Study demonstrates the potential for a new triple combination treatment for hepatitis C patients

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A new combination treatment for hepatitis C has potential for patients who were not cured by current treatment options.

The study, presented at The International Liver CongressTM in Barcelona, Spain, demonstrated that the combination of sofosbuvir, velpatasvir and the investigational drug GS-9857 with or without ribavirin resulted in high rates of sustained virologic response 12 weeks after treatment (SVR12) in genotype 1 HCV patients who had previously received and failed treatment with direct-acting antivirals (DAAs). Overall, 98% of patients in the study achieved SVR12 with this three-drug combination in a single tablet with or without ribavirin.

Between 130 and 150 million people globally have chronic Hepatitis C virus (HCV) infection.1 It is estimated that 15 million people in the World Health Organization's EU Region are living with Hepatitis C, representing 2% of adults.2 Worldwide, genotype 1 HCV is the most common, accounting for approximately half of all hepatitis C infections.3

"Our study set out to evaluate the safety and efficacy of this investigational combination for hard-to-treat patients with genotype 1 hepatitis C," said Dr Eric Lawitz, Clinical Professor of Medicine at the Texas Liver Institute, University of Texas Health Science Centre, San Antonio and lead author of the study. "With the triple combination of

three potent drugs, sofosbuvir, velpatasvir and GS-9857, we demonstrated that high SVR12 results were achieved with or without ribavirin."

Patients previously treated with DAAs were randomised to receive the combination treatment with or without ribavirin for 12 weeks. The primary endpoint of the study was SVR12. SVR12 was achieved in 100% of patients who took sofosbuvir, velpatasvir and GS-9857 without ribavirin and in 96% of patients who additionally took ribavirin.

A total of 49 patients were randomised and treated in the American study. The majority were male (65%), and had HCV genotype 1a (88%). Overall, 41% of patients had previously received an NS5A inhibitor, and 47% of patients had previously received at least two classes of DAA. The triple combination of sofosbuvir, velpatasvir and GS-9857, with or without ribavirin was generally safe and well tolerated. There was one serious adverse event and two patients discontinued treatment with ribavirin due to adverse events. Most frequent adverse events were fatigue and anaemia, which were only observed in patients that received ribavirin.

"This new combination of treatments could add to our arsenal of therapies for patients with Hepatitis C, a disease which could eventually be eradicated. In the hard-to-treat patient population who had previously failed on existing treatment regimens, the combination with GS-9857 could provide these people with another hope," said Professor Tom Hemming Karlsen, EASL Vice-Secretary.

More information: References:

1 World Health Organization. Hepatitis C Fact Sheet N°164. Available from: www.who.int/mediacentre/factsheets/fs164/en/. Last accessed: February 2016.

2 World Health Organization. Global Alert and Response - Hepatitis C. Available from: www.who.int/csr/disease/hepati … o2003/en/index3.html. Last accessed: March 2016.

3 Messina JP, et al. (2015). Global distribution and prevalence of hepatitis C virus genotypes. Hepatology. 61:77-87.