Excellent Results Across Genotypes for Sovaldi and GS-5816

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Gilead Sciences' Sovaldi (sofosbuvir) and GS-5816 cured about 95 percent of treatment-naive people with genotypes 1 through 6 of hepatitis C virus (HCV) who did not have cirrhosis in a recent trial. Aside from achieving excellent pan-genotypic results, the combination is also notable for successfully sidestepping the use of ribavirin. Results from the randomized Phase II GS-US-342-0102 study were presented at the 49th annual meeting of the European Association for the Study of the Liver (EASL) in London.

The 144 participants were randomized to receive the polymerase inhibitor Sovaldi plus either 25 milligrams or 100 mg of the pan-genotypic NS5A inhibitor GS-5816.

A total of 94.8 percent (73/77) of those participants taking the lower dose of GS-5816 achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Meanwhile, 96 percent (74/77) of those who took the higher dose were cured.

"The results of this study of [Sovaldi] with a new pan-genotype NS5A inhibitor demonstrate the curative potential of this combination," Gregory T. Everson, MD, a professor of medicine and director of the section of hepatology at the University of Colorado, Denver, and principal investigator of the study, said in a release. "The combination was not only effective across all genotypes and patient subgroups, but also was well tolerated. These results warrant additional study in future trials, with the hope of providing a potent, pan-genotypic combination with few side effects and a high chance for cure."
The most common adverse side effects, occurring in more than 10 percent of the participants, were fatigue, headache and nausea. None of those enrolled in the study stopped taking therapy because of side effects. Plus, there was no evidence of laboratory abnormalities related to the treatment.

To read the press release, click here.

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