SOFOSBUVIR/LEDIPASVIR WITH AND WITHOUT RIBAVIRIN IN PATIENTS WITH HCV GENOTYPE 1 INFECTION RECEIVING OPIOID SUBSTITUTION THERAPY: PHASE 3 ION TRIALS

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Background: Interferon-based therapy is safe and effective among people receiving opioid substitution therapy (OST), but treatment uptake remains low. The aim of this post-hoc analysis was to evaluate the impact of OST and drug use during therapy on completion, adherence, sustained virologic response (SVR12) and safety of sofosbuvir/ledipasvir (± ribavirin).

Methods: The Phase III ION studies evaluated a fixed-dose combination of sofosbuvir/ledipasvir ± ribavirin administered for 8/12/24 weeks in patients with chronic HCV genotype 1. People with clinically significant drug use (prior 12 months) or non-cannabinoids detected at screening by urine drug tests (not explained by prescriptions) were ineligible. Stored samples were available from ION-1 for retrospective testing for illicit drugs by ELISA.

Results: Among 1,952 patients enrolled in the ION studies, 4% (n=70) were receiving OST. Among those receiving (n=70) and not receiving OST (n=1,882), there was no difference in treatment completion (97% vs. 98%, *P*=0.40) ≥80% adherence (93% vs. 92%, *P*=1.00), SVR12 (94% vs. 97%, *P*=0.28), and serious AEs (4% vs. 3%, *P*=0.43). Among participants in the ION-1 trial, 23% (n=196) had illicit drug use during therapy (15% cannabinoids alone; 8% other illicit drugs + cannabinoids). There was no difference in treatment completion, ≥80% adherence, SVR12 or serious AEs in those with no drug use during treatment compared with those who used cannabinoids and/or other illicit drugs. No cases of HCV reinfection have been observed in the 24 weeks following treatment.

Conclusions: OST and drug use during HCV therapy did not impact treatment completion, adherence, SVR12 or safety.

Disclosure of Interest Statement: This study was supported by Gilead Sciences.