Study demonstrates the efficacy of an investigational treatment in hepatitis C subgroup

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Study results presented today demonstrate that the oral, once-daily treatment regimen of glecaprevir/pibrentasvir (G/P) resulted in 95% sustained virologic response rates at 12 weeks post treatment (SVR12) in patients with Hepatitis C virus (HCV) genotype 3. In the ENDURANCE-3 study, presented at The International Liver Congress 2017 in Amsterdam, The Netherlands, patients infected with HCV genotype 3 without cirrhosis and who had no previous treatment history were treated with the new regimen for eight or 12 weeks, which was well tolerated. G/P had a similar safety profile to the commonly used combination of sofosbuvir and daclatasvir for 12 weeks, to which G/P was actively compared in the study.

Around 180 million people globally have chronic HCV infection,1 including approximately 15 million people in the EU.2 Genotype 3 patients have become the most difficult subgroup of patients to cure.3 Although there have been recent advances in direct-acting antiviral therapies for HCV genotype 1, genotype 3 remains a challenge and is a highly prevalent strain of the virus globally.3

"While there has been great progress made in the treatment of patients with Hepatitis C, there remain limited options for those with genotype 3 disease. As such, we are pleased to see that the investigational combination of glecaprevir/pibrentasvir achieved high SVR12 rates, in treatment naïve, non-cirrhotic patients," said Dr Graham Foster, Queen Mary University of London, United Kingdom and lead study author. "Treatment with this once-daily regimen for eight weeks could provide a highly efficacious and well-tolerated option for treatment naïve, non-cirrhotic patients with Hepatitis C, genotype 3, if approved by the regulatory authorities."

ENDURANCE-3 is a Phase 3, open-label, active-controlled study in which 348 treatment naïve, non-cirrhotic HCV genotype 3 patients were randomised to receive 12 weeks of once-daily therapy with either co-formulated glecaprevir/pibrentasvir, or with sofosbuvir plus daclatasvir. Subsequently, 157 patients were enrolled to receive glecaprevir/pibrentasvir for eight weeks. The primary endpoint of the study was the percentage of patients who achieved SVR12.

SVR12 was achieved in 222/233 (95%) (95% confidence interval 93-98) of patients treated with glecaprevir/pibrentasvir for 12 weeks, and in 111/115 (97%) (95% confidence interval 91-99) of patients treated with sofosbuvir plus daclatasvir for 12 weeks. In patients treated with glecaprevir/pibrentasvir for eight weeks, SVR12 was achieved in 149/157 (95%) (95% confidence interval 92-98) of patients. Relapse occurred in 1% of patients in both 12 week treatment regimens, and in 3% of patients in the eight week regimen. Adverse events (71%) were mostly mild and there were no serious treatment-related adverse events.

"These results are more than encouraging, considering that treatment options for HCV genotype 3 are still suboptimal," said Prof Francesco Negro, Divisions of Gastroenterology and Hepatology of Clinical Pathology, University Hospital of Geneva, Switzerland, and EASL Governing Board Member.

More information: Abstract: ENDURANCE-3: safety and efficacy of glecaprevir/pibrentasvir compared to sofosbuvir plus daclatasvir in treatment-naïve HCV genotype 3-infected patients without cirrhosis (GS007), The International Liver Congress 2017.

References:

1 EASL Recommendation on Treatment of Hepatitis C 2016. Available from: www.easl.eu/medias/cpg/HCV2016/English-report.pdf. Last accessed: April 2017.

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3 Tapper EB, Afdhal N. Is 3 the new 1: perspectives on virology, natural history and treatment for hepatitis C genotype 3. J Viral Hepat. 2013 Oct;20(10):669-77.

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