

Novavax Files for Emergency Use Authorization of COVID-19 Vaccine in Taiwan

May 13, 2022

Novavax today announced the submission of a request for emergency use authorization to Taiwan's Food and Drug Administration for its COVID-19 vaccine, NVX-CoV2373, for active immunization against SARS-CoV-2 in individuals aged 18 and over.

The submission includes data from two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled approximately 30,000 participants aged 18 years and older in the U.S. and Mexico and was published in the [*New England Journal of Medicine* \(NEJM\)](#); and a UK-based trial with almost 15,000 adult participants, also published in [*NEJM*](#). In both trials, the vaccine demonstrated efficacy with a reassuring safety profile. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups. The most common adverse reactions observed during the trials (frequency category of very common ?1/10) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise. Novavax will continue to collect and analyze real-world data, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed.

NVX-CoV2373 has received conditional authorization for use in individuals older than 18 years from multiple regulatory agencies worldwide with additional filings currently under review.