Five-Year Viread Follow-Up: Long-Term Hep B Suppression, Plus Fibrosis and Cirrhosis Improvements

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Studies 102 and 103 were designed to compare Viread to Hepsera (adefovir)—both marketed by Gilead Sciences—over a 48-week follow-up period in people with HBeAg-positive and HBeAg-negative chronic HBV infection. At the end of the "blinded" clinical trials, all participants were offered "open-label" Viread in extension phases of the studies.

The five-year follow-up data were reported by Patrick Marcellin, MD, of the Hopital Beaujon in Clichy, France, and his colleagues. Ninety-one percent of the 641 people initially randomized and treated in the studies entered the open-label extension phase of the trials. These included 196 study volunteers who originally received Hepsera and 389 who continued Viread treatment on an open-label basis.

Volunteers had HBV viral loads above 100,000 copies/mL and elevated ALT (liver enzyme) levels upon entering the studies. The majority were beginning HBV therapy for the first time in the trials.

According to Marcellin's report, the data show that the majority of patients who received Viread continuously for five years, or switched off Hepsera and continued Viread for four years, maintained undetectable HBV viral loads. In Study 102, 64 percent of those who used Viread continuously had HBV viral loads below 400 copies/mL at week 240 of the study; in study 103, 83 percent had HBV viral loads below 400 copies/mL at week 240. As for those who switched from Hepsera to open-label Viread at the end of the initial 48 week study, viral loads remained undetectable in 84 percent and 66 percent in Studies 102 and 103, respectively.

Among the 331 patients who underwent biopsies before therapy was started and again five years later, 88 percent experienced an improvement in overall liver histology, as measured by an improvement of at least two points in what is known as the Knodell score of HAI (histologic activity index), which uses biopsy samples to assess or "stage" liver disease. Of the 94 patients who had cirrhosis at the start of therapy, 73 percent experienced regression of cirrhosis, and 72 percent had at least a two-point reduction in fibrosis scoring.

Among HBeAg-positive volunteers receiving Viread through five years, the likelihood of hepatitis B "s" antigen (HBsAg) loss and seroconversion (HBsAb)—the ultimately goals of treatment—was 9 percent and 7 percent, respectively.

Seventy-two percent of participants in Study 102 and 50 percent of those in Study 103 achieved

normalized ALT at week 240.

Viread was well-tolerated in both studies. The most commonly observed side effects were abdominal pain, head colds, headache, influenza, back pain and hypertension. Across both studies, 2.1 percent of patients who received Viread for five years discontinued treatment because of a side effect.

“These results represent an important advance in HBV therapy because they elucidate Viread’s potential to reduce or reverse signs of liver damage in patients with chronic hepatitis B,” Marcellin remarked.

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