Kaletra Tablets for Children Show Equivalency

October 29, 2007 By Tim Horn

A lower-strength tablet version of Kaletra (lopinavir plus ritonavir) is expected to work well in HIV-positive children, according to new data presented last week at the 11th European AIDS Conference (EACS) in Madrid. Researchers have also come up with pediatric dosing recommendations using the new tablet, which has not yet been approved by the U.S. Food and Drug Administration (FDA).

Kaletra is currently approved for the treatment of HIV-positive adults and children 2 years of age and older. For pediatric patients, Kaletra dosing is based on body surface area (BSA) or body weight and generally requires the use of a liquid formulation of the drug. However, the liquid formulation contains 42 percent alcohol (ethanol) and has been described as "bad tasting." A tablet version of the drug, each containing 200 mg lopinavir and 50 mg ritonavir, is approved and widely available, but only for HIV-positive adults. As it does not contain alcohol and has been reported to be easier on the stomach than other versions of the drug—including the gel-cap and liquid formulation—there has been much interest in seeing a Kaletra tablet developed for HIV-positive children who are able to swallow pills.

Abbott Laboratories has developed pale pink and yellow tablets containing 100 mg lopinavir and 25 mg ritonavir for pediatric patients. The pediatric tablets are still being reviewed for approval by the FDA and other regulatory agencies around the world.

Data from two key studies involving the 100/25 mg tablets were reported at EACS by Abbott researchers. The first compared the bioavailability—the amount of drug in the blood following dosing—in HIV-negative study volunteers taking either four 100/25 mg tablets or two 200/50 tablets (the dose currently approved for HIV-positive adults). The second was a model designed to predict dosing for children of varying BSAs or body weights, including those taking other medications—notably Sustiva (efavirenz), Viramune (nevirapine) and Lexiva (fosamprenavir)—known to interact with Kaletra.

The bioavailability study found that the 100/25 mg tablets were equivalent to the 200/50 mg tablets. In turn, the researchers noted, they can be expected to achieve the necessary therapeutic drug concentrations in HIV-positive children.

The dosing model predicted that, for children weighing between 7 to 10 kg (15.4 to 22 pounds), the dose will need to be one tablet twice a day. For children weighing 10 and 25 kg (22 to 55

pounds), two tablets twice a day will be necessary. For those weighing between 25 and 35 kg (55 to 77 pounds), three tablets twice a day is recommended. And for pediatric patients weighing 35 kg (77 pounds) or more, either four pediatric tablets—or two adult tablets—will be necessary.

Among children taking Sustiva, Viramune or Lexiva, one tablet twice a day is recommended for those weighing between 7 and 10 kg, two tablets twice a day for those weighing between 10 and 20 kg, three tablets twice a day for those weighing between 20 and 30 kg, and four pediatric tablets—or two adults tablets—for those weighing more than 30 kg.

In conclusion, the researchers noted that Kaletra 100/25 mg tablets are “bioequivalent” to the current 200/50 mg Kaletra tablets. “These lower-strength tablets,” they report, “will allow sufficient [Kaletra] dosing flexibility for pediatric patients who can swallow intact tablets.”
