PRO 140 Shows Promise in Single-Dose Study

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Researchers at the fourth IAS Conference on HIV Pathogenesis, Treatment and Prevention, in Sydney, reported encouraging results from an early study of PRO 140, an experimental HIV entry inhibitor. Of particular interest was the fact that viral loads remained 90 percent below pretreatment levels two to three weeks after a single dose of the drug.

PRO 140 is a laboratory-made antibody that binds to a protein on the CCR5 membrane of CD4 cells. Once it does this, HIV cannot successfully bind with the surface of CD4s; thus the virus is prevented from infecting healthy cells.

While Pfizer's maraviroc, which is being considered for approval by the U.S. Food and Drug Administration, works differently than PRO 140, both drugs target CCR5 and are being tested as HIV entry inhibitors.

Progenics' clinical trial, conducted at 10 sites in the United States, examined three single intravenous doses of PRO 140: 0.5 milligram per kilogram (mg/kg) of body weight, 2.0 mg/kg and 5.0 mg/kg. A total of 39 HIV-positive patients, none of whom had used antiretrovirals in the past, were enrolled in the study.

All patients were screened prior to the study for the presence of virus that utilizes only CCR5 as its entry coreceptor (as opposed to the CXCR4 coreceptor). Of the 13 patients in each dosing group, 10 patients received PRO 140 and three received placebo.

No other HIV medications were taken in the study.

Viral load reductions were the chief focus of the study. Patients who received 5.0 mg/kg of PRO 140 achieved an average maximum viral load drop of 1.83 log, with some patients achieving viral load reductions of 2.5 log.

Ten days after receiving single-dose PRO 140, viral loads dropped by an average of 1.7 log in the 5.0 mg/kg group, compared to average reductions of 1.2 log in the 2.0 mg/kg group, 0.58 log in the 0.5 mg/kg group and 0.39 log in the placebo group. And after two to three weeks, patients who received 5.0 mg/kg PRO 140 still averaged viral loads 1.0 log below pretreatment levels.

CD4 counts increased, on average, by 129 cells in the 5.0 mg/kg PRO 140 group by day eight. The

elevations in all groups persisted for approximately three weeks after the drug was administered.

Additionally, the study found PRO 140 to be generally well tolerated with no serious drug-related adverse events reported. Two of the 39 patients in the study experienced a switch in their HIV tropism, from CCR5-using virus to dual-tropic (CCR5 and CXCR4) virus.

Progenics also reported that it has developed a subcutaneous injection version of PRO 140. Based on favorable laboratory tests, the company plans to advance the subcutaneous formulation into clinical trials later this year, with the goal of developing a long-acting self-administered therapy for HIV infection.

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http://beta.docker.poz.com/article/PRO140-HIV-Entry-12672-5546