Gilead’s Interferon-Free Sofosbuvir Regimen Is on Track for FDA Filing

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Gilead Sciences has announced promising Phase III results from a trial of the hepatitis C antiviral sofosbuvir, opening the door for regulatory filing this spring for a new interferon-free treatment for the disease. In the FUSION study, 195 participants who had failed a previous therapy and were infected with either genotype 2 or 3 of the hepatitis C virus (HCV) were randomly divided into two even groups to receive either 12 or 16 weeks of sofosbuvir (400 mg) plus ribavirin (1,000 or 1,200 mg) once a day.

On average, 50 percent of those in the 12-week arm and 73 percent of those in the 16-week arm achieved a sustained virologic response 12 weeks after completing treatment (SVR12, considered a cure). Eighty-six percent of those with genotype 2 in the 12-week arm achieved SVR12, and 30 percent of the genotype 3 participants achieved SVR12. Ninety-four percent of those with genotype 2 and 62 percent of those with genotype 3 achieved SVR12 in the 16-week arm.

Thirty-four percent of the participants had compensated cirrhosis at the beginning of the study; 31 percent of them achieved SVR12 in the 12-week arm; and 66 percent did so in the 16-week arm.

There were no discontinuations due to adverse effects. The most common side effects (reported in 15 percent or more of the participants) were fatigue, headache, insomnia and nausea.

These results, along with those from three other Phase III trials of sofosbuvir, will all support Gilead’s imminent regulatory filing.

To read the Gilead release, click here.

For a link to topline results from the study, click here.