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Novavax Confirms High Levels of NVX-CoV2373 Vaccine Efficacy Against Original and Variant COVID-19 Strains in United Kingdom and South Africa Trials

DATA FACTSHEET

CONCLUSIONS

- **100%** protection against severe disease, including all hospitalization and death
- **United Kingdom**: **96.4%** efficacy against original COVID-19, **86.3%** efficacy against predominant variant (post-hoc)
- **South Africa**: **55.4%** efficacy against predominant B.1.351 escape variant in HIV-negative participants

UNITED KINGDOM PHASE 3 TRIAL

Who: ~15,000 adults 18-84 years of age, including 27% over age 65.

Primary endpoint: PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset ≥7 days after the 2nd dose in serologically negative (to SARS-CoV-2) adults.

Results: See Table 1 for trial data.

- 106 cases were observed: 10 in the vaccine group and 96 in the placebo group.
- 5 severe cases were observed, all in the placebo group (1 hospitalization). Four of the 5 severe cases were attributed to the B.1.1.7 variant.
- The study met its primary endpoint with 89.7% overall vaccine efficacy (95% CI: 80.2, 94.6).
- 14 days after dose 1, vaccine efficacy was 83.4% (95% CI: 73.6, 89.5).
- In volunteers 65 years of age and older, 10 cases of COVID-19 were observed, with 90% of those cases occurring in the placebo group.

	FINAL ANALYSIS	
	Vaccine n=7,020	**Placebo** n=7,020
Total	10	96
Mild	1	28
Moderate	9	63
Severe	0	5
Vaccine Efficacy Original COVID-19	**96.4%** 95% CI: 73.8, 99.5	
Vaccine Efficacy B.1.1.7 variant	**86.3%** 95% CI: 71.3, 93.5	

Table 1. Final analysis of United Kingdom Phase 3 Trial.

SOUTH AFRICA PHASE 2B TRIAL

Who: ~4,400 adults 18-65 years of age, including 245 HIV-positive participants.

Primary endpoint: PCR-confirmed mild, moderate, or severe COVID-19 illness occurring ≥7 days after the 2nd dose in serologically negative (to SARS-CoV-2) adults.

Results: See Table 2 for trial data.

- 147 cases were observed: 51 in the vaccine group and 96 in the placebo group.
- 5 severe cases were observed, all in the placebo group (5 hospitalizations, 2 resulting in death). The vast majority of cases circulating during the efficacy analysis were due to the B.1.351 variant circulating in South Africa.
- 14 days after dose 1, overall vaccine efficacy was 42.7% (95% CI: 25.0, 56.3). In HIV-negative participants 14 days after dose 1, vaccine efficacy was 47.4% (95% CI: 29.9, 60.6).

	COMPLETE ANALYSIS	
	Vaccine n=1,408	**Placebo** n=1,362
Total	51	96
Severe	0	5
Vaccine Efficacy Overall	**48.6%** 95% CI: 28.4, 63.1	
Vaccine Efficacy HIV-negative	**55.4%** 95% CI: 35.9, 68.9	

Table 2. Complete analysis of South Africa Phase 2B Trial.