Harvoni Posts Good Cure Rates for Hepatitis Genotypes 3 and 6

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Twelve weeks of Gilead Sciences’ Harvoni (ledipasvir/sofosbuvir) plus ribavirin cured 73 percent to 89 percent of people with genotype 3 of hepatitis C virus (HCV), while 96 percent of people with genotype 6 were cured without ribavirin in a recent trial, the National AIDS Treatment Advocacy Project (NATAP) reports. Researchers conducted a Phase II study of the once-daily fixed-dose combination tablet of the NS5A inhibitor ledipasvir plus the nucleotide analog polymerase inhibitor sofosbuvir, which was given with ribavirin for 12 weeks to 50 cirrhotic and noncirrhotic treatment-experienced people with genotype 3 of the virus, and without ribavirin for 12 weeks to 25 treatment-naive and treatment-experienced people with genotype 6. They presented their findings at the Annual Meeting of the American Association for the Study of Liver Diseases in Boston.

Overall, 82 percent (41 out of 50) of the participants with genotype 3 achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure), including 73 percent (16/22) of those with cirrhosis and 89 percent (25/28) of those without. Ninety-six percent (24/25) of those with genotype 6 were cured.

Among the genotype 3 participants, 90 percent (45/50) experienced at least one adverse side effect. Two percent (1/50) experienced serious side effects that led to discontinuation of therapy. Among those with genotype 6, 84 percent (21/25) experienced at least one adverse side effect and 4 percent (1/25) experienced serious side effects that let to discontinuation.

The most common side effects (affecting at least 10 percent of participants) reported by the genotype 3 group were fatigue, headache, upper respiratory tract infection, insomnia, rash and nausea. The most common side effects (affecting at least 10 percent of participants) reported by the genotype 6 group were fatigue, upper respiratory tract infection and diarrhea.

To read the NATAP report, click here.