Gilead Prepares to Submit Sovaldi/Ledipasvir Combo to FDA

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Gilead Sciences has announced near-perfect cure results from three recent Phase III trials of a coformulated pill of the recently approved Sovaldi (sofosbuvir) and the investigatory ledipasvir, with or without ribavirin, given to people with genotype 1 of hepatitis C virus (HCV). The pharmaceutical company plans to submit the pair to the U.S. Food and Drug Administration in the first quarter of 2014, Reuters reports.

The results derive from the ION-1, ION-2 and ION-3 trials, in which 1,952 genotype 1 participants were randomly assigned to receive the fixed-dose pill of the nucleotide analog polymerase inhibitor Sovaldi and the NS5A inhibitor ledipasvir, with or without ribavirin, for either 8, 12 or 24 weeks of treatment. A total of 1,512 participants were treatment naive, 440 were treatment experienced, and 224 had compensated cirrhosis. Two of 24-week treatment groups have not yet completed the trial; their results will be presented at a scientific meeting in the future.

Across the board, 96 percent of the participants (1,518) achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

On the low end of the cure results, there was a success rate between 93 and 94 percent for the treatment-naive participants who were treated with or without ribavirin for eight weeks and for the treatment-experienced participants, 20 percent of whom had cirrhosis, who were treated for 12 weeks without ribavirin. In two groups each treated for 12 weeks, the treatment-naive participants treated without ribavirin had a 95.4 percent cure rate and the treatment-experienced participants, 20 percent of whom had cirrhosis, had a 96.4 percent cure rate. In a group including 15.7 percent with cirrhosis that received 12 weeks of treatment, the cure rates were a respective 97.2 percent for those receiving ribavirin and 97.7 percent for those who did not receive the drug. Finally, a group that included 20 percent who had cirrhosis and which received 24 weeks of treatment had a cure rate of 99.1 percent, regardless of whether they took ribavirin.

There were few adverse side effects among those taking just the coformulated pill as compared with those who also took ribavirin. The side effects the participants did experience were typically mild, including fatigue and headache. For those who did take ribavirin, the most common side effects were fatigue, headache, nausea and insomnia. Just 0.5 percent of those who did not take ribavirin experienced anemia, compared with 9.2 percent of those who did take the drug. Less than 1 percent of the participants stopped treatment because of side effects.

To read the Gilead release, click here.

To read the Reuters story, click here.

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