Perfect Results for Sovaldi/Ledipasvir, But Only With Ribavirin

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Combination therapy with Gilead Sciences' fixed-dose combination pill of Sovaldi (sofosbuvir) and the investigational ledipasvir, plus ribavirin, boasted perfect cure rates in treating people with hepatitis C virus (HCV) in a recent trial. This is particularly good news for those with genotype 3 of the virus, who enjoyed halved treatment times compared with current Sovaldi protocol. Results from the ongoing Phase II ELECTRON2 study of 12 weeks of therapy with twice-daily doses of the fixed combination of the polymerase inhibitor Sovaldi and the NS5A inhibitor ledipasvir (LDV/SOF), with and without ribavirin, were presented at the 49th annual meeting of the European Association for the Study of the Liver (EASL) in London.

For treatment-naive study participants with genotype 3, the triple-drug regimen led to a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure) in 100 percent (26/26) of the cases. For those with genotype 3 who did not take ribavirin, the cure rate was only 64 percent (16/25). Similarly, a group of participants with genotype 1 and decompensated or Child-Turcotte-Pugh Class B cirrhosis who also did not take ribavirin only had a cure rate of 65 percent (13/20). Finally, those with genotype 1 who had failed a previous attempt at therapy with Sovaldi and ribavirin were all cured (19/19) with triple therapy.

Thus, it would appear that, at least for the subgroups treated in this study who fared more poorly without the drug, ribavirin may remain a necessary adjunct to a 12-week course of Sovaldi/ledipasvir therapy.

"The ELECTRON2 data suggest that an all-oral regimen of LDV/SOF plus RBV has the potential to provide high cure rates for genotype 3 patients in just 12 weeks—half the duration of current all-oral treatment regimens," Edward Gane, MD, deputy director and hepatologist at the New Zealand Liver Transplant Unit at the Auckland City Hospital in New Zealand, and principal investigator of the ELECTRON2 study, said in a release. "These results also suggest that LDV/SOF may be an effective treatment regimen for HCV genotype 1-infected patients who have failed a previous sofosbuvir-based regimen and those with advanced liver disease, including decompensated cirrhosis."

To read the press release, click here.