Ongoing Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine in the United Kingdom

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Background:
In the primary analysis of this phase 3 United Kingdom (UK) trial, the recombinant protein vaccine NVX-CoV2373 demonstrated an efficacy of 89.7% in preventing Covid-19. Analyses of efficacy and safety data at the end of the placebo-controlled phase of the trial are reported.

Methods:
This continuing phase 3 trial enrolled adults 18-84 years of age into two arms to receive either two doses of NVX-CoV2373 or placebo (1:1). The primary efficacy endpoint was virologically confirmed, symptomatic Covid-19 with onset at least 7 days after second vaccination.

Results:
13,989 of 15,185 participants randomized remained in the per-protocol efficacy population at the time of analysis (6,989 NVX-CoV2373 and 7,000 placebo). At a median of ~4.5 months after trial start, there were 24 cases of Covid-19 among NVX-CoV2373 recipients and 134 cases among placebo recipients, a vaccine efficacy of 82.7% (95% confidence interval [CI], 73.3 to 88.8). Vaccine efficacy was 79.2% (95% CI, 66.7 to 87.0) against moderate to severe disease, 100% (95% CI, 17.9 to 100.0) against severe disease, and 76.3% (95% CI, 57.4 to 86.8) against asymptomatic disease. Fourteen days after NVX-CoV2373 dose two, high anti-S and neutralization responses were evident along with SARS-CoV-2-specific induction of peripheral T cells. The incidence of serious adverse events and adverse events of special interest was low and similar in both groups.

Conclusion:
A two-dose regimen of NVX-CoV2373 conferred ongoing protection against symptomatic, asymptomatic and moderate/severe Covid-19 at ~4.5 months after vaccination. A gradual decline of protection suggests a booster dose may be indicated.

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