ICAAC: Norvir-Boosted Lexiva vs. Reyataz

October 2, 2006 By Tim Horn

October 2, 2006 (AIDSmeds)—Early data from a study comparing Lexiva® (fosamprenavir) to Reyataz® (atazanavir), both combined with low-dose Norvir® (ritonavir), suggest that both drugs have similar effectiveness. The 24-week study results were reported as a late-breaker slide presentation on Friday at the 46th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in San Francisco.

Protease inhibitors (PIs) combined with low-dose Norvir have become increasingly popular treatment options in recent years. 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, remains one of the most widely prescribed boosted PIs.

Other popular PIs, including Lexiva and Reyataz, are frequently boosted with Norvir. But only recently has there been data from clinical trials conducting head-to-head comparisons between boosted PI options. At the International AIDS Conference (IAC) this past summer in Toronto, there was a report from a study suggesting that the effectiveness of Norvir-boosted Lexiva is comparable to Kaletra. And at ICAAC, while no comparison to Kaletra was made, Norvir-boosted Lexiva and Reyataz both appear to be doing well in a clinical trial evaluating the two agents.

Twenty-four week data from the 48-week ALERT study were reported at the conference by Kimberly Smith, MD, of Cook Country Hospital in Chicago and her colleagues. The study has enrolled 106 HIV-positive people starting HIV treatment for the first time. Patients have been randomized to take either Reyataz (300mg) plus Norvir (100mg) once daily or Lexiva (700mg) plus an experimental, lower-than-usual dose of Norvir (100mg, instead of the recommended 200mg) once daily. All patients are also receiving standard doses of once-daily Viread (tenofovir) and Epivir (emtricitabine).

Upon entering the study, the 106 HIV-positive patients enrolled had average viral loads of 79,000 and CD4 (T4 cell) counts of 173.

After 24 weeks, 79% of those in the Lexiva group had viral loads below 50; in the Reyataz group, approximately 83% 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 126 CD4 cell gain in the Lexiva group, compared to a 156 gain in the Reyataz group.

As for side effects, some time was spent reviewing changes in cholesterol and triglycerides, as these aren't significantly affected by Reyataz and are only moderately increased when a Norvir boosted is used. In ALERT, cholesterol levels – including LDL and HDL – increases after 24 weeks were modest and similar in both treatment groups. The only statistically significant difference involved triglyceride levels, which increased by an average of 44 mg/dL in the Lexiva group, compared to an average 6 mg/dL increase 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), occurring in 44% of patients taking Reyataz compared to no bilirubin increases in the Lexiva group.

Final results of ALERT, to be reported after 48-weeks of follow-up data have been collected, are expected in early 2007. Until then, Dr. Smith and her colleagues remarked that the interim data suggest comparable efficacy between Norvir-boosted Reyataz and Lexiva.
