First Data From Injectable PRO 140 Study

February 12, 2009 By Tim Horn

Delegates attending the 16th Conference on Retroviruses and Opportunistic Infections (CROI) in Montreal got a first look at data from a clinical trial testing injections of PRO 140, an experimental entry inhibitor. Two dosings were injected three weeks in a row; a third dose was injected every other week. The data, presented by Melanie Thompson, MD, of the AIDS Research Consortium of Atlanta on Monday, February 9, indicate that Progenics Pharmaceuticals, the drug's developer, can abandon its original intravenous formulation of the drug and continue focusing on the subcutaneously administered formulation.

PRO 140 is a laboratory-made antibody that binds to a protein on the CCR5 membrane of CD4 cells. Once PRO 140 does this, HIV cannot successfully bind with the surface of CD4s; thus the virus is prevented from infecting healthy cells. While Pfizer's Selzentry (maraviroc) works differently from PRO 140, both drugs target CCR5 and are considered HIV entry inhibitors.

The Phase II clinical trial results presented by Thompson's group involved 44 people living with HIV who were either treatment naïve—they'd never been on antiretrovirals—or had been off HIV treatment for at least three months. Patients were randomized to receive three weekly doses of 162 mg PRO 140, two doses of 324 mg PRO 140 administered every other week, three weekly doses of 324 mg PRO 140, or placebo. Volunteers were followed for a total of 58 days to evaluate safety and antiviral effects of the drug compared with placebo.

On day 22 of the study—a week after the last dose of PRO 140 or placebo—a viral load reduction of 1.51 log was reported among patients receiving once-weekly 324 mg PRO 140, compared with an average 0.15 log increase in viral load among the placebo recipients. This finding was highly statistically significant, meaning the difference between the two groups was too great to have occurred by chance.

Statistically significant viral load reductions were also seen in patients receiving the lowest dose of PRO 140 (-0.75 log) and every-other-week dosing (-1.22 log) compared with placebo. More than 90 percent of patients receiving PRO 140, regardless of their dosing group, saw their viral loads decreased by at least 1 log.

Whether or not there were statistically significant differences between the three groups receiving active drug was not reported.

No significant differences in CD4 count increases during this short study were reported, though there was a trend toward greater CD4 gains among those in the highest PRO 140 dose group.

Injection-site reactions were documented in several patients, although these were generally mild and resolved within a few days after drug administration. Other side effects, seen in all study groups, included headaches, diarrhea, constipation, high blood pressure and upper respiratory infections.

Progenics announced that it plans to move forward with Phase II development of PRO 140, using subcutaneous dosing, in light of these encouraging results.

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http://beta.docker.poz.com/article/hiv-PRO140-entry-16098-9423