

EP-089 - EFFICACY AND SAFETY OF 8-WEEKS OF GLECAPREVIR/PIBRENTASVIR IN TREATMENT-NAÏVE ADULTS WITH HCV GENOTYPE 1-6 AND ASPARTATE AMINOTRANSFERASE TO PLATELET RATIO INDEX (APRI) ≤ 1

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Background: Prospective, single arm Phase 3 trial with 43 sites worldwide (NCT03212521) aiming to evaluate the efficacy and safety of G/P (300/120mg) QD administered for 8 weeks in treatment-naïve adults with chronic HCV genotypes (GT) 1-6 infection and Aspartate aminotransferase to platelet ratio index (APRI) ≤ 1 . Here, we report preliminary data from this study.

Method: Efficacy is assessed using intent-to-treat (ITT) and modified ITT analyses as the percentage of patients who received ≥ 1 dose of G/P and achieved sustained virologic response at post-treatment week 12 (SVR12). Safety is assessed in all patients treated with ≥ 1 dose of G/P.

Results: Of the 230 patients enrolled, the median APRI score was 0.41 (range from 0.13 to 1.00). Patients (n, %) were primarily white (207, 90%), < 65 years of age (207, 90%), and had an APRI score ≤ 0.5 (140, 61%). Notably, 35 (15%) patients had GT3 infection, while most others had GT1 infection (151, 66%). For all patients who completed treatment (on G/P for ≥ 52 days), those with available post-treatment week 4 and 12 HCV RNA data (**Figure**) all achieved SVR4 (221/221) and SVR12 (61/61). Two patients who discontinued G/P early did not achieve SVR. Headache (13%) was the only adverse event (AE) reported in $\geq 10\%$ of patients. AEs leading to G/P discontinuation and serious AEs were reported in 2 ($< 1\%$) and 4 (2%) patients, respectively. Post-treatment follow-up is currently ongoing. There are no virologic failures to date. Complete efficacy and safety data will be presented at the Congress.

Conclusions: Preliminary data suggests that 8-week G/P treatment is highly efficacious and safe in HCV treatment-naïve patients with chronic HCV infection and APRI ≤ 1 . These results support the use of this APRI threshold as an acceptable patient selection criterion to aid strategies for HCV elimination or treatment of patients in a primary care setting.