Norvir Tablets Similar to Capsules, Expected in 2009

August 15, 2008 By Tim Horn

Abbott Laboratories has developed a tablet version of its protease inhibitor (PI) Norvir (ritonavir), typically used in drug regimens to boost blood levels and the effectiveness of other PIs. Study results presented at the XVII International AIDS Conference (IAC) in Mexico City indicate that the heat-stable tablet results in similar blood levels of the drug compared with the approved capsule formulation.

The new Norvir tablet uses the same melt extrusion (Meltrex) technology that allowed Abbott to develop a tablet version of Kaletra (lopinavir/ritonavir), which ultimately replaced the older capsule version of that drug. Unlike Norvir capsules, the Norvir tablets will not require refrigeration, making it more convenient for people living with HIV to use, particularly in low- and middle-income countries.

Abbott plans to request approval of the Norvir tablets in the United States and European Union before the end of the year, likely making it available in 2009. It plans to make the new tablets available wherever Kaletra is available—about 157 countries around the world.

The study reported at IAC by Barry Bernstein, MD, of Abbott, involved 93 HIV-negative male and female volunteers. For the most part, blood concentrations using Norvir capsules and the experimental tablets were similar. Dr. Bernstein noted that the peak concentration—the highest level of the drug following a single dose—was 26 percent higher using the tablets compared with the capsules.

In a similar study comparing the Kaletra formulations, Bernstein noted the Kaletra tablets resulted in a 20 percent peak concentration increase over that of Kaletra capsules. This, however, was not associated with a higher risk of side effects. In fact, some studies suggest that Kaletra tablets cause fewer side effects—notably gastrointestinal problems—than Kaletra capsules.

In fact, side effects were similar among the HIV-negative volunteers participating in the current study. Headache, nausea, dizziness and diarrhea were the most common, but they occurred in less than 10 percent of participants with no significant differences between those taking Norvir capsules and those receiving Norvir tablets.

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