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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Abstract

Background. Highly effective hepatitis C virus (HCV) direct-acting antiviral therapies that do not require modification of human immunodeficiency virus (HIV) antiretroviral regimens are needed. We evaluated the efficacy and safety of daclatasvir + sofosbuvir (DCV + SOF) for 12 weeks by antiretroviral (ARV) regimen in HIV-HCV-coinfected patients.

Methods. In the randomized, open-label ALLY-2 study, HIV-HCV-coinfected patients received 8 or 12 weeks of once-daily DCV 60 mg (dose-adjusted as-necessary for concomitant ARVs) + SOF 400 mg. Results were stratified by ARV class for the 151 patients who received 12 weeks of DCV + SOF.

Results. Fifty-one patients were HCV treatment experienced, 100 were treatment naive, 89% male and 33% black. HCV genotypes were: genotype 1a (GT1a; 69%), GT1b (15%), GT2 (8%), GT3 (6%), and GT4 (2%). Sustained virologic response 12 weeks post-treatment (SVR12) was 97% and was similar across ARV regimens (P = .774): protease inhibitor-based, 97% (95% confidence interval [CI], 90%-99.7%); nonnucleoside reverse transcriptase inhibitor-based, 100% (95% CI, 91%-100%); and integrase inhibitor based, 95% (95% CI, 83%-99.4%). SVR12 among patients receiving either tenofovir disoproxil fumarate or abacavir as part of their antiretroviral therapy regimen was 98% (95% CI, 93%-99.5%) and 100% (95% CI, 85%-100%), respectively. Age, gender, race, cirrhosis, HCV treatment history, GT, and baseline HCV RNA did not affect SVR12. No discontinuations were attributed to treatment-related adverse events.

Conclusions. DCV + SOF x12 weeks is a highly efficacious, all-oral, pan-GT HCV treatment for HIV-HCV coinfected patients across a broad range of ARV regimens.

Clinical Trials Registration. NCT02032888.