TREATING THE NEW EPIDEMIC: EFFICACY AND SAFETY OF ELBASVIR/GRAZOPREVIR (EBR/GZR) IN PEOPLE WITH HEPATITIS C VIRUS (HCV) INFECTION AGED 35 YEARS OR YOUNGER

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Background: Young adults are one of the fastest growing populations with chronic HCV infection. The number of new HCV infections in the United States increased from 850 cases in 2010 to 2,436 in 2015, with the most rapid increase seen among people aged 20-29 years who inject drugs. Given that these individuals often have recently acquired infection, shorter disease duration, and less advanced liver disease than older people, young adults may be more responsive to therapy. This analysis assessed the efficacy and safety of EBR/GZR in participants aged ≤35 years enrolled in 12 phase 2/3 clinical trials.

Methods: Participants aged ≤35 years with HCV genotype (GT)1/4 infection who received EBR/GZR for 12 weeks were included. The primary efficacy assessment was sustained virologic response (HCV RNA <lower limit of quantitation at follow-up week 12 [SVR12]) in the modified full analysis set (mFAS), which included participants with SVR12 or virologic failure.

Results: 274 participants aged ≤35 years with GT1/4 infection were included (mean age, 29.6 years [standard deviation 4.35]). Most participants had F0-F2 fibrosis (n=242, 88.3%) and GT1b/1-other (n=162, 59.1%) or GT1a (n=94, 34.3%) infection. In the mFAS population, the SVR12 rate was 98.9% (271/274) in participants aged ≤35 years and 96.9% (2093/2160) in those aged >35 years. Among those aged ≤35 years, SVR12 rates were high in all subgroups, including those with GT1a infection (94/94, 100%) and those receiving opioid agonist therapy (38/38, 100%). All females aged ≤35 years with baseline HCV RNA ≤800,000 IU/mL (59/59, 100%) or with F0-F2 fibrosis (109/109, 100%) achieved SVR12. The safety profile of EBR/GZR in participants aged ≤ and >35 years will be provided, including those with comorbidities or on concomitant medications such as opioid agonists.

Conclusion: EBR/GZR is a safe and highly effective treatment option for participants with HCV GT1/4 infection aged ≤35 years.

Disclosure of Interest Statement:
Dr Asselah has served on advisory committees or review panels for AbbVie, Merck, Gilead, BMS, Roche, and Janssen. Dr Zeuzem has served as a consultant for AbbVie, Gilead, Janssen, and Merck/MSD. Dr Reau has served on advisory committees or review panels for Merck, AbbVie, Intercept, BMS, and Gilead and has received grant/research support from Gilead, Intercept, AbbVie, GenFit, and Shire. Drs Hwang, Long, Talwani, Robertson, and Haber are current employees of and may hold stock in Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.