

# INOVIO Adds Thermo Fisher Scientific To Global Manufacturing Consortium

9/8/2020

INOVIO Plans to Have 100 Million Doses of COVID-19 Vaccine Candidate INO-4800 Manufactured in 2021

PLYMOUTH MEETING, Pa., Sept. 8, 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 Thermo Fisher Scientific, the world leader in serving science, has signed a letter of intent to manufacture INOVIO's DNA COVID-19 vaccine candidate INO-4800.

Thermo Fisher joins other contract development and manufacturing organizations in INOVIO's global manufacturing consortium, enabling INOVIO to potentially scale commercial production of INO-4800. With its consortium of third-party manufacturers, INOVIO plans to have 1001 million doses of INO-4800 manufactured in 2021, subject to FDA approval of INO-4800 for use as a COVID-19 vaccine. Thermo Fisher plans to manufacture INO-4800 drug substance as well as perform fill and finish of INO-4800 drug product at its commercial facilities in the US. At peak capacity, Thermo Fisher projects that it could produce at least 100 million doses of INO-4800 annually.

"INOVIO welcomes Thermo Fisher to our global consortium of commercial scale vaccine manufacturers and we look forward to partnering with them on this critically important endeavor," said Dr. J. Joseph Kim, INOVIO's President & Chief Executive Officer. "Thermo Fisher's global capabilities and scale will be central to our production progress – the organization's commitment to quality, reliable production will be key to our ability to meet the urgent, global demand for a safe and effective vaccine against COVID-19."

Leon Wyszowski, President, Commercial Operations for Thermo Fisher's Pharma Services business, said, "INOVIO has truly embraced the value of our end-to-end capabilities – starting with our initial work on clinical trials through supporting their commercial needs today. We remain extremely well-positioned to support INOVIO on its mission to manufacture 100 million doses of vaccine in 2021."

"INOVIO is very excited to partner with Thermo Fisher for the manufacture of DNA plasmid drug substance and

drug product," said Robert J. Juba Jr., INOVIO's Vice President of Biological Manufacturing and Clinical Supply Management. "Thermo Fisher provides an end-to-end solution for manufacturing, labeling, packaging and distribution that we believe will help us to provide hundreds of millions of doses of INO-4800 to the US and the rest of the world."

Thermo Fisher Scientific will join existing partners Richter-Helm BioLogics and Ology Biosciences in INOVIO's global manufacturing consortium. INOVIO is in active discussions with additional manufacturers to join the consortium as INOVIO seeks to complement its existing members with additional manufacturing partnerships to meet global supply needs. Having multiple manufacturers involved in the production of INO-4800 is intended to support timely, cost-effective and scalable production of this DNA-based vaccine. INOVIO's third-party manufacturers will produce the patent-protected formulation for INO-4800, developed to enhance stability of the vaccine with a favorable tolerability profile. Importantly, INO-4800 has shown an excellent thermo-stability profile. INOVIO's other platform DNA vaccine candidates have demonstrated a shelf life of greater than 5 years when refrigerated and stability for more than 30 days at 37 degrees Celsius, and more than one year at room temperature. INOVIO's candidates also do not need to be frozen during transport or storage, a vital factor when implementing immunizations on a global scale. INO-4800 is administered via INOVIO's proprietary CELLECTRA® smart delivery device, which delivers the vaccine locally into the patient's skin, a process that takes only a few seconds.

INOVIO is conducting a Phase 1 clinical trial of INO-4800 in the United States and has submitted the full trial results for the first 40 subjects for publication in a peer-reviewed journal. The company plans to initiate its Phase 2/3 COVID-19 vaccine trials in September, subject to FDA clearance to proceed.

Earlier this summer, INOVIO received \$71 million in funding from the U.S. Department of Defense (DoD) to support the large-scale manufacture of the company's proprietary CELLECTRA® 3PSP and the procurement of CELLECTRA® 2000 devices. The DoD contract builds upon two separate prior \$5 million grants from the Bill & Melinda Gates Foundation and the Coalition for Epidemic Preparedness Innovations (CEPI), to accelerate the testing of CELLECTRA® 3PSP. Initial development of this next generation CELLECTRA® 3PSP smart device began in 2019 with \$8.1 million in funding from the medical arm of the U.S. Defense Threat Reduction Agency's Medical CBRN Defense Consortium.

## 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 preclinical 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 Biosciences 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 the novel coronavirus SARS-CoV-2, which causes COVID-19. INOVIO has extensive experience working with coronaviruses and was the first company with a Phase 2 vaccine for a related coronavirus that causes Middle East Respiratory Syndrome (MERS).

## 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 a 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 an immune response. 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, Plumblin 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).

## 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 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 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 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.

1 1 mg dose equivalent

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