Prezista Effective and Safe in Positive Kids

February 9, 2008 By Tim Horn

Prezista (darunavir) is showing promise for treatment-experienced HIV-positive children between the ages of six and 17, according to early data from a clinical trial reported this week at the 15th Conference on Retroviruses and Opportunistic Infections (CROI). U.S. Food and Drug Administration (FDA) of Prezista for children will depend on the successful completion of this study.

Like adults, HIV-positive children—many of whom have been receiving antiretroviral (ARV) treatment since birth—rely on the availability of new ARVs that have been shown to work against drug-resistant virus. Unfortunately, several ARVs that have been shown to be effective in treatment-experienced adults have not been adequately studied in HIV-positive children and, consequently, are not yet approved for pediatric patients. Not only do the doses of ARVs need to be tested and confirmed—dosing is usually based on a child's increasing body weight as he or she ages—the safety and efficacy of these medications in children need to be explored as well.

Prezista (darunavir) is one of two approved protease inhibitors (PIs)—Aptivus (tipranavir) is the other—that have been shown to work well in HIV-positive adults with virus resistant to other PIs and have become an integral component of ARV therapy for treatment-experienced patients. Data from a Phase II study exploring the safety and effectiveness of Aptivus in children were first reported at the 16 International AIDS Conference, held in Toronto in July 2006.

At CROI, data from a Phase II study evaluating the dosing, safety and effectiveness of Prezista in HIV-positive children were reported by Sabrina Spinosa-Guzman, MD, of Tibotec and her colleagues. The study enrolled 80 children between six and 17 years of age—the average being 14 years old—and dosed patients according to their body weight. Children weighing between 20 kg (44 pounds) and 30 kg (66 pounds) took 375 mg Prezista with 50 mg Norvir (ritonavir) twice a day, children between 30 and 40 kg (88 pounds) took 450/60 mg twice daily, and those weighing 40 kg or more took the standard adult dose—600/100 mg twice daily.

All children were highly treatment experienced. They had used, on average, nine antiretrovirals in the past. At the start of the study, viral loads averaged 43,600 copies and the median CD4 count was 330 cells. All patients in the study also used an optimized background regimen (OBR).

After six months of treatment, approximately three quarters of the patients had viral loads that were at least 1 log below their baseline levels. Dr. Spinsoa-Guzman and her colleagues reported that this was a primary objective of the study and confirms a virologic response to Prezista

treatment Fifty percent of the children had undetectable viral loads—below 50 copies—after 24 weeks. CD4 counts increased by approximately 117 cells.

The most common side effects, occurring in more than 10 percent of the children, were upper respiratory tract infections, cough, fevers, vomiting, diarrhea, and swollen lymph nodes. Dr. Spinosa-Guzman noted that most of these side effects were mild to moderate. Serious side effects were reported in 9 (11 percent) of the children.

Dr. Spinosa-Guzman's group concluded that Norvir-boosted Prezista is effective in treatment-experienced children, with a favorable tolerability profile. These data will be submitting to the FDA, seeking approval of the PI for HIV-positive pediatric patients.

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