

Sofosbuvir/daclatasvir combination effective treatment for difficult-to-treat hep C patients

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Results presented today at The International Liver Congress 2015 show that the sofosbuvir (SOF)/daclatasvir (DCV) treatment combination is effective amongst hepatitis C virus (HCV) genotype-1 mono-infected patients. These results are significant because whilst other combinations have been widely reported on, there have been few data until now regarding the use of SOF/DCV combination in real world situations.

Overall, the sustained virologic response rate at 4 weeks (SVR4) for SOF/DCV was 81.6% after 12 weeks of treatment and 93.9% following 24 weeks of treatment. The SVR4 rate for SOF/DCV with ribavirin (RBV) was 100% and 96.6% after 12 and 24 weeks, respectively. The 12-week combination of SOF/DCV/RBV achieved a 100% SVR4 rate in cirrhotic patients without the additive effect of extension of the treatment to 24 weeks with or without RBV (95.7% and 92.5%, respectively), and this was also true in experienced patients. All non-cirrhotic patients achieved 100% SVR4 at 12 weeks, demonstrating that the 12-week combination of SOF/DCV is a proven therapeutic option. Importantly, the SVR12 rate was 100% for SOF/DCV/RBV after both 12 and 24 weeks.

"The cohort study has found that the sofosbuvir/daclatasvir combination is associated with a high rate of SVR4 in difficult-to-treat patients infected by genotype-1 hepatitis C. We also found that the combination with ribavirin increases the SVR rate in cirrhotic or experienced patients without the additive effect of the extension of the treatment from 12 to 24 weeks. We hope that this helps support further treatment options for



difficult-to-treat patients," said Professor Stanislas Pol, Hôpital Cochin, Paris, France, principal investigator of the French ANRS CO-22 Hepather cohort.

409 HCV genotype-1 mono-infected patients were given a combination of SOF (400 mg/d) and DCV (60 mg/d) without ribavirin (n=318) or with ribavirin (1-1.2 g/d, n=91). 318 patients had cirrhosis and 306 were previously treated with peginterferon-<u>ribavirin</u> (PR) (n=134) or PR + a first generation protease inhibitor (PI) (n=172).

"This study shows very positive results for hepatitis C genotype-1 monoinfected patients. This is one of the first real-life studies looking into sofosbuvir/daclatasvir combinations and has demonstrated that this is a good therapeutic option for these patients. It represents another treatment option to help patients beat hepatitis C," said Professor Tom Hemming Karlsen, Scientific Committee Member, European Association for the Study of the Liver.

Serious adverse events were reported in 9% of patients and treatment discontinuation related to adverse events in 3.1%.

More information: SAFETY AND EFFICACY OF THE COMBINATION DACLATASVIR-SOFOSBUVIR IN HCV GENOTYPE 1-MONO-INFECTED PATIENTS FROM THE FRENCH OBSERVATIONAL COHORT ANRS CO22 HEPATHER, The International Liver Congress 2015.

Provided by European Association for the Study of the Liver

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