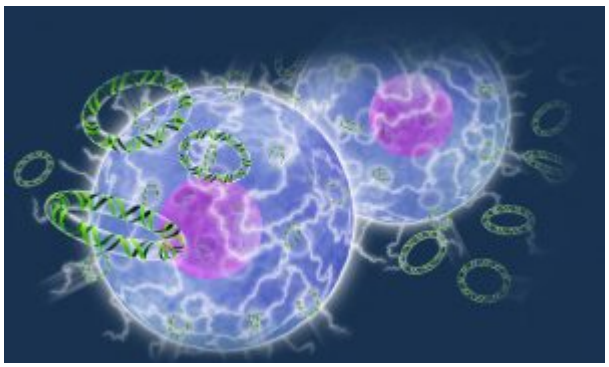
Inovio Completes Enrollment of VGX-3100 PH 3 Trial for the Treatment of HPV-Related Cervical Pre-cancer

Inovio Pharmaceuticals, Inc. (NASDAQ: INO)

Announced the completion of target enrolment of 198 participants for its pivotal Phase 3 registration trial (“REVEAL 1”) of VGX-3100, a novel DNA-based immunotherapy being tested to treat cervical dysplasia caused by human papillomavirus (HPV).



Inovio Completes Enrollment of VGX-3100 Phase 3 Trial (REVEAL

1) for the Treatment of HPV-Related Cervical Pre-cancer

PLYMOUTH MEETING, Pa., June 26, 2019 – Inovio Pharmaceuticals, Inc. (NASDAQ: INO) today announced the completion of target enrollment of 198 participants for its pivotal Phase 3 registration trial ("REVEAL 1") of VGX-3100, a novel DNA-based immunotherapy being tested to treat cervical dysplasia caused by human papillomavirus (HPV).

Left untreated, cervical dysplasia can progress to cervical cancer. If approved, VGX-3100 would be the first immunotherapy and non-surgical alternative for women with late-stage cervical dysplasia.

Dr. J. Joseph Kim, Inovio's President & CEO, said, *"This establishes an important milestone for the company as it brings Inovio another step closer to providing an innovative treatment alternative to the women suffering with cervical dysplasia for whom surgery is the only option today. Both the U.S. and Europe represent large markets in need of a non-invasive treatment option for women, and we're now focused on enrolling the confirmatory study (REVEAL 2) to generate a U.S. FDA submission in 2021."*

Inovio's Phase 3 program is assessing the efficacy of VGX-3100 to regress cervical HSIL (high-grade squamous intraepithelial lesions), a direct precursor to cervical cancer, and to eliminate the HPV infection that causes these lesions. The REVEAL studies are prospective, randomised (2:1), double-blind, placebo-controlled trials evaluating adult women with

HPV 16/18 positive biopsy-proven cervical HSIL, otherwise known as cervical intraepithelial neoplasia (CIN) 2 or 3. REVEAL 1 is designed to provide a one-year safety data for a minimum of 198 patients on VGX-3100. A confirmatory Phase 3 trial (REVEAL 2) is currently enrolling and is designed to provide a one-month safety data for a minimum of 198 patients.

The primary endpoint of the Phase 3 study is regression of cervical HSIL and virologic clearance of HPV 16 and/or HPV 18 in the cervix. The studies will evaluate cervical tissue changes at approximately 9 months after beginning a three dose regimen of VGX-3100 administered at months 0, 1, and 3. Secondary endpoints include safety; tolerability; regression of CIN 2/3 to CIN 1 or normal; virologic clearance of HPV; efficacy measured by non-progression to cancer; and clearance of HPV from non-cervical anatomic locations.

Dr. Prakash Bhuyan, MD PhD, Clinical Development lead for VGX-3100, said, “The completion of REVEAL 1 enrollment is a testament to the dedication of our outstanding investigators and their teams, who span 19 countries – a true global effort – to develop a non-surgical treatment for cervical high-grade dysplasia.”

As previously announced in March of 2019, Inovio has also begun recruitment for the confirmatory Phase 3 trial REVEAL 2 in March 2019. Following the completion of enrolment announcement for REVEAL 1, REVEAL 2 will now be enrolling from all sites both within the U.S. and globally, including sites that that were utilized in REVEAL 1.

Inovio previously reported that VGX-3100 eliminated high grade dysplasia in almost 50% of women in its Phase 2b randomised, placebo-controlled trial. In 80% of the women whose high grade dysplasia was eliminated, the HPV infection was also cleared by VGX-3100. Further data analysis revealed that the combination of HPV detection and cervical cytology (Pap smear) following dosing was predictive early during the treatment period for both elimination of the high grade dysplasia and clearance of HPV.

In addition, Inovio continues to pursue development of pre-treatment biomarker tests in collaboration with QIAGEN that may provide the ability to predict clinical response to VGX-3100, ultimately aiding in patient selection and physician guidance of patient care. These pre-treatment biomarkers could identify patients most likely to respond to treatment with VGX-3100, increasing absolute efficacy of the product.

About VGX-3100

VGX-3100 is a DNA-based immunotherapy under investigation for the treatment of HPV 16 and HPV 18 infection and pre-cancerous lesions of the cervix (Phase 3) and vulva and anus (Phase 2). VGX-3100 has the potential to be the first approved treatment for HPV infection of the cervix and the first non-surgical treatment for pre-cancerous cervical lesions.

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VGX-3100 works by stimulating a specific immune response to HPV 16 and HPV 18, which targets the infection and causes destruction of pre-cancerous cells. In a randomised, double-blind, placebo-controlled Phase 2b study in 167 adult women

with histologically documented HPV 16/18 cervical HSIL (CIN2/3), treatment with VGX-3100 resulted in a statistically significantly greater decrease in cervical HSIL and clearance of HPV infection vs. placebo.

The most common side effect was injection site pain, and no serious adverse events were reported. VGX-3100 utilizes the patient’s own immune system to clear HPV 16 and HPV 18 infection and pre-cancerous lesions without the increased risks associated with surgery, such as loss of reproductive health and negative psychosocial impacts.

About Inovio Pharmaceuticals Inc.

Inovio is an innovative biotechnology company focused on the discovery, development, and commercialisation of its synthetic nucleic technology targeted against cancers and infectious diseases. Inovio’s proprietary technology platform applies antigen sequencing and delivery to activate potent immune responses to targeted diseases. The technology functions exclusively in vivo, and has been demonstrated to consistently activate robust and fully functional T cell and antibody responses against targeted cancers and pathogens. Inovio’s most advanced clinical program, VGX-3100, is in Phase 3 for the treatment of HPV-related cervical pre-cancer. Also in development are Phase 2 immuno-oncology programs targeting HPV-related cancers, bladder cancer, and glioblastoma, as well as platform development programs in hepatitis B, Zika, Ebola, MERS, and HIV. Partners and collaborators include AstraZeneca, Regeneron, Roche/Genentech, ApolloBio Corporation, GeneOne Life Science, The Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations, Defense Advanced Research Projects Agency, National Institutes of Health, National Institute of Allergy and Infectious Diseases,

National Cancer Institute, HIV Vaccines Trial Network, Walter Reed Army Institute of Research, The Wistar Institute, and the University of Pennsylvania.

For more information, visit www.inovio.com