

INOVIO Completes Enrollment of Phase 1B Clinical Trial for its DNA Vaccine Candidate Against Lassa Fever, INO-4500, in West Africa

10/26/2021

Milestone for INO-4500 illustrates INOVIO's commitment to combatting infectious diseases

Trial fully funded by the Coalition for Epidemic Preparedness Innovations (CEPI)

PLYMOUTH MEETING, Pa., Oct. 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 its Phase 1B clinical trial for INO-4500, its DNA vaccine candidate for Lassa fever, completed full enrollment of 220 participants. This trial (LSV-002 - NCT04093076) is ongoing at the Noguchi Memorial Institute for Medical Research in Accra, Ghana, and is the first vaccine clinical trial for Lassa fever conducted in West Africa, where the viral illness is endemic.

INOVIO is advancing INO-4500 with full funding from the Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership between public, private, philanthropic, and civil society organizations to stimulate and accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines for people in need during outbreaks. The company was awarded up to US **\$56 million from CEPI in 2018** under which INOVIO is advancing vaccine candidates against Lassa fever and Middle East Respiratory Syndrome (MERS). INOVIO and CEPI plan to establish a stockpile of these vaccines for emergency use after Phase 2 testing, if successful. As part of CEPI's **\$3.5 billion plan** to reduce, or even eradicate, the risk of epidemics and pandemics, CEPI's goal is to get a licensed Lassa vaccine for use in endemic countries. The forward-looking strategy also includes the aim to advance clinical trial capacity, infrastructure, and expertise in low- and middle-income countries.

Dr. Laurent Humeau, INOVIO's Chief Scientific Officer, said, "Completing enrollment of LSV-002 is an important milestone for the clinical development of INO-4500, our DNA vaccine candidate against Lassa fever. INOVIO and our partners are committed to addressing this significant unmet public health need, considering the prevalence of the Lassa virus, the potential severity of Lassa fever, and the lack of any licensed vaccines or other treatments for this

disease. We are grateful to CEPI for their support as we work with our partners to advance INO-4500."

Dr. Humeau added, "This milestone represents another example of the progress we are making across INOVIO's infectious disease portfolio, including our late-stage development efforts with INO-4800 against COVID-19 as well as advancements with INO-4700 against MERS."

Dr. Melanie Saville, Director of Vaccine R&D at CEPI, said, "I am delighted to see the rapid progress in enrollment for this pivotal trial to assess the safety and immunogenicity of INOVIO's promising Lassa vaccine candidate in Ghana. At a time when much scientific attention is drawn towards COVID-19, it is critical that we continue to progress research against this potentially fatal disease which affects many countries across the West African region. Data provided by this study will be critical for assessing potential of the candidate to advance into late-stage clinical trials and towards our goal, at CEPI, to get a licensed Lassa vaccine for use in endemic countries."

Professor Dorothy Yeboah-Manu, Director of the Noguchi Memorial Institute for Medical Research (NMIMR) in Ghana, said, "This achievement is another feather in our cap that goes to demonstrate the expertise and dedication of the NMIMR in the global fight against infectious diseases. As a leading biomedical institute in the West African sub region and considering the public health importance of Lassa fever in West Africa, we are happy to be part of INO-4500 development, indeed the fight against these emerging infections requires us to work together and we look forward to such further collaborations."

Professor Kwadwo Koran, the PI for the Noguchi Memorial Institute for Medical Research site in Ghana, said, "It has been exciting working on this trial, a great achievement for the Institute and the country as whole. Personally, I see this as NMIMR continuing in the noble ideals of contributing to solutions for public health problems in the sub region. With the successful enrollment, even under the trying conditions engendered by the COVID-19 pandemic for nearly two years now, the Institute and indeed the country as a whole has demonstrated the capacity to be able to conduct early-stage trials in support of product development for emerging and re-emerging diseases such as Lassa Fever. It is my sincere hope that this will be built upon not only for Lassa Fever but other important infections that plague us."

About INOVIO's Phase 1B Clinical Trial for INO-4500

INOVIO's Phase 1B clinical trial, LSV-002, a randomized, blinded, placebo-controlled dose ranging study enrolled 220 healthy adult participants between the ages of 18-50 years old, with the primary endpoints of evaluating safety and immunogenicity profile of INO-4500 DNA vaccine candidate, administered by intradermal (ID) injection followed by electroporation (EP) using CELLECTRA™ 2000 device in Ghana. The dosing regimen involved two intradermal vaccinations at 0 and 28 days with either 1.0 mg or 2.0 mg doses. In addition to providing insights on the INO-4500 safety and immunogenicity profile, this trial will inform dose selection for subsequent Phase 2 studies in West

Africa.

Since its establishment in 1979, the Noguchi Memorial Institute for Medical Research (NMIMR) has gained global recognition as a leading biomedical research institute in Africa, building capacity for prevention and control of endemic diseases, as well as emerging and re-emerging diseases, in Ghana and the West African sub-region. The Institute has been a leader in developing effective diagnosis capabilities and clinical research for the treatment and protection against HIV/AIDS, H1N1 Pandemic Flu, Lassa fever, Yellow fever, Ebola Virus Disease and malaria. The clinical Principal Investigator for LSV-002 is Professor Dr. Kwadwo A. Koram, an expert and specialist in tropical medicines and epidemiologist with more than 20 years of research experience, including malaria vaccines.

About Lassa Fever

Lassa fever is an animal-borne, acute hemorrhagic viral illness primarily observed in parts of West Africa. Infection is spread through contact with infected rodents, as well as person-to-person transmission via bodily fluids (primarily in health care settings). The disease can cause a range of outcomes, including fever, vomiting, and swelling of the face, pain in the chest, back and abdomen, bleeding of various parts of the body including the eyes and nose and death. Of the survivors of Lassa fever, about one-third have sudden-onset hearing loss, with more than half of those cases resulting in permanent hearing loss [Mateer et al. PLoS Negl Trop Dis (2018)].

In addition to funding INOVIO's Lassa vaccine candidate, CEPI has therefore also created and funded the largest ever Lassa fever study, named **Enable**, to provide a more accurate assessment of the incidence of Lassa fever infections in West Africa. The Enable study aims to better understand the rate, location, and spread of Lassa virus across the region.

Data from CEPI's Enable study will also guide the location and implementation of future late-stage Lassa vaccine efficacy trials.

Lassa virus infection in West Africa is estimated to affect 100,000 to 300,000 people annually, and it is responsible for 10 – 16% of hospital admissions in some parts of Liberia and Sierra Leone [US CDC (2019)]. The virus is responsible for approximately 5,000 deaths annually [US CDC (2019)]. Over the last five decades, outbreaks in Nigeria for example have worsened, with increased frequency and geographic breadth, and during this time a broader spread has occurred within West Africa and possibly into West-Central Africa [Agbonlahor et al. Am J Trop Med Hyg (2021)]. The World Health Organization (WHO) classifies Lassa virus as one of the pathogens with epidemic potential to be urgently addressed, thereby making the development of safe and effective vaccines a global health priority [WHO (2016)].

Because of difficulties in diagnosing Lassa fever, the lack of standardized surveillance assays, and the remote

nature of many of the areas in West Africa where outbreaks typically occur, the numbers of reported cases and deaths may be lower than the actual numbers of cases and deaths. Though the majority (about 80%) of Lassa virus-infected persons are asymptomatic or have mild symptoms, the infection can be quite serious or fatal in others [WHO (undated)]. The case-fatality ratio (CFR), aka case-fatality rate, among patients hospitalized for Lassa fever is about 15 – 20%, and, in some epidemics the case-fatality rate has reached 50% in hospitalized patients [Brosh-Nissimov Disaster Mil Med (2016)]. The CFR among pregnant women is particularly high, and in pregnant women infected with Lassa virus the fetal death rate due to spontaneous abortion rate is estimated to be extremely high at about 95% [WHO (2017); US CDC (2014)].

References

Agbonlahor DE, Akpede GO, Happi CT, Tomori O. 52 Years of Lassa Fever Outbreaks in Nigeria, 1969-2020: An Epidemiologic Analysis of the Temporal and Spatial Trends. *Am J Trop Med Hyg*. 2021 Aug 30;tpmd201160. doi: 10.4269/ajtmh.20-1160. Epub ahead of print. PMID: 34460421.

Brosh-Nissimov T. Lassa fever: another threat from West Africa. *Disaster Mil Med*. 2016 Apr 30;2:8. doi: 10.1186/s40696-016-0018-3. PMID: 28265442; PMCID: PMC5330145

Centers for Disease Control and Prevention, United States of America. Lassa Fever. 2019. <https://www.cdc.gov/vhf/lassa/index.html> [accessed Oct. 13, 2021]

Centers for Disease Control and Prevention, United States of America. Lassa Fever Fact sheet. 2014. <https://www.cdc.gov/vhf/lassa/pdf/factsheet.pdf> [accessed Oct. 13, 2021].

Mateer EJ, Huang C, Shehu NY, Paessler S. Lassa fever-induced sensorineural hearing loss: A neglected public health and social burden. *PLoS Negl Trop Dis*. 2018 Feb 22;12(2):e0006187.

World Health Organization. An R&D Blueprint for Action to Prevent Epidemics. Plan of Action. May 2016.

World Health Organization. Health Topics -- Lassa Fever. (undated). https://www.who.int/health-topics/lassa-fever#tab=tab_1 [Accessed Jan. 7, 2021].

World Health Organization. Lassa Fever. 2017. <https://www.who.int/news-room/fact-sheets/detail/lassa-fever> [accessed Oct. 13, 2021].

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 therapeutic 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 segment of which has received regulatory approvals to begin in Colombia, 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.

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 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-completes-enrollment-of-phase-1b-clinical-trial-for-its-dna-vaccine-candidate-against-lassa-fever-ino-4500-in-west-africa-301408429.html>

SOURCE INOVIO Pharmaceuticals, Inc.