INOVIO's COVID-19 DNA Vaccine INO-4800 Demonstrates Robust Neutralizing Antibody and T Cell Immune Responses in Preclinical Models

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- Publication in Nature Communications demonstrates generation of robust neutralizing antibodies and T cell responses against SARS-CoV-2
- Preliminary safety and immune responses data from Phase 1 clinical trial expected in June
- Multiple animal challenge study data expected in coming weeks
- Phase 2/3 efficacy trial planned to start in July/August pending regulatory approval

PLYMOUTH MEETING, Pa., May 20, 2020 /PRNewswire/ -- INOVIO (NASDAQ:INO) today announced the publication of the preclinical study data for INO-4800, its COVID-19 DNA vaccine, demonstrating robust neutralizing antibody and T cell immune responses against coronavirus SARS-CoV-2. The study was published in the peer-reviewed journal Nature Communications titled, "Immunogenicity of a DNA vaccine candidate for COVID-19" by INOVIO scientists and collaborators from The Wistar Institute, the University of Texas, Public Health England, Fudan University, and Advaccine.

Dr. Kate Broderick, INOVIO's Senior Vice President of R&D and the Team Lead for COVID-19 vaccine development, said, "These positive preclinical results from our COVID-19 DNA vaccine (INO-4800) not only highlight the potency of our DNA medicines platform, but also build on our previously reported positive Phase 1/2a data from our vaccine against the coronavirus that causes MERS, which demonstrated near-100% seroconversion and neutralization from a similarly designed vaccine INO-4700. The potent neutralizing antibody and T cell immune responses generated in multiple animal models are supportive of our currently on-going INO-4800 clinical trials."

INO-4800 targets the major surface antigen Spike protein of SARS-CoV-2 virus, which causes COVID-19 disease. The studies demonstrated that vaccination with INO-4800 generated robust binding and neutralizing antibody as well as T cell responses in mice and guinea pigs. Importantly, the authors demonstrated virus neutralizing activity using three separate neutralization assays testing the vaccine's ability to generate antibodies which can block virus
infection by: 1) an assay using live SARS-CoV-2 viruses; 2) an assay using a pseudo-virus assay, where another virus displays the SARS-CoV-2 Spike protein; and, 3) a novel high-throughput surrogate neutralization assay measuring the ability of INO-4800-induced antibodies to block SARS-CoV-2 Spike binding to the host ACE2 receptor. Study authors also detected these antibodies in the lungs of the vaccinated animals which could be important in providing protection from SARS-CoV-2. In addition, high levels of Spike-specific T cell responses were observed with INO-4800 vaccination, which could be important in mediating protection from the virus infection. Collectively, this preclinical dataset demonstrates that INO-4800 is a promising COVID-19 vaccine candidate against this emerging disease threat.

Dr. J. Joseph Kim, INOVIO’s President & CEO, said, "INOVIO and our collaborators are working diligently to advance INO-4800 to help fight the current pandemic. We are planning to utilize these positive preclinical results along with our upcoming animal challenge data and safety and immune responses data from our Phase 1 studies to support rapidly advancing this summer to a large, randomized Phase 2/3 clinical trial."

INOVIO’s swift progress in COVID-19 vaccine development is based on the ideal suitability of its DNA medicine platform to rapidly develop vaccines against emerging viruses with pandemic potential. INOVIO was the first to advance its DNA vaccine INO-4700 against MERS-CoV, a related coronavirus, into evaluation in humans in a collaboration with GeneOne Life Science and the Walter Reed Army Institute of Research. INO-4700 is the only MERS-CoV vaccine with positive data from a Phase 1/2a clinical trial, and INOVIO is currently preparing to initiate a larger Phase 2 vaccine trial for INO-4700 in the Middle East where most MERS viral outbreaks have occurred. These efforts are supported by CEPI funding.

About INO-4800

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

About INOVIO’s Global Coalition Advancing INO-4800

INOVIO has assembled a global coalition of collaborators, partners and funders to rapidly advance INO-4800. R&D collaborators to date include the Wistar Institute, the University of Pennsylvania, the University of Texas, Fudan University and the Laval University. INOVIO has partnered with Advaccine and the International Vaccine Institute to advance 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 also working with a team of contract manufacturers including VGXI, Inc., Richter-Helm BioLogics, and Ology Biosciences to produce INO-4800 and seeking additional external funding and partnerships to scale up the manufacturing capacities to satisfy the urgent global demand for a safe and effective vaccine. To date, the Coalition for Epidemic Preparedness Innovations (CEPI), the Bill & Melinda Gates Foundation, and the US 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). 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 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 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 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 protect and treat 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)/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, Plumbline 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.

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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 planned initiation and conduct of preclinical studies and clinical trials, and the availability and timing of data from those studies and trials. 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, 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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