Novavax Statement on Proof of Vaccination for Phase 3 Clinical Trial Participants: Updated June 30, 2021

The participation of volunteers in clinical trials is critical to medical research, and Novavax is grateful to those who stepped forward to advance COVID-19 vaccine development to help create a safer future for all. Novavax firmly believes that clinical trial participants should not be disadvantaged with respect to providing proof of vaccination. We are actively supporting authorities working to provide proof of vaccination for all who volunteered in our pivotal Phase 3 clinical trials.

In the United States (US), once efficacy data from our PREVENT-19 Phase 3 trial was available and reviewed by the independent Data Safety Monitoring Board (DSMB), US participants who received active vaccine became eligible for modified vaccination cards provided by the Centers for Disease Control and Prevention (CDC). This modified vaccination card states that the participant has been vaccinated through a clinical trial and the individual is to be considered fully vaccinated for public health purposes. These modified vaccination cards are currently being proactively distributed to trial participants through Novavax by ICON, our contract research organization, in coordination with the trial sites. Should NVX-CoV2373 receive regulatory authorization, participants may receive the standard CDC vaccination card if desired and the vaccine can also be recorded in the Immunization Information Systems (IIS).

In the United Kingdom (UK), we continue to work with the National Health Service (NHS), Vaccine Task Force (VTF) and National Institute for Health Research (NIHR) so that those who received NVX-CoV2373 will soon have their vaccination dates entered into the NHS App. As noted in an open letter from Deputy Chief Medical Officer of the UK Department of Health and Social Care (DHSC), the NHS App vaccine certificate is expected to show a ‘green tick’ by the end of July for all UK trial participants, as if they have been fully vaccinated under the standard NHS program. All UK trial participants should also receive a letter by June 30 to this effect. Finally, the letter from Professor Van-Tam stated that while individual countries control their own policies, the UK government will ‘work hard to influence this situation internationally.’ Additional information can be found on NIHR’s ‘Be Part of Research’ website available under Vaccine Passports/Certification and Travel.

The unprecedented COVID-19 pandemic led to extraordinary feats of science to respond to the virus and develop vaccines in record time, all of which would not have been possible without clinical trial participants. The lifting of restrictions by different countries at different times throughout the pandemic presents challenges, and we empathize with those who are navigating the requirements while awaiting additional documentation. Novavax appreciates the long-lasting positive impact clinical trial participants will have on global public health for decades to come. The vaccine development process is complex and we are working to complete regulatory filings for our vaccine as soon as possible. In the meantime, we continue to support efforts to provide proof of vaccination to our volunteers and will share additional updates as they become available.

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