

# INOVIO Reports FDA Partial Clinical Hold for Planned Phase 2 / 3 Trial of COVID-19 Vaccine Candidate INO-4800

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PLYMOUTH MEETING, Pa., Sept. 28, 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, announced that the U.S. Food and Drug Administration (FDA) has notified the company it has additional questions about the company's planned Phase 2/3 trial of its COVID-19 vaccine candidate INO-4800, including its CELLECTRA® 2000 delivery device to be used in the trial. Until the FDA's questions have been satisfactorily addressed, INOVIO's Investigational New Drug Application (IND) for the Phase 2/3 trial is on partial clinical hold. The company is actively working to address the FDA's questions and plans to respond in October, after which the FDA will have up to 30 days to notify INOVIO of its decision as to whether the trial may proceed.

This partial clinical hold is not due to the occurrence of any adverse events related to INOVIO's ongoing expanded Phase 1 study of INO-4800, the conduct of which may continue and is not impacted by the FDA's notification. In addition, this partial clinical hold does not impact the advancement of INOVIO's other product candidates in development. INOVIO and its partners are continuing to prepare for a planned Phase 2/3 trial of INO-4800, following resolution of the FDA's partial clinical hold and subject to the receipt of external funding to conduct the trial.

## 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 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 simple-to-use CELLECTRA device provides a brief electrical pulse to reversibly open small pores in the local skin area cells resulting in more than a hundred-fold increase in product delivery providing dose sparing and consistency. Once inside the cell, the DNA plasmids instruct the cell to produce the targeted antigen. The antigen is processed naturally in the cell and triggers specific T cell and antibody-mediated immune responses. Administration with the CELLECTRA device, which takes only a few seconds, is designed to ensure that the DNA medicine is efficiently delivered directly into the body's cells, where it can go to work to drive the immune responses. INOVIO's DNA medicines are transient, and 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 consistent immune response, safety profile, and tolerability that have been observed in clinical trials with multiple products.

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 an efficacious, 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, Plumline Life Sciences, Regeneron, Richter-Helm BioLogics, Roche/Genentech, Thermo Fisher Scientific, University of Pennsylvania, VGXI, 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 conduct of a 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 June 30, 2020 and other filings we make from time to time with the Securities and Exchange Commission. There can be no assurance that INO-4800 or any other 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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