Victrelis Keeps Hep C Viral Load Undetectable for 24 Weeks in 7 of 10 Coinfected Patients

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Seventy percent of people coinfected with HIV and genotype 1 hepatitis C virus (HCV) have undetectable HCV viral loads after 24 weeks of treatment with Merck's HCV protease inhibitor Victrelis (boceprevir) combined with pegylated interferon and ribavirin, according to interim study results reported at the annual meeting of the Infectious Disease Society of America (IDSA) on Saturday, October 22, in Boston.

Victrelis, like Vertex Pharmaceuticals' Incivek, was approved in May 2011 for the treatment of chronic genotype 1 HCV—the most common, most difficult-to-treat form of the liver infection in the United States. Neither drug has been approved specifically for people coinfected with HIV and HCV, given a lack of safety and efficacy data from clinical trials involving patients living with both diseases. However, Phase II studies are ongoing, and Phase III clinical trials are planned.

Earlier this year, at the 18th Conference on Retroviruses and Opportunistic Infections (CROI), experts got their first glimpse at the efficacy of the HCV protease inhibitors in people living with HIV/HCV coinfection. Twelve-week preliminary results from a Phase II study suggested that 68 percent of those treated with the Incivek plus pegylated interferon and ribavirin had undetectable HCV viral loads at week 12—known as an early virologic response (EVR), an excellent sign of hepatitis C being cured once treatment is stopped—compared with 14 percent of those receiving pegylated interferon/ribavirin alone.

The preliminary Victrelis results, reported at IDSA by Mark Sulkowski, MD, of the Johns Hopkins University School of Medicine, comes from a clinical trial that randomized 100 coinfected individuals who hadn't yet been treated for their HCV disease to receive either Victrelis or a placebo plus pegylated interferon and ribavirin. All patients were on stable antiretroviral therapy—unboosted protease inhibitors, non-nucleoside reverse transcriptase inhibitors, Videx (didanosine) and Retrovir (zidovudine) were not permitted because of possible drug interactions—and all patients had undetectable viral loads upon entering the study.

The analysis reported by Sulkowski involved a total of 98 study volunteers: 64 patients in the Victrelis group and 34 patients in the control group. All patients received a four-week lead-in with pegylated interferon plus ribavirin alone followed by the addition of Victrelis or placebo for 44 weeks.

At 12 weeks, 56.5 percent of patients in the Victrelis group, compared with 25 percent of those in the placebo group, had undetectable HCV viral loads, which translated into a 31.5 percent difference between the two groups.

At 24 weeks, 70.5 percent of those in the Victrelis group had undetectable viral loads, compared with 34.4 percent of those in the placebo group. This translated into a 36.1 percent difference between the two groups.

In the study of Incivek reported at CROI, also by Sulkowski, the difference between the placebo group and treatment group was 44 percent. However, the studies were different enough in their design and study population—for example, nearly one quarter of patients in the Incivek study were not on antiretroviral therapy during the study—to make comparisons between the two drugs difficult at best.

Preliminary safety data for Victrelis involving the coinfected patients were similar to those documented in patients infected only with HCV.

The most common side effects associated with taking Victrelis, compared with placebo, were low neutrophil counts (13 percent versus 3 percent), abnormal taste (25 versus 15 percent), vomiting (25 versus 15 percent), fevers (34 versus 21 percent), headache (28 versus 12 percent) and decreased appetite (30 versus 18 percent).

In conclusion, Sulkowski's group reported, Victrelis plus pegylated interferon/ribavirin was associated with higher rates of undetectable HCV viral loads at weeks 12 and 24. While there were more side effects among those receiving Victrelis, compared with placebo, the overall safety and tolerability profile was similar to that observed in studies of patients only infected with HCV.

Follow-up data from the Phase II studies of Victrelis and Incivek are awaited—notably the rates of undetectable viral loads 24 weeks after the yearlong therapies are discontinued, which determine whether or not the infection has been cured.

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