

# **Inovio Pharmaceuticals Ebola Vaccine Generates Robust Immune Responses in Humans**

**Inovio Pharmaceuticals** {NASDAQ: INO} announced today that its Ebola vaccine, INO-4212, was safe, tolerable, and generated strong T cell and antibody responses in its fully enrolled phase I study of 75 healthy subjects.

**Human immunogenicity data combined with efficacy in multiple animal species warrants further human study**

PLYMOUTH MEETING, Pa. – **Inovio Pharmaceuticals** {NASDAQ: INO} announced today that its Ebola vaccine, INO-4212, was safe, tolerable, and generated strong T cell and antibody responses in its fully enrolled phase I study of 75 healthy subjects.

Detailed immunogenicity and safety data is being prepared for peer-reviewed publication. In previously reported pre-clinical testing in mice and non-human primates, the Ebola vaccine protected 100% of immunized animals from sickness and death following exposure to a lethal dose of Ebola virus.

This human study (CT.gov: NCT02464670) was conducted by an Inovio-led consortium, which was selected and awarded \$45 million by the U.S. Defense Advanced Research Projects Agency (DARPA) in 2015 to take a multi-faceted approach to prevent and treat Ebola infection.

This initial trial evaluated IN0-4212 in five groups of healthy subjects. IN0-4212 consists of two optimised SynCon® DNA plasmids coding for the Ebola glycoprotein antigen from circulating Ebola strains from 1975 – 2014. These plasmids were tested separately and together in muscle and skin in five study arms, one including Inovio's DNA-based IL-12 immune activator.

Of 69 evaluated subjects, 64 (92.7%) seroconverted and mounted a strong antibody response to the Ebola glycoprotein antigen following the three dose immunization regimen; 48 subjects (69.6%) seroconverted after only two doses.

Significantly, in the study arm using intradermal (skin) administration, 13 of 13 evaluable subjects (100%) generated antigen-specific antibody responses after only two doses and all remained seropositive after three immunisations. Similarly, in the study arm receiving the vaccine with intramuscular administration in combination with plasmid IL-12, 12 of 13 evaluable subjects (92.3%) demonstrated strong antibody responses after only two immunizations and 13 of 13 (100%) produced strong antibody responses after three immunisations.

The Ebola glycoprotein specific geometric mean antibody titers measured in the five cohorts ranged from over 2,000 to greater than 46,000. Significantly, a majority of vaccinated subjects in each of the five cohorts produced strong Ebola antigen specific T-cell responses as measured by interferon gamma ELISpot analysis.

To date INO-4212 has been well tolerated and has not demonstrated systemic serious adverse effects, such as fever, joint pain, and low white blood cell counts, reported in association with some viral vector based Ebola vaccines currently in development. Moreover, unlike the viral vectored vaccines which must be kept frozen, INO-4212 was formulated in a solution which was kept refrigerated (2-8 C).

The data was presented today by **Dr. Niranjan Y. Sardesai, Inovio's Chief Operating Officer** and Principal Investigator on the DARPA Ebola program, at The World Vaccine Congress in Washington, DC. **Dr. Sardesai said**, "*The induction of strong Ebola specific antibody and T cell responses has been difficult to achieve in previous human studies. We are pleased by the immune responses achieved using two and three vaccination regimens in humans with our optimized DNA vaccines delivered using electroporation, adding to the successful animal immune response and challenge studies using our approach. We are particularly excited about the positive immunology data using intradermal immunization as this delivery would facilitate even greater clinical and commercial potential for DNA vaccination.*"

*"These initial data from our Ebola DNA vaccine represent just a first step in this DARPA-funded program. We look forward to rapidly moving this DNA vaccine into larger human studies on the path to product licensure. We are also advancing our Ebola dMAb™ product and expect to clinically test that independently of the DNA vaccine approach,"* said **Dr. J. Joseph Kim, President and CEO**.

Under the DARPA-funded program Inovio and its collaborators are developing multiple approaches against Ebola. This program allows for the development and early clinical testing of: Inovio's DNA-based vaccine against Ebola Inovio's therapeutic Ebola dMAb™ product.

This new technology has properties best suited to respond to an Ebola outbreak in that the product could be manufactured expediently on a large scale using proven fermentation technology, is thermal-stable, and may provide more rapid therapeutic benefit (as shown in Inovio's Chikungunya and dengue programs); and a highly potent conventional protein-based therapeutic monoclonal antibody (mAb) product against Ebola virus infection, co-developed with MedImmune, the global biologics research & development arm of AstraZeneca.

### **About Inovio Pharmaceuticals, Inc.**

Inovio is taking immunotherapy to the next level in the fight against cancer and infectious diseases. We are the only immunotherapy company that has reported generating T cells *in vivo* in high quantity that are fully functional and whose killing capacity correlates with relevant clinical outcomes with a favorable safety profile. With an expanding portfolio of immune therapies, the company is advancing a growing preclinical and clinical stage product pipeline. Partners and collaborators include MedImmune, Roche, The Wistar Institute, University of Pennsylvania, DARPA, GeneOne Life Science, Drexel University, NIH, HIV Vaccines Trial Network, National Cancer Institute, U.S. Military HIV Research Program, and University of Manitoba. For more information, visit [www.inovio.com](http://www.inovio.com).

**CONTACT:**

Bernie Hertel

+1 858-410-3101

[bhertel@inovio.com](mailto:bhertel@inovio.com)

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This press release contains certain forward-looking statements relating to our business, including our plans to develop electroporation-based drug and gene delivery technologies and DNA vaccines, our expectations regarding our research and development programs and our capital resources. 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 and product development programs (including, but not limited to, the fact that pre-clinical and clinical results referenced in this release may not be indicative of results achievable in other trials or for other indications, that the studies or trials may not be successful or achieve the results desired, including safety and efficacy for VGX-3100 and INO-3112, that pre-clinical studies and clinical trials may not commence or be completed in the time periods anticipated, that results from one study may not necessarily be reflected or supported by the results of other similar studies and that results from an animal study may not be indicative of results achievable in human studies), 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 vaccines, our ability to support our broad pipeline of SynCon® active immune therapy and vaccine products, our ability to advance our portfolio of immune-oncology products independently, 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 the company or its collaborators, including alternatives that may be more efficacious or cost-effective than any therapy or treatment that the company and its collaborators hope to develop, our ability to enter into partnerships in conjunction with our research and development programs, evaluation of potential opportunities, issues involving product liability, issues involving patents and whether they or licenses to them will provide the company 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 the company can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of the company's 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, 2015, and other regulatory filings from time to time. There can be no assurance that any product in Inovio's pipeline will be successfully developed or manufactured, that final results of clinical studies will be supportive of regulatory approvals required to market licensed products, or that any of the forward-looking information provided herein will be proven accurate.