

Investigational DAA treatment combination effective and improves patient-reported outcomes

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Analysis of patient outcome data from the POLARIS-1, 2, 3 and 4 studies presented today demonstrate that patients with Hepatitis C virus (HCV) and cirrhosis experience the greatest improvement of patient-reported outcome (PRO) scores when taking treatment with sofosbuvir (SOF) + velpatasvir (VEL), with or without voxilaprevir (VOX), an anti-HCV regimen that has been shown to be safe and effective against all HCV genotypes in different populations. The analysis of the four studies, presented at The International Liver Congress 2017 in Amsterdam, The Netherlands, showed that achievement of sustained virologic response at 12 weeks (SVR12) was associated with significant improvements in PROs, which were more prominent in patients with cirrhosis than those without.

Hepatitis C is one of the most widespread transmissible diseases.¹ HCV is a leading cause of [chronic liver disease](#), end-stage cirrhosis and [liver cancer](#).² It is estimated to infect over 185 million people worldwide, of whom 350,000 die each year, with 84,000 of those being in Europe.³ In Europe, [liver cirrhosis](#) is responsible for 1-2% of all deaths,⁴ and was the leading cause of adult liver transplants between 1988 and 2013.⁵ Until the approval of direct-acting antiviral (DAA) drugs, HCV was treated with pegylated interferon alpha and ribavirin, which caused serious adverse effects in many patients, often leading to premature termination of therapy.¹ DAAs have revolutionised [treatment](#), as they are well tolerated and highly efficacious.⁶

"This analysis showed that although patients with HCV and cirrhosis have significantly impaired patient-reported outcomes, they experience the greatest improvement during treatment with SOF/VEL with or without VOX, when compared to those without cirrhosis," said Dr Zobair Younossi, Center for Liver Diseases, Washington, United States, and lead author of the study. "We also found that achieving a sustained virologic response with the drugs was associated with substantial gains in outcomes."

This analysis combined data from 1,908 patients with chronic HCV who were enrolled in four Phase 3 studies (POLARIS 1 to 4) that assessed the efficacy and safety of SOF/VEL/VOX in the treatment of HCV-infected patients. Outcomes from 26 PRO domain scores relating to quality of life, fatigue, work productivity and activity impairment were assessed using questionnaires.

The overall cure rate (SVR12) was 94% for patients with and without cirrhosis in both the SOF/VEL/VOX and SOF/VEL treatment groups. Patients with cirrhosis experienced significant improvements in their PRO scores compared to the start of treatment, which were similar or greater than those in [patients](#) without cirrhosis. Individuals with cirrhosis treated with placebo did not have any PRO improvements.

"Successful treatment of HCV-related [cirrhosis](#) with DAA therapy improves patient-reported outcomes, and this will certainly impact not only the direct but also the significant indirect costs linked to this progressive disease," 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: High efficacy is accompanied with substantial gains in patient reported outcomes in cirrhotic patients with chronic hepatitis C treated with sofosbuvir (SOF), velpatasvir with or

without voxilaprevir (VOX): data from POLARIS 1, 2, 3 and 4 (LBP-544), The International Liver Congress 2017.

References:

- 1 World Health Organization. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. March 2015. Available from: apps.who.int/medicinedocs/docu...21793en/s21793en.pdf. Last accessed: April 2017.
- 2 Mühlberger N et al. HCV-related burden of disease in Europe: a systematic assessment of incidence, prevalence, morbidity, and mortality. BMC Public Health 2009;9:34.
- 3 World Health Organization. Hepatitis C in the WHO European Region Fact Sheet. July 2015. Available from: www.euro.who.int/_data/assets...et-en-hep-c.pdf?ua=1. Last accessed: April 2017.
- 4 European Association for the Study of Liver. The burden of liver disease in Europe. A review of epidemiological data. Available from: www.easl.eu/medias/EASLimg/Dis...845caec619f_file.pdf. Last accessed: April 2017.
- 5 European Liver Transplant Registry. Specific results by disease. Available from: www.eltr.org/Specific-results-by-disease.html. Last accessed: April 2017.
- 6 Liang T, Ghany M. Current and future therapies for hepatitis C virus infection. N Engl Med 2013;369(7):679-680.
- 7 ClinicalTrials.gov. NCT02607735. Safety and efficacy of sofosbuvir/velpatasvir/voxilaprevir in adults with chronic HCV infection who have previously received treatment with direct-acting antiviral therapy (POLARIS-1). Available from: clinicaltrials.gov/ct2/show/NCT02607735. Last accessed: April 2017.
- 8 ClinicalTrials.gov. NCT02607800. Safety and efficacy of sofosbuvir/velpatasvir/voxilaprevir and sofosbuvir/velpatasvir in adults with chronic HCV infection who have not previously received treatment

with direct-acting antiviral therapy (POLARIS-2). Available from:
clinicaltrials.gov/ct2/show/NCT02607800. Last accessed: April 2017.

9 ClinicalTrials.gov. NCT02639338. Safety and efficacy of
SOF/VEL/VOX FDC for 8 weeks and SOF/VEL for 12 weeks in adults
chronic genotype 3 HCV infection and cirrhosis. Available from:
clinicaltrials.gov/ct2/show/NCT02639338. Last accessed: April 2017.

10 ClinicalTrials.gov. NCT02639247. Safety and efficacy of
SOF/VEL/VOX FDC for 12 weeks and SOF/VEL for 12 weeks in DAA-
experienced adults with chronic genotype HCV infection who have not
received an NS5A inhibitor. Available from:
clinicaltrials.gov/ct2/show/NCT02639247. Last accessed: April 2017.

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