of sustained virological response at 12-week (SVR12) was 100%. Patients with deranged ALT showed normalization after 4 weeks which was sustained for 48 weeks (Figure 1B). Patients who were not yet on dialysis showed no renal deterioration after G/P treatment (eGFR were 13.0 ± 5.9 mL/min/1.73 m^2 and 13.8 ± 7.4 mL/min/1.73m2 at baseline and 24 weeks respectively, p = 0.858) (Figure 1C). One PD patient died during treatment due to fungal peritonitis. One patient discontinued G/P at 4 weeks due to unrelated side effects but still achieved SVR12. No other significant adverse event was observed.

Conclusion: G/P treatment was associated with favorable efficacy and tolerability in HCV-infected patients with severe renal impairment.

Abstract #356

12 week Ravidasvir plus ritonavir-boosted Danoprevir and ribavirin achieves 99% SVR12 in treatment-naïve non-cirrhotic HCV GT1 patients: Subanalysis of phase 2/3 clinical trial in China

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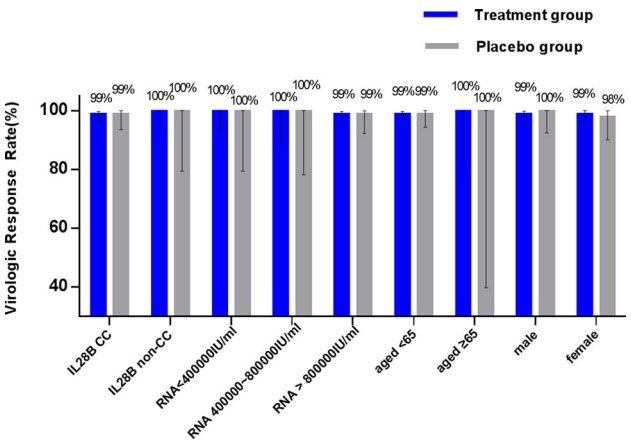
Objectives: Ravidasvir (RDV) is a new generation pan-genotypic NS5A inhibitor. This phase 2/3 study confirmed the efficacy and safety of RDV and ritonavir-boosted Danoprevir (DNVr) in combination with ribavirin regimen for treatment-naïve HCV genotype 1 (GT1) patients without cirrhosis in a large population in China.

Method: in this multi-center, randomized, double-blind, placebo-controlled phase 2/3 trial (NCT03362814), we enrolled 424 patients. These patients were randomized 3:1 to receive a combination of RDV 200 mg once daily plus DNVr 100 mg/100 mg twice daily and ribavirin 1000/1200 mg/day (body weight < 75/≥ 75 kg) (n = 318) or placebo (n = 106) for 12 weeks, then patients in the placebo group went on to receive 12 weeks' treatment with the above combination. The primary efficacy endpoint was SVR12.

Results: Of the 424 patients (mean age 45yrs) enrolled, 47% were male, 94% were under 65 years old, 82% was IL-28B CC genotype, and 72% had HCV RNA ≥ 800,000 IU/mL at baseline. The overall SVR12 was 99.03%(306/309, 95% CI: 97.19%～99.80%, PPS) and 99.01% (100/101, 95% CI: 94.61–99.97%, PPS) respectively for the treatment group and the placebo group. The Figure depicts the SVR12 of patients in both groups stratified by IL28B genotype, baseline HCV RNA level, age and gender. Given the high SVR12 rate, no difference among patient subgroups was discernible.

Conclusion: For Chinese treatment-naïve non-cirrhotic GT1 HCV adult patients, treatment with RDV and DNVr in combination with ribavirin for 12 weeks resulted in high SVR12, regardless of age, gender, IL28B genotypes or viral load.



Abstract #360

High efficacy and safety of the combination HCV Regimen Elbasvir/Grazoprevir for weeks in treatment-Naive, non-severe fibrosis HCV GT1b-infected Patients: STREAGER study

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