

New triple drug combination shows promise in hepatitis C infected patients

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New data presented today at The International Liver Congress 2016 in Barcelona, Spain, demonstrates a high sustained virologic response (SVR) at 12 weeks from the all-oral combination of sofosbuvir/velpatasvir and experimental compound GS-9857 in patients with the Hepatitis C virus (HCV).

This triple combination treatment was generally safe and effective, even in <u>patients</u> who had been unsuccessfully treated with direct acting antivirals (DAAs, medicines which have been used to treat and cure almost all patients with HCV). The study showed that 99% of patients with HCV genotype 1, 2, 3, 4 and 6 who had previously received treatment, achieved SVR 12 weeks after treatment using this triple combination.

Hepatitis C is a virus carried via the blood, which infects and damages the <u>liver</u>. HCV infects liver cells, resulting in inflammation and fibrosis. In chronic HCV cases, such symptoms may continue to increase and result in liver cirrhosis, scarring of the liver. Despite the high overall SVR rate achieved with currently approved DAA therapies, approximately 5% of patients treated with DAAs will not be cured. According to the study authors, for this small proportion of patients who are not cured, retreatment options are significantly limited.

"Our study demonstrates that for HCV patients whose prior treatment has failed with the use of DAAs, this triple combination provides a high rate of sustained virologic response across HCV genotypes," said Dr Eric



Lawitz, Clinical Professor of Medicine at the University of Texas Health Science Center, San Antonio and lead author of the study. "Furthermore, the study indicates that the treatment combination is generally safe and well tolerated by patients, providing a promising alternative for HCV sufferers who have limited re-treatment options."

Two global, open-label Phase 2 studies were conducted among chronic HCV-infected patients that had failed prior HCV treatment. Genotype 1 HCV-infected patients enrolled in the study had previously been treated with an NS5A-inhibitor or multiple classes of DAAs, and genotype 2-6 HCV-infected patients had previously been treated with pegylated-interferon (Peg-IFN) plus ribavarin and/or any DAA. All patients received the triple combination of sofosbuvir/velpatasvir plus GS-9857 for 12 weeks. Frequently reported adverse events (AEs) were headache, fatigue, diarrhea and nausea; most were mild or moderate in severity.

"Having offered promising results, this three drug combination is being further evaluated in Phase 3 trials as a single tablet regimen in DAA-experienced patients," said Professor Laurent Castera, EASL Secretary General.

More information: References:

1 British Liver Trust. Hepatitis C. Published March 2015. Available from: www.britishlivertrust.org.uk/l... ditions/hepatitis-c/. Last accessed: March 2016.

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