

HCV REINFECTION AND INJECTING RISK BEHAVIOR FOLLOWING ELBASVIR/GRAZOPREVR TREATMENT IN PATIENTS ON OPIOID AGONIST THERAPY: CO-STAR THREE YEAR FOLLOW-UP STUDY

Dore G¹, Grebely J¹, Altice F², Litwin AH³, Dalgard O⁴, Gane EJ⁵, Shibolet O⁶, Luetkemeyer A⁷, Nahass R⁸, Peng CY⁹, Conway B¹⁰, Iser DM¹¹, Huang HC¹², Gendrano IN¹², Kelly M¹², Hwang P¹², Robertson M¹², Wahl J¹², Barr E¹², & Platt HL¹²

¹UNSW Sydney, NSW, Australia, ²Yale University, New Haven, CT, United States, ³Albert Einstein/Montefiore Medical Center, Bronx, NY, United States, ⁴Akershus University, Oslo, Norway, ⁵Auckland City Hospital, Auckland, New Zealand, ⁶Liver Unit, Department of Gastroenterology, Tel-Aviv Medical Center and Tel-Aviv University, Tel-Aviv, Israel, ⁷University of California, San Francisco, CA, United States, ⁸ID Care, Hillsboro, NJ, United States, ⁹China Medical University Hospital, Taichung, Taiwan, ¹⁰Vancouver Infectious Diseases Centre, Victoria, BC, Canada, ¹¹St. Vincent's Hospital, Melbourne, VIC, Australia, ¹²Merck & Co., Inc., Kenilworth, NJ, United States.

Background:

High rates of efficacy were observed in Co-STAR, a Phase 3 trial of 12 weeks of elbasvir/grazoprevir (EBR; NS5A inhibitor) / (GZR; NS3/4A protease inhibitor) in patients on opioid agonist therapy (OAT). HCV reinfection was observed in 6/296 (2%) of patients between the end of treatment (EOT) and follow-up week 24. The aim of the Co-STAR Three Year Follow-up Study (3YFU) is to evaluate HCV reinfection and injecting risk behaviours in patients treated with EBR/GZR.

Methods:

This 3 year observational cohort study enrolled patients who received at least one dose of EBR/GZR in the Phase 3 trial. Every 6 months, patients are tested for HCV RNA and if detected, viral genotype and sequencing are performed.

Results:

Of 296 patients treated in Co-STAR, 185 patients (63%) were enrolled in the 3YFU. Enrolled patients were generally representative of the parent trial. Sixty percent of patients in the 3YFU study had a positive urine drug screen (UDS) at enrolment. The median time from EOT to the first visit during the 3YFU was 330 days (range: 206-485). Other than the 6 reinfections, two viral recurrences were identified at the first visit in the 3YFU. One patient had GT1a at baseline and GT3 at follow-up, opiates and cannabinoids were detected by UDS. One patient had GT1b at baseline, a HCV RNA (258 IU/mL) detected at the first visit; however, the genotype was unable to be determined (low viral load), no drugs besides OAT were detected by UDS; this patient is not considered a reinfection while additional follow-up is pending. Of the 185 patients in the 3YFU, 108 (58%) reported any drug use (non-injecting or injecting) in the past 6 months. Injecting drug use in the past 6 months was reported by 47 (25%) patients. Of those reporting injecting drug use in the past 6 months, injected drugs included heroin (n=34; 72%), amphetamines (n=8; 17%), cocaine (n=7; 15%), and other opioids (n=7; 15%).

Conclusion:

HCV reinfection among patients on OAT following EBR/GZR treatment is uncommon despite ongoing drug use. Additional follow-up is ongoing.

Disclosure of Interest Statement:

Greg Dore

- Board Membership: Gilead, Merck, Abbvie, Bristol-Myers Squibb
- Grant/Research Support: Gilead, Merck, Abbvie, Bristol-Myers Squibb
- Speaking and Teaching: Gilead, Merck, Abbvie, Bristol-Myers Squibb: