12 Weeks of Daclatasvir in Combination With Sofosbuvir for HIV–HCV Coinfection (ALLY-2 Study): Efficacy and Safety by HIV Combination Antiretroviral Regimens

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BACKGROUND

Daclatasvir (DCV) and sofosbuvir (SOF) {approved for the treatment of chronic hepatitis C virus (HCV) infection with or without ribavirin (RBV) in adults with GT 1–6 (except GT 3a) who have not been previously treated with an original HCV direct antiviral agent (DAA)}

METHODS

Patients were randomized 1:1 to receive DCV 30/60/90 mg or placebo (PBO) in combination with SOF 400 mg once daily (QD) for 12 weeks. Patients had ≥150 HIV RNA copies/mL, CD4 count ≥20 cells/mm3, and were taking ARV therapy. Key inclusion criteria included: HIV-monoinfected at baseline, no prior HCV treatment, and cirrhosis or post-liver transplant. Patients were stratified by ARV regimen.

RESULTS

There were no serious AEs (SAEs) in the 8-week group and four in the 12-week group. Overall, 149/153 (97%) patients treated with DCV + SOF for 12 weeks achieved SVR12. SVR12 rates were similar regardless of baseline demographic or disease characteristics. DCV + SOF was well tolerated with no discontinuations due to AEs, treatment-related SAEs, or deaths. HIV-HCV coinfected patients can be treated with DCV + SOF QD for 12 weeks without the need to alter most current ARV regimens. An accompanying poster is presented.

REFERENCES


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