

HCV REINFECTION AND INJECTING RISK BEHAVIOR FOLLOWING ELBASVIR/GRAZOPREVR TREATMENT IN PATIENTS ON OPIOID AGONIST THERAPY: CO-STAR PART B

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Background: High efficacy was observed in CO-STAR part A, a phase 3 trial of elbasvir/grazoprevir (EBR/GZR) for 12 weeks in participants on opioid agonist therapy (OAT). Hepatitis C virus (HCV) reinfection was observed in 6 of 296 participants through follow-up week 24 (FW24) (3.4 reinfections/100 person-years; 95% CI: 1.3, 7.5). We provide further analysis of reinfection and injecting drug use risk behavior.

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 performed. Patient-reported surveys are administered at each visit to assess risk behavior.

Results: 199 of 296 participants were enrolled in part B, and 192, 179, 173, 155, and 146 participants have completed follow-up visits at 6, 12, 18, 24, and 30 months, respectively. The percentage of participants with a positive urine drug screen (excluding cannabinoids, methadone, buprenorphine) remained relatively stable throughout parts A and B. A total of 10 participants had 11 cases of viral recurrence categorized as reinfection, 6 during part A and 5 during part B. The reinfection rate was 1.8 per 100 person-years (95% CI: 0.8, 3.3) in the overall population (n=296), 2.8 per 100 person-years (1.0, 6.2) in those who reported injecting drug use (n=80); and 0.3 per 100 person-years (0.0, 1.8) in those who did not report injecting drug use (n=119). Spontaneous clearance of reinfection has been observed only in early cases (3 of 5 reinfections detected through FW12). One of these participants was observed to have a second reinfection at month 30 follow-up.

Conclusion: HCV reinfection among patients on OAT following EBR/GZR therapy is uncommon, despite ongoing drug use. Data from this trial support treatment of patients on OAT to limit HCV transmission.

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. Alain Harris Litwin has served on advisory committees or review panels and received grant research support for Gilead Sciences and Merck. 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. 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; has conducted speaking and teaching activities for AbbVie, Gilead, and Merck. 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. Anne Luetkemeyer has received grant/research support from Merck, Proteus, 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. 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. Olav Dalgard has served on advisory committees or review panels for MSD, Janssen Cilag, Medivir, Gilead, Abbvie; and has received grant/research support from MSD, Medivir, Gilead, and Abbvie. Frederick Altice has served on advisory committees or review panels for Merck and Gilead; has received grant/research support from Merck and National Institutes of Health; and has delivered speaking and teaching activities for Gilead, BMS, Clinical Care Options, and Simply Speaking. Peggy Hwang and Hsueh-Cheng Huang are employees of Merck, Sharp & Dohme, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Isaias Noel Gendrano, Michelle M Kelly, Eliav Barr, Michael Newton Robertson, and Heather Platt are employees of 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.