



NEWS RELEASE

## Inovio Initiates Phase 2 Efficacy Trial with VGX-3100 For HPV-Related Vulvar Pre-Cancers

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New study expands VGX-3100 program for evaluating therapeutic applications in HPV-related pre-cancers with high medical need

VGX-3100 previously demonstrated efficacy in regressing HPV-related cervical pre-cancer

PLYMOUTH MEETING, Pa., April 24, 2017 (GLOBE NEWSWIRE) -- Inovio Pharmaceuticals, Inc. (NASDAQ:INO) today announced that it has commenced a phase 2 trial to evaluate the efficacy of VGX-3100 in patients with pre-cancerous lesions of the vulva, or vulvar intraepithelial neoplasia (VIN). VGX-3100 is an immunotherapy that targets human papillomavirus (HPV) 16 and 18 and is being studied for the treatment of HPV-related pre-cancerous lesions and persistent HPV infection that causes these lesions.

VIN has a very low rate of spontaneous, or natural, regression – below 5%. Currently there are no FDA approved non-surgical treatments for pre-cancerous lesions of the vulva. Surgery, the most common treatment, is associated with high rates of disease recurrence and can cause disfigurement, long-term pain, and psychological distress for the women who undergo the procedure. VIN recurs in approximately one of every two patients who undergo surgical treatment.

This randomized, open label phase 2 study will assess the efficacy of VGX-3100 in 36 women with high-grade HPV-related vulvar lesions. The immunotherapy will be administered with Inovio's CELLECTRA® intramuscular delivery device. The primary endpoint of the study is histologic clearance of high-grade lesions and virologic clearance of the HPV virus in vulvar tissue samples. The study will also evaluate safety and tolerability of VGX-3100.

Inovio's immunotherapy aims to address the unmet medical need for VIN by providing a non-surgical option for women with this disease. In a previously conducted phase 2b randomized, placebo controlled study of 167 women with HPV-associated cervical pre-cancer, VGX-3100 led to a significantly higher rate of lesion regression and clearance of the underlying HPV viral infection. Inovio plans to initiate a phase 3 study of VGX-3100 as a treatment for high grade cervical dysplasia in 2017, and the treatment of VIN represent an important additional indication for its lead product.

Dr. Robert Edwards, Chair of Obstetrics and Gynecology at the University of Pittsburgh School of Medicine at Magee-Women's Hospital and Professor of Medicine in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh, School of Medicine, said, "HPV-induced VIN is one of the major causes of morbidity for young and middle-aged women with HPV-induced pre-cancer. It is associated with repetitive need for surgery, multiple biopsies, and a major cause of pain and sexual dysfunction."

Dr. J. Joseph Kim, Inovio's President and CEO, said, "Inovio's VGX-3100 may provide the first approved non-surgical treatment option for women with this HPV-related pre-cancer with a high recurrence rate. My optimism is based on our phase 2b efficacy results finding clearance of lesions and the HPV virus in many subjects in our evaluation of VGX-3100 in women with high grade cervical dysplasia. Our ultimate goal is for VGX-3100 to become the "go-to" immunotherapy to treat all major HPV-related premalignant diseases."

#### About Vulvar Pre-Cancers

If left untreated vulvar pre-cancers can progress to invasive cancer of the vulva. Approximately 27,000 cases of HPV-related vulvar pre-cancers occur in the U.S. each year and about 12,000 to 24,000 cases in Europe each year. HPV-16 and/or HPV-18 are involved in about 80% of HPV-related vulvar pre-cancers cases in the U.S. and Europe. Once vulvar pre-cancers develop, spontaneous regression (i.e. natural disappearance of the lesion) is rare and occurs in 1.5% to 5% of cases. An estimated 6,000 new cases of vulvar cancer occur in the U.S. each year with about 50% to 80% of those being HPV-associated. About 1,110 deaths occur annually due to vulvar cancer in the U.S. Standard of care treatment of vulvar pre-cancer usually involves surgery, which has significant physical and psychosocial impacts in women (e.g. severe pain, disfigurement, sexual dysfunction), and the success of such surgery is marginal, as the recurrence rate of high grade vulvar pre-cancer is extremely high, i.e. about 50% three years post-treatment.

#### About VGX-3100

VGX-3100 is an HPV-specific immunotherapy that is being developed as a non-surgical treatment for high-grade HPV-caused pre-cancers and other related underlying persistent HPV infections. VGX-3100 works in vivo to activate functional, antigen-specific, CD8 killer T-cells to clear persistent HPV infection and cause regression of pre-cancerous lesions. In a phase 2 trial to treat cervical dysplasia, VGX-3100 demonstrated clinical efficacy and was generally well tolerated, without the side effects and obstetric risks associated with surgical excision. VGX-3100 is a first-in-class HPV-specific immunotherapy that targets the underlying cause of HPV-related pre-cancers, providing an opportunity for women to reduce their risk of cervical cancer without undergoing an invasive surgical procedure.

#### 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. The company is advancing an expanding product pipeline in both early and late stage clinical studies. Partners and collaborators include MedImmune, The Wistar Institute, University of Pennsylvania, DARPA, GeneOne Life Science, Plumblin Life Sciences, ApolloBio Corporation, Drexel University, NIH, HIV Vaccines Trial Network, National Cancer Institute, U.S. Military HIV Research Program, and Laval University. For more information, visit [www.inovio.com](http://www.inovio.com).

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 the immunotherapy VGX-3100, 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 immunotherapy and vaccine 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 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, 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, 2016, 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.

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