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MHRP Phase 2 Clinical Trial Launches to Evaluate IL-15 Agonist as Therapy to Reduce Establishment of HIV Reservoir

SILVER SPRING, Md. – The U.S. Military HIV Research Program (MHRP) at the Walter Reed Army Institute of Research last week launched a Phase 2 clinical trial in Thailand to evaluate an interleukin-15 (IL-15) superagonist, ImmunityBio's Anktiva® (also called N-803), administered during acute HIV infection as an experimental therapy to target establishment of the HIV reservoir at a very early stage.

The trial's participants are identified through MHRP's RV254 acute HIV infection cohort, which identifies individuals in the earliest post-infection stages. Volunteers will receive their first dose of IL-15 agonist and initiate antiretroviral therapy (ART) within days of the diagnosis of acute HIV infection.

A critical barrier to curing HIV is the reservoir of latent virus that remains hidden and infects cells throughout the body, and previous studies have shown that the reservoir is established very early in HIV infection.

"We hope that administering an IL-15 agonist alongside traditional ART will reduce the HIV reservoir in lymphoid tissues," said Dr. Denise Hsu, MHRP's associate director of therapeutics. "Ultimately this trial will help inform a strategy towards inducing long-term HIV remission."

In previous preclinical and clinical testing, ImmunityBio's Anktiva was shown to boost immune activation of natural killer cells and CD8+ T cells.

The study, called RV550, will enroll 15 participants who will receive three total doses of Anktiva, at weeks 0, 3 and 6 of the study. Researchers will compare levels of HIV RNA and DNA in lymph node samples pre- and post-treatment and evaluate the therapy's effects on CD8+ T and natural killer immune cells.

The study is conducted at The Thai Red Cross AIDS Research Centre in Bangkok.

“We’re grateful to the many committed volunteers in this study and the larger acute infection cohort, and also to our dedicated clinical study team,” said Dr. Kiat Ruxrungtham, professor of medicine at Chulalongkorn University and principal investigator of the trial. “Their contributions are vital to ongoing research to find a cure for HIV.”

The RV254 acute HIV infection cohort provides insight into critical early days after infection. The cohort serves as a foundation to help MHRP researchers conduct investigations into long term remission of HIV and tools that can serve to accomplish "functional cure," controlling the virus without the need for long term antiretroviral treatment. RV254 is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

This trial is registered on clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT04505501

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About MHRP

The U.S. Military HIV Research Program (MHRP), part of the Walter Reed Army Institute of Research, is at the forefront of the battle against HIV/AIDS to protect U.S. troops from infection and reduce the global impact of the disease. MHRP has been recognized as a leader in HIV diagnostics, epidemiology and vaccine research for over three decades and, more recently, has built an international reputation for pioneering discoveries in acute infection and remission. Its research is supported by a cooperative agreement (W81XWH-18-2-0040) between the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF), and the U.S. Department of Defense (DOD). The views expressed are those of the authors and should not be construed to represent the positions of the U.S. Army, the Department of Defense, or HJF.