Vicriviroc in Combination Therapy With an Optimized Antiretroviral Regimen for Treatment-Experienced Subjects: The VICTOR-E1 Trial

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To the Editor:}

Background: HIV is a non-gonosomal retrovirus (SIV, simian immunodeficiency virus) that causes a disease with a high variability of presentation and severity. While most patients develop a chronic disease and develop a well-controlled infection, some patients develop a rapid progression of the disease and develop a well-controlled infection, some patients develop a rapid progression of the disease and associated complications. These complications include opportunistic infections, malignancies or other conditions. The introduction of antiretroviral therapy has improved the survival and quality of life of patients with HIV infection. However, the development of resistance to antiretroviral drugs remains a major challenge in the treatment of HIV infection. The use of combination antiretroviral therapy (ART) has been shown to improve virologic suppression and reduce the risk of resistance. However, the emergence of resistance to ART is still a major concern. The use of combination antiretroviral therapy with a new drug, vicriviroc (VCV), has shown promising results in phase 2 and 3 clinical trials. The VICTOR-E1 trial was a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of VCV in combination with an optimized antiretroviral regimen (OBT) in treatment-experienced HIV-infected patients.

Methods: This was a multinational, randomized, double-blind, placebo-controlled study with a 2:2:1 randomization ratio. 116 subjects were randomized 1:1:1 to VCV 20 mg, VCV 30 mg, or Placebo. The primary endpoint was the proportion of subjects with HIV RNA <200 copies/mL and CD4 count ≥200 cells/µL at 48 weeks. Other endpoints included virologic suppression at 24 weeks, change in CD4 count from baseline and change in weight from baseline, and safety and tolerability. The study was conducted at 28 sites in 16 countries.

Results: The median age of the subjects was 50 years, 80% were male, 90% were African-American, 7% were white, 2% were Asian, and 2% were Hispanic. HIV-infected subjects had a median CD4 count of 140 cells/µL and a median HIV RNA of 50,000 copies/mL. The median time on antiretroviral therapy was 7 years. At 48 weeks, 33% of the subjects randomized to VCV 20 mg, 34% of the subjects randomized to VCV 30 mg, and 24% of the subjects randomized to Placebo achieved virologic suppression. The median change in CD4 count was 22 cells/µL for VCV 20 mg, 24 cells/µL for VCV 30 mg, and 17 cells/µL for Placebo. The median change in weight was 1.0 kg for VCV 20 mg, 1.2 kg for VCV 30 mg, and 1.0 kg for Placebo. The most common adverse events were upper respiratory infections, headache, and dizziness. The rate of serious adverse events was similar across all treatment groups.

Conclusions: VCV showed promising results in this study, with a virologic suppression rate of 33% in the VCV 20 mg group and 34% in the VCV 30 mg group, compared to 24% in the Placebo group. The median change in CD4 count was also higher in the VCV groups compared to Placebo. The safety profile was similar across all treatment groups. These results support the further development of VCV in combination with OBT for treatment-experienced HIV-infected patients.

References:


