

# **Inovio announce first patient dosed with universal HIV vaccine**

**Inovio Pharmaceuticals (NASDAQ: INO}** have announced the dosing of the first patient with their universal HIV vaccine phase 1 trial.

The vaccine targets multiple clades (strains) of the HIV virus so as to be universally effective.

## **Inovio Pharmaceuticals Announces First Patient Dosed With Universal HIV Vaccine**

PLYMOUTH MEETING, Pa. – September 8, 2015 – **Inovio Pharmaceuticals, {NASDAQ: INO}** announced today that the first patient has been dosed in a phase I trial to evaluate safety and tolerability of PENNVAX®-GP, Inovio's "universal" DNA vaccine for HIV.

This human study is in collaboration with the HIV Vaccine Trials Network (HVTN). The trial will measure immune responses following administration of the vaccine in four groups of healthy subjects receiving the vaccine with and without an immune activator (IL-12) and delivered into muscle or skin using Inovio's CELLECTRA® delivery technology. This study is conducted by the HVTN and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Development of the PENNVAX-GP vaccine, which targets multiple clades of HIV—providing global coverage—has been funded through a \$25 million NIAID contract awarded to Inovio and its

collaborators. Earlier this year, Inovio and its collaborators were awarded a five-year \$16 million Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) grant from NIAID. This new five-year program grant was awarded based on a peer-reviewed meritorious proposal by Dr. David Weiner, from the University of Pennsylvania and chair of Inovio's scientific advisory board, and Inovio.

**Dr. J. Joseph Kim, President and CEO,** said, *"This latest HIV vaccine trial will allow us to test our universal HIV vaccine, with the potential to provide protection against viruses from all major global clades. This is a major step forward in extending our clinical experience with the PENNVAX platform and the innovation developed from our previous PENNVAX human trials. We are confident that the results of this trial will advance our previous findings that demonstrated best-in-class cellular immune responses. Inovio looks forward to continuing our long-standing and fruitful collaborations with both NIAID and HVTN."*

Results from the previous PENNVAX phase I trial, HVTN 080, were published in Journal of Infectious Diseases in 2013 and showed that 89% (24/27) of subjects developed a robust CD4 or CD8 response. In addition, immune response rates remained strong and persistent six months after vaccination. Achieving a robust CD8 T-cell response in a significant number of patients had been a previous barrier for HIV researchers.

Importantly, PENNVAX was able to generate CD8 T-cell responses with significant magnitude as measured by the HVTN core laboratory at the Fred Hutchinson Cancer Center, whose assays have been standardized to evaluate several different vaccine delivery technologies. Notably, CD4 and CD8 T-cells are both important in cellular immunity, however, CD8 T-cells are

considered especially integral to fighting cancers and chronic infectious diseases. The PENNVAX-GP product was developed as a universal HIV vaccine to expand and improve the coverage of the earlier version of PENNVAX against multiple divergent virus strains and clades across the globe.

### **About HIV Infection**

Nearly 36 million people have died from HIV-related causes and 35 million are living with HIV. HIV is a retrovirus that causes acquired immunodeficiency syndrome (AIDS), a condition in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive. HIV is classified into clades, sub-types within which the virus has genetic similarities. The most prevalent clades are B (found mainly in North America and Europe), A and D (found mainly in Africa), and C (found mainly in Africa and Asia).

HIV clade C accounts for 48% of worldwide and 51% of African-HIV type 1 cases. It is the most rapidly spreading subtype of HIV. Although a highly active antiretroviral therapy regimen has dramatically transformed the treatment of the disease in developed countries, effective HIV vaccines are needed to stop the spread of disease and reduce the need for antiretroviral treatments, which can have harsh side effects and lose their efficacy over time.

### **About Inovio's PENNVAX® HIV Vaccines and Immunotherapies**

Inovio completed initial clinical studies of its HIV immunotherapy PENNVAX-B, targeting clade B viruses, to achieve proof of principle in generating potent immune responses using

its SynCon® immunotherapy technology. In two published phase I studies, PENNVAX-B immunization generated high levels of activated, antigen-specific CD8+ killer T cells with proper functional characteristics. This ability uniquely positions PENNVAX as an important product candidate for both preventing and treating HIV infections.

Using a \$25 million contract from the NIH, Inovio designed its universal, multi-clade, multi-antigen PENNVAX GP immunotherapy targeting the env, gag and pol antigens to provide coverage against all major HIV-1 clades. PENNVAX-GP is Inovio's lead preventive and therapeutic immunotherapy for HIV.

### **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 is generating T cells, in vivo, in high quantity that are fully functional 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, 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).

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