American Gene Technologies®

Where Creativity Cures®

AMERICAN GENE TECHNOLOGIES

IMAGINE A WORLD WITHOUT HIV

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Investment Highlights

American Gene Technologies (AGT) is a clinical-stage cell and gene therapy project focused on the development of **novel mechanisms to treat, and potentially cure, human immunodeficiency virus (HIV)**

AGT103-T, moving to the next human trial and has the potential to be the **first-in-class functional cure**[1] and possible **best-in-class adjuvant treatment** for HIV. This could impact a growing, **highly profitable $35B market**

A cell and gene therapy pipeline with diverse treatment strategies to address the HIV epidemic that is **currently impacting 5 million people across the US and Europe**[2]

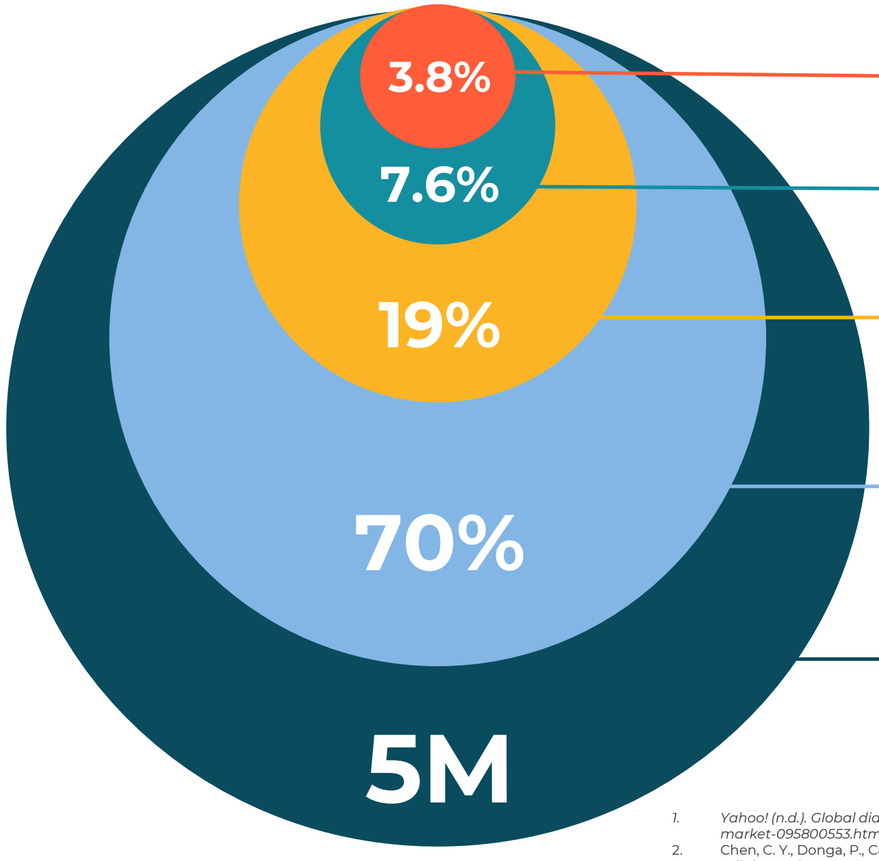
Backed by a dedicated in-house team of scientists and business leaders, and supported by a Scientific Advisory Board comprised of renowned public health and infectious disease experts

Meaningful clinical catalysts expected within the next 24 months, including AGT103-T next human trial initiation and interim data readout

1. Functional cure would enable a patient's immune system to suppress the virus below the level of transmissibility, and possibly detectability, without the use of antiretroviral therapy (ART).
2. World Health Organization. (2023, July 13). *HIV*. World Health Organization. https://www.who.int/data/gho/data/themes/hiv-aids

Commercial Opportunity

Cell and gene therapy has the **potential to disrupt the soon-to-be $39.3B global HIV therapy market**[1], where payers are currently spending up to **$1.7M per patient** on life-long standard of care[2]



Clinically failing first-line ART treatment (e.g., adverse events)[3]
An acute, urgent need ~45k US patients[2,4]

Non-adherent for hard-to-address reasons (e.g., mental health)[5,6,7]
Public health risk ~91k US Patients[4,5,6,7]

Currently non-adherent to ART[6]
Ongoing transmission risk, contributing to 35k-40k new US infections each year[4]

Want longer-acting treatments[8]
Desire to improve quality of life

People living with HIV in the US and Europe[4,9]

1. *Yahoo! (n.d.). Global diagnostics and therapeutics for HIV market expected to reach $39.3 billion by 2028: Advancements in diagnostic technologies drive growth. Yahoo! Finance. https://finance.yahoo.com/news/global-diagnostics-therapeutics-hiv-market-095800553.html?*
2. Chen, C. Y., Donga, P., Campbell, A. K., & Taiwo, B. (2023). Economic Burden of HIV in a Commercially Insured Population in the United States. *Journal of health economics and outcomes research*, *10*(1), 10–19. https://doi.org/10.36469/001c.56928
3. Lailulo, Y., Kitenge, M., Jaffer, S. *et al.* Factors associated with antiretroviral treatment failure among people living with HIV on antiretroviral therapy in resource-poor settings: a systematic review and metaanalysis. *Syst Rev* 9, 292 (2020). https://doi.org/10.1186/s13643-020-01524-1
4. Centers for Disease Control and Prevention. (2023, May 22). *Basic statistics - HIV/AIDS*. Centers for Disease Control and Prevention. https://www.cdc.gov/hiv/basics/statistics.html
5. Mbuagbaw L, Mertz D, Lawson DO, et alStrategies to improve adherence to antiretroviral therapy and retention in care for people living with HIV in high-income countries: a protocol for an overview of systematic reviewsBMJ Open 2018;8:e022982. doi: 10.1136/bmjopen-2018-022982
6. Ahmed, A., Dujaili, J. A., Jabeen, M., Umair, M. M., Chuah, L. H., Hashmi, F. K., ... & Chaiyakunapruk, N. (2022). Barriers and enablers for adherence to antiretroviral therapy among people living with HIV/AIDS in the era of COVID-19: a qualitative study from Pakistan. *Frontiers in Pharmacology*, *12*, 807446
7. Hoare, J., Sevenoaks, T., Mtukushe, B. *et al.* Global Systematic Review of Common Mental Health Disorders in Adults Living with HIV. *Curr HIV/AIDS Rep* **18**, 569–580 (2021). https://doi.org/10.1007/s11904-021-00583-w.
8. Schaecher K. L. (2013). The importance of treatment adherence in HIV. *The American journal of managed care*, *19*(12 Suppl), s231–s237. World Health Organization. (2023, July 13). *HIV*. World Health Organization. https://www.who.int/data/gho/data/themes/hiv-aids
9. World Health Organization. (2023, July 13). *HIV*. World Health Organization. https://www.who.int/data/gho/data/themes/hiv-aids

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HIV Cure Has Made Consistent Development Progress

Two clinical studies completed and published over five years (despite the COVID pandemic)

Our progress has led to line-of-sight on a potential functional HIV functional cure

2020

US IND

FDA authorizes IND to proceed

Ph I Start

HIV cure program Phase I initiated (first patient enrolled)

2021

1st Product Cleared

First AGT103-T product cleared for infusion

1st Patient Dosed

First participant infused with no adverse events

DSMB Safety Report

DSMB report affirms safety of AGT103-T

Blood Marker Data

Blood markers of efficacy documented

2022

HC169 Study Approval

IRB approval for ATI follow on study

Ph I Data Publication

Phase I trial data published in *Frontiers in Medicine*

2023

Ph I Data Submission

Submission of Phase I study to FDA

HC169 Study Readout

Showing the impact of AGT103-T and Multiple ATIs on durable CD8 T cell immunity and viral control

FDA Protocol Discussion

Submitted clinical protocol to FDA for subsequent human trial

2024

ATI Data Publication

ATT trial data published in *Frontiers in Medicine*

Viral Reservoir Data

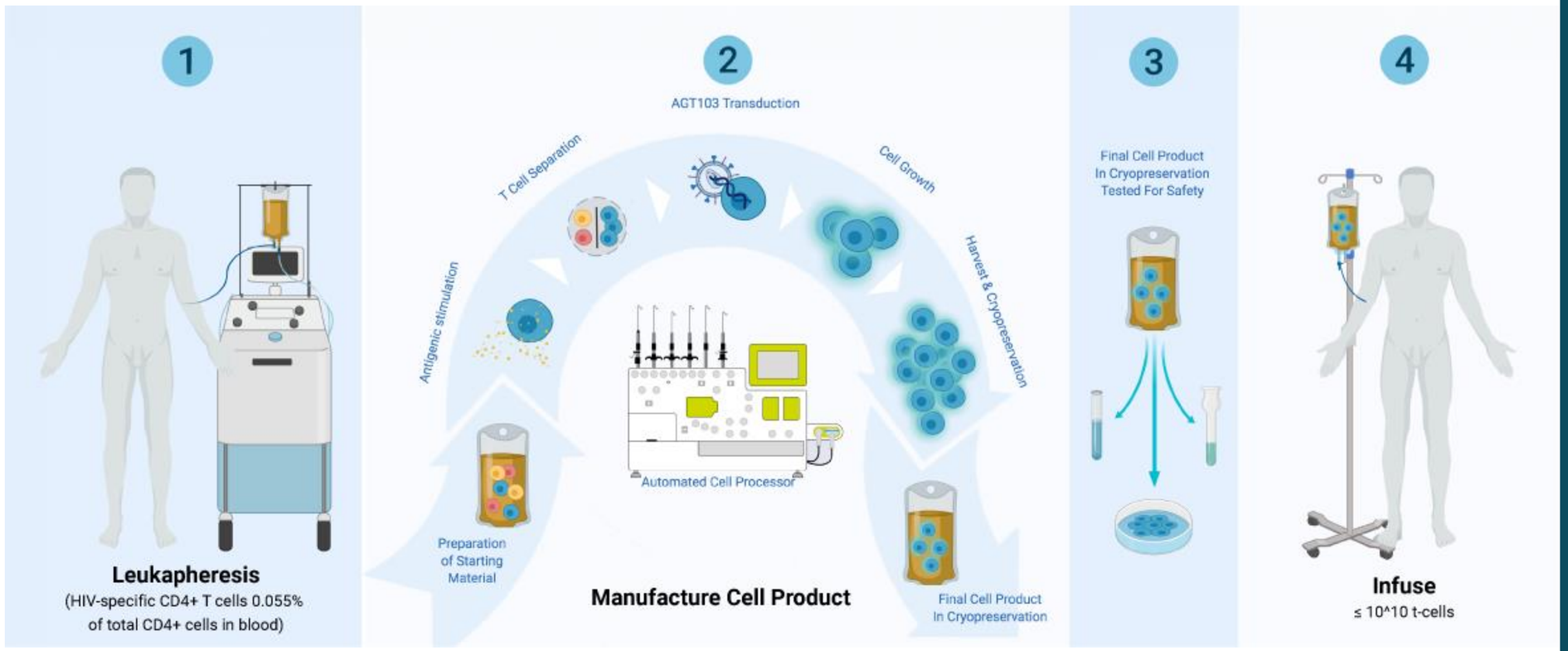
First indications recorded that treatment may substantially reduce HIV viral reservoir

Additional Financing

Merritt Advisory and Cozen O'Connor engaged to target $60M raise to fund additional trials, partnering, and M&A activities via value inflection points at data readouts

AGT103-T Is Delivered as an Autologous Cell Product:

Two Outpatient Visits – No Hospitalization – Can Be Administered in a Clinic



Putting the cells through an automated outpatient process yields AGT103-T which is **cryopreserved**, undergoes QC, and is **shipped frozen** to the clinic for infusion.

DAY 1

DAY 2 - 12 (11 DAYS)

RELEASE TESTING (90 DAYS)

FOLLOWING SAFETY TESTING APPROVAL

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AGT103-T Clinical Trial: Phase Ia Study Design

Safety and durability of autologous T cell therapy in people living with HIV infection

Primary Objective

Evaluate the **safety** and **feasibility** of AGT103-T infusion in HIV+ participants

- *Observed/reported Adverse Events*
- *Successful infusion*

Secondary Objective

Evaluate the **durability** of transduced cells

- *Number of copies of the transgene in PBMC*

Participants

- 7 participants dosed
- Minimum of 2 years on ART
- Median age: 41 years
- Median absolute CD4+ T cell count at screening: 577 cells per microliter
- Median duration of HIV infection (from time of diagnosis): 14.2 years

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1. Modified from: Muvarak, N., Li, H., Lahusen, T., Galvin, J. A., Kumar, P. N., Pauza, C. D., & Bordon, J. (2022). Safety and durability of AGT103-T autologous T cell therapy for HIV infection in a Phase 1 trial. *Frontiers in Medicine*, 9, 1044713.

AGT103-T: Phase Ia Study Results

Gag-specific CD4 T cells increased up to 300-fold over baseline post infusion [1]

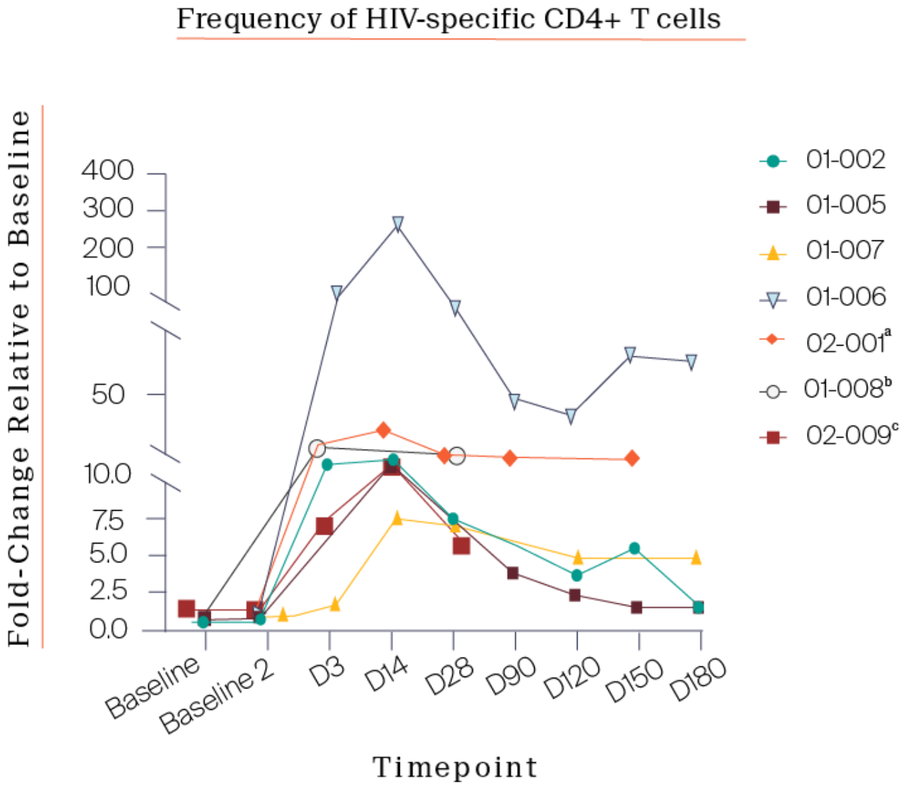
7 Patients

Primary Objective - Achieved

- No serious adverse events observed
- Successful engraftment and persistence of modified CD4+ T cells

Secondary Objective - Achieved

- Functional immune response to HIV Gag antigen was preserved and expanded in all patients who completed the study



[a]The clinic failed to draw blood from 02-001 for research samples on the Day 180.
[b]Additional data unavailable at time of publication, see follow-on ATI study for additional detail
[c]Day 90 sample for 02-009 arrived clotted and could not be processed.

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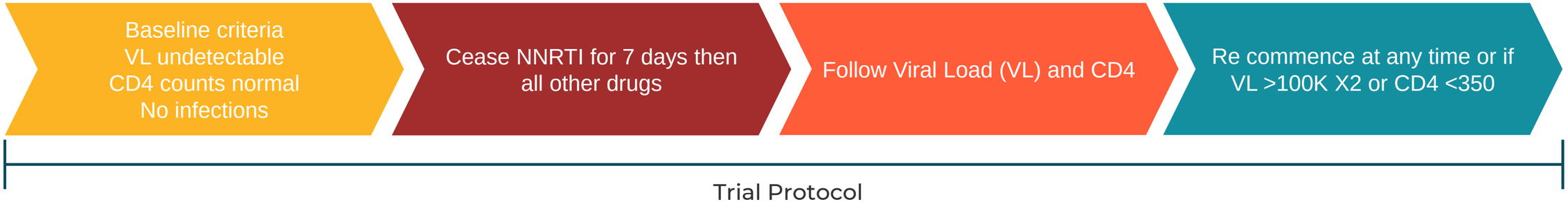
1. Modified from: Muvarak, N., Li, H., Lahusen, T., Galvin, J. A., Kumar, P. N., Pauza, C. D., & Bordon, J. (2022). Safety and durability of AGT103-T autologous T cell therapy for HIV infection in a Phase 1 trial. *Frontiers in Medicine*, 9, 1044713.

AGT103-T: Phase Ia – Follow-on ATI Protocol

A study to assess the impact of AGT103-T and Multiple Analytical Treatment Interruptions (ATIs) on durable CD8 T cell immunity and viral control



Primary Objective

- An informational study to:
  - Evaluate the host's capacity to suppress HIV replication following AGT103-T therapy
  - Evaluate product and participant immunological, virologic, and molecular parameters related to viral suppression
- Follow-On ATI study commenced after obtaining IRB approval and participant informed consent

Patient ID	Infused Product Dose (modified cells)	Days between Infusion and the Start of ATI-1
01-008	1.67 E+9	150
02-009	1.38 E+9	99
01-002	0.192 E+9	490
02-001	0.62 E+9	246
01-005	0.46 E+9	411
01-007	0.19 E+9	390

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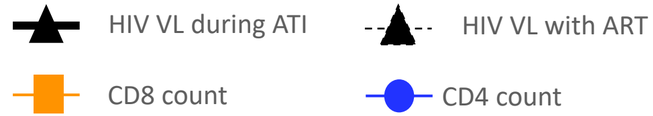
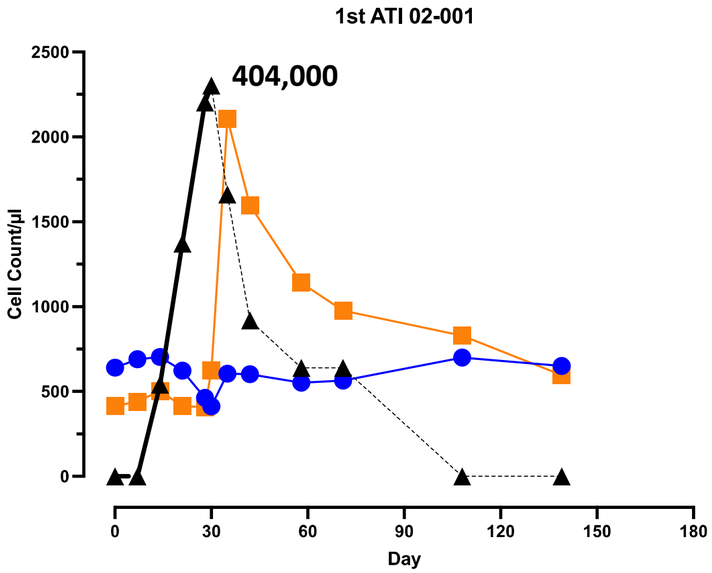
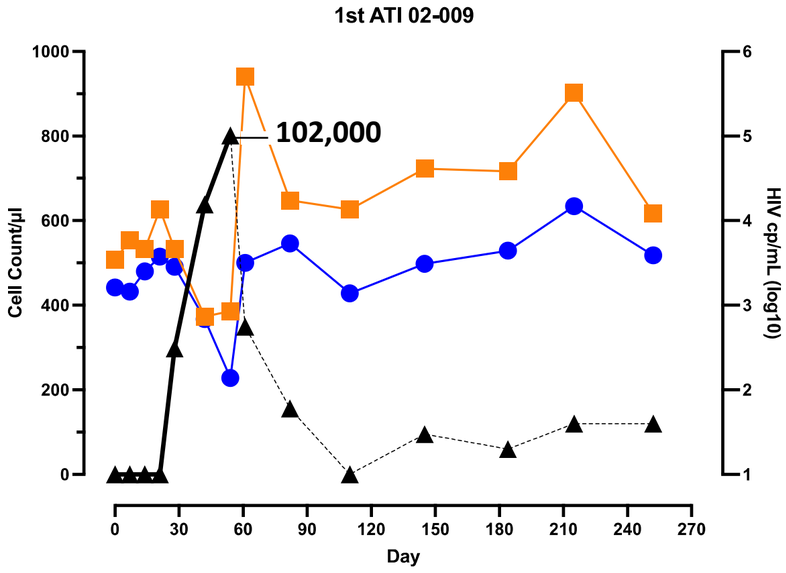
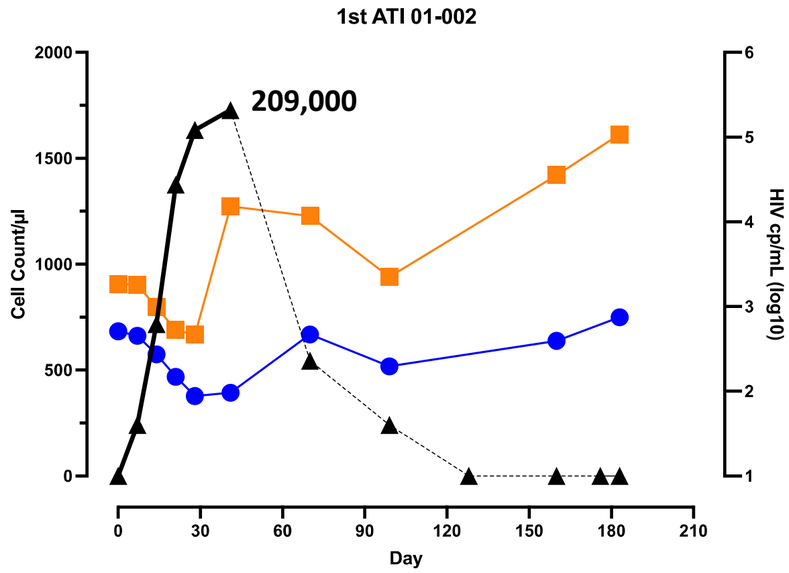
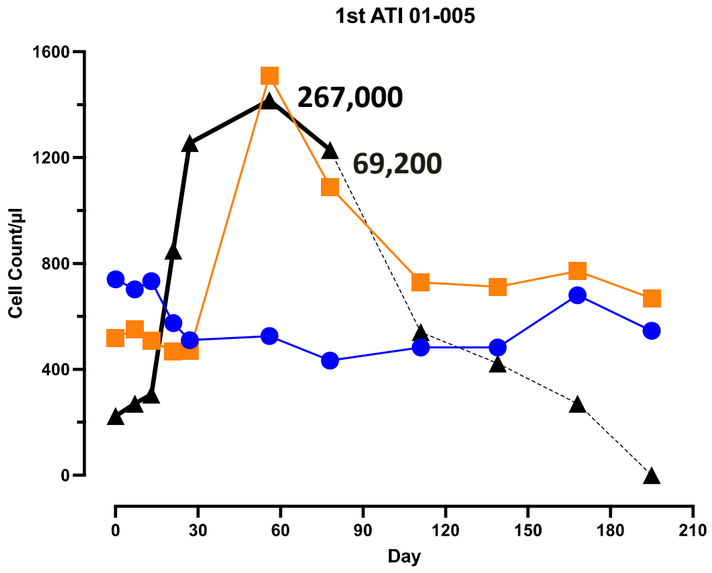
CD8 T Cell Count Rose After Viremia in All Participants

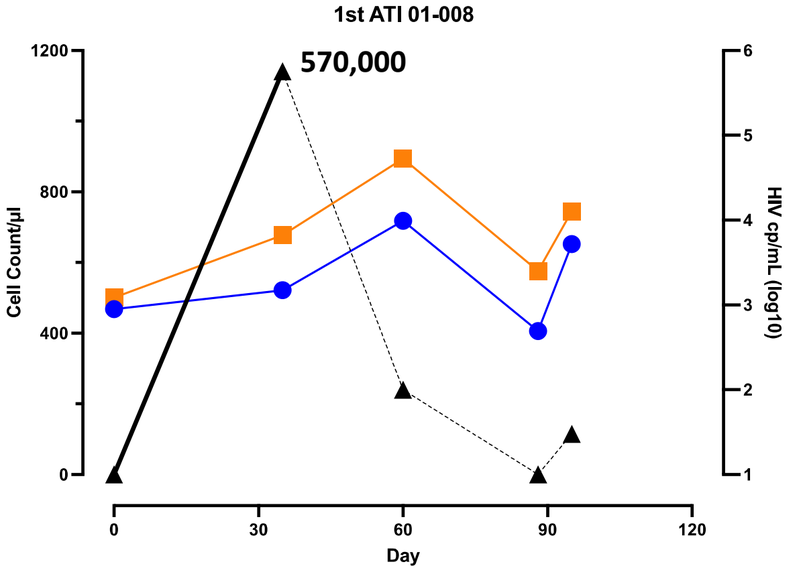


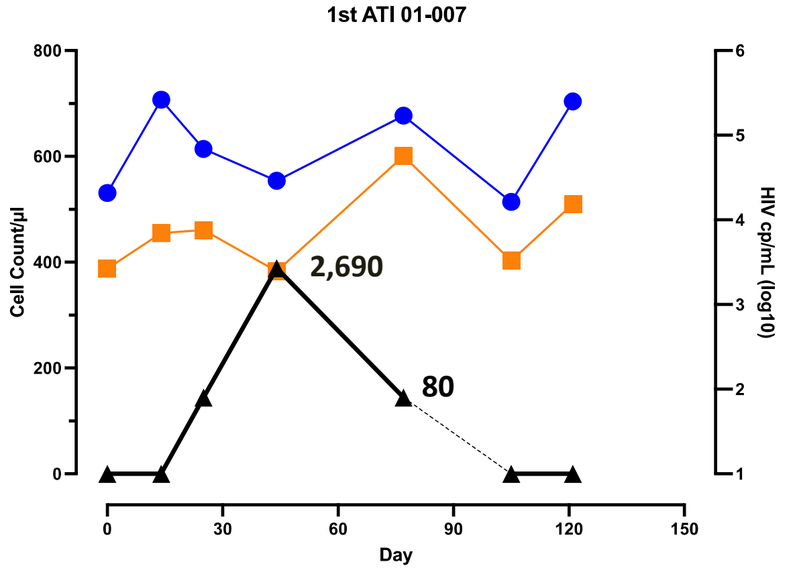






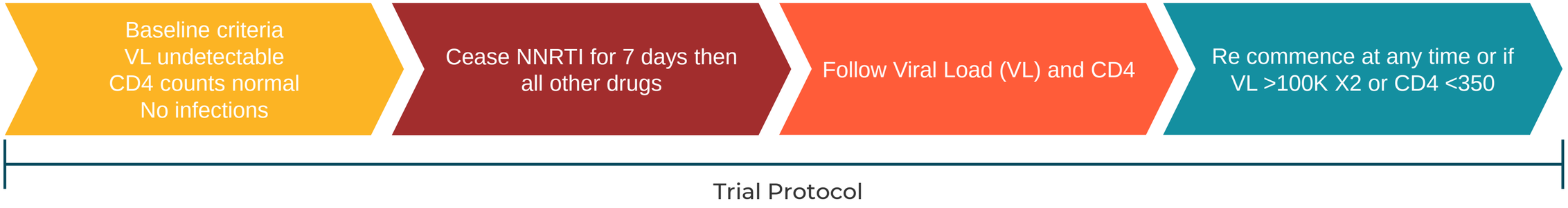






AGT103-T: Phase Ia – Follow-on ATI Clinical Study

A study to assess the impact of AGT103-T and Multiple Analytical Treatment Interruptions (ATIs) on durable CD8 T cell immunity and viral control



Primary Objective

- An informational study to:
  - Evaluate the host's capacity to suppress HIV replication following AGT103-T therapy
  - Evaluate product and participant immunological, virologic, and molecular parameters related to viral suppression
- Follow-On ATI study modified to include 2nd ATI after obtaining IRB approval and participant informed consent

4 Participants continued

Patient ID	Infused Product Dose (modified cells)	Days between Infusion and the Start of ATI-1
01-008	1.67 E+9	150
01-002	0.192 E+9	490
02-001	0.62 E+9	246
01-005	0.46 E+9	411

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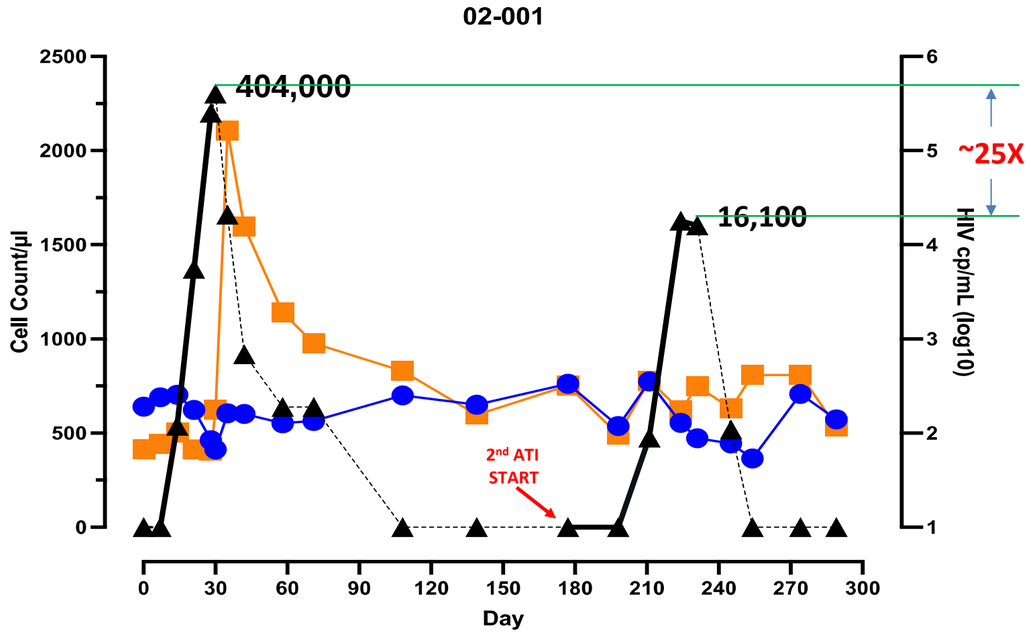
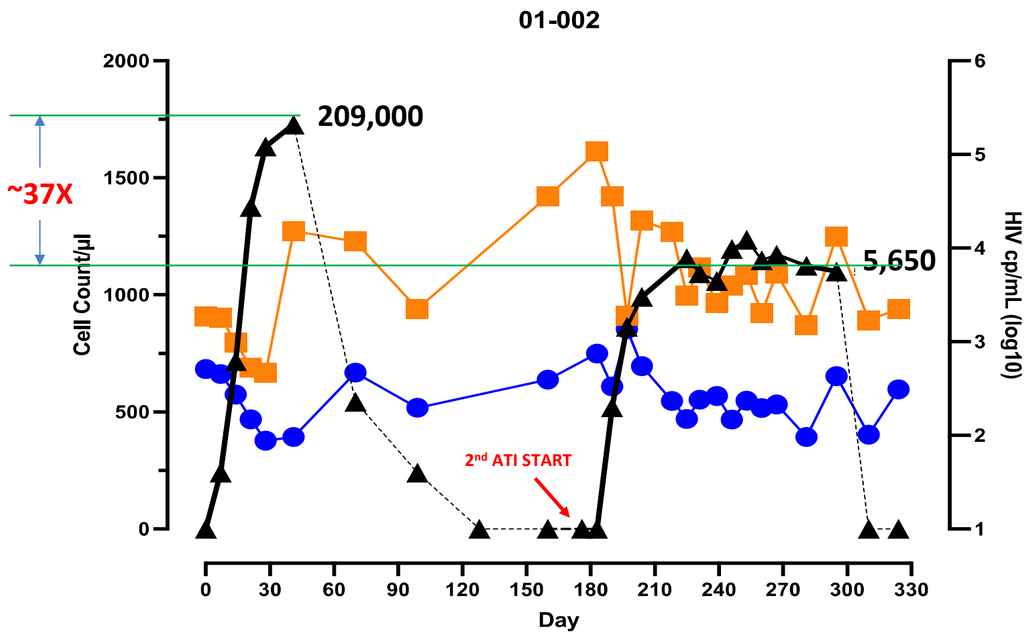
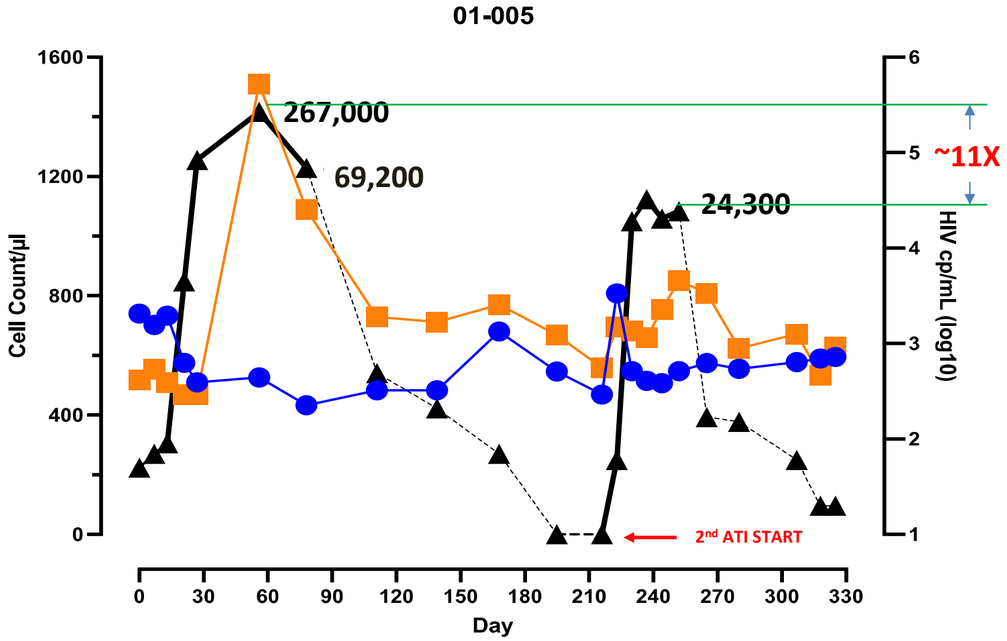
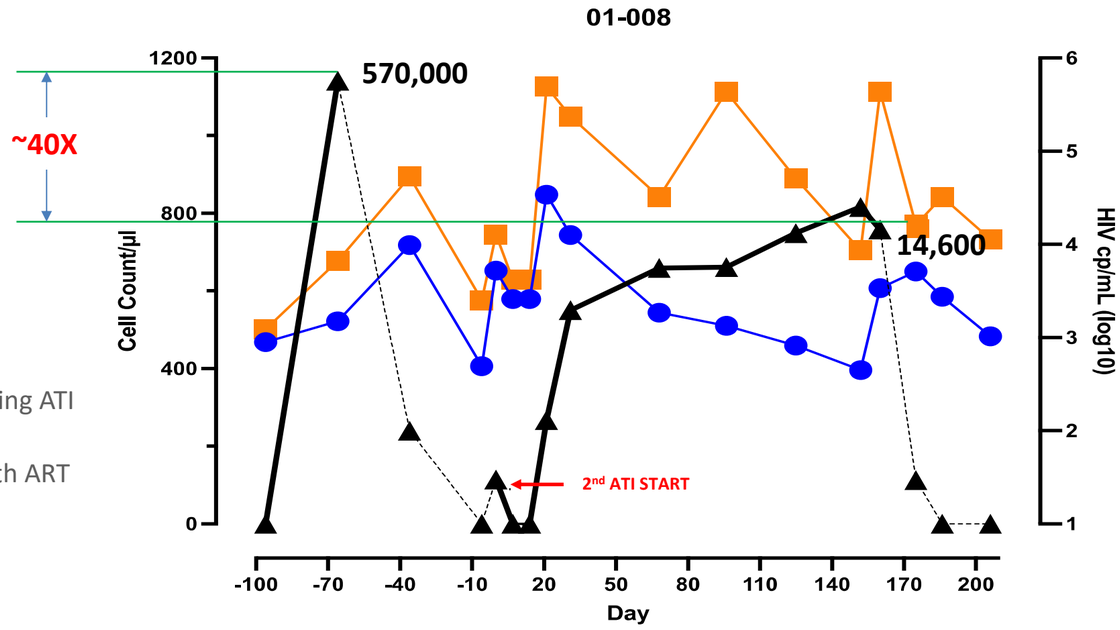
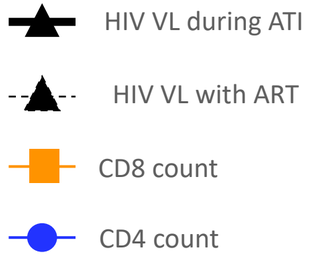
CD8 T Cell Count Remained Higher After 2nd ATI. End-of-study Viral Loads All Below 25K p/ml





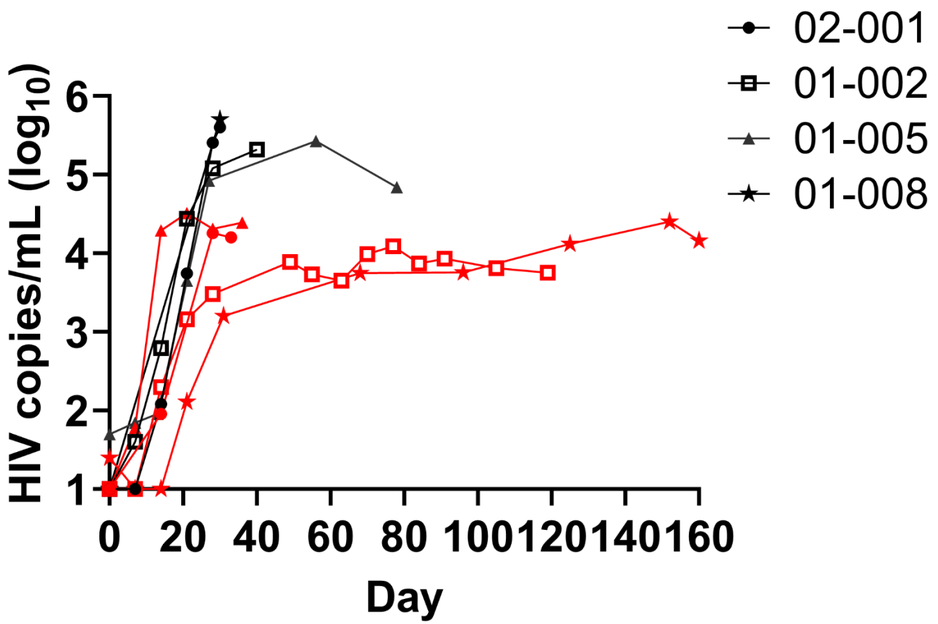






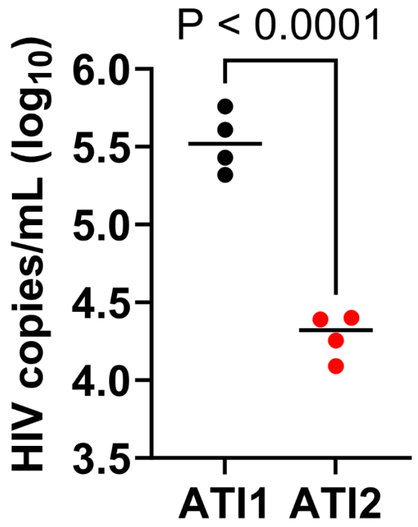
Two ATIs Enable Viral Suppression in AGT103-T Treated Participants

Evidence for viral suppression: **Peak viremia was an average 16-fold lower in patients after their 2nd ATI** and stabilizing to setpoints of ~7K-25K HIV copies/ml

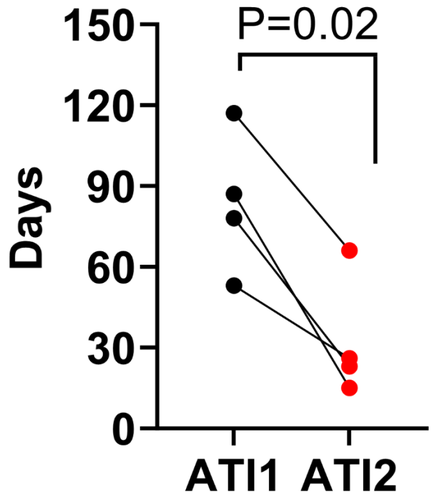


	01-008	02-001	01-005	01-002
1ATI Post-Infusion (d)	152	246	412	490
2ATI Post-Infusion (d)	248	444	628	666
Between ATIs (d)	59	168	138	135

Peak Viremia following 2nd ATI



Treatment response following 2nd ATI



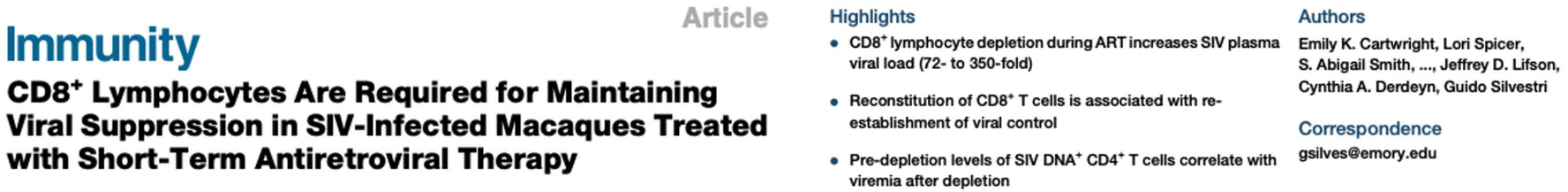
ATI #1 ATI #2

All patients quickly controlled virus after resumption of ART

- 4/4 patients return to <50 cp/mL faster after 2nd ATI
- No evidence of resistance observed

AGT103-T has the potential to improve treatment response in combination with new and existing therapies

Phase 1a study outcome	Potential for synergy
4/4 participants with setpoints below 25K	✅
HIV specific T cell response	✅
Increased CD8 T cell count	✅
Persistent HIV resistant CD4 T cells	✅



Article

Immunity

CD8⁺ Lymphocytes Are Required for Maintaining Viral Suppression in SIV-Infected Macaques Treated with Short-Term Antiretroviral Therapy

Highlights

- CD8⁺ lymphocyte depletion during ART increases SIV plasma viral load (72- to 350-fold)
- Reconstitution of CD8⁺ T cells is associated with re-establishment of viral control
- Pre-depletion levels of SIV DNA⁺ CD4⁺ T cells correlate with viremia after depletion

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How AGT could improve clinical response in next human trial

- 1st ATI within 30 days of infusion to increase the number of activated Gag-specific CD4 T cells. (Between 100 and 490 days elapsed between the infusion of the Phase 1a participants and their initial ATI. The number of original AGT103-T modified cells was significantly lower at the time that participants were withdrawn from antiretrovirals).

- 1st ATI limit to 1VL >20K to allow immune response ("auto-vaccination") but limit the HIV reservoir increase. (The Phase 1a protocol allowed a high limit on the viral load in the first withdrawal, which could impact the modified cells and immune system's ability to control the virus on the second withdrawal).

- 2nd ATI 28 days after 1st ATI to limit decline of Gag-specific CD4/CD8 T cells. (This could improve the "auto-vaccination" effect. The Phase 1a protocol left up to 168 days between the auto-vaccination and the second withdrawal, which could have reduced the immune system response).

- **Small changes in the Phase 1b protocol could yield substantial outcome improvements**

AGT103-T: Redefine Standard of Care? or Possibly Cure…

The Phase 1 and ATI data is already in a promising range in a $35B market:

We believe AGT103-T can potentially improve the effect and durability of existing therapies, prevent disease progression, limit transmissibility, and could functionally cure HIV.

Set Point is the steady state of an HIV patient's viral load following their initial peak that persists until progression to AIDS. [1]

GOOD

Improved Therapeutic Response

BETTER

Long-term Nonprogressor (LTNP)

100% of ATI participants completing two ATIs fell in this range and were within 1 log of LNTP levels

70% of patients want longer-acting therapy [5]

Poor adherence to ART leads to immediate health and long-term resistance threats to patients [3]

Typical LNTP is: <0.5% of people living with HIV [4]

LTNPs are people with HIV who do not take ART and still maintain CD4 counts in the normal range indefinitely.[2]

Treatment protocol changes could increase the effect

Nontransmissible

1.3M people globally acquired HIV in 2022 [7]

According to the CDC, a viral load below 200 copies/ml is virtually untransmittable.[6]

BEST

Durably Undetectable (Functionally Cured)

Our goal is to deliver the world's first single-dose treatment for people living with HIV

1. Mei, Y., Wang, L., & Holte, S. E. (2008). A comparison of methods for determining HIV viral set point. *Statistics in medicine*, *27*(1), 121–139. https://doi.org/10.1002/sim.3038
2. Paul Thoueille and others, Long-acting antiretrovirals: a new era for the management and prevention of HIV infection, *Journal of Antimicrobial Chemotherapy*, Volume 77, Issue 2, February 2022, Pages 290–302, https://doi.org/10.1093/jac/dkab324
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Pharma Partners Could Gain Advantage From AGT103-T

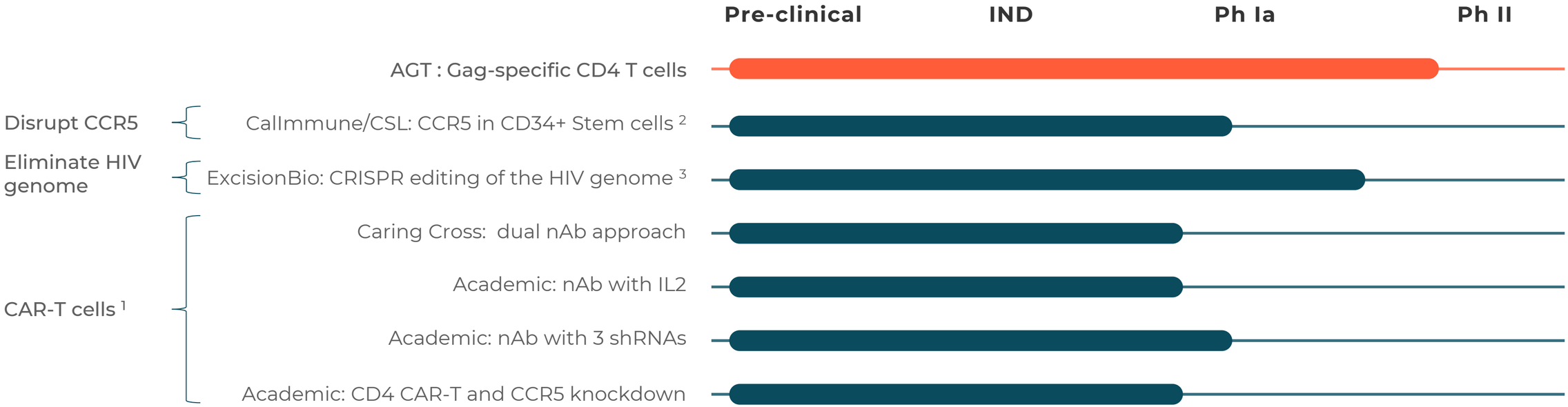
In the Intense Competition Over Lower-Toxicity and Greater-Convenience Treatments in the $35B Market

	Target	Stage	Efficacy
GILEAD	Lenacapavir with Broadly Neutralizing Antibodies as a Potential Twice-Yearly Approach for the Treatment of HIV [1]	Ph I	90% (18/20) efficacy at week 26 and injection site issues in 3 patients. Moving to dosing study Ph II [1]
ViiV Healthcare	Novel ART pipeline with new mechanism of action [2]	Ph I - Ph II	Efficacy TBD
ViiV Healthcare | qura THERAPEUTICS	Induction of HIV that may be in hiding via a signaling pathway to then treat with ART for potential elimination [3]	Pre-Clinical	Efficacy TBD

We believe there are opportunities for use as both monotherapy and in potential combination with standard of care. AGT103-T could be a strategic asset for a Pharma partner

1. Tuan, J., & Ogbuagu, O. (2023). Lenacapavir: a twice-yearly treatment for adults with multidrug-resistant HIV infection and limited treatment options. *Expert review of anti-infective therapy*, *21*(6), 565–570. https://doi.org/10.1080/14787210.2023.2203913
2. *Medicines in development*. HIV Medicines in Development | ViiV Healthcare US. (n.d.). https://viivhealthcare.com/en-us/hiv-research/medicines-in-development/
3. Nixon, C.C., Mavigner, M., Sampey, G.C. *et al.* Systemic HIV and SIV latency reversal via non-canonical NF-κB signalling in vivo. *Nature* 578, 160–165 (2020). https://doi.org/10.1038/s41586-020-1951-3

HIV Gene Therapy: AGT leads (with published data)



AGT has completed a Phase 1 Clinical Trial and an Analytical Treatment Interruption (ATI) study. Three articles have been published that present data on safety and effect.

1. Choudhary, M.C, Cyktor, J.C, Riddler, S.A., (2002)Advances in HIV-1-specific chimeric antigen receptor cells to target the HIV01 reservoir, *Journal of Virus Eradication*, https://doi.org/10.1016/j.jve.2022.100073
2. *Safety Study of a dual anti-HIV gene transfer construct to treat HIV-1 infection - full text view*. ClinicalTrials.gov. (n.d.). https://classic.clinicaltrials.gov/ct2/show/NCT01734850
3. *Study of EBT-101 in aviremic HIV-1 infected adults on stable art - full text view*. ClinicalTrials.gov. (n.d.-b). https://classic.clinicaltrials.gov/ct2/show/NCT05144386

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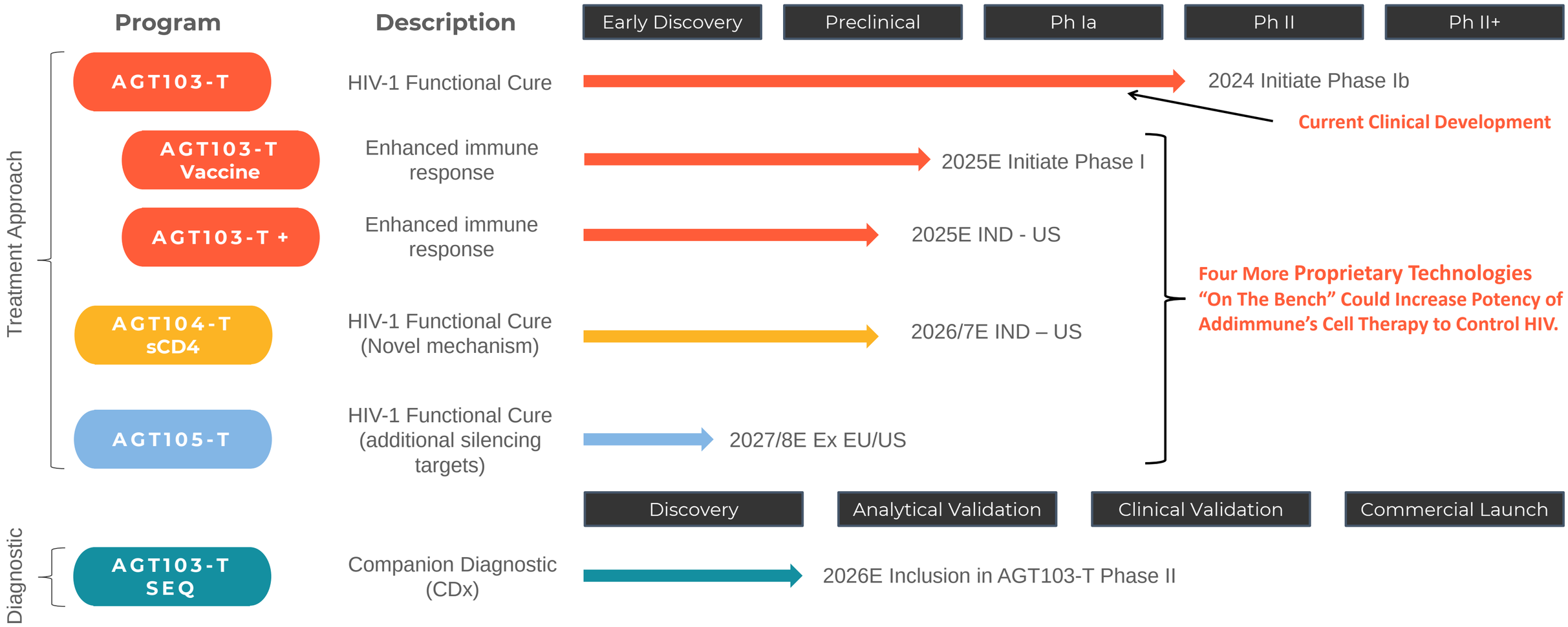
Pipeline: Multiple Ways to Potentially Treat and Cure HIV[1,2]

Additional AGT Technologies give four extra "shots on goal" to improve HIV treatment or potentially provide a cure.



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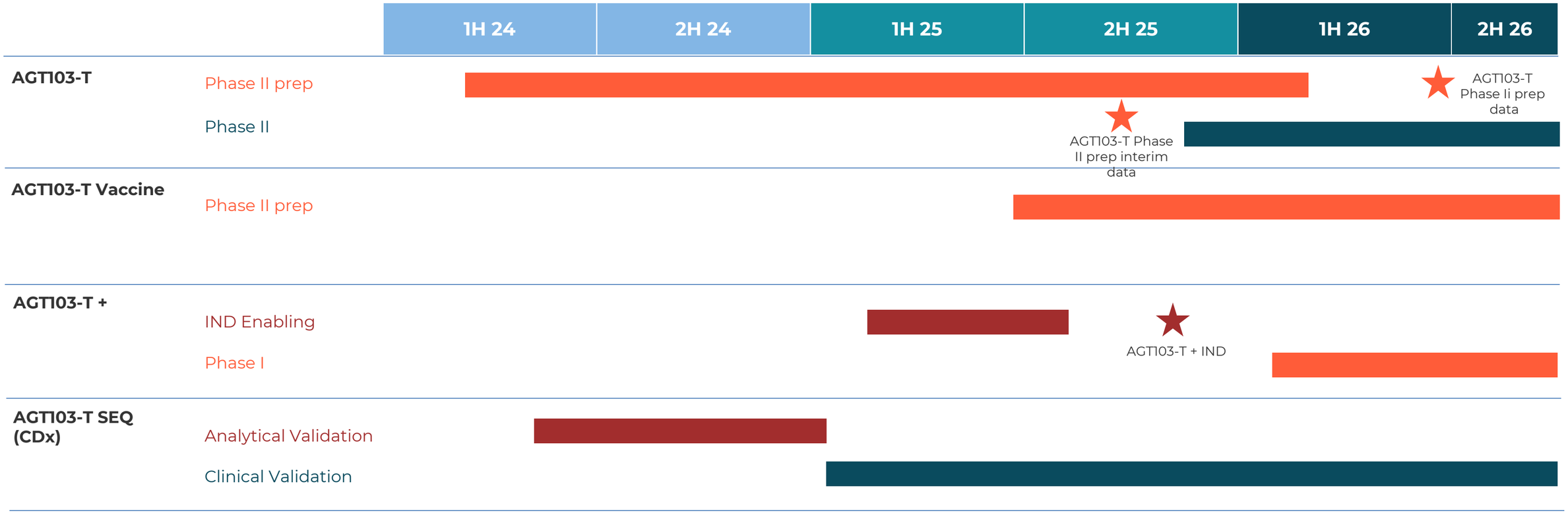
1. Pipeline composition and milestone timing are based on management's industry experience and expectations, subject to change
2. Note, this chart does not reflect all steps or trials required to seek and obtain potential regulatory approval for our product candidates from the U.S. FDA or other comparable foreign regulatory authorities.

Path to Value Inflection Points

Our goal is to continue delivering consistent progress toward a potential HIV Functional Cure



Based on management's current estimations, subject to change

★ Key milestones to be delivered – Expected valuation inflection points

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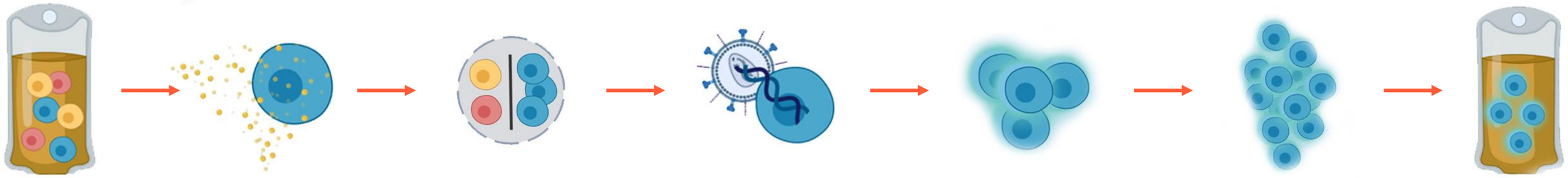
Scalable Manufacturing Process, Capable of Supporting Future Clinical and Commercial Production

- Process development, validation, transfer, and manufacturing successful at CDMO for Phase I
- End-to-End process comprised of readily available materials and equipment
- Successful AGT103-T doses produced in support of Phase I study
- No significant changes of production methods required for dosing and efficacy study

CELL PRODUCT MANUFACTURING PROCESS (11 DAYS)



Preparation of starting material

Antigenic Stimulation

T cell Separation

AGT103-T Transduction

Cell Growth

Harvest & Cryopreservation

Final Cell Product

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Existing Industry Capacity Has Potential to Support AGT103-T Through Multiple Years of Commercialization

- Current available CDMO production capacity can support pivotal study and at least 3 years of projected commercial demand
- Growing list of potential CDMO partners capable of meeting projected manufacturing needs
- Leveraging CDMO capabilities through commercial launch to enable future investment in in-house manufacturing capabilities

Source: BioInformant - The dominance of cell and gene therapy CDMOS in 2023

	Ph Ib	Ph II	Ph III	Commercial Y1	Commercial Y2	Commercial Y3	Commercial Y4+
Est. Demand (patient doses)	24	50-100	150-300	~400	~600	~1000	>1000
Vector	50L	200L	200L	200L	500L	500L	500L
Est. Capacity (doses/month)	~6	~6-12	20+	50+	100+	200+	200+
CDMO	Clinical Scale	Clinical Scale / Tech Transfer	Pivotal Study and Early Commercial Scale	Pivotal Study and Early Commercial Scale	Pivotal Study and Early Commercial Scale	Pivotal Study and Early Commercial Scale	
In-house					Facility Investment	Site Dev & Tech Transfer	Commercial Scale

Estimates are based on management's expectations, subject to change

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Experienced Management Team Backed by Expert Advisors

JEFF GALVIN
FOUNDER & CEO
Education & Experience

HARVARD UNIVERSITY

DREW PALIN, MD
PRESIDENT
Education & Experience

INTELLiVISIT SOLUTIONS
Stanford University
Preventice SOLUTIONS
MAYO CLINIC

BARRY WELLS, MD
DIRECTOR OF BUSINESS DEVELOPMENT
Education & Experience

KU SCHOOL OF MEDICINE
The University of Kansas
UNIVERSITY of MARYLAND MEDICAL SYSTEM

Advisors & KOLs

TOMMY THOMPSON
ADVISOR

United Therapeutics CORPORATION
Deloitte.

ROBERT REDFIELD, MD
Scientific Advisor

CDC
INSTITUTE OF HUMAN VIROLOGY

MARCUS CONANT MD
Clinical Advisor

- **One of the first physicians to diagnose HIV in San Francisco**
- **70+ published articles on treatment of AIDS**

MICHAEL SAAG, MD
Scientific Advisor

UAB CENTER FOR AIDS RESEARCH
Clinical Core

W. DAVID HARDY, MD
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Cedars Sinai
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