Once- vs. Twice-Daily Kaletra for Treatment Veterans

July 28, 2009 By Tim Horn

Once-daily Kaletra (lopinavir/ritonavir) dosing may be an option for treatment-experienced people living with HIV, according to study results presented July 21 at the Fifth International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention in Cape Town. Caution may be necessary, however, for individuals with more than three key mutations in their HIV's protease gene, because once-daily dosing might not be potent enough to keep viral load undetectable.

In the United States, Kaletra has been approved by the U.S. Food and Drug Administration (FDA) for use once or twice daily in people starting HIV treatment for the first time, with a total daily dose of 800 mg lopinavir and 200 mg ritonavir using either schedule. Data reported in February 2008 at the 15th Conference on Retroviruses and Opportunistic Infections helped confirm that once- and twice-daily doses of Kaletra tablets have similar tolerability and comparable efficacy in first-time treatment takers.

Twice-daily Kaletra is approved by the FDA—and is the only recommended dosing option—for treatment-experienced patients. However, there has been an interest in exploring the possibility of once-daily dosing for antiretrovirals (ARVs) that currently must be taken twice-a-day by treatment-experienced individuals, many of whom suffer from adherence struggles that might be easily remedied with a simplified dosing schedule.

To better understand the safety and efficacy of once- and twice-daily dosing of the Kaletra tablets in treatment-experienced individuals, Abbott funded an international clinical trial involving 599 HIV-positive patients who had been on ARVs in the past (not not Kaletra) and had pre-study viral loads of at least 1,000 copies. For 48 weeks, 300 people took four Kaletra tablets plus at least two nucleoside reverse transcriptase inhibitors (NRTIs) once a day, whereas 299 took two Kaletra tablets plus at least two NRTIs twice a day.

According to Sharlaa Badal-Faesen, MD, of the University of Witwatersrand in Johannesburg, slightly less than half of the study volunteers had been on at least one protease inhibitor in the past.

About 55 percent of those in the once-daily Kaletra group and 51 percent in the twice-daily Kaletra group had viral loads below 50 copies after 48 weeks. As this difference was so slight, the once-daily results were said to be "non-inferior" to the twice-daily findings—meaning there was comparable efficacy between the two groups.

It's important to note, though, that those who entered the study with HIV containing at least three

key resistance mutations associated with the earlier use of protease inhibitors were much less likely keep viral loads undetectable for 48 weeks in the once-daily group compared with the twice-daily group: 30.8 percent versus 57.1 percent, respectively. Among those with HIV harboring fewer than three protease inhibitor mutations, no significant differences in effectiveness were reported.

CD4 cells increased equally in both treatment groups—about 130 cells after 48 weeks of treatment.

As for side effects, diarrhea was not less common in the once-daily Kaletra group than in the twice-daily Kaletra group. However, nausea occurred in 2.7 percent of those in the once-daily Kaletra group compared with 7.4 percent of those in the twice-daily group—a statistically significant difference.

It is unclear if these encouraging data will be enough to support the FDA approval of once-daily Kaletra for treatment-experienced people living with HIV.

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