Isentress, Intelence and Prezista Combo Shines for Treatment Veterans

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A drug regimen containing Isentress (raltegravir), Intelence (etravirine) and Norvir (ritonavir)-boosted Prezista (darunavir) has pushed viral loads to undetectable levels in 90 percent of heavily treatment-experienced patients, according to astonishing new data from the Agence Nationale de Recherches sur le Sida et les Hépatites Virales (ANRS) 139 TRIO study reported at the XVII International AIDS Conference (IAC) in Mexico City.

Isentress, Intelence and Prezista are three of the newest antiretrovirals (ARVs), approved specifically for treatment-experienced people living with HIV. Because these compounds were being evaluated in clinical trials around the same time, studies evaluating the use of all three agents together were not possible. However, because these three drugs have demonstrated effectiveness against HIV resistant to older ARVs, they were expected to perform well when used together.

Only now have researchers documented exactly how much regimens containing these three agents have to offer patients with a great deal of previous treatment experience under their belts.

The TRIO study, reported at IAC by Yazdan Yazdanpanah, MD, PhD, of the Centre Hospitalier de Tourcoing in Tourcoing, France, enrolled 103 HIV-positive patients to take Insetress, Intelence and Norvir-boosted Prezista with an optional background regimen of nucleoside reverse transcriptase inhibitors (NRTIs) with or without Fuzeon (enfuvirtide).

Eighty-eight percent of the patients were male, and the average age was 45. The average viral load upon entering the study was 10,000 copies, and the average CD4 cell count was 255. Patients had been on ARV treatment for an average of 13 years.

As for pre-treatment resistance profiles, patients in TRIO had an average of four major PI mutations, five major NRTI mutations and one major NNRTI mutation in their HIV, which was evidence of significant drug resistance. Additionally, 96 percent and 65 percent of patients had between one and three HIV mutations conferring at least partial resistance to Prezista and Intelence, respectively. The authors also reported that 59 percent of the patients were using a background regimen that didn't contain any ARVs that were fully active against their HIV.

Yet the results after six months were remarkable. According to Dr. Yazdanpanah, 90 percent of

patients had viral loads below 50 copies after 24 weeks. The average viral load reduction, from the start of the study, was 2.4 log.

Of the 10 patients with detectable virus at week 24, only three had viral loads in excess of 400 copies. Another three saw their viral loads drop to below 50 by week 32 of the study.

Yazdanpanah and his colleagues also observed an average CD4 count increase of 99 cells after 24 weeks.

The regimens containing Isentress, Intelence and Norvir-boosted Prezista were also reported to be “generally well tolerated.” Two possible severe side effects were reported: rash and fever in one patient and kidney stones in another. Significant increases in creatinine levels-a sign of muscle damage-were noted in five patients, and in one patient with hepatitis C virus coinfection, a sharp increase in the liver enzyme GGT was reported.

Only one treatment discontinuation due to side effects-the patient with rash and fever-has been reported thus far.

Yazdanpanah said that the study is ongoing and that additional data from the 48- and 96-week time points will be reported.

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