American Gene Technologies™
Where Creativity Cures™

1. What is AGT?

American Gene Technologies (AGT) https://www.americangene.com/ is a biotechnology gene therapy platform company developing techniques, components, and specific gene constructs for the cell and gene therapy industry. AGT has created a diverse and deep IP portfolio of 52 patents of reusable components that can be combined in different ways to form the foundation of new gene and cell therapy drugs, thus substantially lowering the cost, time, and risk of developing drugs in the emerging gene and cell therapy industry. AGT's first clinical product is a cure for HIV. AGT103-T is a gene therapy product that has undergone a successful clinical phase 1 trial and follow-on analytical treatment interruption study showing strong safety and efficacy signals (equivalent to typical Phase 2a results). The project is named Addimmune https://www.addimmune.com/, and we believe that the next clinical trial may show that AGT103-T is a one-and-done single-administration cure for HIV.

2. What is special about AGT103-T?

We believe that AGT103-T can become a cure for HIV and disrupt the $35 billion annual treatment market with better outcomes, better quality of life, and lower lifetime costs for the treatment of people living with HIV (PLWHIV)

PLWHIV are currently estimated to cost the US economy $3 million per person, and AGT103-T could save the healthcare system half to two-thirds of that cost by reducing or eliminating the side effects of lifetime antiretroviral treatments and the inflammation that results from chronic HIV viremia.

Additionally, a cure would help reduce the nearly epidemic spread of HIV in the US, which adds close to $100 billion in lifetime costs to the healthcare burden from 35,000-45,000 new infections per year. Treated individuals may never require any other treatments; they can never develop AIDS, infect others, or be reinfected by HIV.

AGT103-T is less expensive than other autologous cell therapies. It was designed to be manufactured in a benchtop automated cell processing machine. The processing is reliable, scalable, and transportable. At scale, we believe an individual product can be manufactured locally at a hospital or clinic for less than $50,000 per patient and administered in two outpatient visits approximately one month apart—essentially the cost of one year of current antiretroviral medications.

3. How does AGT103-T work? How is it unique?

AGT103-T is applied to HIV-specific CD4 helper T cells responsible for managing the immune response to the virus, preventing the CD4 cells from being depleted, and allowing the body to maintain an effective immune response that protects it from HIV and AIDS. 100% of participants in the analytical treatment withdrawal study showed an effective immune response to HIV. The three genetic elements of AGT103-T give broad protection against most known strains of HIV, and 100% of participants chosen randomly for Phase 1 demonstrated a therapeutic response.

4. Current HIV treatment landscape

The market for this product is the 1.2 million people living with HIV in the US alone; including the EU, the number is closer to 5 million. Within this group is the 3.8% (45,000 in the US alone) who cannot tolerate ART or are not controlled with medication—representing a large unmet medical need. $3M is the estimated cost over the lifetime of a person with HIV, including ART, medical costs, and lost productivity. Due to inconsistent adherence to the medical regimen for a variety of reasons, there are an additional 35-45,000 new infections per year in the US alone. The cost of ART alone has risen 6% annually since 2013.

5. **Timeline to value harvesting**

Preliminary results from the next study (estimated 12 months from initiation) would create a value inflection point that could provide M&A opportunities for AGT103-T. Completion of the study could provide a subsequent value inflection point (estimated to take an additional six to nine months). Favorable interim data could spark interest from ART manufacturers (Gilead Sciences, ViiV Healthcare, CIPLA) whose science and business development teams have been kept abreast of our published and unpublished data and could excite the 1.2M PLWHIV in the US and nearly 40M globally to create objective, measurable demand for the product to boost further the market value of AGT.

6. **Executive Team**

Jeff Galvin, Founder and CEO of AGT; Dr. W. Drew Palin, MD, President; and Dr. Barry Wells, MD, VP of Business Development.