Elbasvir/Grazoprevir Does Not Worsen Renal Function in Patients With Hepatitis C Virus Infection and Pre-existing Renal Disease

Background

- Hepatitis C virus (HCV) infection in patients with chronic kidney disease (CKD) is associated with an increased risk for loss of kidney function, kidney transplant failure, and death.
- Decreased estimated glomerular filtration rate (eGFR) has been reported in patients with HCV infection receiving direct-acting antiviral agents.
- Among patients receiving sofosbuvir/ledipasvir, those with baseline eGFR <60 mL/min/1.73 m² were more likely to experience worsening of kidney function than those with normal eGFR.
- Elbasvir (EBR) is a once-daily NS5A inhibitor and grazoprevir (GZR) is a once-daily HCV NS3A protease inhibitor (Figure 1).
- APPROVED IN EUROPE, THE US, CANADA, AND OTHER COUNTRIES WORLDWIDE.

Patients and Methods

- Study Design: This was an integrated analysis of data from the EBR/GZR phase 2/3 clinical development program.
- Pooled dataset of 1689 patients who received EBR/GZR (50 mg/100 mg) with or without ribavirin (RBV) for 8, 12, 16, or 18 weeks.
- 32 patients with CKD 3 were identified.
- Patients were treatment-naive or treatment-experienced, and included cirrhotics and those with HIV co-infection.

Demographics and Characteristics

- Participants and treatment were similar in patients with normal renal function (baseline eGFR >60 mL/min/1.73 m²) and those with CKD 3 (baseline eGFR <60 to <90 mL/min/1.73 m²).
- Mean age, years (range): 58.5 (30-82).
- Black Africa, n (%): 22 (11%
- Treatment-naive, n (%): 25 (78%)
- Cirrhotic, n (%): 8 (25%)
- HIV co-infected, n (%): 10 (31%)
- Mean baseline viral load (×10^6 IU/mL): 3.3
- Treatment duration, n (%): 12 weeks (27/84), 16 weeks (2/6), 18 weeks (3/9).
- Treatment outcome: 27/84 with improvement in renal function, 2/6 with no change, and 3/9 with worsening of renal function.

Results

- There was no decline in median eGFR in patients with HCV infection and CKD 3 receiving EBR/GZR for 8-18 weeks (n = 32) (Figure 3).
- No patient with CKD 3 at baseline exhibited a decline in CKD stage during treatment with EBR/GZR (Figure 4).
- 12 of 32 patients with CKD 3 showed an improvement in CKD stage during treatment with EBR/GZR (Figure 5).

Conclusions

- eGFR remained stable or improved in patients with HCV infection and CKD 3 who received EBR/GZR for 8-18 weeks.
- No patient with CKD 3 at baseline exhibited a decline in CKD stage during treatment with EBR/GZR.
- Future studies should focus on identifying factors associated with improvements in renal function after successful HCV therapy.

References

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