Gene Therapy Cure Claims Are Premature, Advocates Say

An experimental approach to protect HIV-fighting T cells has been cleared for its first human trial.

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Journalists received not one but three announcements this week from American Gene Technologies (AGT) touting the "most promising potential cure for HIV in the world." But such claims amount to unjustified hype, advocates say. The experimental therapy has not yet been tested in humans and—if it works—it could be years before it's ready for clinical use.

AGT just received clearance from the Food and Drug Administration (FDA) to start the first Phase I human clinical trial of its genetically modified T-cell product, dubbed AGT103-T, which the company is developing in collaboration with researchers at the National Institute of Allergy and Infectious Disease.

"From its research, AGT believes a cure is attainable and is now taking the significant step of testing in humans," the company announced in a press release. Added AGT founder and CEO Jeff Galvin, "I am confident AGT103-T will be an important step toward an eventual cure for HIV."

But advocates say such claims are not only premature, but also harmful because they give people with HIV the false impression that a cure is around the corner.

AGT's public relations strategy "preys on the emotions of people living with HIV" and "has a deleterious effect on the understanding of the cure field overall," Seattle advocate Michael Louella told POZ. "They make their outrageous comments, and these are then picked up and believed to be certain truth. Any attempt to promote a more nuanced and better-grounded understanding of gene therapy or the clinical process becomes impossible."

Although HIV can be suppressed indefinitely with combination antiretroviral therapy, it has proved exceedingly difficult to cure because a so-called reservoir of latent virus can remain hidden from the drugs in resting immune cells. Only two people appear to have been cured after bone marrow transplants from donors with HIV-resistant stem cells—a procedure far too dangerous for people who don't have life-threatening blood cancer.

Nonetheless, researchers are exploring numerous cure strategies, ranging from flushing HIV out of resting cells to genetically engineering immune cells to make them resistant to the virus. Most

experts expect that a combination approach will likely be needed to maintain durable control of HIV after stopping antiretroviral therapy—the definition of a functional cure.

AGT's process involves collecting immune cells from a patient and selecting those cells that target HIV antigens. A harmless lentivirus vector is then used to insert genes into the HIV-specific CD4 T cells that disable CCR5 receptors—which most strains of HIV use to enter cells—as well as genes involved in HIV replication. The genetically modified CD4 cells are then reinfused back into the same patient in a single dose. The entire process takes 11 days.

The company said it expects the approach will provide durable control of genetically diverse strains of HIV, including those that use a different receptor (known as CXCR4) to enter cells. The experimental therapy "should work to remove infected cells from the body and decrease or eliminate the need for lifelong antiretroviral treatment," AGT claims.

Another company, Sangamo BioSciences, previously reported promising results from early studies using a different gene therapy technique (a zinc finger nuclease) to edit out CCR5 receptors from T cells. Although it did not cure HIV, some study participants saw a reduction in the size of their viral reservoir and a long-term increase in CD4 counts. More recently, Chinese researcher He Jiankui used yet another technique (CRISPR-Cas9) to disable the CCR5 gene in human embryos in an effort to protect them from HIV.

AGT's approach not only uses a different gene-editing method to disable CCR5, but it also selects CD4 T cells that target HIV and protects them from destruction by the virus, thereby helping the selected cells survive and avoiding the wasted effort of modifying cells that won't attack HIV.

A recent medical journal report described preclinical studies of the approach, which showed that it is feasible to manufacture the modified HIV-specific CD4 T cells. AGT claims that in laboratory studies, "the product demonstrates the ability to clear itself of HIV when challenged with the virus and HIV-infected human cells." The company has not yet reported results from studies of the experimental therapy in animals.

These findings were used to support AGT's investigational new drug application to the FDA to allow the company to proceed with a Phase I study in human volunteers, which will be conducted in Baltimore and Washington, DC. Eligible participants must have been on antiretroviral therapy for one to three years, have an undetectable viral load, have a stable CD4 count above 500 and may not have any AIDS-defining conditions.

AGT expects to enroll the first participant in September, with the first infusion of genetically modified T cells to be administered in December. The company said it expects initial data by the end of the year.

But this will be far too soon to determine whether the altered T cells persist in the body or whether they can maintain long-term viral suppression after antiretroviral therapy is discontinued.

"Saying 'AGT believes there is a high likelihood that participants in the upcoming trial will be

cured’ is beyond outrageous and completely undermines informed consent because it’s an unethical inducement to participate [in trials],” Richard Jefferys of the Treatment Action Group told POZ.

“And it’s not based on a shred of evidence. To my knowledge, there’s no humanized mouse data, no macaque data—it’s all theory,” he continued. "I would hope that they pause to reconsider their PR strategy and broaden their consultation with stakeholders, including community-based advocates.

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