NOVAVAX
Creating Tomorrow's Vaccines Today

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September 21, 2020

The Honorable Richard J. Durbin
United States Senate
711 Hart Senate Office Building
Washington, DC 20510

Dear Senator Durbin,

I am writing in response to your letter dated September 3, 2020 requesting information related to the clinical development of and regulatory plans for Novavax' COVID-19 vaccine candidate, NVX-CoV2373. We share your goal of ensuring public confidence in vaccines, and we are upholding the highest standards of scientific rigor and regulatory review while also committing to the transparency of our clinical trial results.

Earlier this month, I joined eight other biopharmaceutical company CEOs in a public pledge to uphold the integrity of the scientific process as we work toward global regulatory filings and approvals of COVID-19 vaccines. Novavax will always make the safety and well-being of vaccinated individuals our top priority, and I assure you that Novavax is not taking any shortcuts on safety. During this pandemic, we continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes.

Novavax is a late-stage biotechnology company headquartered in Gaithersburg, Maryland that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Novavax is undergoing clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, our quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant in order to enhance the immune response and stimulate high levels of neutralizing antibodies. Novavax is a leading innovator of recombinant vaccines; our proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles in order to address urgent global health needs.

Clinical Development Plans

Novavax has worked with coronaviruses for almost two decades, including SARS in 2003 and MERS in 2012. Due to our scientific expertise, Novavax was able to quickly initiate development of a SARS-CoV-2 vaccine candidate in mid-January 2020, shortly after the virus was isolated. Our vaccine candidate, NVX-CoV2373, consists of a stable, prefusion protein made using Novavax' proprietary nanoparticle

technology and includes our exclusive Matrix-M™ adjuvant to enhance immune responses and stimulate high levels of neutralizing antibodies. NVX-CoV2373 has a favorable product profile; it is stable and will allow handling in a liquid formulation at 2°C to 8°C, allowing for successful cold chain management with existing infrastructure.

In early August, Novavax announced positive results from the Phase 1 portion of the Phase 1/2 clinical trial of NVX-CoV2373, and within a month, the data were published in *The New England Journal of Medicine*. The trial was randomized, observer-blinded, and placebo-controlled, and we enrolled 131 healthy adults 18-59 years of age. NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera.

NVX-CoV2373 is currently in multiple Phase 2 clinical trials. The Phase 2 portion of the Phase 1/2 clinical trial to evaluate the safety and immunogenicity of NVX-CoV2373 began in August in the United States and Australia and expands the age range of the Phase 1 portion by including older adults 60-84 years of age as approximately 50 percent of the trial population. Secondary objectives include preliminary evaluation of efficacy. In addition, a Phase 2b clinical trial to assess efficacy began in South Africa in August.

Novavax is planning late-stage clinical studies necessary to determine the safety and efficacy of NVX-CoV2373, including a pivotal Phase 3 clinical trial in the US with up to 30,000 subjects. We also plan additional efficacy studies in other countries, including a pivotal Phase 3 trial in the United Kingdom. The large US study is likely to begin within a month's time depending on completion of commercial scale manufacturing and completion of FDA review of our clinical data and plans. Because we plan to use over a hundred clinical sites, we anticipate full enrollment can be achieved by December. The completion and read-out of all our efficacy studies, including the US government-supported Phase 3 study largely depends on the infection rate in the study participants. This pandemic has proved to be difficult to predict, so the timing of the study completion is difficult to predict.

The entire clinical development plan has been conducted in compliance with the International Conference on Harmonization Good Clinical Practice (ICH-GCP) guidelines and the principles contained in the Declaration of Helsinki. No shortcuts have been taken and all global safety, regulatory, and ethical standards are being complied with.

Regulatory Plans

As noted in our public pledge, the safety and efficacy of vaccines, including any potential vaccine for COVID-19, is reviewed and determined by expert regulatory agencies around the world, including the FDA. FDA has established clear guidance for the development of COVID-19 vaccines and clear criteria for their potential authorization or approval in the US. FDA's guidance and criteria are based on the

scientific and medical principles necessary to clearly demonstrate the safety and efficacy of potential COVID-19 vaccines. More specifically, the agency requires that scientific evidence for regulatory approval must come from large, high quality clinical trials that are randomized and observer-blinded, with an expectation of appropriately designed studies with significant numbers of participants across diverse populations. We are not cutting corners in adherence to the research, development, submission or regulatory review process required under the FD&C or PHSA for our vaccine candidate.

Data from the Phase 3 clinical study are intended to support an application for approval or emergency use authorization (EUA) of our candidate vaccine. Novavax is working closely with FDA, and other regulatory agencies, to provide agreed upon data packages, which will follow the established regulatory review process. Data from other countries might be considered if they are deemed to be representative of the US population and clinical studies meet the clear guidance and criteria established by FDA. At this time it is unclear when an EUA or BLA for another COVID-19 vaccine candidate might be available, or how that would impact our timelines. Novavax will be attending the VRBPAC meeting on October 22nd.

Operation Warp Speed Contract

I applaud this Congress for its extraordinary leadership during the COVID-19 pandemic, acting quickly to support vaccine innovation through significant investments in vaccine development, manufacturing, and procurement. Novavax is working closely with US government partners as well as non-governmental organizations and industry partners to advance development of NVX-CoV2373.

In June, Novavax was awarded a contract by the U.S. Department of Defense (DoD) for the manufacturing of NVX-CoV2373. The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense Enabling Technologies (JPEO-CRBND-EB), through funding provided by the Defense Health Program, agreed to fund up to $60 million to support Novavax in its production of several components of the vaccine that will be manufactured in the U.S. The agreement includes a 2020 delivery of 10 million doses of NVX-CoV2373 for the DoD.

In July, Novavax was selected to participate in Operation Warp Speed (OWS) and was awarded up to $1.6 billion by the federal government to complete late-stage clinical development, including a pivotal Phase 3 clinical trial; establish large-scale manufacturing; and deliver 100 million doses of NVX-CoV2373, Novavax' COVID-19 vaccine candidate, beginning as early as Q4, 2020. The agreement also allows for a follow-on agreement with the US government for additional production and procurement to support OWS' vaccine production goal. This latest federal funding supports Novavax plans to file submissions for licensure with FDA. Notably, the federal government does not hold any patents related to our vaccine candidate. While we are working closely with US government partners to advance our clinical development program, we have *not* received any incentives, outside of our contract agreements, or political pressure regarding our vaccine candidate, NVX-CoV2373. With respect to communications with

the White House regarding our vaccine candidate, I attended a meeting with President Trump and members of the Coronavirus Task Force, along with other biopharmaceutical industry executives, on March 2, 2020 and the transcript is publicly available. On July 27, 2020, Novavax and Fujifilm Diosynth Biotechnologies jointly hosted the president for a tour of the manufacturing site in Morrisville, North Carolina, where components of NVX-CoV2373 are being produced. The event was covered by local and national media outlets.

Vaccine Confidence

We commend Congress for their attention to the critical issue of vaccine confidence, and Novavax stands ready to inform the US government as our nation's leaders work with state and local officials to ensure providers, patients, and community leaders have the most evidence-based information to bolster confidence that an approved COVID-19 vaccine is safe and effective. As part of this effort, Novavax is committed to transparency and accountability, which are critical to public confidence in COVID-19 vaccines. Novavax is committed to ensuring transparency around our scientific data, which we believe is one of the top ways to ensure public confidence in any vaccine that will ultimately be authorized for use. To this end, approximately within one week after we received the data from our Phase 1 COVID vaccine trial, we had written and posted a manuscript detailing these data on the public server medRxiv.org, and less than four weeks later, these data were published in the top-tier, peer-reviewed journal *The New England Journal of Medicine*.

Conclusion

Novavax is at the forefront of vaccine development and we are committed to producing a safe and effective vaccine to combat the COVID-19 pandemic. Novavax has always been a workplace that values respect and diversity as well as talent, dedication, and hard work. Our team is working nonstop to make our vaccine for the global pandemic a reality. I am proud of the community we have built and are continuing to grow, and the progress we've made together thus far. We stand ready to work with Congress and the Administration to support the US supply chain of COVID-19 vaccines, which are essential to combat this urgent health theat. If at any point you have additional questions, please do not hesitate to reach out to me directly.

Sincerely,

Stanley C. Erck
President and Chief Executive Officer
Novavax, Inc.