

# INOVIO Expands Partnership with Advaccine to Conduct Global Phase 3 Efficacy Trial of COVID-19 DNA Vaccine Candidate, INO-4800

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Phase 3 efficacy trial planned to commence this summer in areas of the world underserved by vaccines  
News follows recently announced Phase 2 data, which showed INO-4800 to be well-tolerated and immunogenic in all age groups

PLYMOUTH MEETING, Pa., June 8, 2021 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on bringing to market precisely designed DNA medicines to treat and protect people from infectious diseases, cancer, and HPV-associated diseases, today announced an expansion of its previously announced partnership with Advaccine Biopharmaceuticals Suzhou Co., Ltd. ("Advaccine") to jointly conduct a global Phase 3 segment of the ongoing Phase 2/3 trial called INNOVATE (INOVIO INO-4800 Vaccine Trial for Efficacy). Together, the companies will evaluate the safety and efficacy of INO-4800 in a two-dose regimen (2.0 mg), administered one month apart, in a two-to-one randomization in subjects 18 years and older across several countries, primarily in Latin America and Asia. The primary endpoint of the Phase 3 segment will be virologically confirmed COVID-19 disease. The 2.0 mg dose was selected from the Phase 2 segment, where INO-4800 was shown to be generally well-tolerated and immunogenic in all tested age groups.

Dr. J. Joseph Kim, President and CEO of INOVIO, said, "With most countries in the world currently registering COVID vaccination rates of less than 10%, INOVIO and Advaccine feel the urgency to advance INO-4800 into a global Phase 3 trial this summer. INOVIO is encouraged by our recently **published** Phase 2 data for INO-4800, which showed the vaccine to be well-tolerated and immunogenic in all tested age groups. In a **previously announced study**, INO-4800 was also found to generate broad cross-reactive immune responses against tested SARS-CoV-2 variants of concern, which may enable it to provide greater protection for more people globally."

Dr. Kim continued, "We believe that INO-4800, if approved, will be well-positioned to serve the vaccine needs of the global community. Based on trial results to date, this vaccine has shown to be well-tolerated; produces balanced

neutralizing antibodies and favorable T cell response (CD8 and CD4) and is easy to administer. It is uniquely positioned to support vaccine rollout to underserved countries globally with a strong thermostability profile that is stable at room temperature for more than a year and does not require cold or ultra-cold-chain transport. In addition to the potential approval as a primary vaccine, INO-4800 also has the potential to be used as a booster vaccine since the early clinical data supports that INO-4800 can be safely re-administered."

Founder and Chairman of Advaccine, Dr. Bin Wang said, "The expansion of our partnership with INOVIO has a lot of synergy and we are excited about the global Phase 3 trial of INO-4800. We look forward to bringing a well-tolerated and immunogenic COVID-19 vaccine to more people around the world. Advaccine has built up large scale GMP manufacturing facilities of DNA vaccine and recently obtained the vaccine manufacturing permit from Chinese regulatory authorities, becoming one of a few companies in China that have the license. We are working to expand our manufacturing capacities further, in order to meet the unmet global need for nucleic acid-based COVID-19 vaccines."

Under their expanded collaboration, INOVIO and Advaccine intend to share equally, subject to specified limitations and conditions, the total cost of the planned global Phase 3 trial, which is estimated to be approximately \$100 million. The expanded partnership is an extension of an existing relationship between the two companies, including an exclusive agreement **announced** in January 2021 under which Advaccine has the exclusive rights to develop, manufacture and commercialize INO-4800 within Greater China, inclusive of mainland China, Hong Kong, Macao and Taiwan. Under the expanded agreement, Advaccine obtains rights to additional Asian countries outside of Greater China. Advaccine has extensive experience in co-development of INO-4800 with INOVIO, including sponsoring both Phase 1 and Phase 2 clinical trials in China for INO-4800.

The global Phase 2/3 trial builds upon INOVIO's Phase 2 segment, which was funded by the U.S. Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, (JPEO-CBRND) in coordination with the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) and the Defense Health Agency. Results from the trial can be found in the paper entitled "Safety and immunogenicity of INO-4800 DNA vaccine against SARS-CoV-2: A Preliminary Report of a Randomized, Blinded, Placebo-controlled, Phase 2 Clinical Trial in Adults at High Risk of Viral Exposure," which has been published as a pre-print in MedRxiv prior to peer review. Early INO-4800 research and development funding were provided by the Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill & Melinda Gates Foundation.

In addition to the initiation of the clinical trial itself, INOVIO is in discussions with several countries which are expected to provide clinical trial sites, regarding advanced market contracts to potentially supply INO-4800 upon respective regulatory approvals in those countries.

## About the INO-4800 "INNOVATE" Phase 2/3 Clinical Trial

The Phase 2 segment of INNOVATE Phase 2/3 trial was designed to evaluate the safety, tolerability and immunogenicity of INO-4800 in a two-dose regimen (1.0 mg or 2.0 mg) in a three-to-one-randomization to receive either INO-4800 or placebo in three age groups (18-50 years, 51-64 years and 65 years and older). The Phase 2 data showed that INO-4800 was well-tolerated and immunogenic in all tested age groups, and the 2.0 mg dose was selected to advance into the Phase 3 segment of the trial.

The global Phase 3 segment of the trial intends to enroll healthy men and non-pregnant women 18 years of age and older, to evaluate the efficacy of INO-4800 (2.0 mg) in a two-dose regimen based on the Phase 2 dose-confirmation data. The trial will be predominantly conducted in vaccine underserved countries in Latin America and Asia. Participants will be enrolled in a two-to-one randomization to receive either INO-4800 or a placebo. The Phase 3 segment will be case-driven with the final number of enrollees to be determined by the incidence of COVID-19 during the Phase 3 segment. The primary endpoint of the Phase 3 segment will be virologically confirmed COVID-19 disease.

## About INO-4800

INO-4800 is INOVIO's DNA vaccine candidate against SARS-CoV-2, the novel coronavirus that causes COVID-19. INOVIO has extensive experience working with coronaviruses and was the first company to initiate a Phase 2a trial for INO-4700, a DNA vaccine candidate for a related coronavirus that causes Middle East Respiratory Syndrome (MERS).

Composed of a precisely designed DNA plasmid, INO-4800 is injected intradermally followed by electroporation using a proprietary smart device delivering the DNA plasmid directly into cells in the body and is intended to produce a well-tolerated immune response. INO-4800 is the only nucleic-acid based vaccine that is stable at room temperature for more than a year, at 37°C for more than a month, has a five-year projected shelf life at normal refrigeration temperature and does not need to be frozen during transport or storage – all of which are important considerations when preparing for mass immunizations.

## About INOVIO's DNA Medicines Platform

INOVIO has 15 DNA medicine clinical programs currently in development and focused on HPV-associated diseases, cancer, and infectious diseases, including coronaviruses associated with MERS and COVID-19 that are being developed under grants from the Coalition for Epidemic Preparedness Innovations (CEPI) and the U.S. Department of Defense. DNA medicines are composed of precisely designed DNA plasmids, which are small circles of double-stranded DNA that are synthesized or reorganized by a computer sequencing technology and designed to produce

a specific immune response in the body.

INOVIO's DNA medicines deliver optimized plasmids directly into cells intramuscularly or intradermally using INOVIO's proprietary hand-held smart device called CELLECTRA®. The CELLECTRA® device uses a brief electrical pulse to reversibly open small pores in the cell to allow the plasmids to enter, overcoming a key limitation of other DNA and other nucleic acid approaches. Once inside the cell, the DNA plasmids enable the cell to produce the targeted antigen. The antigen is processed naturally in the cell and triggers the desired T cell and antibody mediated immune responses. Administration with the CELLECTRA® device ensures that the DNA medicine is efficiently delivered directly into the body's cells, where it can go to work to drive an immune response. INOVIO's DNA medicines do not interfere with or change in any way an individual's own DNA. The advantages of INOVIO's DNA medicine platform are the relative speed at which DNA medicines can be designed and manufactured; the stability of the products, which do not require freezing in storage and transport; and the robust immune response, and tolerability that have been observed in clinical trials.

With more than 3,000 patients receiving INOVIO investigational DNA medicines in more than 7,000 applications across a range of clinical trials, INOVIO has a strong track record of rapidly generating DNA medicine candidates with the potential to meet urgent global health needs.

## About INOVIO

INOVIO is a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to treat and protect people from infectious diseases, cancer, and diseases associated with HPV. INOVIO is the first and only company to have clinically demonstrated that a DNA medicine can be delivered directly into cells in the body via a proprietary smart device to produce a robust and tolerable immune response. Specifically, INOVIO's lead candidate VGX-3100 is the first DNA medicine to achieve efficacy endpoints in a Phase 3 clinical trial, REVEAL 1, for the treatment of precancerous cervical dysplasia caused by HPV-16 and/or HPV-18. VGX-3100 also demonstrated positive Phase 2 efficacy results in separate trials evaluating the treatment of precancerous vulvar dysplasia and anal dysplasia. Also in development are programs targeting HPV-related cancers and a rare HPV-related disease, recurrent respiratory papillomatosis (RRP); non-HPV-related cancers glioblastoma multiforme (GBM) and prostate cancer; as well as externally funded infectious disease DNA vaccine development programs in Zika, Lassa fever, Ebola, HIV, and coronaviruses associated with MERS and COVID-19. Partners and collaborators include Advaccine, ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), Defense Advanced Research Projects Agency (DARPA)/Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)/Department of Defense (DoD), HIV Vaccines Trial Network, International Vaccine Institute (IVI), Kaneka Eurogentec, Medical CBRN Defense Consortium (MCDC), National Cancer Institute, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Ology

Bioservices, the Parker Institute for Cancer Immunotherapy, Plumblin Life Sciences, Regeneron, Richter-Helm BioLogics, Thermo Fisher Scientific, University of Pennsylvania, Walter Reed Army Institute of Research, and The Wistar Institute. INOVIO also is a proud recipient of 2020 Women on Boards "W" designation recognizing companies with more than 20% women on their board of directors. For more information, visit [www.inovio.com](http://www.inovio.com).

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This press release contains certain forward-looking statements relating to our business, including our plans to develop and commercialize DNA medicines, our expectations regarding our research and development programs, including the planned initiation and conduct of preclinical studies and clinical trials and the availability and timing of data from those studies and trials, and our ability to successfully manufacture and produce large quantities of our product candidates if they receive regulatory approval. Actual events or results may differ from the expectations set forth herein as a result of a number of factors, including uncertainties inherent in pre-clinical studies, clinical trials, product development programs and commercialization activities and outcomes, our ability to secure sufficient manufacturing capacity to mass produce our product candidates, the availability of funding to support continuing research and studies in an effort to prove safety and efficacy of electroporation technology as a delivery mechanism or develop viable DNA medicines, our ability to support our pipeline of DNA medicine products, the ability of our collaborators to attain development and commercial milestones for products we license and product sales that will enable us to receive future payments and royalties, the adequacy of our capital resources, the availability or potential availability of alternative therapies or treatments for the conditions targeted by us or collaborators, including alternatives that may be more efficacious or cost effective than any therapy or treatment that we and our collaborators hope to develop, issues involving product liability, issues involving patents and whether they or licenses to them will provide us with meaningful protection from others using the covered technologies, whether such proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity and whether we can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of our technology by potential corporate or other partners or collaborators, capital market conditions, the impact of government healthcare proposals and other factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2020, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 and other filings we make from time to time with the Securities and Exchange Commission. There can be no assurance that any product candidate in our pipeline will be successfully developed, manufactured or commercialized, that

final results of clinical trials will be supportive of regulatory approvals required to market products, or that any of the forward-looking information provided herein will be proven accurate. Forward-looking statements speak only as of the date of this release, and we undertake no obligation to update or revise these statements, except as may be required by law.

View original content:<http://www.prnewswire.com/news-releases/inovio-expands-partnership-with-advaccine-to-conduct-global-phase-3-efficacy-trial-of-covid-19-dna-vaccine-candidate-ino-4800-301307352.html>

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