Glecaprevir/pibrentasvir is effective and well tolerated in individuals with hepatitis C

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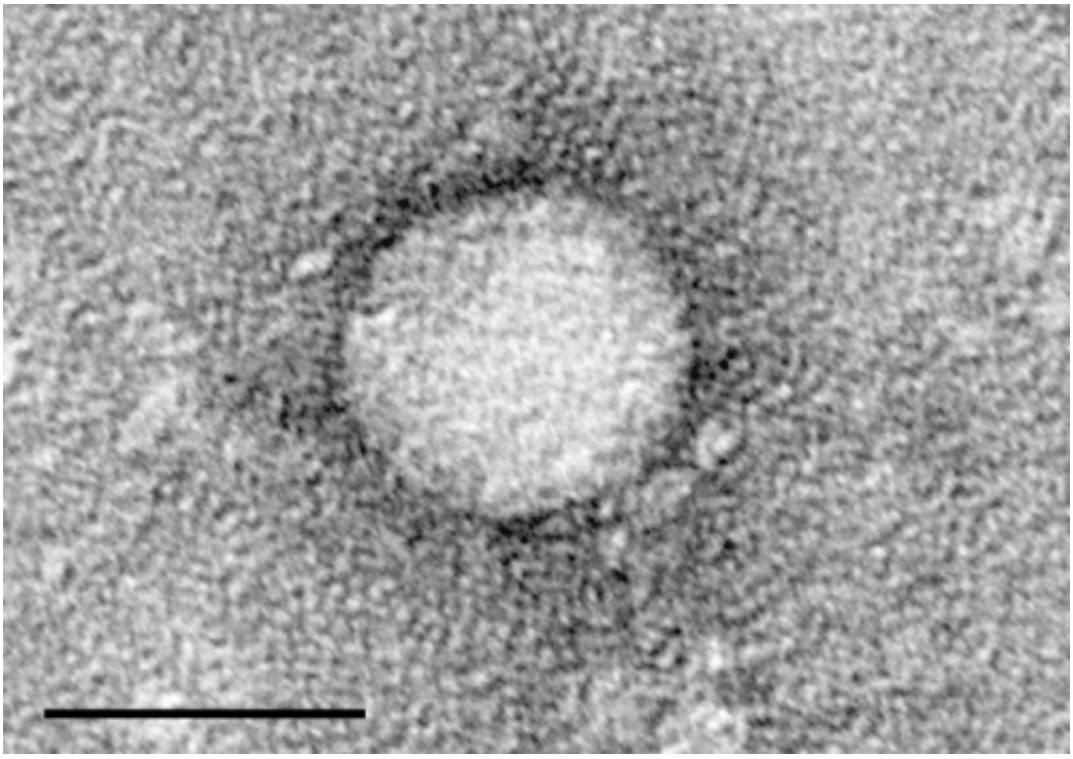

Electron micrographs of hepatitis C virus purified from cell culture. Scale bar is 50 nanometers. Credit: Center for the Study of Hepatitis C, The Rockefeller University.

Two large 'real-world' studies conducted in Germany and the USA have confirmed the high rates of sustained virological response (SVR) observed in controlled clinical studies of glecaprevir/pibrentasvir (G/P) involving individuals with hepatitis C virus (HCV) infection. Across the

two studies, which were presented today at The International Liver Congress 2019 in Vienna, Austria, a range of treatment-naïve and treatment-experienced individuals received G/P therapy, including those who are usually underrepresented in clinical trials such as patients receiving opioid substitution therapy, those with alcohol and/or active drug abuse, and those with psychiatric conditions and/or HIV coinfection.

Chronic infection with HCV remains a leading cause of morbidity and mortality, with an estimated 71 million individuals infected worldwide. The availability of direct-acting antivirals (DAAs) has transformed the outlook for people with HCV infection, with recent drug development efforts focusing on simplifying treatment. Glecaprevir/pibrentasvir (G/P) is a fixed-dose pan-genotypic DAA combination tablet that was approved in Europe in July 2017 for the treatment of adults with HCV infection. In Phase 2 and 3 studies, G/P treatment led to an SVR in >95% of recipients, with no safety issues emerging. Real-world experience with the treatment is gradually expanding, and several post-authorization studies have recently been reported.

The first study presented today involved an analysis of data from 1,698 adults with HCV genotype (GT) 1-6 infection who received G/P treatment and were included in the German Hepatitis C-Registry (DHC-R). Most individuals (84%) were treatment-naïve and free of cirrhosis, and therefore were treated for 8 weeks. In total, 439 individuals (26%) were receiving opioid substitution therapy (OST), 247 (15%) had a psychiatric disease, 106 (6%) had substantial alcohol abuse, and 47 (3%) were active drug abusers.

'These are all important comorbidities encountered in clinical practice that often have led to treatment being deferred in the past,' explained Professor Markus Cornberg from Hannover Medical School in Germany, who presented the study findings.

In the intent-to-treat (ITT) population, the SVR rate at 12 weeks (SVR12) after the end of G/P treatment was 97% (964/998). Mental and physical component scores of the 36-Item Short Form Health Survey (SF-36) improved in key study subgroups, particularly in individuals with comorbidities. G/P was generally well tolerated with three patients discontinuing due to adverse events. Six individuals had HCV reinfection post-treatment and six individuals had a virological relapse.

'We found G/P treatment to be safe and highly effective, and to lead to significant improvements in reported physical and mental well-being, across this large, primarily treatment-naive cohort of HCV-infected individuals with typical comorbidies,' said Professor Cornberg.

Similarly, positive results were also reported by a team of researchers in the USA, who analysed the data from 1,131 individuals who started G/P treatment between August 2017 and April 2018 and were included in the Trio Health disease management program. Data were also analysed from 777 individuals who initiated treatment with sofosbuvir/velpatasvir (SOF/VEL) during the same period. In the ITT populations, the SVR12 rates were 93% (1,049/1,131) with G/P and 90% (701/777) with SOF/VEL; rates were higher (98% for both treatment regimens) in the per-protocol populations. Seventeen individuals (2%) completed G/P treatment and did not achieve SVR12. Factors found to be associated with virological failure with G/P were treatment experience (OR 0.14 [0.05-0.36]; p?0.001), cirrhosis (OR 0.29 [0.11-0.80]; p=0.017), and viral load >6 MM in GT3 HCV (OR 0.14 [0.03-0.60]; p=0.008). Fifteen individuals (2%) completed SOF/VEL treatment and did not achieve SVR12. Patients that were treated with SOF/VEL plus RBV had a higher risk for virological failure (OR 0.16 [0.04-0.60]; p=0.007).

More information: Session title: 'General session II'
Time, date and location of session: 08:30-08:45, 12 April 2019, Main Plenary

Presenter: Markus Cornberg, Germany
Abstract: Real-world safety, effectiveness, and patient-reported outcomes in patients with chronic hepatitis C virus infection treated with glecaprevir/pibrentasvir: Data from the German Hepatitis C-Registry (GS-07)

Session title: 'Viral hepatitis C: Therapy and resistance'
Time, date and location of session: 09:00-19:00, 11 April 2019, Poster Area
Presenter: Michael Curry, USA
Abstract: Clinical Practice experience with pan genotypic therapies glecaprevir-pibrentasvir and sofosbuvir-velpatasvir in the TRIO Network (THU-127)

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