Novavax Nuvaxovid COVID-19 Vaccine

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Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) Description

Novavax COVID-19 vaccine (Nuvaxovid, Covovax) (NVX-CoV2373,) is a protein-based vaccine candidate engineered from the genetic sequence of the first strain of the SARS-CoV-2 coronavirus. The vaccine was made using Novavax's proprietary nanoparticle technology, Matrix-M, an adjuvant to enhance immune responses and stimulate high levels of neutralizing antibodies.

Novavax Inc.'s COVID-19 vaccine creates an engineered baculovirus containing a gene for a modified coronavirus spike protein. The baculovirus then infects a culture of Sf9 moth cells, which generate the spike protein and display it on their cell membranes. Next, the spike proteins are harvested and assembled onto a synthetic lipid nanoparticle about 50 nanometers across, each displaying up to 14 spike proteins.

Novavax's 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 and helping an immunized person make antibodies against the virus.

Novavax identified the recombinant nanoparticle Nuvaxovid vaccine as its lead COVID-19 candidate following preclinical testing that demonstrated high immunogenicity and high levels of neutralizing antibodies.

The IgG antibody response was significantly correlated with neutralization titers, demonstrating that a significant proportion of antibodies were functional. This study was published on August 6, 2020. And, the adjuvant was dose-sparing, with the lower five µg dose of NVX-CoV2373 performing comparably with the 25 µg dose. Cellular immune responses were measured in a subset of participants, and NVX-CoV2373 induced antigen-specific polyfunctional CD4+ T cell responses with a strong bias toward the Th1 phenotype (IFN-g, IL-2, and TNF-a).

On January 28, 2021, NVX-CoV2373 became the first protein-based vaccine candidate to demonstrate clinical efficacy against the original strain of COVID-19 and both of the rapidly emerging variants in the United Kingdom and South Africa. The Company announced the final efficacy of 96.4% against mild, moderate, and severe disease caused by the original COVID-19 strain in a pivotal Phase 3 trial in the United Kingdom.

On June 20, 2021, the NEJM published an ORIGINAL ARTICLE: Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine. Conclusion - A two-dose regimen of the NVX-CoV2373 protein-based vaccine administered to adult participants conferred 89.7% protection against SARS-CoV-2 infection and showed high efficacy against the B.1.1.7 variant.' Followed by another NEJM Original Article published on June 30, 2021, which concluded: A two-dose regimen of the NVX-CoV2373 vaccine administered to adult participants conferred 89.7% protection against SARS-CoV-2 infection and showed high efficacy against the B.1.1.7 variant.

The NEJM published an ORIGINAL ARTICLE on September 23, 2021 - Safety and

Efficacy of NVX-CoV2373 Covid-19 Vaccine: A two-dose regimen of the NVX-CoV2373 vaccine administered to adult participants conferred 89.7% protection against SARS-CoV-2 infection and showed high efficacy against the B.1.1.7 variant. EU study number: EudraCT number, 2020-004123-16.

On October 20, 2021, the Company 'confirmed its ongoing commitment to the stringent production and manufacturing standards for our recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. As of November 2021, Novavax's COVID-19 vaccine candidate remains under review by the European Medicines Agency, the U.S. CDC, and regulatory agencies in Australia, Canada, Japan, India, New Zealand, the Philippines, the UK, and the WHO.

A global listing of NovaVax studies is available at this link. NNVX-CoV2373's Drugbank Accession Number: DB15810; UNII: UK9AK2IN1P.

Novavax COVID-19 vaccine brands: Nuvaxovid, Covovax, NVX-CoV2373.

Gaithersburg, MD-based Novavax, Inc. (NVAX) is a biotechnology company that promotes improved health globally by discovering, developing, and commercializing innovative vaccines to prevent serious infectious diseases. Our vaccine candidates are genetically engineered using three-dimensional nanostructures of recombinant proteins critical to disease pathogenesis.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) History

On August 4, 2020, Novavax announced the Phase 1 data from its Phase 1/2 clinical trial found the recombinant COVID-19 vaccine candidate adjuvanted with Matrix-M was generally well-tolerated elicited robust antibody responses numerically superior to that seen in human convalescent sera.

A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older was last updated on October 28, 2020.

The federal government awarded Novavax $1.6 billion as part of Operation Warp Speed. The Coalition for Epidemic Preparedness Innovations is also investing up to $388 million, and the Department of Defense is investing up to $60 million of funding to advance the clinical development of NVX-CoV2373. As of September 24, 2020, Novavax stated it "continued to scale-up its manufacturing capacity, currently at up to 2 billion annualized doses, once all capacity has been brought online by mid-2021."On November 4, 2020, Novavax confirmed various supply agreements with the USA, the United Kingdom, Canada, Australia and partnerships with Japan, South Korea, and India.

On August 30, 2021, the U.S. CDC provided updated guidance for those vaccinated as part of a clinical trial in the U.S. The new guidance states that participants in the Novavax PREVENT-19 Phase 3 clinical trial meets the criteria to be considered fully vaccinated two weeks after they have completed the vaccine series.

Novavax, Inc. and Serum Institute of India Pvt. Ltd. confirmed on September 23, 2021; they had filed a regulatory submission with the WHO for emergency use listing of Novavax's COVID-19 vaccine (COVOVAX). Separately, an ORIGINAL ARTICLE - Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine, was published by the NEJM. CONCLUSIONS: A two-dose regimen of the NVX-CoV2373 vaccine administered to adult participants conferred 89.7% protection against SARS-CoV-2 infection and showed high efficacy against the B.1.1.7 variant. These research findings are summarized in a short

video.

Novavax confirmed on October 20, 2021, it "expects 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. In addition, along with SII, the companies have already filed for authorization in India, Indonesia, and the Philippines, as well as for Emergency Use Listing (EUL) with the WHO. Additionally, we expect to file for Emergency Use Authorization in the U.S. before the end of 2021.'

COVID-NanoFlu™ Combination Vaccine

The Company's COVID-NanoFlu™ combination vaccine candidate combines NanoFlu™ and NVX-CoV2373. Both previously demonstrated strong results as standalone vaccines in Phase 3 clinical trials. In preclinical studies, the COVID-NanoFlu Combination Vaccine demonstrated robust immune responses to each component of the quadrivalent influenza vaccine and the SARS-CoV-2 spike protein, with Matrix-M adjuvant playing a key role. A non-peer-reviewed study was published in May 2021.

On June 14, 2021, the Company announced a non-peer-reviewed manuscript, "safety, Immunogenicity, and Efficacy of a COVID-19 Vaccine (NVX-CoV2373) Co-administered With Seasonal Influenza Vaccines," available at medRxiv.org. As part of Novavax's Phase 3 clinical trial of NVX-CoV2373 in the United Kingdom, 431 volunteers were also enrolled in a co-administration sub-study. All received an approved seasonal influenza vaccine (aTIV, QIVc), with approximately half the participants co-vaccinated with NVX-CoV2373. The study demonstrated that vaccine efficacy appeared to be preserved in those receiving both vaccines compared to those vaccinated with NVX-CoV2373 alone.

COVID-19 Vaccine (TAK-019)

Takeda Pharmaceutical Company Limited (TSE:4502 / NYSE: TAK) confirmed it would receive a manufacturing technology transfer from Novavax and be responsible for developing and commercializing based on a manufacturing capacity of over 250 million doses of TAK-019. Furthermore, on February 24, 2021, the first subject was dosed in its Phase 1/2 immunogenicity and safety study of Novavax's COVID-19 vaccine candidate (TAK-019) in Japan. This placebo-controlled Phase 1/2 study in Japan will evaluate the safety and immunogenicity of two vaccinations of TAK-019 given 21 days apart. ClinicalTrials.gov Identifier: NCT04712110.

On September 7, 2021, Takeda announced that the Government of Japan'sMinistry of Health, Labour, and Welfare would purchase 150 million doses of NNovavax'svaccine candidate (TAK-019) manufactured in Japan by Takeda, subject to licensing and approval. Novavax confirmed on September 10, 2021, the distribution of NNovavax'svaccine in Japan by Takeda is expected to begin in early 2022. Takeda anticipates the capacity to manufacture more than 250 million doses of NNovavax'sCOVID-19 vaccine per year.

On October 28, 2021, Takeda confirmed its partnership with Novavax in Japan for development, manufacturing (250 million doses per year), and commercialization of TAK-019, their COVID-19 vaccine candidate with distribution in Japan expected to begin in early calendar year 2022, subject to regulatory approval.

CovoVax Vaccine

Serum Institute conducted a trial of its COVID-19 vaccine Covovax, a domestically produced version of the Novavax vaccine, in the 12-17 age group. This version of the Novavax vaccine was initially authorized in Indonesia on November 1, 2021.

Media reported SII has been allowed to export 50 lakh vials, equivalent to 5 crore doses, of Covovax to Indonesia, as of November 15, 2021.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) Indication

Nuvaxovid NVX-CoV2373 is a vaccine candidate indicated as a SARS-CoV-2 coronavirus vaccine to prevent COVID-19. NVX-CoV2373 demonstrated efficient binding with receptors targeted by the virus in preclinical trials, a critical aspect for effective vaccine protection.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) Pediatric Plans

On May 3, 2021, the Company announced the pediatric expansion of its Phase 3 clinical trial for NVX-CoV2373. The additional arm of the ongoing PREVENT-19 pivotal trial will evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373 in up to 3,000 adolescents aged 12-17 across up to 75 sites in the USA.

On March 15, 2021, the company filed European Medicines Agency P/0126/2021 for use in Europe. The EMA's Committee for medicines for children confirmed on November 17, 2021, it had issued its opinion on the company's pediatric investigation plan, which describes how the medicine should be developed and studied for use in children, in accordance with the accelerated timelines for COVID-19 medicines.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) Variant Protection

Novavax, Inc. announced preliminary data on August 5, 2021, demonstrating that functional ACE-2 binding inhibition antibodies cross-reactive with the Delta (B.1.617.2) variant were more than 6-fold higher than the primary vaccination series. And the analysis of sera from primary vaccination series also showed cross-reactive functional antibodies to Alpha, Beta, and Delta variants, all of which increased 6- to 10-fold with boost. The results come from an ongoing Phase 2 study in the U.S. and Australia. Select participants in the 5-microgram dose cohort received a 5-microgram booster dose 189 days after the initial two-dose regimen to examine the functional immune system response.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) Dosage

Novavax evaluated two intramuscular immunizations of 5 and 25 µg NVX Cov2373, with and without its Matrix-M adjuvant, in a Phase I trial. NVX-CoV2373 was reported stable and will allow handling in a liquid formulation that can be stored at 2°C to 8°C, allowing for successful cold chain management with existing infrastructure.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) Side Effects

The U.S. NIH reported "safety data indicate the investigational vaccine was generally well-tolerated. Mild-to-moderate injection site pain and tenderness were the most common local

symptoms among participants, and fatigue, headache, and muscle pain lasting less than two days were the most common systemic symptoms.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) Cost

Reuters reported Denmark announced it would buy 280,000 doses of Novavax's COVID-19 vaccine for roughly $20.9 per dose as part of a European Union pending agreement.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) Authorizations

As of November 17, 2021, Indonesia and The Philippines had issued authorizations. And, UK and Mexico Phase 3 Clinical Trial Participants are considered by the U.S. CDC Fully Vaccinated regarding travel requirements.

Novavax Inc. (Nasdaq: NVAX) Financial News

November 15, 2021 - SeekingAlpha published an article: Novavax: So Near And Yet So Far.

November 15, 2021 - Bronstein, Gewirtz & Grossman, LLC notifies investors that a class action lawsuit has been filed against Novavax, Inc.

November 4, 2021 - Novavax reported a net loss of $322.4 million, or $4.31 per share, for the third quarter of 2021, compared to a net loss of $197.3 million, or $3.21 per share, for the third quarter of 2020. Latest Earnings Presentation.

Novavax COVID-19 Vaccine (Nuvaxovid, Covovax, NVX-CoV2373) News

November 17, 2021 - The Company announced Nuvaxovid (NVX-CoV2373) is being evaluated by the EMA for conditional marketing authorization. The EMA has indicated that its assessment will proceed under an accelerated timeline, with an opinion issued potentially within weeks. If EMA concludes that the benefits of Nuvaxovid outweigh its risks in protecting against COVID-19, it will recommend granting conditional marketing authorization.

November 16, 2021 - Alcami announced today that they have signed a master laboratory services agreement with Novavax. With the execution of the agreement, Novavax has immediately secured full-time equivalent resources to provide analytical testing support for its recombinant nanoparticle protein-based COVID-19 vaccine candidate.

November 15, 2021 - Novavax, Inc. and SK bioscience, Co. Limited confirmed the submission of a Biologics License Application for Novavax's COVID-19 vaccine to South Korea's Ministry of Food and Drug Safety, the final review stage for authorization in Korea.

November 12, 2021 - When will the Novavax vaccine become available in Australia? The Minister of Health and Care Greg Hunt responded: So Novavax is in process of putting in submissions around the world. The UK, I believe, was there first and they've indicated Australia. So we're hoping that in the coming weeks, they'll be putting in their application to the TGA for approval.

November 8, 2021 - The journal Nature published an article: How protein-based COVID vaccines could change the pandemic.

November 7, 2021 - Local media reported Belgium is ordering the Novavax vaccine, says Dirk Ramaekers of the vaccination task force.

November 4, 2021 - Novavax, Inc. today announced the completion of its rolling submission to the World Health Organization for emergency use listing of NVX-CoV2373. The grant is a prerequisite for exports to numerous countries participating in the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies. Novavax continues to work closely with governments, regulatory authorities, and non-governmental organizations in its commitment to ensuring equitable global access to its COVID-19 vaccine.

November 4, 2021 - Local media reported Novavax filing for approval of its vaccine with Health Canada, Montreal is poised to be the first Canadian city to manufacture a COVID-19 vaccine.

November 3, 2021 - Novavax, Inc. has filed for provisional approval of the vaccine to the New Zealand Medicines and Medical Devices Safety Authority. This submission was facilitated by the company's local partner, Biocelect Pty. Ltd., as the sponsor.

November 1, 2021 - Novavax, Inc. and Serum Institute of India Pvt. Ltd. announced that the National Agency of Drug and Food Control of the Republic of Indonesia, or Badan Peng was Obat dan Makanan, has granted emergency use authorization for Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. It will be manufactured by and marketed by SII in Indonesia under the brand name COVOVAX™.

November 1, 2021 - Novavax, Inc. announced the completion of its rolling submission to Health Canada for authorization of its COVID-19 vaccine candidate, the first filing of a protein-based COVID-19 vaccine in Canada. In addition, the company has completed the submission of all data and modules to the European Medicines Agency to support the final regulatory review of its dossier.

October 29, 2021 - Novavax, Inc. announced the completion of its rolling submission to Australia's Therapeutic Goods Administration for provisional approval of its protein-based COVID-19 vaccine candidate.

October 27, 2021 - Novavax, Inc. announced the completion of its rolling regulatory submission to the U.K. Medicines and Healthcare products Regulatory Agency for authorization of its COVID-19 vaccine candidate. The company’s application for Conditional Marketing Authorization marks the first submission for authorization of a protein-based COVID-19 vaccine in the United Kingdom.

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.

October 19, 2021 - Novavax confirmed topline immunogenicity and reactogenicity data from Comparing COVID-19 Vaccine Schedule Combinations – Stage 2 (Com-COV2), a

Phase 2 clinical study conducted by the University of Oxford, were presented at the World Vaccine Congress taking place in Barcelona. NNovavax'srecombinant nanoparticle protein-based COVID-19 vaccine candidate, NVX-CoV2373, was one of four COVID-19 vaccines studied to provide data regarding heterologous primary immunization. The study showed that NVX-CoV2373 remains well-tolerated and generates a robust immune response when given as the second dose in a mixed, or heterologous, regimen after either the Oxford/Astra Zeneca or Pfizer/BioNTech vaccines as the first dose. Across all six study arms, local and systemic reactogenicity was favorable after the 2nd dose of NVX-CoV2373, with a low frequency and severity of reactogenicity events after both the Oxford/AstraZeneca and Pfizer/BioNTech vaccines.

October 15, 2021 - Yale Medicine published: Comparing the COVID-19 Vaccines: How Are They Different?

October 8, 2021 - The UUK'sDepartment of Health and Social Care confirmed there are around 52,000 people currently taking part in vaccine clinical trials across the UK, with 21,000 given a vaccine not yet approved for deployment by the Medicines and Healthcare products Regulatory Agency. Around 15,000 of these are taking part in the Novavax clinical trial.

October 4, 2021 - Novavax, Inc. announced the appointment of Denny Kim, M.D., MPH to the newly created role of Senior Vice President, Chief Safety Officer, and Head of Global Vaccine Safety. Dr. Kim will report to Filip Dubovsky, M.D., MPH, FAAP, Executive Vice President, and Chief Medical Officer. Novavax also announced the promotions of Raburn Mallory, M.D. to Senior Vice President, Head of Clinical Development, and Marco Cacciuttolo, Ph.D. to Senior Vice President, Process and Analytical Development.

September 24, 2021 - Yale Medicine published: Comparing the COVID-19 Vaccines: How Are They Different?

September 23, 2021 - Novavax, Inc. and its partner, Serum Institute of India Pvt. Ltd. announced a regulatory submission to the World Health Organization (WHO) for emergency use listing of NNovavax'srecombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. The submission to WHO is based on the ccompanies'previous regulatory submission to the Drugs Controller General of India.

September 23, 2021 - The Australian Technical Advisory Group on Immunisation anticipates that additional booster doses for other populations may be required in the future. Consideration is required as to the timing and the type of vaccine to be used as boosters and the potential for newer vaccine types (e.g. protein subunit vaccines [e.g. Novavax], variant vaccines) to become available.

September 23, 2021 - Novavax, Inc. announced that it will participate in a fireside chat at the 2021 Cantor Virtual Global Healthcare Conference.

September 22, 2021 - Stuff in New Zealand reported the vaccine was emerging as a top contender for a potential mass vaccination booster campaign next year, although no formal advice has been given.

September 17, 2021 - The U.S. Centers for Disease Control and Prevention recently provided updated guidance stating that participants in the Novavax PREVENT-19 Phase 3 clinical trial meet the criteria to be considered fully vaccinated two weeks after they have completed the active vaccine series.

September 17, 2021 - Yale Medicines published "omparing the COVID-19 Vaccines: How Are They Different?

September 16, 2021 - Novavax, Inc. announced its participation in a newly expanded Phase 2 clinical trial called Comparing COVID-19 Vaccine Schedule Combinations – Stage 3 (Com-COV3), led by the University of Oxford and funded by the UK Vaccines Taskforce and the National Institute for Health Research. NNovavax'srecombinant nanoparticle COVID-19 vaccine candidate, NVX-CoV2373, is one of the three COVID-19 vaccines that will be studied in adolescents to evaluate the potential for combined regimens that mix vaccines from different manufacturers to achieve immune protection against COVID-19. Novavax is also participating in the University of OOxford'sCom-COV2 study, in which NVX-CoV2373 is one of four COVID-19 vaccines being studied to evaluate the potential for combined regimens that mix vaccines from different manufacturers to achieve immune protection against COVID-19. Results from Com-COV2 are expected in the coming weeks.

September 10, 2021 - NNovavax'slatest SEC 8-k filing revealing the CCompany'smilestones for the end of 2021, which include, but are not limited to, establish extensive distribution for its COVID-19 vaccine in various countries.

September 10, 2021 - Novavax issued a press statement confirming Takeda Pharmaceutical Company Limited had finalized an agreement with JJapan'sgovernment to purchase 150 million doses of NNovavax'srecombinant nanoparticle COVID-19 vaccine candidate, NVX-CoV2373 (TAK-019). ""his agreement demonstrates confidence in and the ongoing global demand for NVX-CoV2373 as a significant additional option to control the COVID-19 pandemic,""stated Stanley C. Erck, President, and CEO, Novavax.

September 8, 2021 - Novavax, Inc. announced enrollment of participants in a Phase 1/2 study to evaluate the safety and immunogenicity of a combination vaccine using NNovavax'sseasonal influenza and COVID-19 vaccines. Both NVX-CoV2373 and NanoFlu have previously demonstrated strong results as standalone vaccines in Phase 3 clinical trials.

August 30, 2021 - Novavax confirmed the CDC provided updated guidance for those vaccinated as part of a clinical trial in the USA. The CDC guidance states that participants in the Novavax PREVENT-19 Phase 3 clinical trial meets the criteria to be considered fully vaccinated two weeks after completing the vaccine series.

August 26, 2021 - Yale Medicine published: Comparing the COVID-19 Vaccines: How Are They Different?

August 25, 2021 - Novavax, Inc. (Nasdaq: NVAX) announced that NNovavax'srecombinant nanoparticle protein vaccine candidate is being studied in OCTAVE-DUO in the UK to evaluate the safety and immunogenicity of a third COVID-19 vaccine dose in participants with impaired immune systems.

August 16, 2021 - Novavax, Inc. announced the appointment of Jim Kelly as EVP, CFO, and Treasurer, and Nasir Egal, Ph.D. as SVP, Quality Assurance.

August 9, 2021 - Local media reported the Philippines FDA has started evaluating the application from Novavax for an emergency use authorization of its coronavirus vaccine.

August 6, 2021 - Science published an article: COVID-19 vaccine maker Novavax faces manufacturing setbacks.

August 5, 2021 - Novavax, Inc. announced its financial results and operational highlights for the second quarter ended June 30, 2021. Novavax revenue in the second quarter of 2021 was $298 million, compared to $36 million in the same period in 2020. This increase was due to increased development activities relating to NVX-CoV2373 for services performed under the U.S. government and Coalition for Epidemic Preparedness Innovations agreements.

August 5, 2021 - Novavax, Inc. announced preliminary data demonstrating a single booster dose of its recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant, NVX-CoV2373, given six months after an initial two-dose regimen, elicited a 4.6-fold increase in functional antibody titers.

August 5, 2021 - Novavax, Inc., with its partner, Serum Institute of India Pvt. Ltd., announced that the companies had filed regulatory submissions for emergency use authorization of NNovavax'srecombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. The submissions were made to the Drugs Controller General of India and regulatory agencies in Indonesia and the Philippines.

August 4, 2021 - Novavax, Inc. announced that it had reached an agreement with the European Commission to purchase up to 200 million doses of NVX-CoV2373, the CCompany'srecombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. The agreement covers the purchase of up to 100 million doses of the vaccine, with the option for an additional 100 million doses through 2023. Furthermore, Novavax confirmed completing its rolling submission for NVX-CoV2373 to the European Medicines Agency in the third quarter of 2021, with the delivery of initial vaccine doses expected to begin following the approval.

July 15, 2021 - The EEMA'swebsite continues to indicate: the rolling review of NNovavax'sCOVID-19 vaccine (NVX-CoV2373) is ongoing.

July 6, 2021 - Novavax, Inc. announced it would report its second-quarter 2021 financial results and operational highlights on August 5, 2021, following the close of U.S. financial markets.

June 30, 2021 - Novavax, Inc. announced the publication of results from the final analysis of a pivotal Phase 3 clinical trial of its COVID-19 vaccine candidate conducted in the United Kingdom in the New England Journal of Medicine. The final analysis confirmed an overall efficacy of 89.7%, with over 60% (half) of the cases caused by the B.1.1.7 (Alpha) variant and a 96.4% efficacy against non-B.1.1.7 (non-Alpha) variants represent strains most similar to the original virus. ""t is quite remarkable how well the vaccine efficacy from our United Kingdom trial matches the results seen in the United States in the recently released PREVENT-19 trial results, giving even more confidence in the potential role of this vaccine in helping to control the pandemic,""said Professor Paul Heath, FRCPCH, Vaccine Institute, St GGeorge's University of London and St GGeorge'sHospital, London, who is chief investigator of the Novavax United Kingdom trial. ""t really highlights the consistent performance of this vaccine in different populations and against a variety of evolving strains.""June 24, 2021 - *The Atlantic* published an article: The mRNA Vaccines Are Extraordinary, but Novavax Is Even Better.

June 22, 2021 - The Honourable François-Philippe Champagne, Minister of Innovation, Science and Industry, announced today the new Biologics Manufacturing Centre (BMC) construction at the National Research Council of CCanada's(NRC) "sRoyalmount location in Montréal, Québec has been completed. The partnership will enable the first manufacturing capabilities in Canada for a COVID-19 vaccine once the facility and NVX-CoV2373, NNovavax'srecombinant nanoparticle protein-based COVID-19 vaccine candidate, receive the required Health Canada approvals. Novavax and the NRC are working closely on technology transfer to establish the step-by-step process of producing NVX-CoV2373 at the BMC.

June 14, 2021 - Novavax, Inc. announced data from the first co-administration study of a SARS-CoV-2 vaccine candidate [Novavax, NVX-CoV2373] and an approved influenza vaccine [Seqirus, adjuvanted, trivalent seasonal influenza vaccine (aTIV) or a cell-based, quadrivalent seasonal influenza vaccine (QIVc)], suggest simultaneous vaccination may be a viable immunization strategy. In addition, the protection afforded by the candidate vaccine

was consistent with the main study at 87.5% and 89.8%, respectively.

June 14, 2021 - Novavax, Inc. announced that NVX-CoV2373, its vaccine candidate demonstrated 100% protection against moderate and severe disease, 90.4% efficacy overall, and met the primary endpoint in its PREVENT-19 pivotal Phase 3 trial. The study enrolled 29,960 participants across 119 sites in the U.S. and Mexico to evaluate the efficacy, safety, and immunogenicity, emphasizing recruiting a representative population of communities and demographic groups most impacted by the disease.

June 11, 2021 - Novavax announced preclinical and clinical data on the NVX-CoV2373 vaccine and a new vaccine directed against the SARS-CoV-2 Beta (B.1.351) variant. The data show that the vaccines demonstrated strong immunogenicity and protection against both the Alpha (B.1.1.7) and Beta (B.1.351) variants and the original SARS-CoV-2 in animal and human studies. A preprint of the manuscript, "mmunogenicity and In vivo protection of a variant nanoparticle vaccine that confers broad protection against emerging SARS-CoV-2 variants,"is available at bioRxiv.org.

May 22, 2021 - Novavax, Inc. announced signing a non-binding memorandum of understanding (MoU) with the Ministry of Health and Welfare of Korea (MOHW) and SK bioscience, Co. Limited, a vaccine business subsidiary of SK Group, explores further cooperation in developing and manufacturing vaccines, including NVX-CoV2373, NNovavax'srecombinant protein COVID-19 vaccine candidate.

May 13, 2021 - Novavax and the University of Maryland School of Medicine began testing the COVID-19 vaccine on adolescents 12- 15 years old, reported the Baltimore Sun.

May 10, 2021 - Novavax, Inc. announced data from a preclinical study of the CCompany'scombination quadrivalent seasonal flu vaccine (NanoFlu™) and COVID-19 vaccine candidate (NVX-CoV2373). The NanoFlu/NVX-CoV2373 combination vaccine demonstrated positive immune responses to both influenza and SARS-CoV-2. A pre-print of the manuscript published on May 5, 2021, is available at bioRxiv.org.

May 6, 2021 - Novavax, Inc. announced that it had finalized an advance purchase agreement (APA) with Gavi, the Vaccine Alliance (Gavi). Under the APA, Novavax is expected to manufacture and distribute 350 million doses of NVX-CoV2373 to countries participating under the COVAX Facility. In addition, under a separate purchase agreement with Gavi, the Serum Institute of India is expected to manufacture and deliver the balance of the 1.1 billion doses of the Novavax COVID-19 vaccine.

May 5, 2021 - Novavax, Inc. announced results from the initial primary analysis of a Phase 2b clinical trial conducted in South Africa of its NVX-CoV2373 COVID-19 vaccine candidate in the New England Journal of Medicine (NEJM). The Phase 2b randomized, observer-blinded, placebo-controlled trial conducted in South Africa evaluated the efficacy, safety, and immunogenicity in healthy adults and a small cohort of medically stable adults living with human immunodeficiency virus (HIV). The study met its primary endpoint. NVX-CoV2373 demonstrated an overall efficacy of 49% in the initial analysis (published NEJM) and 49% in the subsequent complete analysis (unpublished). Among healthy adults without HIV, NVX-CoV2373 demonstrated the efficacy of 60% in the initial analysis and 55% in the subsequent complete analysis. In the initial analysis, cases were predominantly mild-to-moderate and due to the B.1.351 variant. However, in the subsequent complete analysis, circulation of the B.1.351 variant continued to dominate, and all five cases of severe disease observed in the trial occurred in the placebo group. The initial analysis, published in NEJM, suggested that prior infection with the original COVID-19 strain did not protect against subsequent infection by the variant predominantly circulating in South Africa through 60 days of follow-up. However, with additional follow-up, the complete analysis of the South Africa trial indicates that there may be a modest protective effect of prior exposure with the original COVID-19 strain. At 90 days of follow-up, the illness rate

was 8.0% among placebo recipients in baseline seronegative participants and 5.9% in baseline seropositive participants.

May 3, 2021 - Gregory M. Glenn, M.D., President, Research and Development, Novavax, said in a press release, ""hrough the expansion of our PREVENT-19 clinical trial, we hope to build upon the encouraging safety and efficacy data generated to date in adults for our vaccine candidate and to play a significant global role in offering vaccination to as many people as possible across age groups to end the suffering caused by the pandemic.""April 29, 2021 - Reuters reported South KKorea'sMinistry of Food and Drug Safety had submitted NNovaVax'sNVX-CoV2373 vaccine for preliminary regulatory approval.

April 14, 2021 - Novavax, Inc. announced its participation in a newly expanded investigator-initiated Phase 2 clinical trial called Comparing COVID-19 Vaccine Schedule Combinations – Stage 2 (Com-COV2), to be conducted by the University of Oxford and supported by the UK Vaccines Taskforce. NNovavax'srecombinant protein vaccine candidate, NVX-CoV2373, is one of four COVID-19 vaccines that will be studied to evaluate the potential for combined regimens that mix vaccines from different manufacturers to achieve immune protection against COVID-19.

April 6, 2021 - Novavax, Inc. announced the initiation of crossover arms for two of their ongoing clinical trials. Crossover ensures that all the participants in the clinical trials receive the active vaccine. This has been initiated for Phase 2B in South Africa and Phase 3 in the UK. The Company intends to offer crossover vaccinations to the other COVID-19 trials.

March 29, 2021 - GSK announced an agreement in principle with Novavax and the UK Government Vaccines Taskforce to support manufacturing up to 60 million doses of NNovavax'sCOVID-19 vaccine candidate (NVX-CoV2373) for use in the UK. GSK will provide "ill 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.

March 27, 2021 - Serum Institute of India CEO Adar Poonawalla announced clinical trials of Covovax have started in India, and the vaccine is expected to be launched by September 2021.

On March 11, 2021, Novavax, Inc. announced a final efficacy of 96.4% against mild, moderate, and severe disease caused by the original COVID-19 strain in a pivotal Phase 3 trial in the United Kingdom (U.K.) NVX–CoV2373, the CCompany'svaccine candidate. The Company also announced the complete analysis of its Phase 2b trial in South Africa, with an efficacy of 55.4% among the HIV- negative trial participants in a region where most strains are B1.351 escape variants. Across both trials, NVX-CoV2373 demonstrated 100% protection against severe disease, including all hospitalization and death.

February 25, 2021 - Novavax, Inc. announced progress in its collaboration with Takeda Pharmaceutical Company Limited, originally announced in August 2020. In Japan, the companies have signed an exclusive license agreement for TTakeda'sdevelopment, manufacturing, and commercialization of NVX-CoV2373, NNovavax'sCOVID-19 vaccine candidate.

February 24, 2021 - Takeda Pharmaceutical announced the first subject was dosed in its Phase 1/2 immunogenicity and safety study of NNovavax'sCOVID-19 vaccine candidate (TAK-019) in Japan. Takeda previously announced (August 2020) its commitment to providing rapid and sustained access to COVID-19 vaccines in Japan through partnerships with Novavax.

February 22, 2021 - Novavax, Inc. announced the complete enrollment of PREVENT-19, its pivotal Phase 3 study in the United States and Mexico to evaluate the efficacy, safety, and

immunogenicity of the COVID-19 vaccine candidate. Novavax has previously reported positive interim efficacy results of NVX-CoV2373, its recombinant protein-based vaccine candidate, in an ongoing Phase 3 clinical trial in the United Kingdom.

February 18, 2021 - Novavax, Inc. announced a Memorandum of Understanding with Gavi, the Vaccine Alliance (Gavi), to provide 1.1 billion cumulative doses of NVX-CoV2373, NNovavax'recombinant protein-based COVID-19 vaccine candidate, for the COVAX Facility. The vaccine doses will be manufactured and distributed globally by Novavax and Serum Institute of India (SII) under an existing agreement between Gavi and SII.

February 15, 2021 - Novavax, Inc. and SK Bioscience announced an expanded collaboration and license agreement. In addition to the already existing manufacturing arrangement, SK Bioscience has obtained a license to manufacture and commercialize the NVX-CoV2373, NNovavax'sCOVID-19 vaccine, for sale to the Korean government.

February 4, 2021 - Novavax, Inc. announced the start of the rolling review process for authorization of NVX-CoV2373, its COVID-19 vaccine, by multiple regulatory agencies. The reviews will continue while the Company completes its pivotal Phase 3 trials in the United Kingdom and the United States and through initial authorization for emergency use granted under country-specific regulations.

February 3, 2021 - Novavax, Inc. announced that the Company had executed a binding Heads of Terms agreement with SSwitzerland'sgovernment to supply six million doses of its protein-based COVID-19 vaccine candidate NVX-CoV2373 to the country. Novavax and Switzerland will negotiate a final agreement, with an initial delivery of vaccine doses slated to ship following successful clinical development and regulatory review.

February 2, 2021 - Novavax, Inc. announced a memorandum of understanding with the Canadian government to produce NVX-CoV2373, the CCompany'sprotein-based vaccine candidate against COVID-19, in Canada. Novavax plans to produce its COVID-19 vaccine at the National Research CCouncil'sBiologics Manufacturing Centre in Montréal once the vaccine candidate and the facility receive Health Canada approvals.

January 28, 2021 - Novavax, Inc. announced that NVX-CoV2373, its protein-based COVID-19 vaccine candidate, met the primary endpoint, with a vaccine efficacy of 89.3%, in its Phase 3 clinical trial conducted in the United Kingdom (UK). The study assessed efficacy during high transmission and a new UK variant strain of the virus emerging and circulating widely.

January 22, 2021 - Novavax, Inc. announced that it had finalized an agreement with the Government of Canada to supply up to 76 million doses of NVX-CoV2373, the CCompany'srecombinant protein-based COVID-19 vaccine. Canada has committed to purchase 52 million doses of the vaccine with the option of up to an additional 24 million doses.

January 14, 2021 - The journal Nature published: SARS-CoV-2 spike glycoprotein vaccine candidate NVX-CoV2373 immunogenicity in baboons and mice protection. In mice, low-dose NVX-CoV2373 with saponin-based Matrix-M adjuvant elicit high titer anti-S IgG blocks hACE2 receptor binding, neutralizes the virus, and protects against SARS-CoV-2 challenge with no evidence of vaccine-associated enhanced respiratory disease. In addition, NVX-CoV2373 also elicits multifunctional CD4+ and CD8+ T cells, CD4+ follicular helper T cells (Tfh), and antigen-specific germinal center (GC) B cells in the spleen. In baboons, low-dose levels of NVX-CoV2373 with Matrix-M were also highly immunogenic. They elicited high titer anti-S antibodies and functional antibodies that block S-protein binding to hACE2 and neutralize virus infection and antigen-specific T cells.

January 11, 2021 - Howard University Joins Novavax Phase 3 Clinical Trial of NVX-CoV2373 Vaccine Candidate Against COVID-19. ""e believe that diverse participation in COVID-19 trials will go a long way toward encouraging potentially life-saving vaccination when it is available,""said President Wayne A. I. Frederick, M.D., MBA.

January 11, 2021 - Illinois-based Baxter International Inc. announced that Baxter BioPharma Solutions has agreed to provide sterile manufacturing services for NVX-CoV2373, NNovavax'COVID-19 recombinant nanoparticle vaccine candidate with Matrix-M™ adjuvant.

January 7, 2021 - Novavax, Inc. announced that it had executed an Advance Purchase Agreement with the Commonwealth of Australia for 51 million doses of NVX-CoV2373, NNovavax'sCOVID-19 vaccine candidate. This follows an agreement in principle announced in November 2020.

January 6, 2021 - Researchers at the University of Maryland School of Medicine will participate in Phase 3 clinical trial of an investigational COVID-19 vaccine to protect against SARS-CoV-2, the coronavirus causing COVID-19 that continues to impact millions of people around the world. The clinical trial will test the safety and effectiveness of NVX-CoV2373, being developed by U.S. biotechnology company Novavax, Inc., based in Gaithersburg, MD.

December 28, 2020 - Novavax said Monday it is starting a late-stage trial of its COVID-19 vaccine candidate NVX-CoV2373, with plans to enroll up to 30,000 volunteers at about 115 sites in the USA and Mexico. The trial will be randomized, placebo-controlled, and evaluate the ttreatment'sefficacy in patients aged 18 and older. ""We'vecome this far, this fast, but we need to get to the finish line,""said NIH Director Francis S. Collins, M.D., Ph.D.

December 16, 2020 - Novavax, Inc. announced an Advance Purchase Agreement with New ZZealand'sgovernment to purchase 10.7 million doses of NVX-CoV2373, NNovavax'scandidate vaccine against COVID-19. Under the terms of the agreement, Novavax will manufacture NVX-CoV2373 with a target of delivering initial doses by mid-2021.

December 10, 2020 - Study published by the NEJM: Phase 1–2 Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine.

November 9, 2020 - Novavax, Inc. announced that the U.S. FDA had granted Fast Track Designation for NVX-CoV2373, the CCompany'sCOVID-19 vaccine candidate, a stable, prefusion protein made using NNovavax'nanoparticle technology and includes its proprietary MatrixM™ adjuvant. Novavax said it expects to begin its pivotal Phase 3 clinical trial in the USA and Mexico by the end of November.

October 27, 2020 - Novavax, Inc. announced updates on its Phase 3 clinical development program of NVX-CoV2373. The Company also announced that it would present data from its ongoing Phase 1/2 clinical trial, including new Phase 2 reactogenicity data, on October 30, 2020, during the U.S. Center for Disease Control and PPrevention'sAdvisory Committee on Immunization Practices.

September 24, 2020 - Novavax, Inc. announced that it had initiated its first Phase 3 study to evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373, NNovavax'sCOVID-19 vaccine candidate. The trial is being conducted in the United Kingdom (UK) in partnership with the UK GGovernment'sVaccines Taskforce.

September 15, 2020 - Novavax announced an amendment to its existing agreement with Serum Institute of India Private Limited (SIIPL), under which SIIPL will also manufacture the antigen component of NVX-CoV2373, NNovavax'COVID-19 vaccine

candidate. With this agreement, Novavax increases its manufacturing capacity of NVX-CoV2373 to over 2-billion doses annually, when all planned capacity has been brought online by mid-2021.

September 2, 2020 - Novavax announced the publication in The New England Journal of Medicine of Phase 1 data from its Phase 1/2 clinical trial of NVX-CoV2373, its COVID-19 vaccine candidate. The publication offers further detail on the previously announced results. NVX-CoV2373 demonstrated a reassuring safety and reactogenicity profile and induced robust antibody responses numerically superior to that seen in human convalescent sera.

August 31, 2020 - Novavax, Inc. announced it had agreed in principle with the Government of Canada to supply up to 76 million doses of NVX-CoV2373, NNovavax'sCOVID-19 vaccine candidate. Maryland-based Novavax stated that Novavax expects to supply doses of NVX-CoV2373 to Canada as early as the second quarter of 2021.

August 24, 2020 - Novavax announced that the first volunteers had been enrolled in the Phase 2 portion of its ongoing clinical trial to evaluate the immunogenicity and safety of NVX-CoV2373, Novavax COVID-19 vaccine candidate. The Phase 2 clinical trial expands on the age range of the Phase 1 portion by including older adults 60-84 years of age as approximately 50 percent of the ttrial'spopulation.

August 13, 2020 - Novavax and SK bioscience announced a development and supply agreement for the antigen component of NVX-CoV2373, NNovavax'sCOVID-19 vaccine candidate, for supply to global markets, including the COVAX Facility. Besides, the companies have signed a letter of intent with the Republic of KKorea'sMinistry of Health and Welfare to work toward broad and equitable access to NVX-CoV2373 in South Korea.

August 7, 2020 - Novavax and Takeda announced a partnership for developing, manufacturing, and commercializing NVX-CoV2373, NNovavax'sCOVID-19 vaccine candidate, in Japan. NVX-CoV2373 is a stable, prefusion protein made using NNovavax'srecombinant protein nanoparticle technology and includes NNovavax'sproprietary Matrix-M™ adjuvant.

August 6, 2020 - Novavax announced a license agreement with Serum Institute of India Private Limited to develop and commercialize NVX-CoV2373 in low- and middle-income countries and India. This agreement excludes major upper-middle and high-income countries, for which Novavax continues to retain rights.

July 27, 2020 - The US government issued a federal task order reserving production capacity at one of Texas A&M University System College SStation'sfacilities. This task order is valued at about $265 million, announced by the university on July 27, 2020.

July 23, 2020 - Novavax, Inc. and FUJIFILM Diosynth Biotechnologies (FDB) announced an agreement to manufacture bulk drug substances NVX-CoV2373, NNovavax'COVID-19 vaccine candidate. FFDB'ssite in Morrisville, North Carolina, has begun production of the first batch of NVX-CoV2373.

July 7, 2020 - Novavax, Inc. announced that it has been selected to participate in Operation Warp Speed and has been awarded $1.6 billion by the U.S. 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, NNovavax'COVID-19 vaccine candidate, as early as late 2020.

June 8, 2020 - Novavax announced that Gregory M. Glenn, M.D., President of Research and Development, will join other vaccine industry leaders for a panel discussion at 2020 BIO Digital. ""e see neutralizing titers in the 10,000 range in non-human primates.""The Company expects results and plans to start a Phase II trial and manufacture 100 million

doses in 2020.

June 4, 2020 - Novavax announced that the Company had been awarded a contract by the U.S. Department of Defense (DoD) to manufacture NVX-CoV2373, NNovavax'sCOVID-19 vaccine candidate. NVX-CoV2373 consists of a stable, prefusion protein antigen made using its proprietary nanoparticle technology and includes NNovavax'sproprietary Matrix-M™ adjuvant.

May 11, 2020 - Novavax, Inc. announced that the Coalition for Epidemic Preparedness Innovations (CEPI) would invest up to $384 million of additional funding, on top of $4 million it invested in March, to advance the clinical development of NVX-CoV2373, NNovavax'coronavirus vaccine candidate against SARS-CoV-2.

April 8, 2020 - Novavax, Inc announced it had identified a coronavirus vaccine candidate, NVX-CoV2373. The NVX-CoV2373 clinical development plan combines a Phase 1/Phase 2 approach to allow rapid advancement during the current coronavirus pandemic.

March 10, 2020 - CEPI provides an initial $4 million to accelerate vaccine development to prepare for Phase 1 clinical study.

Novavax COVID-19 Vaccine (NVX-CoV2373) Clinical Trials

The NVX-CoV2373 vaccine continues to be evaluated in multiple clinical trials.

The U.S. Centers for Disease Control and Prevention (CDC) provided updated guidance on August 30, 2021, for those vaccinated as part of a clinical trial in the U.S. The CDC guidance states that participants in the Novavax PREVENT-19 Phase 3 clinical trial meets the criteria to be considered fully vaccinated two weeks after completing the vaccine series.

On August 25, 2021, the Company confirmed as part of OCTAVE-DUO, 320 participants with lymphoid malignancies from OCTAVE and similar studies which demonstrated low or no response to two doses of a primary COVID-19 vaccine regimen would be randomly assigned to receive a third vaccine dose from one of three manufacturers at least 14 days after completing the initial 2-dose regime. The individuals may receive the same vaccine as the first two doses or one from another manufacturer. Of these participants, one-third will be administered NNovavax'srecombinant nanoparticle protein-based COVID-19 vaccine, NVX-CoV2373. It is a follow-on to OCTAVE (Observational Cohort Trial -T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2), which evaluated the immune response to COVID-19 vaccines in participants with impaired immune systems due to cancer, inflammatory arthritis, kidney or liver diseases, or a stem cell transplant.

On August 5, 2021, the Company confirmed final analysis from PREVENT-19 U.S. and Mexico Phase 3 trial: Achieved primary efficacy endpoint with an overall efficacy of 90.4% against mild, moderate, and severe disease; Demonstrated 100% protection against moderate and severe disease; Demonstrated 91.0% efficacy among high-risk populations; Demonstrated 92.6% efficacy against Variants of Concern/Variants of Interest (VoC/VoI) and 100% efficacy against variants not considered VoC/VoI.