A SINGLE TABLET REGIMEN OF LEDIPASVIR + SOFOSBUVIR IS EFFICACIOUS AND WELL-TOLERATED AMONG PEOPLE RECEIVING OPIATE SUBSTITUTION THERAPY

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Introduction: Although interferon (IFN)-based therapy has been shown to be safe and effective among people receiving opiate substitution therapy (OST), treatment uptake remains low due to poor tolerability to IFN. The aim of this study was to compare the safety and efficacy of IFN-free ledipasvir (LDV) and sofosbuvir (SOF) ± ribavirin (RBV) among patients receiving and not receiving OST enrolled in the Phase III ION studies.

Methods: The Phase III ION studies evaluated a fixed-dose combination of LDV/SOF administered for 8, 12, or 24 weeks ± RBV in patients with chronic HCV genotype 1 and included patients who were treatment experienced and with compensated cirrhosis. People with active injecting drug use at baseline were not eligible for inclusion. Safety and efficacy, as measured by SVR12, were compared between those receiving and not receiving OST

Results: Among 1952 patients enrolled in the ION studies, 4% (n=70) were receiving OST. Among people receiving OST (mean age 47 years), 69% were male, 90% white, 89% treatment naive, and 10% had cirrhosis. Overall SVR12 rates were comparable between people receiving and not receiving OST (94% vs. 97%, p=0.244). There was no benefit with the addition of RBV (SVR12 97% in both groups). Treatment was well-tolerated among people receiving OST with no patients discontinuing treatment. Following the end of treatment, there have been no cases of HCV reinfection among people receiving OST.

Conclusion: Patients receiving OST achieve high and comparable response rates compared with those not receiving OST. Adverse events and discontinuations were low. LDV/SOF offers patients an interferon-free single tablet regimen which can be completed in as little as 8-24 weeks.

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