

Novavax Reconfirms Confidence in Regulatory Filing Timelines and Manufacturing Quality

October 20, 2021

In response to a recent news article citing anonymous sources, Novavax confirms our confidence in our ability to deliver our high-quality vaccine. Further, we underscore our ongoing commitment to the stringent standards of production and manufacturing for our recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. Since March 2020, Novavax has worked diligently, methodically and transparently to develop our novel COVID-19 vaccine candidate, taking on the challenge of developing and producing at large scale a proven biologic-based vaccine amid unprecedented circumstances. Throughout, we have maintained active conversations with various regulatory agencies in key markets and have incorporated their feedback into the submissions for authorization that we are in the process of completing.

We have made significant progress in mobilizing a global manufacturing network over the past 18 months with sites that are now routinely producing high-quality product at commercial scale at multiple sites across the world. Our global supply chain is expected to achieve a capacity of 150 million doses per month by the end of the fourth quarter through:

- Partnership with the Serum Institute of India (SII), the world's largest vaccine manufacturer
- A state-of-the-art, wholly owned manufacturing site in the Czech Republic
- Manufacturing at established vaccine makers including SK bioscience in South Korea and Takeda in Japan
- Additional manufacturing arrangements around the world

We expect to complete multiple ongoing rolling regulatory submissions within the next couple of weeks in key markets, including the United Kingdom, Europe, Canada, Australia and New Zealand. We, along with SII, have already filed for authorization in India, Indonesia and The Philippines, as well as for Emergency Use Listing (EUL) with the World Health Organization (WHO). The WHO EUL will allow Novavax and SII to deliver on our combined commitment to the COVAX Facility for a cumulative 1.1 billion doses of our vaccine, around which we maintain ongoing conversations with CEPI, Gavi and UNICEF. Additionally, we expect to file for Emergency Use Authorization in the U.S. before the end of 2021.

"We are confident that our vaccine will soon play a significant role in the global COVID-19 vaccine arsenal, differentiated by its potential to help address two major issues slowing the world's ability to end the pandemic: global distribution challenges and vaccine hesitancy," said Stanley C. Erck, President & Chief Executive Officer, Novavax.

Novavax would like to thank the hardworking Novavax employees, manufacturing and other partners, and clinical community who are working diligently every day to deliver the first COVID-19 protein-based vaccine with Phase 3 data showing a robust safety profile, strong immunogenicity, and high efficacy against multiple strains of the coronavirus. The company also extends its deepest appreciation to the clinical trial participants who made a vital contribution during a global pandemic.