

# Inovio – Strong T cell results for head and neck cancer for HPV in small trial

**Inovio Pharmaceuticals {NASDAQ: IMO} HPV Immunotherapy Activates Robust In Vivo T Cell Responses in Head & Neck Cancer Patients**

DNA-based immunotherapy generates strong immune responses similar to those in patients treated for cervical dysplasia

## *Comment*

*Inovio have published multiple news releases, all of them positive, in the last few days, and seem to be on an awareness campaign!*

*This latest news, to be fair, was on a very small patient sample, only 4 people, so early days, but it was positive in 75% of the cases, so that at least is a positive they can take to the next level, and they intend to extend to up to 20 patients.*

*The main purpose of the limited test is to assess patient safety and tolerability.*

## **News release**

Plymouth Meeting. – April 9, 2015 – **Inovio Pharmaceuticals,**

**Inc. {NASDAQ:INO}** announced today preliminary data showing that its INO-3112 DNA-based immunotherapy generated strong CD8+ T cell responses in 3 of 4 patients with head and neck cancer associated with human papillomavirus (HPV) types 16 and 18. INO-3112, an active immunotherapy that targets HPV 16 and 18 and simultaneously expresses IL-12, is designed to activate in vivo (in the body) immune responses to antigens from high risk HPV types and eliminate precancerous and cancerous cells displaying these antigens. The data, which are T cell measurements from the first four treated patients of this phase I/IIa study, are being presented today at the World Vaccine Congress 2015 by Inovio's COO, Dr. Niranjan Y. Sardesai.

These positive results represent the first study and first report of T cell immune responses generated in cancer patients after treatment with an Inovio DNA immunotherapy. The magnitude and characteristics of these interim immune response data mirror immune responses previously observed in human studies of VGX-3100 for HPV-associated cervical dysplasia; in a placebo-controlled phase II study, strong T cell immune responses were positively correlated with achievement of primary and secondary efficacy endpoints.

Dr. J. Joseph Kim, Inovio's President and CEO, said, *"This initial data set from Inovio's first cancer study provides encouraging evidence that we are on an important path to better optimized immunotherapy products. Regardless of whether it is an infectious disease, a precancer, or a cancer: the immune system uses the same mechanism to eliminate infected or mutated cells. In immune-oncology, it's all about the T cells. Here we show in cancer patients that we can generate antigen-specific CD8+ killer T cell responses, which are essential to an effective immunotherapy."*

*"We look forward to completing our currently enrolling studies for HPV-associated head & neck and cervical cancers, completing the preparations for our planned phase III study"*

*for cervical precancer, and launching new studies for hepatitis B and prostate cancer that all rely on the same targeted T-cell-based killing activity.”*

This open label study of HPV-caused head and neck cancer is intended to assess the safety, tolerability, and immunogenicity of INO-3112 in up to twenty adults with HPV-positive head and neck squamous cell carcinoma. The study (NCT02163057) includes patients who are being treated with INO-3112 before and after resection of their tumor as well as patients being treated with INO-3112 after completion of chemotherapy and radiation therapy.

### **About HPV-Caused Head & Neck Cancer**

Human papillomavirus (HPV) is the most common sexually transmitted disease in the United States, infecting 79 million Americans. HPV is known to play a major role in the development of head and neck cancers, which include cancers of the oral cavity, oropharynx, nose/nasal passages and larynx. Head and neck cancers associated with HPV account for nearly 3 percent of all cancers in the United States and are twice as prevalent in men as in women. Incidence rates of HPV-caused head and neck cancers have been on the rise, especially HPV-associated oropharyngeal cancer in men, and are expected to continue growing. By 2025, researchers believe that HPV will be the causative factor of 90% of all head/neck cancers.

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

Inovio is revolutionizing the fight against cancer and infectious diseases. Our immunotherapies uniquely activate best-in-class immune responses to prevent and treat disease, and have shown clinically significant efficacy 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 Roche, MedImmune, University of Pennsylvania, DARPA, 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).

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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, 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, including INO-5150, and to commence a phase I clinical trial for INO-5150 in the first half of 2015, 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, 2014, 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.