Prezista Women's Study Opens for Enrollment

September 28, 2006 By Tim Horn

September 28, 2006 (AIDSmeds)—Tibotec Therapeutics has announced the initiation of a clinical trial evaluating different responses to HIV treatment among women and men. The Gender, Race, and Clinical Experience (GRACE) study will be the largest clinical trial conducted to date to explore this important issue.

Community advocates and healthcare providers frequently argue that there is an urgent need for clinical trials designed specifically for women with HIV. Statistics show that the ratio of women to men among Americans diagnosed with HIV has grown substantially since the HIV epidemic first emerged. While women account for almost 30% of new HIV diagnoses in the United States, they have been underrepresented in HIV clinical trials. This has been a major source of concern, in light of research indicating that women may have different tolerability issues to HIV medications than men.

The phase IIIb study will compare gender differences in the efficacy, safety, and tolerability of Prezista™ (darunavir) taken with other HIV medications over a 48-week treatment period. The study will also explore racial differences in treatment responses.

"The need for an increased focus on women living with HIV/AIDS was a key theme of the XVI International AIDS Conference in Toronto," said Dawn Averitt-Bridge, founder and Chair of the Board of The Well Project. "GRACE is an example of the steps that need to be taken to address the evolving HIV epidemic. The development of this trial included extensive collaboration with the HIV community. Women who participate in GRACE will play a very important role in advancing the understanding of HIV treatment in women."

The study will include approximately 50 sites in the U.S., Mexico, and Canada, and will seek to enroll approximately 420 participants, 70% of whom will be women. Participants must be of 18 years or older, have a viral load of 1000 or greater, and have previous intolerance or failure to prior therapy consisting of a protease inhibitor (PI) and/or non-nucleoside reverse transcriptase inhibitor (NNRTI). All participants will receive Prezista boosted with a low dose of Norvir, combined with other HIV drugs chosen by the investigator and based on resistance testing and prior treatment history.

For additional information regarding the GRACE study, see www.clinicaltrials.gov, call 1-866-512-7943, or email GRACEstudy@wilm.ppdi.com.

© 2026 Smart + Strong All Rights Reserved.

http://beta.docker.poz.com/article/Prezista-Women-s-Study-Opens-for-Enrollment-10628-1497