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

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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-naïve 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-naïve 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-naïve patients, SVR12 rates were 99% (66/67) in HCV monoinfected patients, 97% (57/59) in HIV/HCV coinfected patients, and among SOF-experienced patients, the SVR rate was 96% (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.

Disclosures:

Vasily Isakov - Advisory Committees or Review Panels: Abbvie, Gilead, Merck, Janssen, R-pharm; Speaking and Teaching: Abbvie, BMS, Gilead, Merck, Janssen, R-pharm

Vladimir P. Chulanov - Advisory Committees or Review Panels: Gilead, Bristol Myers Squibb; Grant/Research Support: Bristol Myers Squibb; Speaking and Teaching: Bristol Myers Squibb, Hoffman la Roche, MSD, AbbVie, Gilead

Kai Zilmer - Advisory Committees or Review Panels: MSD; Consulting: GSK; Grant/Research Support: Pfizer, Gilead

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Konstantin Zhdanov - Advisory Committees or Review Panels: Janssen; Consulting: BMS; Grant/Research Support: Abbvie, Gilead, R-pharm; Speaking and Teaching: MSD, Roche, Novartis, Biocad

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Incidence, predictors and outcome of ventilator associated pneumonia in critically ill cirrhotics admitted to a liver intensive unit.

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Background and Aim: Ventilator associated pneumonia (VAP) represents one of the most important causes of mortality in ICU. There is limited data on the incidence, predictors and outcome of VAP in critically ill cirrhotics.**Patients and Methods:** We prospectively studied 318 consecutive cirrhotic patients requiring mechanical ventilation (MV) during June 2014 to Feb 2015. Patients who developed pneumonia within 48 hours of admission (n=15) were excluded. VAP was diagnosed based on clinical pulmonary infection scoring system (CPIS) having six variables including temperature (<36.5°C or >38.5°C), elevated leukocytes (>12,000/mm3), tracheal secretions, a need for increase FiO2, lung infiltrates or opacities on a chest X-ray and bacteriology. VAP was diagnosed when a score of ≥6 was obtained. Study end-points included development of VAP, new organ failure, ICU stay and 30 day mortality. Multivariate logistic regression was used to determine predictors and outcome