

# INOVIO Initiates Phase 1 Clinical Trial Of Its COVID-19 Vaccine and Plans First Dose Today

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- Up to 40 Healthy Volunteers To Participate at Two Trial Locations
- Preclinical Animal Studies Show Promising Immune Responses
- Rapid Advancement Possible Through a Global Coalition of Collaborators, Partners, and Funders

PLYMOUTH MEETING, Pa., April 6, 2020 /PRNewswire/ -- INOVIO Pharmaceuticals, Inc. (NASDAQ:INO) today announced that the U.S. Food and Drug Administration has accepted the company's Investigational New Drug (IND) application for INO-4800, its DNA vaccine candidate designed to prevent COVID-19 infection, paving the way for Phase 1 clinical testing of INO-4800 in healthy volunteers beginning this week. The first dosing is planned for today.

Dr. J. Joseph Kim, INOVIO's President and CEO, said, "This is a significant step forward in the global fight against COVID-19. Without a new safe and effective vaccine, the COVID-19 pandemic is likely to continue to threaten lives and livelihoods. It also demonstrates the power of our DNA medicines platform to rapidly develop and advance a vaccine for COVID-19 into Phase 1 clinical testing. Our dedicated team of staff, partners and funders have been mobilized since the genetic sequence of the virus became available in early January and continues to work around the clock to ensure that we are rapidly advancing INO-4800 through this Phase 1 study towards planned efficacy trials."

Richard Hatchett, CEO of the Coalition for Epidemic Preparedness Innovations (CEPI), said, "This development is an important step forward in the world's search for a COVID-19 vaccine. INOVIO's DNA vaccine platform was one of the first technologies selected by CEPI to develop a vaccine candidate against COVID-19. We are pleased to see the rapid advancement of their vaccine candidate into clinical safety testing. Producing a COVID-19 vaccine within the next 12 to 18 months is not only a scientific challenge; it will also require new levels of collaboration and investment across industry and government. There is still a long road ahead before we have a safe, effective, and globally accessible vaccine ready for broader use, but today we have reached an important milestone on that journey."

The Phase 1 study of INO-4800 will enroll up to 40 healthy adult volunteers in Philadelphia, PA (at the Perelman School of Medicine at the University of Pennsylvania) and Kansas City, MO (at the Center for Pharmaceutical Research), where screening of potential participants has already begun. Study supplies of INO-4800 arrived at the sites last week. Each participant will receive two doses of INO-4800 four weeks apart, and the initial immune responses and safety data from the study are expected by late summer. Preclinical data, which have been shared with global regulatory authorities and submitted as part of the IND, have shown promising immune response results across multiple animal models. Additional preclinical trials, including challenge studies, will continue in parallel with the Phase 1 clinical trial.

Dr. Ami Shah Brown, INOVIO's Senior Vice President of Regulatory Affairs said, "Development and manufacture of a new vaccine with preclinical data to support a first-in-human trial in ten weeks from funding is a major milestone for INOVIO and our collaborators."

To date, preclinical results for INOVIO's COVID vaccine have been consistent with our completed Phase 1 vaccine study for Middle East Respiratory Syndrome (MERS), also caused by a coronavirus, in which INOVIO's DNA vaccine was well tolerated and induced high levels of antibody responses in 95% of subjects, while also generating broad-based T cell responses in nearly 90% of study participants. Durable antibody responses to its DNA vaccine (INO-4700) used in that trial were maintained through 60 weeks following dosing.

Upon attaining initial safety and immunogenicity data from Phase 1 studies, INOVIO plans to advance INO-4800 to Phase 2 efficacy studies as rapidly as possible. In 10 weeks from funding, INOVIO has manufactured thousands of doses of INO-4800 to support on-going Phase 1 and planned Phase 2 clinical trials. In parallel, INOVIO is working to scale up the manufacturing of INO-4800. INOVIO plans to have one million doses of the vaccine available by year-end for additional trials and emergency use, pending appropriate regulatory guidance and funding.

"We anticipate rapid enrollment of this initial study," said Pablo Tebas, MD, infectious disease specialist and professor of Medicine at the Hospital of the University of Pennsylvania and Principal Investigator of the study. "There has been tremendous interest in this vaccine among people who want to do what they can to help protect the greater public from this pandemic as soon as possible."

"INOVIO's leadership and the team's experience combined with the consistency of this DNA technology for clinical translation continue to be a major asset for the program," said Dr. David B. Weiner, Director of the Wistar Institute's Vaccine and Immunotherapy Center and Executive Vice President of the Institute.

INOVIO has assembled a global coalition of collaborators, partners, and funders to rapidly advance INO-4800. The scientific team at the Wistar Institute has provided key research contributions. The INOVIO program has been supported by generous funding from the Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill and

Melinda Gates Foundation. VGXI, Inc., a wholly-owned subsidiary of GeneOne Life Science (KSE: 011000) and INOVIO's manufacturing partner for the last 13 years, enabled the expedited manufacture, testing, and release of the INO-4800 plasmid clinical product. The U.S. Department of Defense (DOD) has also funded INOVIO's collaborator Ology Bioservices to manufacture additional doses of INO-4800.

## 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). 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®. CELLECTRA® uses a brief electrical pulse to open small pores in the cell reversibly to allow the plasmids to enter, overcoming a key limitation of other DNA and mRNA approaches. Once inside the cell, the plasmids are used by the cell's own machinery to generate specific coded antigens, which then stimulate an immune response. Administration with the CELLECTRA device ensures that the DNA medicine is delivered directly into the body's cells, where it can go to work immediately mounting 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 constructed 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 demonstrated in clinical trials.

With more than 2,000 patients receiving INOVIO investigational DNA medicines in more than 6,000 applications across a range of clinical trials, INOVIO has a strong track record of rapidly generating DNA medicine candidates 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, cure, and protect people from diseases associated with HPV, cancer, and infectious diseases. 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, 90% 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)/DOD, GeneOne Life Science/VGXI, HIV Vaccines Trial Network, Medical CBRN Defense Consortium (MCDC), National Cancer Institute, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Ology Bioservices, Plumblin Life Sciences, Regeneron, Roche/Genentech, 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 DNA medicine candidates, including INO-4800, our expectations regarding our research and development programs, as well as commercialization activities, including the planned initiation and conduct of clinical trials, the availability and timing of data from those trials and our manufacturing and commercialization strategy and tactics. 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 manufacturing and commercialization activities and outcomes, 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 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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