

# INOVIO Announces Initiation of Phase 2 Segment of its Phase 2/3 Clinical Trial for its COVID-19 DNA Vaccine Candidate, INO-4800; Trial Will Be Funded by the U.S. Department of Defense

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PLYMOUTH MEETING, Pa., Nov. 16, 2020 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on bringing to market precisely designed DNA medicines to treat and protect people from infectious diseases and cancer, today announced that it has received clearance from the U.S. Food & Drug Administration (FDA) to proceed with the Phase 2 segment of its planned Phase 2/3 clinical trial for INO-4800, its COVID-19 vaccine candidate. The planned Phase 2/3 clinical trial, called INNOVATE (INOVIO INO-4800 Vaccine Trial for Efficacy), is a randomized, blinded, placebo-controlled safety and efficacy trial of INO-4800 to be conducted in adults in the U.S. The INNOVATE trial will be funded by the U.S. Department of Defense (DoD) 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 (DHA).

The Phase 2 segment of the trial is designed to evaluate safety, tolerability and immunogenicity of INO-4800 in a 2-dose regimen (1.0 mg or 2.0 mg), in a three-to-one randomization to receive either INO-4800 or placebo for each dose to confirm the more appropriate dose(s) for each of three age groups with high risks of infection (18-50 years, 51-64 years and 65 years and older) for the subsequent Phase 3 efficacy evaluation. The Phase 3 segment of the INNOVATE trial remains on partial clinical hold until INOVIO satisfactorily resolves the FDA's remaining questions related to the CELLECTRA® 2000 device that will be used to deliver INO-4800 directly into the skin. The company plans to resolve the remaining device questions during the conduct of Phase 2 segment and prior to the start of the Phase 3 segment of the trial.

"I am extremely proud of the INOVIO team, which has been working tirelessly to develop a safe and effective vaccine in the fight against the COVID-19 pandemic. Initiation of our Phase 2 trial marks a pivotal milestone for INO-4800," said INOVIO's President and CEO, Dr. J. Joseph Kim. "We are especially pleased to continue our partnership

with the DoD to advance the development of INO-4800 for active duty service members and civilian personnel and are grateful for the Department's continued confidence in our technology to combat COVID-19."

Dr. Kim continued, "INO-4800's key differentiators are the safety and tolerability data we have observed thus far, as well as its excellent thermostability profile – making it possible to manufacture at scale and transport without frozen cold chain requirements. INO-4800 also maintains the ability to be safely re-administered and is differentiated by its ability to stimulate both CD4+ and CD8+ T cell responses."

The FDA's authorization to proceed is based on its review of INOVIO's non-clinical data, device information and interim Phase 1 safety and immunogenicity data as well as its design and plans for the Phase 2 and Phase 3 segments of the planned clinical trial. The Phase 2 segment of the trial is expected to enroll approximately 400 participants at up to 17 U.S. sites to evaluate safety and immunogenicity in order to confirm the dose(s) for the subsequent efficacy evaluation planned for the Phase 3 segment.

The DoD has agreed to provide funding for both the Phase 2 and Phase 3 segments of the INNOVATE clinical trial, in addition to the \$71 million of funding previously announced in June for the large-scale manufacture of the company's proprietary smart device CELLECTRA® 3PSP and the procurement of CELLECTRA® 2000 devices.

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

The lead Principal Investigator for the INNOVATE trial is Dr. Pablo Tebas, Professor of Medicine at the Hospital of the University of Pennsylvania. The Phase 2 segment of the trial is designed to evaluate safety, tolerability and immunogenicity of INO-4800 in a 2-dose regimen (1.0 mg or 2.0 mg), in a three-to-one randomization to receive either INO-4800 or placebo for each dose, to confirm the more appropriate dose(s) for each of three age groups (18-50 years, 51-64 years and 65 years and older) for the subsequent Phase 3 efficacy evaluation. The company intends to work diligently to ensure diversity in enrollment, targeting specific populations that are working or residing in environments with high infection rates and/or areas where there is greater risk of exposure to SARS-CoV-2, for whom exposure may be relatively prolonged or for whom personal protective equipment (PPE) may be inconsistently used, especially in confined settings.

In the Phase 3 segment of the trial, INOVIO intends to enroll healthy men and non-pregnant women 18 years and older, to evaluate the efficacy of the proposed dose(s) based on the data from the Phase 2 evaluation. Participants will be enrolled in a one-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 INOVIO's Global Coalition Advancing INO-4800

INOVIO has assembled a global coalition of collaborators, partners and funders to rapidly advance the development of INO-4800. R&D collaborators to date include the Wistar Institute, the University of Pennsylvania, the University of Texas, Fudan University and Laval University. INOVIO has partnered with Advaccine and the International Vaccine Institute to conduct clinical trials of INO-4800 in China and South Korea, respectively. INOVIO is also assessing nonclinical efficacy of INO-4800 in several animal challenge models with Public Health England (PHE) and Commonwealth Scientific and Industrial Research Organization (CSIRO) in Australia. INOVIO is working with a team of contract manufacturers including Thermo Fisher Scientific, Richter-Helm BioLogics, and Ology Bioservices to manufacture INO-4800 on a commercial scale and is seeking additional external funding and partnerships to further scale up manufacturing capacities to satisfy the urgent global demand for safe and effective vaccines. To date, the Coalition for Epidemic Preparedness Innovations (CEPI), the Bill & Melinda Gates Foundation, and the U.S. Department of Defense have contributed significant funding to the advancement and manufacturing of INO-4800.

## About INO-4800

INO-4800 is INOVIO's DNA vaccine candidate intended to protect 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 vaccine for Middle East Respiratory Syndrome (MERS), another coronavirus related to SARS-CoV-2.

INO-4800 is the only nucleic-acid based vaccine that is stable at room temperature for more than a year and does not need to be frozen in transport or storage, which are important factors when implementing mass immunizations.

## About INOVIO's DNA Medicines Platform

INOVIO has 15 DNA medicine clinical programs currently in development focused on HPV-associated diseases, cancer, and infectious diseases, including coronaviruses associated with MERS and COVID-19 diseases being developed under grants from the Coalition for Epidemic Preparedness Innovations (CEPI) and the U.S. Department of Defense. DNA medicines are composed of optimized 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, such as mRNA. 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 how fast 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, safety profile, and tolerability that have been observed in clinical trials.

With more than 2,000 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 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, currently in Phase 3 trials for precancerous cervical dysplasia, destroyed and cleared high-risk HPV 16 and 18 in a Phase 2b clinical trial. High-risk HPV is responsible for 70% of cervical cancer, 91% of anal cancer, and 69% of vulvar cancer. 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 diseases. 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), 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 manufacture DNA medicines, our expectations regarding our research and development programs, including the planned initiation and conduct of the Phase 2/3 clinical trial of INO-4800, 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 preclinical 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 our 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, 2019, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 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.

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