RUBY-I: Safety and Efficacy of Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir with or without Ribavirin in Adults with Genotype 1 Chronic Hepatitis C Virus (HCV) Infection with Severe Renal Impairment or End-Stage Renal Disease


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Abstract Body

BACKGROUND: Combinations of direct acting antiviral agents (DAAs) have demonstrated high rates of sustained virologic response (SVR) in patients with chronic hepatitis C virus (HCV) infection in compensated cirrhotics and non-cirrhotics. However, clinical data are limited for DAAs in patients with comorbid renal dysfunction. RUBY-I is a phase 3b, open-label, multi-center study assessing the safety and efficacy of OBV/PTV/r + DSV ± RBV in GT1 HCV-infected patients with severe renal impairment or end-stage renal disease, including dialysis. Results from the first cohort were previously presented; here we present safety and efficacy data from the second cohort (Arms C-E), including patients with compensated cirrhosis.

METHODS: Participants were either treatment naïve (TN) or treatment experienced (TE) with IFN/pegIFN and RBV. Patients with GT1a HCV infection and fibrosis stages <F4 were assigned to Arm C and received the 3-DAA regimen with RBV 200 mg QD for 12 weeks, while those with fibrosis stage F4 were assigned to Arm D and treated with the same regimen for 24 weeks. Patients with GT1b HCV infection with fibrosis stages F0-F4 were assigned to Arm E and treated with the 3-DAA regimen without RBV for 12 weeks. Efficacy is assessed by SVR at post-treatment week 12 (SVR12). Safety is assessed in all patients who received at least 1 dose of the study drugs.

RESULTS: A total of 48 patients with chronic HCV infection (31% with and 69% without cirrhosis) and with severe renal impairment or end stage renal disease were enrolled in this cohort: 28 in Arm C, 9 in Arm D and 11 in Arm E. Among them, 83% were male and 54% were black. All patients had either stage 4 (17%) or 5 chronic kidney disease, including 69% on hemodialysis. As of the data cut-off date (May 5, 2016), SVR4 was achieved in 29/31 (94%) patients (16/17, 2/3 and 11/11 in Arms C, D and E, respectively) in the intent-to-treat population. Both patients not achieving SVR4 prematurely discontinued treatment. Most treatment emergent adverse events (AEs) were mild or moderate in severity, with anemia (27%), decreased hemoglobin (23%) and fatigue (21%) the most frequently reported. Ten patients experienced serious AEs and one patient discontinued treatment in each of Arms C and D.

CONCLUSIONS: Preliminary data from this ongoing study demonstrated an SVR4 rate of 94%. Most AEs were mild or moderate in severity. These results support the use of this regimen in patients with advanced renal disease, for whom treatment options are limited.