NEWS RELEASE

INOVIO Receives Regulatory Authorization to Conduct Phase 3 Efficacy Trial of its COVID-19 DNA Vaccine Candidate, INO-4800, in Mexico

9/22/2021

News follows recent regulatory authorizations to proceed with the trial in Brazil and the Philippines

INOVIO and partner Advaccine are collaborating on the global Phase 3 trial in regions underserved by COVID-19 vaccines; to focus on Latin America, Asia, and Africa

PLYMOUTH MEETING, Pa., Sept. 22, 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 COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios), the national health regulatory agency of Mexico, to conduct a clinical trial in that country as part of the Phase 3 segment of INOVIO's global Phase 2/3 trial, INNOVATE (INOVIO INO-4800 Vaccine Trial for Efficacy), for its DNA vaccine candidate for COVID-19, INO-4800. INOVIO is working with its partner Advaccine Biopharmaceuticals Suzhou Co., Ltd. (Advaccine) on the INNOVATE Phase 3 segment in multiple countries. INOVIO recently announced that it has received regulatory authorization to proceed with Phase 3 clinical trials in **Brazil** and the **Philippines** and is seeking authorization to conduct trials in additional countries.

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 looks forward to working with the health authorities and investigators in Mexico – as well as in Brazil and the Philippines – to advance the evaluation of INO-4800 as a solution in the fight against the COVID-19 pandemic. With the virus threatening to become an endemic threat worldwide, while millions of people around the globe remain unvaccinated, we are committed to supporting the international public health response. I am extremely pleased that we are now positioned to evaluate the efficacy of INO-4800 which is an important developmental milestone. We feel that INOVIO's COVID-19 vaccine is uniquely

suited to contribute to the global response given its strong safety and thermostability profile, ability to generate cross-reactive immune responses, and its potential to function in a primary series as well as a booster vaccine."

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 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 **announced** in August 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 and Sinovac Biotechnology's CoronaVac®, an inactivated COVID-19 vaccine developed by Sinovac and authorized for emergency use by the World Health Organization.

About INO-4800

INOVIO's DNA vaccine candidate against SARS-CoV-2, INO-4800, 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 for first-in line usage as well as for boosting.

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 global Phase 3 clinical trial, 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, 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, Plumbline 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 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 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:**https://www.prnewswire.com/news-releases/inovio-receives-regulatory-authorization-to-conduct-phase-3-efficacy-trial-of-its-covid-19-dna-vaccine-candidate-ino-4800-in-mexico-301382333.html**

SOURCE INOVIO Pharmaceuticals, Inc.