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.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Placebo</th>
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<tbody>
<tr>
<td>Total</td>
<td>10</td>
</tr>
<tr>
<td>Mild</td>
<td>1</td>
</tr>
<tr>
<td>Moderate</td>
<td>9</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
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</tbody>
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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).

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<td>Total</td>
<td>51</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
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Table 2. Complete analysis of South Africa Phase 2B Trial.