# HCV Protease Inhibitor Telaprevir Shows Well at Liver Meeting

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Patients in the two Phase III studies—dubbed ADVANCE and ILLUMINATE—were given telaprevir with pegylated interferon and ribavirin for the first several weeks of the studies, followed by treatment with pegylated interferon and ribavirin alone for a total of either 24 weeks or 48 weeks, based on their response to treatment at weeks 4 and 12. ADVANCE enrolled more than 1,000 patients with genotype 1 HCV to receive telaprevir for 8 or 12 weeks or placebo, whereas ILLUMINATE enrolled 540 genotype 1 patients to receive telaprevir for 12 weeks (no placebo group was used).

Overall in ADVANCE, 75 percent of people treated with a telaprevir-based combination regimen for 12 weeks, followed by an additional 12 or 36 weeks of pegylated-interferon and ribavirin alone, achieved an SVR, compared with 44 percent of people treated with 48 weeks of pegylated-interferon and ribavirin alone.

Encouraging results were also documented in people of color living with HCV genotype 1. For example, 62 percent of black study volunteers achieved SVR with telaprevir, compared with 25 percent of black subjects treated with pegylated-interferon and ribavirin alone.

Significant benefits were also noted in patients with more advanced liver disease. About 62 percent of people with advanced liver fibrosis or cirrhosis (scarring of the liver) achieved an SVR with telaprevir compared with 33 percent who were treated with pegylated-interferon and ribavirin alone.

Response-guided therapy was used in ADVANCE, whereby patients whose HCV viral load was undetectable at weeks 4 and 12 of treatment with telaprevir-based therapy were eligible to reduce their treatment time by half—from 48 weeks to 24 weeks. ILLUMINATE, which did not have a pegylated interferon/ribavirin control group, was designed both to confirm the use of response-guided therapy and to evaluate whether there was any benefit in extending therapy from 24 weeks to 48 weeks in people who met these criteria.

In ADVANCE and ILLUMINATE, 58 percent and 65 percent of people, respectively, met these criteria for 24-week total treatment.

In ILLUMINATE, 72 percent of people overall achieved SVR with telaprevir-based therapy. New data

from this study showed that 60 percent of black patients and 63 percent of people with advanced liver fibrosis or cirrhosis achieved SVR with telaprevir-based therapy in the overall study analysis. Of the black study volunteers with undetectable HCV viral loads at weeks 4 and 12, 88 percent of people achieved SVR in both the 24-week and 48-week randomized treatment arms, suggesting there was no benefit in extending therapy.

The safety and tolerability results of telaprevir-based combination regimens were consistent in the ADVANCE and ILLUMINATE studies. Treatment discontinuation rates of all drugs due to adverse events during the telaprevir treatment phase in the ADVANCE study were low in the telaprevir arms (7 to 8 percent) and the control arm (4 percent). The most common adverse events, occurring in more than 25 percent of study volunteers, reported in both studies, regardless of treatment group, were rash, fatigue, itching, headache, nausea, anemia, insomnia, diarrhea, flu-like symptoms and fevers. The majority of these adverse events were mild to moderate.

The Phase III studies—ADVANCE, ILLUMINATE and a third study dubbed REALIZE—will form the basis of the clinical portion of the telaprevir New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA), which is expected to be complete before the end of 2010.

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