Lexiva vs. Reyataz: Comparable Efficacy

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New data from a study comparing Lexiva (fosamprenavir) to Reyataz (atazanavir), both combined with Norvir (ritonavir), indicates that these top-choice protease inhibitor (PI) options for HIV-positive patients beginning therapy for the first time are similar in their effectiveness. The 48-week results, along with a second study reported at the fourth IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2007) in Sydney, also suggest that the Norvir dose currently used to boost Lexiva levels in the bloodstream can be halved without compromising the drug combination's effectiveness.

PIs combined with low-dose Norvir have become increasingly popular treatment options. This is based on a litany of research conducted over the past several years indicating that Norvir boosting can help maximize effectiveness and ease dosing. Kaletra, containing lopinavir and Norvir, is already a widely prescribed boosted PI; given the accumulation of positive data from ongoing studies, regimens containing Norvir-boosted Lexiva or Reyataz are gaining in popularity as well.

The ALERT study, reviewed at IAS 2007 by Keith Pappa, MD, of GlaxoSmithKline, enrolled 106 HIV-positive people starting HIV treatment for the first time. Patients were randomized to receive Reyataz (300 mg) plus Norvir (100 mg) once daily or Lexiva (700 mg) plus an experimental, lower-than-usual dose of Norvir (100 mg, instead of the recommended 200 mg) once daily. All patients also received standard doses of once-daily Truvada (tenofovir plus emtricitabine).

Upon entering the study, the 106 HIV-positive patients enrolled had average viral loads of 80,000 copies and CD4 counts of 190 cells.

After 48 weeks of treatment, 75 percent of those in the Lexiva group had viral loads below 50 copies; in the Reyataz group, approximately 83 percent had viral loads below 50. The difference between the two groups wasn't statistically significant, meaning that it could have been due to chance.

CD4 count improvements were also similar in both groups. There was a gain of 170 CD4 cells in the Lexiva group, compared to 183 cells in the Reyataz group.

As for side effects, moderate cholesterol level increases, including "bad" LDL and "good" HDL, were documented in both groups. The only statistically significant difference involved triglyceride levels, which increased by an average of 34 mg/dL in the Lexiva group, compared to an average increase of only 7 mg/dL in the Reyataz group.

The most notable side-effect difference between the two groups was an increase in bilirubin levels (which can cause otherwise harmless yellowing of the eyes, skin and nails), which occurred in 30 percent of patients taking Reyataz compared to no one in the Lexiva group.

Rates of diarrhea, while relatively rare in both groups, were twice as common among those in the Lexiva group (8 percent vs. 4 percent).

Also of note are data from a second study exploring key differences between the 100 mg and 200 mg Lexiva-boosting dose of Norvir. Among the 115 patients starting therapy for the first time—they received Lexiva, one of the two Norvir doses, plus Epzicom (abacavir plus lamivudine)—84 percent of the patients in the 100 mg group had viral loads below 400 copies after 48 weeks, compared to 67 percent of patients in the 200 mg group. This difference was statistically significant.

According to Duke University's Charles Hicks, MD, who presented the dose comparison at IAS 2007, clinically meaningful—greater than 20 percent—declines in arm and leg fat (a possible sign of lipoatrophy) and increases in trunk fat (a possible sign of lipohypertrophy) occurred in both groups of patients. While he report that these more pronounced changes occurred less frequently in patients receiving the 100 mg Norvir booster once a day, compared to those in the 200 mg group, the differences were not statistically significant.

Changes in cholesterol and triglyceride levels were similar between the two groups.

Dr. Hicks pointed out that the 100 mg boosting dose of Norvir, while not yet approved, is currently being reviewed by the U.S. Food and Drug Administration.
