

Update on Status of Novavax's COVID-19 Vaccine BLA

April 10, 2025

As we have previously stated, we believe that our Biologics License Application (BLA) for our COVID-19 vaccine included robust Phase 3 clinical trial data that showed our vaccine is safe and effective for the prevention of COVID-19.^{1,2} We have not yet received an official response from the U.S. Food and Drug Administration regarding the status of our BLA.

References:

1. Dunkle LM. et al; 2019nCoV-301 Study Group. Efficacy and safety of NVX-CoV2373 in adults in the United States and Mexico. *New England Journal of Medicine*. 2022;386(6):531-543. doi:10.1056/NEJMoa2116185.
2. Áñez G. et al. Safety, Immunogenicity, and Efficacy of the NVX-CoV2373 COVID-19 Vaccine in Adolescents: A Randomized Clinical Trial. *JAMA Netw Open*. 2023;6(4):e239135. doi:10.1001/jamanetworkopen.2023.9135.