

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

April 21 2017

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.

2 World Health Organization. Global Alert and Response - Hepatitis C. Available from: www.who.int/csr/disease/hepatitis/2003/en/index3.html. Last accessed: April 2017.

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.

Provided by European Association for the Study of the Liver

Citation: Study demonstrates the efficacy of an investigational treatment in hepatitis C subgroup (2017, April 21) retrieved 2 May 2024 from <https://medicalxpress.com/news/2017-04-efficacy-treatment-hepatitis-subgroup.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--