

Daclatasvir-sofosbuvir combination highly effective and well tolerated in patients with hepatitis C

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Phase III results revealed today at The International Liver Congress 2015 show that once-daily treatment with daclatasvir (DCV) plus sofosbuvir (SOF) resulted in an overall 97% sustained virologic response (SVR) at 12 weeks post-treatment in patients with hepatitis C virus (HCV) and HIV co-infection, including cirrhotic patients.

HIV co-infection more than triples the risk of hepatitis C-related liver disease, liver failure and liver-related death. Co-infection can also complicate the management of HIV infection.

In the ALLY-2 randomised, open-label study, the combination of DCV+SOF was well tolerated and effective across the four different genotypes. Importantly, due to their limited pharmacokinetic interactions with other agents, DCV+SOF was able to work effectively across a broad range of concomitant combination antiretroviral therapy (cART) regimens without compromising HIV virologic control (98% of [patients](#) were on cART).

The study included [treatment](#)-naive (n = 151) and treatment-experienced (n = 52) adults co-infected with HIV and HCV. Treatment-naive patients were randomised 2:1 to receive 12 or 8 weeks of SOF 400 mg + DCV 60 mg (dose adjusted for cART); experienced patients received DCV+SOF for 12 weeks. The primary endpoint was SVR at post-treatment week 12 in treatment-naive [genotype](#)-1 patients who received

12 weeks of DCV+SOF.

A total of 98% of patients completed the study treatment. In genotype-1 patients, SVR was achieved by 96% of treatment-naïve and 98% of experienced patients after 12 weeks of DCV+SOF. These positive results were also seen in genotype-2, -3 and -4 patients, with SVR at post-treatment week 12 reaching 100% (13/13), 100% (10/10) and 100% (3/3), respectively. Eight weeks of treatment appeared less effective with an SVR at 12 weeks post treatment of 76% in genotype-1 patients.

There were no treatment-related serious adverse events (AEs) and none of the patients stopped treatment due to AEs.

The results show that 12 weeks of DCV-SOF is a highly effective and well-tolerated treatment regimen for HCV in patients with HIV co-infection, including [cirrhotic patients](#).

Provided by European Association for the Study of the Liver

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