



## NEWS RELEASE

# INOVIO Announces Positive Interim Phase 1 Data For INO-4800 Vaccine for COVID-19

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### INO-4800 Selected for the U.S. Government's Operation Warp Speed

- 94% of Phase 1 trial participants demonstrated overall immune responses at Week 6 after two doses of INO-4800 in trial with 40 healthy volunteers in preliminary analyses
- Through Week 8 INO-4800 regimen was deemed safe and well-tolerated with no serious adverse events; all reported adverse events were grade 1 in severity
- In preclinical animal challenge study, INO-4800 provided full protection against SARS-CoV-2 replication in the lungs in mice challenged with the virus
- INOVIO to begin U.S. Phase 2/3 efficacy study this summer upon regulatory concurrence

PLYMOUTH MEETING, Pa., June 30, 2020 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to protect and treat people from infectious diseases and cancer, today announced positive interim clinical data of INO-4800, its vaccine candidate against novel coronavirus (SARS-CoV-2), from the first two Phase 1 clinical trial cohorts. In addition, INO-4800 has been selected to participate in a non-human primate (NHP) challenge study as part of the U.S. government's Operation Warp Speed, a new national program aiming to provide substantial quantities of safe, effective vaccine for Americans by January 2021. Furthermore, INOVIO has expanded its Phase 1 trial to add older participants in additional cohorts and plans to initiate a Phase 2/3 efficacy trial this summer upon regulatory concurrence.

Dr. J. Joseph Kim, President and CEO of INOVIO, said, "INOVIO would like to thank all of the trial participants and the investigator staff who have made this trial possible. We are very encouraged by the positive interim safety and preliminary cellular and humoral immune response results to date as well as the inclusion of INO-4800 in Operation Warp Speed. We are also pleased that INO-4800 vaccination abrogated viral replication in the lungs of mice challenged with SARS-CoV-2. We look forward to urgently advancing INO-4800, as it is the only nucleic-acid based vaccine that is stable at room temperature for more than a year and does not require to be frozen in transport or for years of storage, which are important factors when implementing mass immunizations to battle the current pandemic."

The Phase 1 clinical trial of INO-4800 initially enrolled 40 healthy adult volunteers 18 to 50 years of age at two U.S. sites with funding from the Coalition for Epidemic Preparedness Innovations (CEPI). The participants were enrolled into 1.0 mg and 2.0 mg dose cohorts; each participant received two doses of INO-4800 four weeks apart. Each dose was administered by intradermal injection using INOVIO's CELLECTRA® 2000 device. An independent Data Safety Monitoring Board reviewed the safety data. INO-4800 was generally safe and well-tolerated in all participants in both cohorts through week 8; all ten reported adverse events (AEs) were grade 1 in severity, and most were local injection site redness. There were no reported serious adverse events (SAEs).

Multiple immunology assays including those for humoral and cellular immune responses are being conducted for both 1.0 mg and 2.0 mg dose cohorts after two doses at week 6. Analyses to date have shown that 94% (34 out of 36 total trial participants) demonstrated overall immunological response rates based on preliminary data assessing humoral (binding and neutralizing) and T cell immune responses. One participant in the 1.0 mg dose cohort and two participants in the 2.0 mg dose cohort were excluded in the immune analyses as they tested positive for COVID-19 immune responses at study entry, indicating prior infection. One participant in the 2.0 mg dose cohort discontinued the study for reasons unrelated to safety or tolerability. INOVIO plans to publish the full data set in a peer-reviewed medical journal.

One key feature of INOVIO's DNA vaccines is the ability to generate balanced antibody and T cell immune responses, which in the case of SARS-CoV-2 infection could be important in the development of potential COVID-19 vaccines. In this regard, recent scientific reports have highlighted that SARS-CoV-2-specific T cells found in convalescent patients have been positively implicated in controlling the severity of their COVID-19 disease (Grifoni et al, Cell 2020) while other studies have shown that a significant proportion (33% to 40%) of convalescent individuals in their reports had neutralizing antibody below detectable levels (Robbiani et al, Nature 2020 and Payne et al, MMWR 2020).

In addition to positive interim Phase 1 data, INO-4800 has been shown to protect mice in SARS-CoV-2 viral challenge studies, where vaccination with INO-4800 prevented viral replication in the lungs of animals challenged with SARS-CoV-2. Moreover, INO-4800 is currently being tested in a ferret challenge model as well as in NHP challenge studies as part of Operation Warp Speed.

"While the pathophysiologic profile of SARS-CoV-2 is not completely understood, research and clinical studies suggest that both T cell and antibody immune responses will be important for protection in both mild and serious infections. Leveraging our previous expertise in MERS with INO-4700, where we demonstrated significant antibody and cellular responses, the breadth and profile of the responses observed to date with INO-4800 targeting SARS-CoV-2 provide a promising read towards further development and addressing the existing public health threat,"

said Dr. Kate Broderick, Senior Vice President of R&D at INOVIO.

As previously announced, INOVIO received \$71 million funding from the U.S. Department of Defense to support the large-scale manufacture of the company's proprietary CELLECTRA® 3PSP smart device and the procurement of CELLECTRA® 2000 devices. INO-4800 development has also been supported by generous funding from CEPI and the Bill & Melinda Gates Foundation.

## About INO-4800

INO-4800 is INOVIO's DNA vaccine candidate being developed to protect against the novel coronavirus SARS-CoV-2, which causes COVID-19. INO-4800 was designed rapidly using INOVIO's proprietary DNA medicine platform after the publication of the genetic sequence of the coronavirus that causes COVID-19. INOVIO has extensive experience working with coronaviruses and is the only company with a Phase 2 vaccine for a related coronavirus that causes Middle East Respiratory Syndrome (MERS).

INO-4800 is the only nucleic-acid based vaccine that is stable at room temperature for more than a year and does not require to be frozen in transport or storage, which are important factors when implementing 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 DoD. 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 intradermally or intramuscularly 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 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 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 demonstrated 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 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), GeneOne Life Science/VGXI, 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, 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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## 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 DNA medicines, our expectations regarding our research and development programs, including the availability and timing of data from the company's ongoing Phase 1 clinical trial of INO-4800 and the company's plans and ability to outsource manufacturing of its delivery devices to contract manufacturers. 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, 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, our ability to secure adequate third-party manufacturing resources for the production of our product candidates, including the transfer of necessary processes, 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 March 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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