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Effectiveness of Ledipasvir/Sofosbuvir in Treatment Naïve Genotype 1 Patients Treated in Routine Medical Practice

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L.I. Backus, P.S. Belperio, T. Shahoumian, T.P. Loomis, Office of Public Health/Population Health, Veterans Affairs Palo Alto Health Care System, Palo Alto, California, UNITED STATES; L.I. Backus, L.A. Mole, Department of Medicine, VA Palo Alto Healthcare System, Palo Alto, California, UNITED STATES

Aim: Assess the effectiveness of ledipasvir/sofosbuvir±ribavirin (LDV/SOF±RBV) in treatment naïve genotype 1 (GT1) hepatitis C virus (HCV)-infected veterans treated in routine medical practice.

Methods: This observational, intent-to-treat cohort analysis used the Veterans Affairs' Clinical Case Registry to identify all treatment naïve GT1 HCV-infected veterans initiating 8 or 12 weeks of LDV/SOF±RBV by 31 December 2014. Patients were excluded for liver transplantation or baseline HCV RNA<1000 IU/mL. Undetectable (UD) rates at the end of treatment (EOT) were determined from the HCV RNA results on or after the EOT with data available through 3 May 2015. Veterans without an EOT test who were UD on the most recent test prior to the EOT were considered EOT UD. EOT UD rates of those on LDV/SOF and LDV/SOF+RBV were compared with Chi-Square. Multivariate models of EOT UD included age, sex, race/ethnicity, cirrhosis by ICD-9, diabetes, HIV, baseline HCV RNA, genotype subtype and regimen.

Results: In total, 569 treatment naïve GT1 veterans initiated LDV/SOF±RBV; 524 LDV/SOF and 45 LDV/SOF+RBV. The mean age was 61.2 years, 95% were male, 32% were black, 32% had cirrhosis. Patients receiving LDV/SOF+RBV were more likely to have cirrhosis than patients receiving LDV/SOF (73.3% vs 28.4%, p<0.001). At the time of this abstract, 93.3% (531/569) of all patients were EOT UD; the remaining 38 patients were considered treatment failures with HCV RNA detectable after EOT (n=17), no EOT test and HCV RNA detectable on their last on treatment test (n=17) or died <12 weeks after EOT (n=4). Among patients who received LDV/SOF, cirrhotics had lower EOT UD rates than non-cirrhotics (88.6% (132/149) vs. 94.7% (355/375), p=0.02); EOT UD rates were 97.0% (32/33) in cirrhotic patients receiving LDV/SOF+RBV. Among non-

cirrhotics with baseline HCV RNA<6,000,000 IU/ml receiving LDV/SOF±RBV, EOT UD rates were 93.2% (110/118) for those who completed 8 weeks of therapy and 96.6% (172/178) for those who completed 12 weeks of therapy (p=0.28). In multivariate models, patients were less likely to achieve EOT UD with cirrhosis (OR 0.48, 95%CI 0.23-0.99, p=0.04).

Conclusions: In this large real-world cohort, treatment naïve GT1 HCV-infected patients had very high EOT UD rates with LDV/SOF±RBV. Non-cirrhotics with HCV RNA<6,000,000 IU/mL were as likely to achieve EOT UD with 8 weeks as 12 weeks of therapy. Patients with cirrhosis were significantly less likely to achieve EOT UD. SVR data for the cohort will be presented.

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