

# INOVIO and Advaccine Announce First Dosing of Subject in Phase 2 Clinical Trial for COVID-19 DNA Vaccine Candidate INO-4800 in China

12/10/2020

Dosing marks a key milestone for INO-4800 in China and its second Phase 2 clinical trial globally. The Phase 2 clinical trial is being conducted in PLYMOUTH MEETING, Pa. and SUZHOU, China, Dec. 10, 2020. 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, and Advaccine Biopharmaceuticals Suzhou Co., Ltd. ("Advaccine"), an emerging biotech company with next-generation technology in vaccines – both preventive and therapeutic, today announced the successful dosing of its first subject in its Phase 2 clinical trial for COVID-19 DNA vaccine candidate, INO-4800, in China. The Phase 2 clinical trial being conducted in China is independent of the INNOVATE Phase 2/3 clinical trial of INO-4800 being advanced in the U.S. and will enroll approximately 640 participants who are 18 years or older. Advaccine is conducting and funding the Phase 2 trial in China, which is expected to fully enroll by the end of this month.

Dr. J. Joseph Kim, President and CEO of INOVIO, said, "We have accelerated the development of INO-4800, our DNA vaccine candidate for COVID-19, in China by working together and leveraging Advaccine's expertise with Chinese regulatory authorities and clinical trial management. We are grateful for our collaboration with Advaccine and its founder Dr. Bin Wang, China's premier DNA vaccine expert and Emeritus Professor from Fudan University. Our teams are pleased with the progress to date and our ability to accelerate our clinical work in China with the goal of developing and delivering a safe, tolerable, effective and lasting vaccine for COVID-19.

Dr. Bin Wang, Founder of Advaccine, said, "We are truly grateful for Advaccine to co-develop INO-4800 against COVID-19 with INOVIO's team around the clock since January of this year, having maintained a very close collaboration together. INOVIO's great advantage of rapid DNA plasmid and delivery technologies are very important to the success of this vaccine candidate. After the completion of dosing for Phase 1 trial subjects at Huashan Hospital in Shanghai, China, with regulatory approval, Advaccine quickly launched the Phase 2 clinical trial

with Jiangsu Provincial CDC team. With the support of Fengcai ZHU, MD the principle investigator and a well-known vaccine clinical professor and his excellent team members as well as advanced clinical trial infrastructure in Jiangsu Province, I believe we can achieve China Phase 2 enrollment target of 640 subjects by the end of 2020."

INOVIO and Advaccine have been working together to advance the clinical development of INO-4800 in China. The Phase 2 clinical trial of INO-4800 in China will enroll both 18-59 years old adults and older adults (60 years and older) with the primary endpoints of evaluating safety and immunogenicity within the Chinese population. The dosing regimen involves two vaccinations at 0 and 28 days with either 1.0 mg or 2.0 mg dosing levels and is similar to the Phase 2 segment of Phase 2/3 clinical trial in U.S. This trial in China will provide valuable insights on INO-4800 safety and immunogenicity profile to support further evaluation of this vaccine candidate.

INOVIO recently announced it has dosed the first subjects in the Phase 2 segment of its Phase 2/3 clinical trial for INO-4800 in the U.S., called INNOVATE (INOVIO INO-4800 Vaccine Trial for Efficacy). For more information about the clinical trial, see [www.clinicaltrials.gov](http://www.clinicaltrials.gov), identifier NCT04642638.

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

The lead Principal Investigator for INNOVATE is Dr. Pablo Tebas, Professor of Medicine at the Hospital of the University of Pennsylvania. The Phase 2 segment of the clinical 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 (in a planned total of 400 subjects) to receive either INO-4800 or placebo, to confirm the more appropriate dosing level 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 strives to ensure diversity in enrollment, targeting specific populations that are working or residing in environments with high 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.

The INNOVATE trial is 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). 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 dosing level(s) for each age group 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. 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. 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 Kaneka Eurogentec S.A, 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.

## 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 an optimized DNA plasmid, INO-4800 is delivered directly into cells in the body via a proprietary smart device to produce a robust, safe and tolerable 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 and does not need to be frozen during transport or storage – 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 focused on HPV-associated diseases, cancer, and infectious diseases, including coronaviruses associated with MERS and COVID-19, 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 Advaccine

Advaccine Biopharmaceuticals Suzhou Co., Ltd. ("Advaccine") is an emerging clinical stage immunotherapy company pioneering novel preventive and therapeutic vaccines against infectious diseases, cancers and autoimmune diseases. Advaccine exploits a wide range of vaccine applications, with innovative antigen technologies, its adjuvant platform and along with a cellular immunity assessment platform for the swift development of novel vaccine and immunotherapeutic candidates. Through years of innovative preclinical and clinical research, Advaccine has successfully built a broad portfolio of vaccine candidates including a preventive vaccine based on a novel adjuvant targeting respiratory syncytial virus (RSV) infection in the elderly and infants, an immunotherapeutic vaccine against chronic hepatitis B (CHB), and also immunotherapeutic vaccine candidates against autoimmune diseases and various cancers. Based on its deep expertise in vaccine research and in-house large-scale manufacturing capabilities, Advaccine has been able to bring several vaccine candidates to clinical stages and ready for late stage clinical testing and commercial launch in the near future.

## 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), 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).

## CONTACTS:

Media: Jeff Richardson, 267-440-4211, [jrichardson@inovio.com](mailto:jrichardson@inovio.com)

Investors: Ben Matone, 484-362-0076, [ben.matone@inovio.com](mailto:ben.matone@inovio.com)

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.

View original content:<http://www.prnewswire.com/news-releases/inovio-and-advaccine-announce-first-dosing-of-subject-in-phase-2-clinical-trial-for-covid-19-dna-vaccine-candidate-ino-4800-in-china-301190178.html>

SOURCE INOVIO Pharmaceuticals, Inc.