

INOVIO's COVID-19 Vaccine Candidate, INO-4800, Provides Broad Cross-reactive Immune Responses In Humans Against Variants of Concern

4/15/2021

Results in new study showed INO-4800 vaccine-induced neutralizing antibodies and T cell responses against UK, South African and Brazilian variant strains

Paper entitled, "INO-4800 DNA Vaccine Induces Neutralizing Antibodies and T cell Activity Against Global SARS-CoV-2 Variants," submitted for peer review and available via preprint in bioRxiv

PLYMOUTH MEETING, Pa., April 15, 2021 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to treat and protect people from infectious diseases, and cancer, today announced the results of a study focusing on the human immune responses induced by INOVIO's DNA vaccine candidate for COVID-19, INO-4800, against variants of concern. The results showed that INO-4800 induced a robust T cell response against all spike protein variants tested, which the company believes will be key in providing protection against SARS-CoV-2 variants, in addition to providing similar levels of neutralizing activity against both the UK and Brazilian variants as those against the original strain. The study, entitled "INO-4800 DNA Vaccine Induces Neutralizing Antibodies and T cell Activity Against Global SARS-CoV-2 Variants," has been submitted for peer review and can be viewed at <https://www.biorxiv.org/content/10.1101/2021.04.14.439719v1>.

Dr. J. Joseph Kim, INOVIO's President & CEO, said, "These results are consistent with our expectation that INO-4800, which was found to be well-tolerated and able to produce a balanced immune response in our Phase 1 trial, is able to generate both neutralizing antibodies and robust T cell responses – both of which will be essential to protect against the emerging variants of concern."

Regarding INO-4800 development Dr. Kim said, "We will report Phase 2 results in 2Q, and, with FDA concurrence, expect to move into Phase 3 in the second quarter of this year. Our COVID vaccine's projected safety profile, its stability at room temperature for more than a year, and likely ability to safely boost numerous times positions INOVIO's COVID-19 vaccine as an important factor in addressing the virus in its pandemic and endemic states."

In the study, clinical samples were collected at varying timepoints post-immunization from subjects in INOVIO's Phase 1 US-based INO-4800 clinical trial. Antibodies capable of neutralizing activity were measured against the spike protein variants tested, including B.1.1.7 (UK variant), B.1.351 (South African variant) and P.1. (Brazilian variant). The study showed the T cell responses induced by INO-4800 vaccination were fully maintained against the UK, South African and Brazilian variants when compared to the T cell responses to the original Wuhan strain. The neutralization levels of INO-4800 against South Africa and UK variants were reduced to the levels similar to the previous reports of mRNA or viral vector vaccines. Furthermore, despite recent reports showing a reduction in neutralizing activity against the Brazilian variant by the mRNA or viral vector vaccines, INO-4800 generated robust neutralizing antibodies at levels against Brazilian variant which were comparable to those against the Wuhan strain. Taken together with the data showing the maintenance of T cell activity, the results reported in this study provide a comprehensive overview of cross-reactive cellular and humoral immune responses against SARS-CoV-2 variants for INO-4800 vaccinated individuals that may be important for protection against variant strains of SARS-CoV-2.

Collectively, the studies showcase how the combination of robust T cell responses in conjunction with neutralizing antibody responses provide an important defense against both emerging and potential future viral variants, exhibiting broad protection against the virus and less impacted by the mutational changes a virus may undergo.

About INO-4800

INO-4800 is INOVIO's DNA vaccine candidate against SARS-CoV-2, the novel coronavirus that causes COVID-19. Composed of an optimized DNA plasmid, INO-4800 is delivered directly into cells in the body via a proprietary smart device to produce a robust and tolerable immune response. INO-4800 is the only nucleic-acid based vaccine that is stable at room temperature for more than a year, at 37°C for more than a month, has a five-year projected shelf life at normal refrigeration temperature and does not need to be frozen during transport or storage – all of which are important considerations when preparing for mass immunizations.

About INOVIO's DNA Medicines Platform

INOVIO has 15 DNA medicine clinical programs currently in development focused on infectious diseases, cancer and HPV-associated diseases. 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 CELLECTRA® 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 nucleic acid approaches, such as mRNA. Once inside the cell, the DNA plasmids enable the cell to produce the

targeted antigen, which is processed naturally in the cell and triggers the desired T cell and antibody-mediated immune responses. 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 cold storage or transport; and the robust immune response, safety profile, and tolerability that have been observed in clinical trials.

With more than 3,000 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 met primary and secondary endpoints for all evaluable subjects in REVEAL 1, in the first of two Phase 3 trials for precancerous cervical dysplasia, demonstrating ability to destroy and clear both high-grade cervical lesions and the underlying high-risk HPV 16 and 18. INOVIO is also evaluating INO-4800, a DNA vaccine candidate against COVID-19, in a Phase 2 clinical trial in the U.S., as well as Phase 2 trials in China and South Korea. 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), Kaneka Eurogentec, 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, Thermo Fisher Scientific, University of Pennsylvania, Walter Reed Army Institute of Research, and The Wistar Institute. For more information, visit www.inovio.com.

CONTACTS:

Media: Jeff Richardson, 267-440-4211, jrichardson@inovio.com

Investors: Ben Matone, 484-362-0076, ben.matone@inovio.com

This press release contains certain forward-looking statements relating to our business, including our plans to develop DNA medicines and in particular our clinical work relating to INO-4800 and its potential effectiveness

against SARS-CoV-2 variants, 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, 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.

View original content:<http://www.prnewswire.com/news-releases/inovios-covid-19-vaccine-candidate-ino-4800-provides-broad-cross-reactive-immune-responses-in-humans-against-variants-of-concern-301269572.html>

SOURCE INOVIO Pharmaceuticals, Inc.