

# GSK to support manufacture of Novavax' COVID-19 vaccine

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LONDON and GAITHERSBURG, Md., March 29, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, GSK and the UK Government Vaccines Taskforce announced that they have reached an agreement in principle to support manufacturing of up to 60 million doses of Novavax' COVID-19 vaccine candidate (NVX-CoV2373) for use in the UK. GSK will provide 'fill and finish' manufacturing capacity at its Barnard Castle facility in the North East of England beginning as early as May 2021, with a rapid technology transfer between the two companies beginning immediately. GSK and Novavax will negotiate a final agreement to include additional terms and conditions.

The UK Government has secured 60 million doses of the vaccine under an advance purchase agreement with Novavax. The protein antigen component of NVX-CoV2373 is also produced in the North East of England by Novavax' manufacturing partner, FUJIFILM Diosynth Biotechnologies, at their site in Billingham, Stockton-on-Tees.

Fill and finish, to be provided by GSK, is the completion stage of vaccine manufacturing, preparing vials of the final vaccine and packaging them for distribution and use. The GSK site at Barnard Castle, which will deliver the vaccine doses under this collaboration, is a specialised facility in GSK's global manufacturing network, which supports production of GSK pharmaceutical and vaccine products.

Roger Connor, President, GSK vaccines, said: "GSK is delighted to support Novavax and the UK Vaccines Taskforce with this manufacturing arrangement for the UK and our Barnard Castle facility is now undertaking the rapid preparation work required to manufacture up to 60m doses of this vaccine. We have ensured that we can deliver these volumes without impacting supply of our other vital medicines and vaccines, and without disruption to the other COVID-19 collaborations GSK is engaged in globally."

"This partnership with GSK continues the expansion of our global supply network, which we expect to increase overall production capacity and, if approved by regulatory agencies, support access to a potentially important new vaccine against COVID-19," said Rick Crowley, Executive Vice President and Chief Operations Officer, Novavax. "We thank the UK government's Vaccine Taskforce for its instrumental role in ensuring the progress of our COVID-19 vaccine, from both a clinical and now manufacturing perspective, as well as GSK for making their facilities available to help fight the pandemic."

Prime Minister Boris Johnson said: "I'm delighted by GSK's investment, which shows the strength of UK manufacturing, and will further boost our vaccine rollout. The Vaccines Taskforce has worked hand in glove with business to successfully deliver vaccines to the whole of the UK, and this agreement will continue to support our approach. We remain on track to offer a first jab to all over 50s by 15 April, and all adults by the end of July, and I want to once again encourage everyone to come forward for a vaccine when you're called."

Health and Social Care Secretary Matt Hancock said: "We've all seen just how important onshore vaccine manufacturing capabilities are, and this fantastic deal will ensure more of these vital products can be produced here in the UK. The UK's vaccination programme has been a national success, with over 30 million people now having received a first dose of a COVID-19 vaccine. Should the Novavax vaccine meet our medicines regulator's high standards of safety and effectiveness, the agreement reached today will boost these efforts over the coming months."

The Novavax vaccine candidate has demonstrated strong potential efficacy in Phase 3 clinical trials, including against the B.1.1.7 variant circulating in the UK. Submission of the vaccine for review by regulatory authorities in the UK is expected during the second quarter.

## GSK commitment to tackling COVID-19

GSK's response to COVID-19 has been one of the broadest in the industry, with two potential treatments in addition to our vaccine candidates in development.

GSK is collaborating with several organisations around the world on COVID-19 vaccines by providing access to our adjuvant technology. Our collaboration with Canada's Medicago, combining our pandemic adjuvant with its plant-derived vaccine candidate is in Phase 3 clinical trials, and a collaboration with French company Sanofi on an adjuvanted, protein-based vaccine candidate is in Phase 2. An earlier stage collaboration with SK Bioscience of South Korea, with funding from CEPI and the Bill and Melinda Gates Foundation, aims to develop differentiated, affordable COVID-19 vaccines for supply

globally through the COVAX facility. The use of an adjuvant can be of particular importance in a pandemic since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and contributing to protecting more people.

GSK is working with German mRNA specialist, CureVac, to jointly develop next generation, multi-valent mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine. GSK will also support manufacturing of up to 100m doses of CureVac's first generation COVID-19 vaccine at our facilities in Belgium.

GSK is also exploring potential therapeutic or treatment options for COVID-19 patients. We are collaborating with Vir Biotechnology to develop existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options for COVID-19. We recently reported that an Independent Data Monitoring Committee recommended that the Phase 3 COMET-ICE trial evaluating VIR-7831 as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalisation be stopped for enrolment due to evidence of profound efficacy, based on an interim analysis of data from the trial. We are now seeking Emergency Use Authorization in the US and authorisations in other countries. We are also assessing whether an investigational monoclonal antibody, otilimab, can help severely ill COVID-19 patients aged over 70 who experience an overreaction of their immune system.

#### About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit [www.gsk.com/about-us](http://www.gsk.com/about-us).

#### About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence of SARS-CoV-2, the virus that causes COVID-19 disease. NVX-CoV2373 was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike (S) protein and is adjuvanted with Novavax' patented saponin-based Matrix-M™ to enhance the immune response and stimulate high levels of neutralizing antibodies. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19. In preclinical studies, NVX-CoV2373 induced antibodies that block binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response numerically superior to that seen in human convalescent sera in Phase 1/2 clinical testing. NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials, a trial in the U.K that demonstrated efficacy of 96.4% against the original virus strain and 89.7% overall, and the PREVENT-19 trial in the U.S. and Mexico that began in December 2020. It is also being tested in two ongoing Phase 2 studies that began in August: a Phase 2b trial in South Africa that demonstrated 48.65% efficacy against a newly emerging escape variant, and a Phase 1/2 continuation in the U.S. and Australia. NVX-CoV2373 is stored and stable at 2°- 8°C, allowing the use of existing vaccine supply chain channels for its distribution. It is packaged in a ready-to-use liquid formulation in 10-dose vials.

#### About Matrix-M™

Novavax' patented saponin-based Matrix-M™ adjuvant has demonstrated a potent and well-tolerated effect by stimulating the entry of antigen presenting cells into the injection site and enhancing antigen presentation in local lymph nodes, boosting immune response.

#### About Novavax

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

For more information, visit [www.novavax.com](http://www.novavax.com) and connect with us on [Twitter](#) and [LinkedIn](#).

#### Novavax Forward Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at [sec.gov](http://sec.gov), for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no

obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

#### GSK Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

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