

# INOVIO Planning for ex-US Global Phase 3 Trial for INO-4800

4/23/2021

Given universal eligibility and broad availability of COVID-19 vaccines in the U.S., DoD JPEO-CBRND has notified INOVIO that it will discontinue funding for the Phase 3 INO-4800 trial. INOVIO adjusts INO-4800 clinical development strategy to focus on global unmet COVID-19 vaccine needs. PLYMOUTH MEETING, Pa., April 23, 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 that it is planning for a predominantly ex-U.S. Phase 3 trial for its COVID-19 vaccine candidate, INO-4800. Given the increasing availability of vaccines authorized for emergency use, the 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 (DHA), will discontinue funding for the Phase 3 segment of the INNOVATE trial, while continuing to fund the completion of the ongoing Phase 2 segment. In correspondence, JPEO informed INOVIO: "The decision results from the changing environment of COVID-19 with the rapid deployment of vaccines. This decision is not a reflection of the awardee or product, rather a fast-moving environment associated with the former Operation Warp Speed on decisions related to future products."

This decision does not impact other work that INOVIO does with the US government and is neither a result of the partial clinical hold nor a reflection of the data generated to date for INO-4800 vaccine. With existing global collaborators such as INOVIO's China partner, Advaccine, and the **International Vaccine Institute (IVI)**, the company is planning for a predominantly ex-US global Phase 3 trial based on upcoming evaluation of Phase 2 safety and immunogenicity data. INOVIO continues to evaluate its pan-COVID variant vaccine, INO-4802, to protect against current and future variants of concern, as well as assessing boosting capabilities for INO-4800. INOVIO remains well-positioned to support both pandemic and endemic vaccine needs with INO-4800 and INO-4802. INOVIO and its partners and collaborators look forward to being part of the global solution to prevent the spread of COVID-19 – including both current and future variants.

## About INO-4800

INO-4800 is INOVIO's DNA vaccine candidate against SARS-CoV-2, the 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 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 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 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 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 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 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 (JPED-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 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 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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