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Combination therapy offers new hope for difficult-to-treat patients with chronic hepatitis C

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Results presented today at The International Liver Congress 2015 show that the use of the fixed-dose combination of ledipasvir/sofosbuvir (LDV/SOF) in combination with ribavirin (RBV) was well tolerated and demonstrated high sustained virologic response rates 12 weeks post treatment (SVR12) in patients with chronic hepatitis C virus (HCV) infection who have decompensated liver disease (cirrhosis) or have undergone liver transplantation.

SOLAR 2 data are presented for 328 HCV genotype-1 or -4 treatment-naive or treatment-experienced patients with decompensated liver disease or recurrent HCV following a liver transplant. More than 75 percent of patients in the study were treatment-experienced.

The participants were randomized to receive either 12 or 24 weeks of LDV/SOF plus RBV. Ten patients were excluded from the analysis because of transplantation (n=7) or because they were pre-transplantation, but not decompensated (n=3); an additional 27 of these patients have not yet reached post-treatment week 12.

Of the 32 genotype 4 patients, 27 (84%) achieved SVR12. Additionally, among patients with cirrhosis and decompensated cirrhosis before and after liver transplantation, virologic response was associated with improvements in Model for End-Stage Liver Disease (MELD) and CPT scores.

"Current treatment options are limited for HCV patients with decompensated liver disease or in those where the virus persists even after having a liver transplant," said Professor Michael Manns, Professor and Chairman, Department of Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, Germany. "We are therefore pleased that the combination of LDV/SOF+RBV has proved to be so effective, and consider this a significant step forward in the management of these difficult-to-treat patients," he added.

"As we constantly seek to improve the lives of people with chronic HCV, results from trials such as SOLAR 2 give hope to those with an advanced form of the disease such as cirrhosis and disease persisting even after a liver transplant," said Professor Markus Peck, Secretary General, European Association for the Study of the Liver.

In the study, the most common adverse events were fatigue, anaemia, nausea and headache. Sixty-nine patients (21 percent) experienced serious adverse events (SAEs). Nine patients had SAEs considered to be related treatment-related: anaemia (five), fall, diarrhoea, vomiting and hyperbilirubemia. Six patients have discontinued treatment.

Provided by European Association for the Study of the Liver