Inovio Pharmaceuticals HIV Immunotherapy shows characteristics vital to Treating HIV

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A small patient study confirmed that immune response characteristics within the test group generated by the immunotherapy were similar to the small group of HIV positive people whose are not progressing to the latter stages of the disease, without treatment of any kind.

Comment

This is quite a small trial (12 people) to base a study on, so, whilst the medical world may not be jumping up and down at the result here, it is certainly a good start for Inovio in this area.

The key here is immune therapy activates the HIV-specific CD8+ T cells in infected patients, and has the potential to go beyond virus control, and reach into reservoirs of the infection to halt progression of HIV.

Official News Release

Phase I Trial Reveals DNA Immunotherapy Results Were Similar To HIV-Infected Patients Whose Disease Did Not Progress

Inovio Pharmaceuticals, Inc. {NASDAQ: INO} announced today that results from a 12-patient phase I study of Inovio's HIV immunotherapy, PENNVAX®-B, in HIV-infected patients revealed that immune response characteristics generated by the immunotherapy were similar to those observed in HIV-infected individuals who without treatment do not progress to further stages of the disease.

These extremely rare individuals who self-regulate their HIV infection are called "long-term non-progressors" and it is believed that part of their ability to control infection may lie in their unique immune responses. In this phase I study, Inovio's HIV immunotherapy, which had been previously tested only in disease prevention, drove the expansion of activated HIV-specific CD8+ T cells with functional characteristics similar to those of long-term non-progressors.

Results from this clinical study appeared in the peer-reviewed journal, Molecular Therapy in the article, "Synthetic consensus HIV-1 DNA induces potent cellular immune responses and synthesis of granzyme B, perforin in HIV infected individuals," authored by Inovio researchers and collaborators.

Dr. J. Joseph Kim , President & CEO of Inovio, said, "These results show the ability of our HIV immune therapy to activate HIV-specific CD8+ T cells in infected patients and the potential to go beyond virus control and reach into reservoirs of the infection to halt progression of HIV. Based on these initial results, Inovio plans to conduct a treatment-focused trial with its lead HIV vaccine, PENNVAX®-GP, that broadly targets globally significant HIV strains. This therapeutic study will complement our planned phase I vaccine study of PENNVAX®-GP in healthy subjects."

HIV targets the immune system, specifically CD4+ T cells, which are responsible for activating CD8+ killer T cells that

can kill the virus and infected cells. Unfortunately, with fewer CD4+ and CD8+ T cells, most infected individuals are unable to fight the virus. Independent studies have shown, however, that some untreated HIV-infected individuals have controlled viral replication and are long-term non-progressors (up to 30 years). One reason this may occur is due to the presence of CD8+ T cells with particular functional characteristics. While today's commonly used antiviral drugs can control viral replication, they cannot eliminate the virus, their long term effect often diminishes, and they have other associated side effects and disadvantages. Immunotherapies capable of generating antigen (disease)-specific CD8+ killer T cells are therefore considered a promising avenue to achieve long term prevention, viral load control, and elimination of HIV.

Inovio's synthetic immunotherapy technology is very effective at generating disease-specific killer T cells in the body. In this phase I study, HIV-infected individuals whose viral load was already effectively suppressed (below detection level) using a highly active antiviral therapy (HAART) received a four-dose regimen of PENNVAX®-B. Investigators observed that Inovio's HIV immunotherapy, which in a prior published study in healthy subjects generated best-in-class CD8+ T cell responses, significantly increased antigen-specific CD8+ T-cell responses in all patients.

The investigators also observed that the cell-killing substances granzyme B and perforin (both necessary to kill targeted cells and viruses) produced by activated CD8+ killer T cells were present in quantities and characteristics similar to those of long-term non-progressors. This result mirrors those of the previously published HIV study as well as those of Inovio's HPV immunotherapy, which also generated best-in-class functional T cells in a phase I study and achieved statistically significant clinical efficacy in a phase II study.

Another striking result of this HIV study was that PENNVAX®-B increased the number of HIV-specific CD8+ killer T cells displaying the receptor integrin, which is associated with the ability to carry T cells to the gastrointestinal tract (GIT). The GIT hosts 40-65% of the body's total immune cells, hence is the most important target organ for HIV, which targets CD4+ T cells and hides in "gut mucosa." The increased presence of integrin suggests the potential of such an immunotherapy to better fight or eradicate these reservoirs of HIV infection in the GIT.

The therapy was well-tolerated and did not result in any adverse events.

About PENNVAX® HIV Vaccines and Immunotherapies

Human immunodeficiency virus (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).

Inovio completed initial clinical studies focused on its HIV immunotherapy PENNVAX®-B, targeting clade B viruses, to achieve proof of principle in generating potent immune responses using its SynCon® vaccine technology. In two published phase I studies, PENNVAX®-B administration has been shown to generate high levels of antigen-specific CD8+ T cells with proper functional characteristics. This ability to generate high level of activated CD8+ killer T cells uniquely positions PENNVAX® as an important product candidate for preventing and treating HIV infections.

Using a $25 million grant from the NIH, Inovio designed its multi-clade PENNVAX®-GP immunotherapy targeting viruses from

clades A, B, C and D. PENNVAX®-GP is now Inovio's lead preventive and therapeutic immunotherapy.

A phase I clinical study of PENNVAX®-GP in a preventive setting is planned for the first half of 2015. A phase I clinical study of PENNVAX®-GP as an immune therapy is planned for the second half of 2015.

About Inovio Pharmaceuticals, Inc.

Inovio is revolutionizing the fight against cancer and infectious diseases.

For more information, visit www.inovio.com.