Ledipasvir/Sofosbuvir for 8 Weeks Results in High SVR Rates in Treatment-Naïve Patients with Chronic HCV Infection and HIV/HCV Coinfection

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Abstract Body Background and Aims: Ledipasvir/sofosbuvir (LDV/SOF) for 8 weeks resulted in a SVR12 rate of 94% in non-cirrhotic, treatment-naïve patients with chronic genotype (GT) 1 HCV infection in the phase 3 ION-1 study. In addition, 98% (44/45) of patients who had failed prior treatment with SOF+ ribavirin (RBV) ± pegylated interferon were successfully treated with LDV/SOF+RBV for 12 weeks in a retreatment study. The aims of this study were to evaluate the safety and efficacy of i) LDV/SOF for 8 weeks in HCV infected patients with or without HIV coinfection and ii) LDV/SOF+RBV for 12 weeks in patients who failed prior treatment with SOF+RBV.

Methods: The study is being conducted at 18 sites in the Russian Federation and 2 sites in Estonia. Treatment-naive patients with GT1 HCV infection without cirrhosis and with or without HIV coinfection were enrolled and received 8 weeks of LDV/SOF (90mg/400mg daily). Patients with GT1 or GT3 infection, with or without cirrhosis, who had relapsed after treatment with SOF+RBV in a previous study (SOF-experienced) were treated with 12 weeks LDV/SOF+RBV (1000-1200 mg daily). The primary efficacy endpoint was sustained viral response 12 weeks after treatment (SVR12). Safety assessments included adverse events (AEs) and clinical laboratory tests.

Results: 126 treatment-naive GT1 HCV-infected patients, of whom 59 had HIV coinfection, were enrolled and treated; 54% patients were male, and 59% had baseline HCV RNA viral load ≥800,000 IU/mL. A total of 27 SOF-experienced patients were enrolled; 67% were male, 22% had GT3 HCV, 37% had compensated cirrhosis, and 70% had baseline HCV RNA viral load ≥800,000 IU/mL. Among treatment-naive patients, 111 (88%) had HCV infection, were enrolled and treated, 94% patients were male, and 55% had baseline HCV RNA viral load ≥800,000 IU/mL. Among SOF-experienced patients, the SVR rates were 98% (26/27). AEs occurring in >5% of patients were headache in the LDV/SOF treatment arm and headache, dyspepsia, upper abdominal pain, asthenia, irritability, and increased bilirubin in the LDV/SOF+RBV arm. One grade 3 AE of neutropenia was reported in a patient receiving LDV/SOF; no AEs leading to treatment discontinuation and no serious AEs have been reported in either treatment arm.

Conclusions: These results support an 8 week treatment regimen of LDV/SOF for HCV monoinfected and HIV/HCV coinfected, treatment-naïve, non-cirrhotic patients. Successful retreatment with LDV/SOF in combination with RBV for 12 weeks is possible for those who have failed prior treatment with SOF+RBV.