HIGH SVR RATES WITH EIGHT AND TWELVE WEEKS OF PANGENOTYPIC GLECAPREVIR/PIBRENTASVIR: INTEGRATED EFFICACY AND SAFETY ANALYSIS OF GENOTYPE 1-6 PATIENTS WITHOUT CIRRHOSIS

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Background: The pangenotypic direct-acting antivirals (DAAs) glecaprevir (NS3/4A inhibitor developed by AbbVie and Enanta) and pibrentasvir (NS5A inhibitor), comprise the interferon (IFN)- and ribavirin (RBV)-free regimen G/P. In seven phase 2/3 clinical trials, G/P achieved SVR12 rates of 92-100% across all six major HCV genotypes (GTs). Here we present an integrated analysis from these studies on the efficacy of 8 and 12 weeks of G/P treatment in non-cirrhotic patients with GT1-6 infection.

Methods: Data were pooled from 7 phase 2 and 3 studies. Patients with chronic HCV GT 1, 2, 3, 4, 5 or 6 infection without cirrhosis received G/P for either 8 or 12 weeks. Patients were either treatment-naïve or treatment-experienced with IFN-based or sofosbuvir (SOF)-based regimens. Patients experienced with a DAA other than SOF were excluded. Efficacy was evaluated as the rate of sustained virologic response (HCV RNA <lower limit of quantification) 12 weeks after the end of treatment (SVR12). Safety was assessed in all patients.

Results: In total, 1981 patients without cirrhosis were enrolled and 1975 received study drug. 74% of patients were treatment naïve and 81% had F0-F1 fibrosis. In the intent-to-treat population (ITT), 1911/1953 (98%) patients achieved SVR12, with similar rates of 97% and 98% in patients treated for 8 and 12 weeks, respectively. Across all genotypes, there were 4 breakthroughs (0.2%), 14 relapses (0.7%) and 11 discontinuations (0.6%). G/P was well-tolerated; discontinuations due to adverse events, DAA-related serious adverse events and grade 3 or higher laboratory abnormalities were rare.

Conclusions: The G/P regimen yielded high SVR12 rates across all genotypes, regardless of prior treatment experience or treatment duration. The results from this integrated analysis suggest that the G/P regimen could provide an effective 8-week IFN- and RBV-free treatment option for patients with HCV GT1-6 infection without cirrhosis.

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