DRUG USE AND REINFECTION DURING AND FOLLOWING HCV TREATMENT WITH ELBASVIR/GRAZOPREVIR (EBR/GZR) AMONG PATIENTS RECEIVING OPIOID AGONIST THERAPY: FINAL RESULTS FROM THE CO-STAR STUDY

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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 opioid agonist therapy (OAT). CO-STAR part B is the ongoing 3-year observational study in participants who received ≥1 dose of EBR/GZR in part A. We provide final results from the 3-year follow-up phase, which includes reinfection rates, urine drug screen (UDS) results, and reported drug use.

Methods: UDS was performed at each visit in parts A and B; additionally, in part B, patient-reported surveys were administered at each 6-month visit to assess risk behavior. If HCV RNA was detected, viral genotype and sequencing were assessed.

Results: 199 participants enrolled in part B. Overall from the end of treatment through 3 years of follow-up, HCV recurrence consistent with reinfection was observed in 10/286 participants, with a rate of 1.7 reinfections/100 person-years (95% CI: 0.79, 3.0). Six participants were found to have reinfection in part A, and 5 reinfections were identified in part B (enrollment, 6M, 18M, 24M, 30M), with 1 participant from part A having a second reinfection in part B. During part B, the percentage of participants with positive UDS results (excludes cannabinoids, methadone, buprenorphine) remained relatively constant, with positive results in 67%, 56%, 51%, 45%, 43%, 46%, and 45% at part B day 1, 6M, 12M, 18M, 24M, 30M, and 36M, respectively. Similarly, participant-reported injection drug use within the month prior to each visit was 15%, 19%, 17%, 15%, 16%, and 18% at 6M, 12M, 18M, 24M, 30M, and 36M, respectively.

Conclusion: Rates of drug use remained comparable from the start of treatment through the 3-year follow-up. Final data from this trial in participants on OAT demonstrate that HCV reinfection following EBR/GZR therapy is uncommon, despite ongoing drug use. Additional data including specific risk behaviors will be reported.

Disclosure of Interest Statement:
Jason Grebely has served on advisory committees or review panels for AbbVie, Gilead, and Merck/MSD; received grant/ research support from AbbVie, Cepheid, Gilead, and Merck/MSD; and has conducted speaking and teaching activities for Cepheid, Gilead, and Merck/MSD. Brian Conway has served on advisory committees or review panels for AbbVie, Gilead, and Merck; has received grant/research support from AbbVie, Gilead, and Merck; and has conducted speaking and teaching activities for AbbVie, Gilead, and Merck. Alain Harris Litwin has served on advisory committees or review panels and received grant research support for Gilead Sciences and Merck. Olav Dalgard has served on advisory committees or review panels for MSD, Janssen Cilag, Medivir, Gilead, and Abbvie; and has received grant/research support from MSD, Medivir, Gilead, and Abbvie. Oren Shibolet has served on advisory committees or review panels for and received grant/research support from Merck and AbbVie; and has provided consultancy for Gilead. Ronald Nahass has received grant/research support from Merck, Gilead, ViiV, and Janssen, and has served on advisory committees and review panels for Assembly Bio. Frederick Altice has served on advisory committees or review panels for Merck and Gilead; has received grant/research support from Merck and the National Institutes of Health; and has delivered speaking and teaching activities for Gilead, BMS, Clinical Care Options, and Simply Speaking. Edward J. Gane has conducted speaking and teaching activities for Gilead and Janssen; and has served on advisory committees or review panels for Janssen and Roche. Anne Luetkemeyer has received grant/research support from Merck, Proteus, and AbbVie. David M. Iser has served on advisory committees or review panels for AbbVie, and has provided speaking teaching services for AbbVie, BMS, Gilead Sciences, and MSD. Isaias Noel Gendrano, Michelle M. Kelly, Peggy Hwang, Eliav Barr, Michael Newton Robertson, and Heather Platt are employees of Merck, Sharp & Dohme, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, and hold stock in Merck & Co., Inc., Kenilworth, NJ, USA. Gregory Dore has conducted speaking and teaching activities for Merck, Gilead Sciences, AbbVie, and Bristol-Myers Squibb. Cheng-Yuan Peng has nothing to disclose.