Isentress-Inclusive HIV Regimen Safe, Effective for Women, Blacks in Merck Study

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Results from Merck's REALMRK study conclude that Isentress (raltegravir) is both safe and effective, regardless of race or gender, among women and men either starting HIV treatment for the first time or switching to the integrase inhibitor after stopping other therapies because of treatment failure or intolerance. The 48-week data from the study were reported Sunday, September 18, at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Chicago.

Women and people of color account for increasing proportions of people living with HIV/AIDS in the United States, yet data on the efficacy and safety of antiretroviral (ARV) therapy in these populations remain limited. According to REALMRK study presenter Kathleen Squires, MD, of Jefferson Medical College of Thomas Jefferson University in Philadelphia and her colleagues, several challenges, including socioeconomic factors, have led to difficulties in recruiting—and keeping (retaining)—women in HIV treatment studies.

Isentress has been approved in the United States as an integrase inhibitor for treatment-experienced patients. It is also approved—and a "preferred" regimen component in the eyes of the U.S. Department of Health and Human Services—for people living with HIV starting ARV therapy for the first time.

REALMRK was designed to enroll a high proportion of women and people of color in order to assess gender- and race-based differences in efficacy and safety of Isentress. The study enrolled 209 people living with HIV, 156 (75 percent) of whom were black and 98 (47 percent) of whom were women. Twenty-two people who entered the study were set to begin HIV treatment for the first time; 98 had been on a failing regimen in the past; and 89 enrolled because they were intolerant to their previous regimen.

All participants, who were seen at clinics in North American, South America, the Caribbean and Southern Africa, received 400 milligrams (mg) Isentress for up to 48 weeks. The ARVs to be used in combination with Isentress were selected upon entering the study and were limited to approved and licensed agents.

After 48 weeks, about 70 percent of the entire study population using an Isentress-inclusive regimen had undetectable viral loads. Roughly 68 percent of the female volunteers and 72 percent of the male volunteers had viral loads below 50 copies. In addition, nearly 68 percent of the black patients and 78.0 of non-black patients had
undetectable viral loads after 48 weeks.

As for those who entered REALMRK after failing an earlier treatment, 66 percent of the males, 61 percent of the females, 64 percent of blacks and 64 percent of non-blacks had viral loads below 50 after 48 weeks.

Some differences in efficacy among those who entered the study because they weren't tolerating their previous regimen were reported. Undetectable viral loads were documented in nearly 81 percent of the males and 72 percent of the females who fell into this category. Even more notable was the comparison between blacks and non-blacks: 100 percent of non-blacks who entered REALMRK because of intolerance had undetectable viral loads after 48 weeks, compared with 69 percent of blacks who started an Isentress-inclusive regimen for the same reason.

As for those receiving an Isentress-inclusive regimen as first-time therapy, 71 percent of the males, 86 percent of the women, 79 percent of blacks and 71 percent of non-blacks had undetectable viral loads after 48 weeks. It is important to note, however, that the number of patients starting therapy for the first time in REALMRK was very small and, thus, scientific comparisons remain difficult.

The overall average CD4 count gain in the study was 111 cells. CD4 increases were most pronounced among those starting therapy for the first time—an average gain of 193 cells was reported—and weakest among those switching because of previous intolerance (an average gain of 64 cells was seen after 48 weeks of treatment).

About 15 percent of the study volunteers—17 percent of the females and 13 percent of the males—discontinued their study regimen before the end of the 48-week study.

Drug-related side effects were documented in 27 percent of the female study volunteers and 15 percent of the male volunteers. About 3 percent of the females, compared with 1 percent of the males, discontinued treatment because of these adverse events.

Roughly 22 percent of the black patients and 17 percent of non-black patients experienced drug-related side effects, with a little over 3 percent of the blacks and none of the non-blacks discontinuing treatment as a result.

The most commonly reported side effects included abdominal discomfort, diarrhea, nausea, vomiting, muscle pain/soreness and headache.

"Results from the REALMRK study demonstrate the benefits of Isentress in combination therapy in a diverse patient population that reflects the faces of many people living with HIV today," Squires

concluded of the data.