

ACTG Launches HIV Cure Study Evaluating Novel Approach Targeting the HIV Reservoir

Small trial will test whether dasatinib, an approved leukemia medication, can help reduce the viral reservoir and enable HIV remission.

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Chapel Hill, N.C. -- ACTG, a global clinical trials network focused on HIV and other infectious diseases, today announced the recent opening of study A5413, a study that expands upon the network's commitment to finding a cure for HIV by looking at the HIV reservoir in people living with HIV who are on antiretroviral therapy (ART). A5413 is a randomized, double-blind, placebo-controlled clinical trial evaluating the safety, tolerability, and impact on the HIV reservoir of oral dasatinib among people living with HIV whose viral load is controlled by taking ART.

While current ART can manage HIV very well, it cannot cure it. To suppress their virus and protect their immune systems, people living with HIV must take ART for the rest of their lives. When taking ART, people living with HIV have latent HIV reservoirs – groups of immune cells that contain HIV but do not produce new copies of the virus. When people stop taking ART, the virus in the latent cells reactivates and infects new CD4 cells, thereby increasing the amount of HIV in a person's body. Very few clinical trials have evaluated the approach being studied in A5413, which is to stop CD4 cells with latent HIV from multiplying to reduce the reservoir.

"Research toward an HIV cure is a crucial area of investigation for ACTG, and we are dedicated to studying multiple approaches that have the potential to reduce, control, and ultimately eliminate the HIV reservoir," said ACTG Chair Joseph J. Eron, MD, University of North Carolina. "A5413 adds to our robust portfolio of clinical trials in this space, and we expect it will expand upon our understanding of dynamics related to the HIV reservoir."

A5413 will enroll 14 participants aged 18 years and above who have been taking ART continuously for at least four years and have been virally suppressed for at least three years. Participants will be randomized to either receive 100 mg of oral dasatinib [Sprycel, a leukemia medication] daily (eight participants) or matched placebo (six participants) for 12 weeks, and then followed for 24 weeks.

"Dasatinib is unique in that it has been shown to block the process by which T-cells divide and

multiply, which is known as cellular proliferation,” said Adam Spivak, MD, Study Chair, University of Utah School of Medicine. “A5413 will evaluate whether doing so can reduce the HIV reservoir and will hopefully provide insights more broadly into the role of cellular proliferation on HIV persistence.”

A5413 is the first study through ACTG’s Small Clinical Trials Advancing HIV Remission and Cure program to enroll participants. This program was developed to support small experimental trials that aim to advance efforts related to HIV remission and cure utilizing ACTG’s sites, laboratories, and other infrastructure in partnership with lab-based and translational scientists. These studies are typically small and involve one to three existing ACTG clinical research sites that have experience with these types of trials. The pathway aims to support trials that are intensive by nature and may include specialized assays or procedures, which would render them unsuitable for ACTG’s larger multi-site studies. For more information about the Small Clinical Trials program, [please click here](#).

A5413 is led by Dr. Spivak (Chair) and Jeffrey Jacobson, MD, Case Western University (Vice Chair). ACTG is led by Dr. Eron and Rajesh T. Gandhi, MD, Massachusetts General Hospital and Harvard Medical School (ACTG Vice Chair). It is sponsored by the National Institutes of Health’s (NIH) National Institute of Mental Health (NIMH) and National Institute of Allergy and Infectious Diseases (NIAID, which also funds ACTG) under award numbers UM1 AI068636, UM1 AI107716, and UM1 AI068634.

For more information about A5413, please visit clinicaltrials.gov.

About ACTG

ACTG is the world’s largest and longest running clinical trials network focused on HIV and other infectious diseases and the people living with them. It is funded by NIAID and collaborating NIH Institutes. Founded in 1987, ACTG conducts research and implementation science studies to improve the management of HIV and its comorbidities; develop a cure for HIV; and discover treatments for tuberculosis, hepatitis B, and emerging infectious diseases. It comprises thousands of dedicated researchers, staff, and community members who are pursuing research into novel treatments and cures for infectious diseases at 65 locations across four continents, with the ultimate goal of advancing science that meaningfully impacts the lives of the people we serve.

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