Capsule Summary

Encouraging Safety and Efficacy Data of the COVID-19 vaccine NVX-CoV2373 manufactured by Novovax from the United States and Mexico Trial

NVX-CoV2373 manufactured by Novovax is a protein-based vaccine, which offers protection against SARS-COV2 infection. It contains the spike protein of the coronavirus, which is formulated as a nanoparticle. Currently, the vaccine has received emergency-used authorization in Indonesia and the Philippines(1).
The data from the phase 3 trial carried out in the US and Mexico was published recently in the New England Journal of Medicine.

Study Methodology

This was a phase 3, randomized, observer-blinded, placebo-controlled trial in the United States and Mexico during the first half of 2021. This trial was designed to assess the efficacy and safety of NVX-CoV2373 in patients who are at least 18 years or above and did not have acute SARS-Cov2 infection earlier.

Study participants were randomly assigned in a 2:1 ratio to receive 2 doses of either NVX-CoV2373 or placebo 21 days apart.

Primary Objective

Determining vaccine efficacy against reverse-transcriptase–polymerase-chain-reaction–confirmed Covid-19 occurring at least 7 days after the second dose.
Vaccine efficacy against moderate-to-severe disease and against different variants was also assessed.

Results

29,582 study participants (median age, 47 years; 12.6% ≥65 years of age) received at least one dose: 19,174 received the vaccine while 9868 received a placebo.

Efficacy Data

Most sequenced viral genomes (48 of 61, 79%) were variants of concern or interest — largely B.1.1.7 (alpha) (31 of the 35 genomes for variants of concern, 89%). Vaccine efficacy against any variant of concern or interest was 92.6% (95% CI, 83.6 to 96.7).

Treatment Group	COVID-19 cases	Moderate to Severe COVID-19 cases
NVX-CoV2373	18	0
Placebo	63	14 (Moderate) 10 (Severe)
Vaccine Efficacy	90.4% (95% CI, 82.9-94.6)	100% (95% CI- 87-100)

Safety Data

Adverse Events	NVX-CoV2373	Placebo
Any Local Adverse Event	58% after Dose 1	21.1% after Dose 1
	78.9% after Dose 2	21.7% after Dose 2
Systemic Adverse Event	47.7% after Dose 1	40% after Dose 1
	69.5% after Dose 2	35.9% after Dose 2

Solicited local and systemic adverse events were predominantly mild to moderate and transient and occurred more frequently among NVX-CoV2373 recipients compared to placebo.

Conclusion

NVX-CoV2373 was safe and effective for the prevention of Covid-19.
It has extended stability and easy storage requirements (up to 6 months at refrigerator temperatures), which make it very well suited for global, use.

References

1. *https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html. Accessed on 16th December 2021.*

Information Source:
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