Two-Year Vicriviroc Benefit in Treatment-Experienced Patients

September 20, 2007 By Tim Horn

Schering-Plough's vicriviroc may offer long-lasting viral load reductions in treatment-experienced patients who combine the drug with an optimized background regimen (OBR). The two-year follow-up data—the longest study of a CCR5-blocking entry inhibitor reported to date—were reported this week at the 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Chicago.

After HIV binds to the CD4 protein on T-cells, the virus must then latch onto another receptor on the cell's surface—either CCR5 or CXCR4. Vicriviroc, like Pfizer's recently approved Selzentry (maraviroc), is specifically active against virus that uses the CCR5 receptor. A laboratory test—Monogram Bioscience's Trofile assay—was used to make sure that all patients enrolled in the vicriviroc study had virus that was tropic for the CCR5 receptor.

The primary goal of the study, conducted by the AIDS Clinical Trials Group (ACTG study 5211), was to see how well three different doses of vicriviroc—5, 10 and 15mg, all taken once a day—worked without other medications over 14 days in HIV-positive people who had tried other HIV treatments in the past.

The study was then expanded to evaluate vicriviroc's safety and efficacy when used in combination with OBR in 118 treatment-experienced patients. During this phase of the study, the 5mg dose of vicriviroc was discontinued, due to poor efficacy.

After successfully completing 48 weeks in the expanded trial, patients were invited to participate in an open-label extension of the study, providing 15mg vicriviroc to be used in combination with OBR.

The original 48-week data from ACTG 5211 were reported this past summer at the Fourth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Sydney. Participants taking either 10mg or 15mg vicriviroc decreased their viral loads by approximately 1.92 log and 1.44 log, respectively. Undetectable viral loads (below 50 copies) were seen in 37 percent of those in the 10mg group and 27 percent of those in the 15mg group by week 48.

Results from the extension study, presented at ICAAC by Roy M. Gulick, MD, MPH, of Weill Medical College of Cornell University in New York, involved 39 HIV-positive patients. After two years of 15mg vicriviroc plus OBR, viral loads were approximately 2.2 log copies below pre-study levels. Sixty percent of the patients maintained viral loads below 50 copies.

CD4 counts, after a total of two years of vicriviroc-inclusive treatment, were approximately 84 cells above pre-study levels. Other than pulmonary tuberculosis in one patient, no opportunistic infections were documented during the study. There were no reports of liver toxicity or new cancers—encouraging news in light of earlier data suggesting that vicriviroc might be associated with an increased risk of these problems.

During the open-label extension, two patients saw their viral loads rebound while on vicriviroc. Six patients saw their HIV switch from CCR5-using to either CXCR4-using or dual/mixed virus, thereby limiting the effectiveness of vicriviroc.

Schering-Plough is currently conducting a Phase II clinical trial of its own, testing higher doses of vicriviroc in treatment-experienced patients. The study, dubbed VICTOR-E1, is comparing 20mg and 30mg doses of the drug to placebo, in combination with an optimized Norvir-boosted, protease inhibitor–containing antiretroviral regimens.

On September 17, the company announced that it has initiated two Phase III studies, dubbed VICTOR-E3 and VICTOR-E4, evaluating the safety and effectiveness of 30mg vicriviroc plus OBR in treatment-experienced patients throughout the Americas, Africa, Australia and Europe. Information about the trials can be found on the U.S. National Institutes of Health's clinicaltrials.gov website.

Source:

Gulick R, Haas D, Collier A, et al. **Two-year follow-up of treatment-experienced patients on vicriviroc (VCV)** [Abstract H-1030]. 47th Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, 2007.

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