HEPATITIS C VIRUS (HCV) REINFECTION AND INJECTING RISK BEHAVIOR FOLLOWING ELBASVIR (EBR)/GRAZOPREVIR (GZR) TREATMENT IN PARTICIPANTS ON OPIATE AGONIST THERAPY (OAT): CO-STAR PART B

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Background: High efficacy was observed in Co-STAR Part A, a phase 3 trial of EBR/GZR for 12 weeks in participants on OAT. HCV recurrence consistent with reinfection was observed in 6/296 participants through follow-up week (FW)24, with a reinfection rate of 3.4 reinfections/100 person years (95% confidence interval [CI]: 1.3, 7.5). We provide further analysis of HCV reinfection and injection drug use risk behavior within the ongoing Co-STAR observational study.

Methods: Co-STAR Part B is a 3-year observational study of participants who received ≥1 dose of EBR/GZR in Part A (n = 296). During Part B, follow-up occurs every 6 months; if HCV RNA is detected, viral genotype and sequencing are investigated. Participant-reported surveys are also administered at each visit to assess risk behavior.

Results: Of 296 participants treated in Part A, 199 were enrolled in Part B (180 and 43 participants have completed follow-up visits at 12M and 24M, respectively). Urine drug screen (UDS) and reported drug use have remained stable in Parts A and B (58-61% had positive UDS and 45-50% reported drug use in the previous month). A further 3 viral recurrences were identified in Part B (n=1 each at the enrollment, 6M, and, 18M visits). Spontaneous clearance was seen in 3 of 5 reinfections detected through FW12 and in none of 4 reinfections detected after FW12. The incidence of reinfection from end of treatment through all completed visits is 2.3 reinfections/100 person-years (95% CI: 1.1, 4.4). Including only those with evidence of persistence of reinfection, the effective incidence of reinfection is 1.5 reinfections/100 person years (95% CI: 0.6, 3.3).

Conclusion: HCV reinfection among participants on OAT following EBR/GZR therapy is uncommon, despite ongoing drug use. Additional follow-up data, including risk factors related to incidence of reinfection and specific risk behaviors, will be reported.

[Abstract = 297 words; limit = 300 words (tables/graphs/pictures not permitted)]

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