Sofosbuvir/Ledipasvir Combo Cures 97% of Hep C Genotype 1

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Promising interim results of a Phase II study of the hotly anticipated fixed-dose combination of Gilead Sciences' sofosbuvir and ledipasvir have paved the way for a Phase III study of the hep C drugs, MedPage Today reports. The early findings of the current research shows a 97 percent cure rate among people with genotype 1 of the virus after eight to 12 weeks of treatment, both with and without ribavirin. Eric Lawitz, MD, of the University of Texas Health Science Center in San Antonio presented the so-called LONESTAR findings at the 64th Annual Meeting of the American Association of the Study of Liver Diseases (AASLD) in Washington, DC.

In the study, 100 participants with genotype 1 of hepatitis C were divided into five groups, each of whom took the fixed-dose combination therapy of the nucleotide polymerase inhibitor sofosbuvir and the NS5A inhibitor ledipasvir. Three of the groups were comprised of treatment-naive people: 20 took the therapy for eight weeks; 21 took the therapy plus ribavirin for eight weeks; and 19 took the therapy for 12 weeks. Two more groups were comprised of treatment-experienced people: 19 took the therapy for 12 weeks, and 20 took the therapy plus ribavirin for 12 weeks.

Ninety-five percent (19/20) of the participants in the ribavirin-sparing group taking therapy for eight weeks achieved a sustained virologic response eight weeks after completing therapy (SVR8; an SVR12 is considered a cure), with one person relapsing. One hundred percent (21/21) of the treatment-naive participants who included ribavirin for eight weeks of therapy achieved an SVR8. One hundred percent (19/19) of those treatment-naive participants who were on therapy for 12 weeks achieved an SVR4. Ninety-five percent (18/19) of the ribavirin-sparing treatment-experienced group achieved an SVR4, with one cirrhotic participant relapsing. Ninety-five percent (20/21) of those in the treatment-experienced group taking ribavirin achieved an SVR4, with one person lost to follow-up

To read the MedPage Today story, click here.

To read a Gilead release on the study, click here.

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