

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

8/26/2021

INOVIO's global Phase 3 efficacy trial receives authorization to proceed from Brazil; other countries to follow  
INOVIO to conduct INNOVATE Phase 3 efficacy trial with partner Advaccine in areas of world in need of COVID-19 vaccines

PLYMOUTH MEETING, Pa., Aug. 26, 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 regulatory authorization from Brazil's **ANVISA** (Agência Nacional de Vigilância Sanitária), the national health regulatory agency of Brazil, to initiate the global Phase 3 segment of its Phase 2/3 trial, INNOVATE (INOVIO INO-4800 Vaccine Trial for Efficacy), for INO-4800, its DNA vaccine candidate for COVID-19. INOVIO plans to conduct the global INNOVATE Phase 3 segment in multiple countries, including Brazil, with partner Advaccine Biopharmaceuticals Suzhou Co., Ltd. (Advaccine).

The global Phase 3 segment of the INNOVATE Phase 2/3 clinical trial will evaluate the efficacy of INO-4800 in a two-dose regimen (2.0 mg per dose), administered one month apart, in a two-to-one randomization in men and non-pregnant women 18 years of age and older in several countries across Latin America, Asia, and Africa. 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, "With many countries in the world experiencing low vaccination rates and seeing an increase in infections, we feel the urgency to advance INO-4800 globally. I am incredibly proud of the INOVIO team and grateful to the health authorities in Brazil for their commitment to advancing the fight against COVID-19. INOVIO's focus on supporting the global response to the pandemic is unwavering – and will bring forward the potential advantages of INO-4800, which in addition to being well-tolerated with balanced neutralizing antibodies and T cell responses (CD8 and CD4), has a strong thermostability profile, and potentially offers the ability to serve as both a primary as well as a booster vaccine."

INOVIO's DNA medicines have shown the following overall characteristics:

- **Well-tolerated and Easy to Administer:** INO-4800 has a strong safety profile and, unlike other COVID-19 vaccine candidates, INO-4800 is administered intradermally and has caused only very limited side effects (mostly mild injection site reactions).
- **Immunogenic:** INO-4800 demonstrated robust immune responses: 100% of Phase 1 participants demonstrated overall immunological response rates and had balanced neutralizing antibodies and favorable T-cell responses (CD8 and CD4).
- **Stable and Transportable:** INO-4800 has a favorable thermostability profile. The vaccine candidate is projected to be stable at room temperature for more than a year, at 37°C for more than a month, has a 3 to 5-year projected shelf life at 2-8°C and does not need to be frozen during transport or storage – a critical element when considering the feasibility of global distribution.
- **Characterizable and Scalable:** INO-4800 is highly characterizable, scalable to population levels, and safe. The highly characterizable nature of the vaccine enables timely scaling of manufacturing with multiple manufacturing facilities able to be utilized.
- **Repeat Administration:** INO-4800 can be safely readministered offering the potential for seasonal boosting usage without any concerns of generating an anti-vector response or formulation related issues.

The global Phase 3 segment of the Phase 2/3 INNOVATE trial builds upon the Phase 2 segment conducted in the U.S., which was funded by the U.S. Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, (JPEO-CBRND) in coordination with the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) and the Defense Health Agency. Results from the trial can be found in the paper entitled "Safety and immunogenicity of INO-4800 DNA vaccine against SARS-CoV-2: A Preliminary Report of a Randomized, Blinded, Placebo-controlled, Phase 2 Clinical Trial in Adults at High Risk of Viral Exposure," which has been disclosed in a pre-print in MedRxiv prior to peer review. Early INO-4800 research and development funding were provided by the Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill & Melinda Gates Foundation. The Phase 2 data showed INO-4800 was 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 the SARS-CoV-2 virus as it shifts from pandemic to endemic spread.

Earlier this month, INOVIO **announced** the authorization to proceed in China with two clinical trials investigating heterologous boosting with INO-4800 through Advaccine as the trial sponsor. Working with Sinovac Biotechnology (Sinovac), Advaccine will evaluate the safety, tolerability, and immunogenicity of heterologous prime-boost sequential immunizations using INO-4800 and CoronaVac®, an inactivated COVID-19 vaccine developed by Sinovac

and authorized for emergency use by the World Health Organization.

## About INO-4800

INO-4800 is INOVIO's DNA vaccine candidate against SARS-CoV-2, the coronavirus that causes COVID-19. Composed of a precisely designed DNA plasmid, INO-4800 is injected intradermally followed by electroporation using a proprietary smart device delivering the DNA plasmid directly into cells in the body and is intended to produce a well-tolerated 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 which INOVIO believes are important considerations for mass immunizations.

## 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, 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](http://www.inovio.com).

## 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 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-authorization-to-conduct-phase-3-efficacy-trial-of-its-covid-19-dna-vaccine-candidate-ino-4800-301363258.html>

SOURCE INOVIO Pharmaceuticals, Inc.