**EFFICACY AND SAFETY OF SOFOSBUVIR/VELPATASVIR IN PATIENTS WITH CHRONIC HEPATITIS C VIRUS INFECTION RECEIVING OPIOID SUBSTITUTION THERAPY: ANALYSIS OF PHASE 3 ASTRAL TRIALS**

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**Background:** HCV infection is highly prevalent among patients with a history of injecting drug use, including those receiving opioid substitution therapy (OST).The Phase 3 ASTRAL studies demonstrated that treatment with the once-daily fixed-dose combination tablet of sofosbuvir/velpatasvir (SOF/VEL) was well-tolerated and results in SVR12 rates >95% across all HCV genotypes. Limited data exists for patients on OST treated with DAAs for HCV.

**Methods**: This was a post-hoc analysis of data among patients treated with SOF/VEL in the Phase 3 ASTRAL-1, ASTRAL -2, and ASTRAL -3 studies. Records of concomitant mediations were reviewed for use of OST. The safety and efficacy of SOF/VEL were compared between patients receiving, and not receiving OST.

**Results:** Among 1,035 enrolled, 51 (5%) patients were receiving OST. Compared to those not receiving OST (n=984), those receiving OST were more often male (77% vs. 60%) and had HCV genotype 3 infection (47% vs. 24%). Adherence to ≥90% SOF/VEL was numerically lower in patients receiving OST compared with patients not receiving OST (90% vs. 96%, *P*=0.06). Overall, the incidence of adverse events (AEs) was similar between those receiving and not receiving OST, although patients receiving OST had a higher incidence of Grade 3 and 4 AEs (14%) compared with non-OST patients (3%). SVR12 was similar in those receiving OST (96%, 49/51) and not receiving OST (98%, 966/984, *P*=0.26). Two patients did not achieve SVR12 in the OST group (anxiety, headache and attention disturbance, n=1; non-adherence, n=1). One patient not on OST and without a history of drug use and was determined to have HCV re-infection by deep sequencing of virus at time of virologic failure.

**Conclusions:** The pangenotypic SOF/VEL FDC provides a well-tolerated and highly effective treatment for HCV infection for patients on OST. Further prospective evaluation of SOF/VEL in people who inject drugs (PWIDs) is ongoing.