

## Merck's Zepatier shows high response rates in hep C trials

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Merck's hepatitis C drug Zepatier has induced cure rates as high as 96 percent across two niche patient populations investigated in Phase III trials, according to data presented at The International Liver Congress.

The C-EDGE IBLD study evaluated Zepatier (elbasvir/grazoprevir) in patients with HCV genotypes 1,4 or 6 with inherited blood disorders, including haemophilia A/B, von Willebrand disease, beta thalassaemia and sickle cell anaemia. After 12 weeks' treatment with Zepatier, 93 percent of patients achieved SVR12 (considered a virologic cure), though six patients subsequently relapsed, five of which had detectable NS5A resistance-associated polymorphisms at baseline.

The C-EDGE CO-STAR assessed the drug in patients with chronic HCV GT1, GT4 and/or GT6 infection taking an opioid agonist therapy such as methadone or buprenorphine. Data show that 94 percent and 96 percent of patients achieved SVR24 in the blinded and open-label arms of the trial, respectively.

The analysis of 296 patients showed six probable HCV reinfections occurred, representing an incidence of 8.4 cases per 100 person years after 24 weeks of follow-up. Patients in the trial will be evaluated regularly for three years following the 24-week period, the firm noted.

"Many current or former injection drug users with chronic hepatitis C infection are on opioid agonist therapy, but historically there has been reluctance to treat these patients due to concerns about reinfection and compliance with treatment," said Eliav Barr, vice president, infectious diseases, Merck Research Laboratories.

"These results from C-EDGE CO-STAR help contribute to our understanding of the incidence of hepatitis C reinfection in these patients following treatment with Zepatier."

### Head-to-head with Sovaldi

Merck also presented data at the congress showing that Zepatier was superior to Gilead's Sovaldi (sofosbuvir) plus peginterferon/ribavirin on efficacy and safety endpoints in treatment naive and experienced hepatitis C patients.

"Overall in this study, the elbasvir and grazoprevir regimen showed superior SVR rates and improvement on pre-specified safety endpoints compared to the sofosbuvir plus peginterferon and ribavirin regimen in these genotype 1- or 4-infected patients," noted Jan Sperl, Department of Hepatogastroenterology, Institute for Clinical and Experimental Health, Prague, Czech Republic and lead study investigator.

"Sofosbuvir in combination with peginterferon and ribavirin continues to be a prescribed treatment regimen in many regions, and this comparative study versus combination treatment with elbasvir and grazoprevir provides interesting and important insights."

Zepatier, a fixed-dose combination of the NS5A inhibitor elbasvir and an NS3/4A protease inhibitor grazoprevir, was approved by the US Food and Drug Administration earlier this year for use, with or

without ribavirin, to treat of adult patients with chronic HCV-1 or HCV-4 infection with or without cirrhosis. It is currently under review in Europe.