

INOVIO Expands INNOVATE Phase 3 for INO-4800, its DNA Vaccine Candidate for COVID-19, to include Colombia following Regulatory Authorization

10/11/2021

Authorization to conduct INNOVATE Phase 3 in Colombia builds on recent regulatory authorizations from Brazil, Philippines, and Mexico

PLYMOUTH MEETING, Pa., Oct. 11, 2021 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on bringing to market precisely designed DNA medicines to treat and protect people from infectious diseases, cancer, and HPV-associated diseases, today announced that it has received authorization from Colombia's **INVIMA** (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, or the National Food and Drug Surveillance Institute), to conduct the Phase 3 segment of INOVIO's global Phase 2/3 trial, INNOVATE (INOVIO INO-4800 Vaccine Trial for Efficacy) in Colombia, for INO-4800, its DNA vaccine candidate for COVID-19. INOVIO is working with partner Advaccine Biopharmaceuticals Suzhou Co., Ltd. (Advaccine) on the INNOVATE Phase 3 segment in multiple countries, with a focus on countries in Latin America, Asia, and Africa. INOVIO recently announced that it has received regulatory authorization to proceed in **Brazil, Philippines, and Mexico**.

The global Phase 3 segment of INNOVATE will evaluate the efficacy of INO-4800 in a two-dose regimen (2.0 mg per dose), administered one month apart, in a 2-to-1 randomization in men and non-pregnant women 18 years of age and older. The primary endpoint of this case-driven Phase 3 trial is virologically confirmed COVID-19.

Dr. J. Joseph Kim, President and CEO of INOVIO, said, "INOVIO is pleased to share the news of the regulatory authorization to proceed with our Phase 3 trial in Colombia. With COVID-19 rates continuing to rise in many areas, and with continued limitations to vaccine access in many countries globally, we are grateful to the multiple health authorities who are supporting our efforts to advance the efficacy evaluation of our COVID-19 vaccine. INO-4800 is well-positioned to support vaccination efforts in Colombia and beyond, if approved – with the prospects of potentially serving both as a primary series and as a booster vaccine, with a strong thermostability profile and ability to generate neutralizing antibodies and robust T cell responses."

INNOVATE's Phase 3 segment builds upon the Phase 2 segment, which was conducted in the U.S. and funded by the U.S. Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, in coordination with the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency. Phase 2 data was **disclosed** in a pre-print in MedRxiv in May 2021 and found INO-4800 to be well-tolerated and immunogenic in adults 18 and older in the trial. In another previously disclosed study using clinical samples, INO-4800 was also **found** to provide broad cross-reactive immune responses, including neutralizing antibodies and robust T cell responses, against variants of concern (alpha, beta, gamma and, in subsequent research, delta) – factors which could be critical in containing COVID-19 as it shifts from pandemic to endemic spread.

INOVIO also recently **announced** the authorization to proceed in China with two Advaccine-sponsored clinical trials investigating the safety, tolerability, and immunogenicity of heterologous boost combinations with INO-4800.

About INO-4800

INO-4800, INOVIO's DNA vaccine candidate against SARS-CoV-2, is composed of a precisely designed DNA plasmid that is injected intradermally followed by electroporation using a proprietary smart device, which delivers the DNA plasmid directly into cells in the body and is intended to produce a well-tolerated immune response. As one of the only nucleic-acid based vaccines 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, INO-4800 is anticipated to be well-positioned as a primary series as well as a booster.

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 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, 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-16/18. INOVIO is also evaluating INO-4800, a DNA vaccine candidate against COVID-19, in a Phase 2/3 clinical trial; the Phase 3 efficacy segment of which has received regulatory approvals to begin in Mexico, Brazil and Philippines. INOVIO's partners, Advaccine Biopharmaceuticals, and International Vaccine Institute, are also evaluating INO-4800 in ongoing clinical trials in China and South Korea, respectively.

Partners and collaborators include Advaccine, ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates

Foundation, Coalition for Epidemic Preparedness Innovations, Defense Advanced Research Projects Agency/Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense/Department of Defense, HIV Vaccines Trial Network, International Vaccine Institute, Kaneka Eurogentec, Medical CBRN Defense Consortium, 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.

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This press release contains certain forward-looking statements relating to our business, including our plans to develop and commercialize DNA medicines, our expectations regarding our research and development programs, including the planned initiation and conduct of pre-clinical 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 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, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 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 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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