

# INOVIO Doses First Participant in Phase 2 Trial for its DNA Vaccine Against Middle East Respiratory Syndrome (MERS), a Coronavirus Disease

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MERS is caused by a coronavirus that is 100 times deadlier than COVID-19 and fatal to approximately 34% of those who have the disease

Trial is funded by Coalition for Epidemic Preparedness Innovations (CEPI)

There is no approved vaccine for MERS

PLYMOUTH MEETING, Pa., Aug. 4, 2021 /PRNewswire/ -- INOVIO (NASDAQ: INO), a biotechnology company bringing to market precisely designed DNA medicines to treat and protect people from infectious diseases, cancer, and HPV-associated diseases, today announced that the company has dosed the first Phase 2 trial subject in its quest to develop the first vaccine against the Middle East Respiratory Syndrome (MERS). INOVIO's Phase 2 trial is designed to evaluate INO-4700, its DNA vaccine candidate for the prevention of MERS, a disease in the coronavirus family for which there are no approved vaccines.

The multi-center Phase 2 trial is a randomized, double-blinded, placebo-controlled study designed to evaluate the safety, tolerability, and immunogenicity of INO-4700 administered with INOVIO's smart device, the CELLECTRA® 2000, in approximately 500 healthy adult volunteers. The study, which is sponsored by INOVIO and fully funded by the Coalition for Epidemic Preparedness Innovations (CEPI), is being conducted at sites in Jordan and Lebanon where MERS cases have been reported.

This trial builds on the positive results of the Phase 1 trial, which were published in a peer-reviewed article in *The Lancet Infectious Diseases* entitled, "Safety and immunogenicity of an anti-Middle East respiratory syndrome coronavirus DNA vaccine: A phase 1, open-label, single-arm, dose-escalation trial." Results from this first-in-human Phase 1 trial found high levels of binding antibodies in 92% (57 of 62) of evaluated subjects. Significant antigen-specific cytotoxic T-lymphocyte (CTL) responses were also observed. Importantly, 98% (61 of 62) of vaccinated subjects generated an antibody and/or T cell response against the MERS vaccine.

Dr. J. Joseph Kim, President and CEO of INOVIO, said, "We are pleased to collaborate with CEPI to combat one of the most virulent pathogens of the coronavirus family for which there is no approved vaccine. This advancement not only complements our late-stage efforts with COVID-19, but it also represents an important milestone for INOVIO's infectious disease platform. We look forward to continuing our collaboration with CEPI and moving another step closer to providing patients with a safe and effective preventive vaccine against MERS."

INOVIO's pursuit of a MERS vaccine is funded by a previously announced \$56 million grant from CEPI under which INOVIO is advancing two vaccine candidates through Phase 2 field trials against MERS and Lassa fever, respectively. INOVIO and CEPI plan to make a stockpile of these vaccines available for emergency use as soon as possible following Phase 2 testing.

Richard Hatchett, CEO of CEPI, said, "I'm delighted to see the progress made by INOVIO in its MERS vaccine program. As we've seen with COVID-19, coronaviruses pose a significant threat to global health. Prior to the COVID-19 pandemic, CEPI had identified the MERS coronavirus, in particular, as an epidemic threat and partnered with INOVIO in 2018 to advance its promising vaccine candidate. This Phase 2 trial is the first of its kind to assess a vaccine candidate against MERS and represents an important step towards combatting this deadly coronavirus."

Despite the continuing threat of MERS outbreaks, there are no licensed vaccines or treatments for MERS. Since the virus was first identified in Saudi Arabia in 2012, the World Health Organization has reported more than 2,500 people with MERS disease globally and approximately 34% of those patients died. Twenty-seven countries have reported cases, including Korea where an outbreak in the summer of 2015 resulted in 186 cases with 20% dying. In contrast, the case-fatality ratio for COVID-19 before population vaccination was approximately 0.3% to 0.5%; while the case-fatality ratio for the 2003 SARS epidemic was 10%. MERS causes a rapidly progressive respiratory illness that may require intensive care treatment and mechanical ventilation in many patients.

## About INOVIO's DNA Medicines Platform

INOVIO has 15 DNA medicine clinical programs currently in development focused on HPV-associated diseases, cancer, and infectious diseases, including coronaviruses associated with MERS and COVID-19 diseases being developed under grants from the Coalition for Epidemic Preparedness Innovations (CEPI) and the U.S. Department of Defense. DNA medicines are composed of optimized DNA plasmids, which are small circles of double-stranded DNA that are synthesized or reorganized by a computer sequencing technology and designed to produce a specific immune response in the body.

INOVIO's DNA medicines deliver optimized plasmids directly into cells intramuscularly or intradermally using INOVIO's proprietary hand-held smart device called CELLECTRA®. The CELLECTRA® device uses a brief electrical pulse to reversibly open small pores in the cell to allow the plasmids to enter, overcoming a key limitation of other

DNA and other nucleic acid approaches, such as mRNA. Once inside the cell, the DNA plasmids enable the cell to produce the targeted antigen. The antigen is processed naturally in the cell and triggers the desired T cell and antibody mediated immune responses. Administration with the CELLECTRA® device ensures that the DNA medicine is efficiently delivered directly into the body's cells, where it can go to work to drive an immune response. INOVIO's DNA medicines do not interfere with or change in any way an individual's own DNA. The advantages of INOVIO's DNA medicine platform are how fast DNA medicines can be designed and manufactured; the stability of the products, which do not require freezing in storage and transport; and the robust immune response, safety profile, and tolerability that have been observed in clinical trials.

With more than 3,000 patients receiving INOVIO investigational DNA medicines in more than 7,000 applications across a range of clinical trials, INOVIO has a strong track record of rapidly generating DNA medicine candidates with potential to meet urgent global health needs.

## 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 and only 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, in 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 and 18. INOVIO is also evaluating INO-4800, a DNA vaccine candidate against COVID-19, in a Phase 2 clinical trial in the U.S., 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 (CEPI), Defense Advanced Research Projects Agency (DARPA)/Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)/Department of Defense (DOD), HIV Vaccines Trial Network, International Vaccine Institute (IVI), Kaneka Eurogentec, Medical CBRN Defense Consortium (MCDC), 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).

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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 preclinical 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 March 31, 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.

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