

Potential for an Innovative New HIV Treatment to Become the Preferred Therapy

Annandale, VA; June 26, 2023 - Gilead Sciences, Inc. has been a global leader in developing HIV/AIDS therapies for over 3 decades. The leaders and researchers of the Clinical Alliance for Research and Education-Infectious Diseases (CARE-ID) are proud to have collaborated with Gilead over the years for many of its developments. We are now partnering with Gilead again in pursuing what could be a truly monumental innovation in HIV treatment. This new clinical trial has just gotten started, and we are extremely excited to welcome our first study participants into the screening process.

Optimizing outcomes and reducing the laborious regimens of care for people living with HIV has been a goal for as long as HIV therapies have been offered. One key to achieving this goal has been developing longer acting options for patients. Lenacapavir (LEN) is a Gilead innovation with the potential to be a preferred and versatile foundational long-acting agent due to its therapeutic potency and a range of dosing frequencies and administration options.

Gilead HIV Clinical Development vice-president Jared Baeten said, “We’re excited to share promising Phase Ib clinical trial results that reinforce lenacapavir’s potential to be a foundational agent for long-acting combination HIV treatment options, and we are especially pleased to see the potential of the combination of lenacapavir plus bNAbs dosed once every six months. We are committed to exploring novel therapy approaches that may help deliver care for all people living with HIV, with a focus on developing person-centric options that fit into the diverse lives of people living with the virus, as we continue in our pursuit of ending the HIV epidemic for everyone, everywhere.”

CARE-ID yearslong focus on HIV research will take another step forward with this new clinical trial. This study will assess the efficacy and safety of the investigational combination regimen of lenacapavir with teropavimab and zinlirvimab as a potential twice-yearly approach in selected adult HIV patients, who were virologically suppressed for more than two years while taking antiretroviral therapy (ART).

“We are extremely excited about this new therapeutic approach not only for the long-acting benefit it potentially offers but also because the early phase study findings showed that the investigational combination was well tolerated and had high efficacy in select virologically suppressed HIV patients”, says David Wheeler, MD, FACP, FIDSA, principal study investigator, managing partner of Infectious Diseases Physicians, Inc. (IDP), the private clinical practice partner of CARE-ID. In the study, 90% of the participants who were receiving the complete study regimen maintained virologic suppression at week 26 and no serious adverse events (AEs) were overserved in the trial.”

Enrollment for screening with CARE-ID to participate in this new Phase II HIV clinical trial began on June 20th of this month. “Dr. Wheeler along with our entire staff will be supporting this study”, says Stephen Poretz, RN, MSHA, MBA, CARE-ID Chief Operating Officer. “Our study will be tightly focused on a select number of participants who be closely followed for the main phase of the study which will run for one year. But there may also be an extension phase that will run until the drug is available commercially.”

The basic qualification to participate in this study is for a person with HIV to have their condition stable and suppressed on current treatment for at least 6 months. Participants must also complete a 10-week screening period.

“Once enrolled, our study participant will have about 5 office visits in the first month. The subsequent follow up frequency will be every 3 months”, said Mr. Poretz. “The results of this trial are extremely important in establishing the long-acting nature of this therapy. Therefore, our study investigators and office support staff will each be acutely attentive to the results for each and every one of our participants. I am confident there will be multiple ongoing discussions and interactions to confirm every detail.”

Anyone interested in this clinical trial should visit the [CARE-ID website](#) for more detail or call the CARE-ID office between the hours of 9:00 AM and 5:00 PM Monday through Friday.

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About CARE-ID

The Clinical Alliance for Research and Education-Infectious Diseases, CARE-ID, conducts clinical research trials in the field of infectious diseases with particular focus on the safety and confidentiality of study participants, quality of data, and integrity of results. It partners with pharmaceutical and biotechnology companies to develop experimental therapies for both the prevention and treatment of infectious diseases.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. [Gilead](#) operates in more than 35 countries worldwide, with headquarters in Foster City, California.

Gilead was founded in 1987 under the name Oligogen by Michael L. Riordan. The original name was a reference to oligomers, small strands of DNA used to target genetic sequences. Gilead has successfully developed the drugs Biktarvy®, Truvada®, Hepsera®, Viread®, and Tamliflu® and many others.