

INOVIO Reports Positive Phase 1b Results for INO-4201 as an Ebola Booster for rVSV-ZEBOV (Ervebo®)

2/2/2023

- INO-4201 found to be well-tolerated in the trial
- Humoral responses were boosted in 100% (36 of 36) of treated participants

PLYMOUTH MEETING, Pa., Feb. 2, 2023 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-associated diseases, cancer, and infectious diseases, today announced positive results from a Phase 1b clinical trial evaluating INO-4201, a DNA vaccine candidate, as a booster in healthy adult participants who previously received a single injection of Ervebo. In the trial, INO-4201 was well-tolerated and boosted humoral responses in 100% (36 of 36) of treated participants.

INO-4201 was evaluated in a 46-participant randomized, placebo-controlled Phase 1b trial ([NCT04906629](#)) to assess its safety, tolerability, and immunogenicity in healthy adult participants who previously received a single injection of Ervebo, a vaccine approved by the U.S. Food and Drug Administration for the prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older. The participants were dosed with 1 mg of INO-4201 injected intradermally followed by electroporation using our investigational proprietary smart device, CELLECTRA®. The trial was designed to test whether INO-4201 can be used as a booster in healthy participants previously vaccinated with Ervebo. The trial was spearheaded by Global Urgent and Advanced Research and Development (GuardRX), sponsored by Geneva University Hospitals, and funded by the U.S. Defense Advanced Research Projects Agency (DARPA).

Dr. Angela Huttner, MD, Infectious Disease Consultant, Geneva University Hospitals, and the lead investigator of the study, said, "INO-4201 was well-tolerated and all treated participants responded to the booster vaccine. These are encouraging results since our participants were initially vaccinated with Ervebo three to seven years ago. We remain grateful to our participants for their critical role in the development of this vaccine candidate, which we hope will be a key player in future Ebola Virus Disease prevention."

Dr. Gary Kobinger, microbiologist, GuardRX ex-officio (President) and Board Member and Director of the Galveston National Laboratory at the University of Texas Medical Branch, said, "We are particularly pleased with INO-4201's boost effect on neutralizing titers. To our knowledge, this is one of the highest responses we have ever seen across multiple vaccine platforms. Indeed, our results showed that the neutralizing titers were significantly higher in the individuals who received the INO-4201 boost compared to the placebo and the response was maintained even 24 weeks later."

Dr. Laurent Humeau, PhD, INOVIO's Chief Scientific Officer, said, "We are very encouraged by today's data, which demonstrates the versatility of our platform and reinforces our belief in DNA medicines' ability to elicit immune responses across multiple indications, from HPV-associated tumors to infectious diseases. We also believe DNA medicines' ability to be readministered can be an important factor in a booster. We thank our collaborators, DARPA, GuardRX, and the University of Geneva, for conducting the trial and we look forward to the data being published in a peer-reviewed journal."

About INO-4201

INO-4201 is a DNA vaccine targeting Zaire Ebola virus (ZEBOV) glycoprotein (GP), designed to prevent ZEBOV infection. INO-4201 encodes for a synthetic consensus antigen that encompasses ZEBOV genetic variability from various outbreak strains to broaden immune coverage for divergent ZEBOV virus variants.

About Ebola Virus Disease

The Ebola virus family includes four virus species that cause periodic outbreaks of a highly contagious and lethal human infectious disease – called Ebola Virus Disease (EVD). The virus is transmitted from wild animals to people then easily spreads via human-to-human transmission. Disturbingly, new research suggests dormant Ebola virus in a previously infected survivor could re-emerge up to nearly 5 years later and again allow human-to-human transmission [Keita et al Nature (Sept. 15, 2021)]. Ebola virus is classified as a Category A Priority Pathogen by the U.S. Centers for Disease Control and Prevention (CDC). This designation indicates a national security risk, and the U.S. FDA has an accelerated development approval pathway for vaccines against such pathogens. Also, the World Health Organization (WHO) continues to list Ebola Virus Disease as a priority for research and development in emergency contexts and coordinates planning to prevent and respond to Ebola epidemics.

About INOVIO

INOVIO is a biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-associated diseases, cancer, and infectious diseases. INOVIO's DNA medicines in development are delivered using its investigational proprietary smart device, CELLECTRA®, to produce immune

responses against targeted pathogens and cancers. For more information, visit www.inovio.com.

About GuardRX

Established in 2018, GuardRX executes preclinical and clinical development strategies on prophylactic and therapeutic products for neglected diseases. GUARD is a non-profit, non-governmental organization whose goal is to bring prophylactic and therapeutic products that do not have a traditional commercialization pathway. GUARD is committed to facilitating the availability of lifesaving products to the global community including in the event of an infectious disease emergency. GUARD expertise includes preclinical and clinical development of vaccines and therapeutics, regulatory submissions and production of cGMP material; humoral immune responses evaluation using tailored sensitive plate-based ELISA; establish & standardize new diagnostics protocols; submission to appropriate regulatory agencies for Therapeutic Products and Institutional Review Boards (IRBs); production of study final reports, and award data management.

GUARD's main objective is to accumulate clinical data packages within rigorous regulatory processes to support further clinical progression or long-term solutions to orphan diseases for the betterment of the global population. For more information, visit www.guardrx.org.

Contacts

Media: Jennie Willson (267) 429-8567 jennie.willson@inovio.com
Investors: Thomas Hong (267) 440-4298 thomas.hong@inovio.com

Forward-Looking Statement

This press release contains certain forward-looking statements relating to our business, including the potential of our DNA vaccine candidates. 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, 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, 2021, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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 the 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-reports-positive-phase-1b-results-for-ino-4201-as-an-ebola-booster-for-rvsv-zebov-ervebo-301737110.html>

SOURCE INOVIO Pharmaceuticals, Inc.