Global Medical Information
Novavax
2022-0005753

NVX-CoV2540 – General Overview

NVX-CoV2540 has not been given 'conditional approval' by the European Commission. Hence efficacy and safety have not been established.

Novavax is providing this material as information and does not constitute any recommendation for use.

Relevant Information

NVX-CoV2540 is an investigational vaccine which contains the recombinant spike protein from the **omicron BA.5 variant**. It is not authorized or approved in any country.[1]

Novavax does not have a timeline regarding when this vaccine will be authorized or approved or when it will be available. The commercial post-authorization presentation of this product as monovalent or bivalent is unknown currently.

Clinical Study Information[1]

A study is being conducted to assess the effectiveness (i.e., immune responses) and safety of the Novavax Omicron NVX- CoV2515 (BA.1) and **NVX-CoV2540 (BA.5) subvariant vaccines**. The subvariant vaccines were administered alone or in combination with the original COVID-19 Wuhan strain vaccine (NUVAXOVID) and compared responses to NUVAXOVID alone.

Enrolled trial participants were adults ages ≥18 and ≤64 years old who previously received 2, 3, or ≥3 doses of approved messenger ribonucleic acid (mRNA) vaccines. The clinical trial is taking place in Australia.[1]

Clinical trial status[1]:

- The study is currently ongoing and is no longer recruiting participants.
- Study results are not yet available.

Reference(s):

1. A 2 Part, Phase 3, Randomized, Observer Blinded Study to Evaluate the Safety and Immunogenicity of Omicron Subvariant and Bivalent SARS-CoV-2 rS Vaccines in Adults Previously Vaccinated With Other COVID-19 Vaccines. ClinicalTrials.gov identifier: NCT05372588. Updated September 2, 2022. Accessed September 7, 2022. https://clinicaltrials.gov/ct2/show/NCT05372588.