Sofosbuvir, Ledipasvir Cure All of Hard-to-Treat Hep C Cases

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Twelve weeks of an interferon-free regimen of sofosbuvir and ledipasvir plus either ribavirin or GS-9669 cured 100 percent of treatment-experienced study participants in a recent trial who had genotype 1 of hepatitis C virus (HCV) and advanced liver fibrosis or cirrhosis. Edward Gane, MD, of Auckland Clinical Studies in New Zealand, presented findings from the Phase II ELECTRON study at the 64th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington, DC.

In this division of Gilead Sciences' ELECTRON study, 20 treatment-experienced participants with genotype 1 of hep C and cirrhosis were randomly assigned to take a fixed-dose combination pill of the polymerase inhibitor sofosbuvir and the NS5A inhibitor ledipasvir either with or without ribavirin for 12 weeks. Another 50 treatment-experienced people with genotype 1 and advanced fibrosis or cirrhosis were randomly assigned to take the combination pill plus either ribavirin or the non-nucleoside polymerase inhibitor GS-9669 for 12 weeks.

In the first group, 100 percent of those who took ribavirin achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure), compared with 70 percent of those who just took the combination tablet. One hundred percent of the second group achieved an SVR12.

The various regimens proved generally safe and well tolerated, with only one participant experiencing a serious adverse side effect and no discontinuations because of side effects. Nine percent of the treatment-experienced participants had grade 3 to 4 lab abnormalities, compared with 36 percent of the treatment-naive participants. The most common side effects were headache, fatigue and nausea.

To read the aidsmap story, click here.

To read the study abstract, click here.

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