AMERICAN GENE TECHNOLOGIES ANNOUNCES PROGRESS TOWARD PHASE I CLINICAL TRIAL OF AGT103-T FOR HIV FUNCTIONAL CURE

Completes process development for the AGT103-T automated cell manufacturing protocol

ROCKVILLE, MD, USA, January 31, 2018 /EINPresswire.com/ -- American Gene Technologies International Inc. (AGT), a leading gene and cell therapy company, today announced completion of the pilot runs of its HIV Functional Cure automated cell processing protocol. This completes a key milestone of AGT's planned Phase I clinical trial of AGT103-T, a genetically modified autologous T cell product in development as an HIV functional cure.

"This accomplishes the second of two key developments that prepare AGT for an IND submission," said David Pauza, Ph.D., AGT's Chief Science Officer. "We have now produced a GMP-grade lentiviral vector stock that will modify HIV-specific T cells to make them immune to HIV entry and depletion. We fully developed the process for treating cells, in an automated unit, which reliably manufactures the cell product. The results from the most recent pilot run were nearly four times the level that we believe is necessary to restore HIV immunity in HIV-positive individuals."

The devastating impact of HIV/AIDS was dramatically relieved due to the development and global distribution of antiretroviral drugs. While these drugs marked a landmark achievement for medicine, even decades of treatment do not cure HIV and the virus re-emerges within just a few weeks off therapy. AGT103-T is the result of advances in genetic research to develop an immunotherapeutic that will potentially create a functional cure by reconstituting each person's immunity to HIV disease. The approach taken by AGT differs substantially from other companies' strategies by focusing on HIV-specific immune cells responsible for building and maintaining strong immunity against the virus. AGT's product protects these HIV-specific immune cells through genetic modifications that knock down CCR5, a key surface protein utilized by HIV, and prevents replication of HIV already resident in those T cells. AGT's cell therapy is expected to enable HIV-infected individuals to control and eliminate their viremia over time without the need for lifelong antiretroviral chemotherapy, render them non-contagious, protect them from developing AIDS, and provide immunity to reinfection for life.

Jeff Galvin, Chief Executive Officer, added, "This product is the most complex cell therapy the industry has delivered to date, and is a further indication of the sophistication, depth and breadth of AGT's gene technology platform for drug development. We hope to show efficacy for our HIV treatment this year and add several infectious disease therapeutics to our pipeline in 2019, while continuing to develop our monogenic disease portfolio and our gamma delta T cell immuno-oncology programs."

American Gene Technologies

AGT is an emerging gene and cell therapeutics company with a proprietary lentiviral platform capable of broad applications including large and orphan indications, infectious disease, immune-oncology, and monogenic disorders. AGT expects to take its lead candidate for an HIV functional cure into the clinic in 2018 and is pioneering a novel immuno-oncology approach of stimulating gamma-delta (γδ) T cells to attack multiple cancers. AGT has a diverse portfolio of patent filings surrounding key tools and components in viral vectors, gene therapy, and regenerative medicine, and a key patent in AGT's novel immuno-oncology approach has already been granted. AGT has developed a modified gene (patent-pending) able to express therapeutic levels of phenylalanine hydroxylase (PAH) that it is deploying, along with other proprietary AGT technologies, in pursuit of a cure for Phenylketonuria (PKU). AGT expects to begin clinical activities for PKU in 2019, and for liver cancer (AGT's first immuno-oncology therapy) in 2020.

More information can be found at www.americangene.com.

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