ILC 2017: High efficacy with investigational direct-acting antiviral treatment combination is accompanied with substantial gains in patient-reported outcomes

Patients with Hepatitis C and cirrhosis experience the greatest improvements in patient-reported outcomes with sofosbuvir/velpatasvir with or without voxilaprevir compared to those without cirrhosis

April 20, 2017, Amsterdam, The Netherlands: 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.

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POLARIS 1, 2, 3 and 4
POLARIS-1 was a double-blind, placebo-controlled study of SOF/VEL/VOX for 12 weeks in adults with chronic HCV infection who had been treated previously with DAA therapy.[7] POLARIS-2 was an open-label study that randomised patients with chronic HCV infection who had not previously received DAA therapy to treatment with SOF/VEL/VOX for eight weeks or SOF/VEL for 12 weeks.[8] POLARIS-3 was an open-label study that randomised patients with genotype 3 HCV infection and cirrhosis to receive SOF/VEL/VOX daily for eight weeks or SOF/VEL for 12 weeks.[9] The open-label POLARIS-4 study randomised patients with chronic HCV infection who had previously received DAAs, but not an NS5A inhibitor (a DAA that is a protease inhibitor), to treatment with either SOF/VEL/VOX or SOF/VEL for 12 weeks.[10]

About The International Liver Congress™
This annual congress is the biggest event in the EASL calendar, attracting scientific and medical experts from around the world to learn about the latest in liver research. Attending specialists present, share, debate and conclude on the latest science and research in hepatology, working to enhance the treatment and management of liver disease in clinical practice. This year, the congress is expected to attract approximately 10,000 delegates from all corners of the globe. The International Liver Congress™ 2017 will take place from April 19 – 23, at the RAI Amsterdam, Amsterdam, The Netherlands.

About The European Association for the Study of the Liver (EASL) (www.easl.eu)
Since its foundation in 1966, this not-for-profit organisation has grown to over 4,000 members from all over the world, including many of the leading hepatologists in Europe and beyond. EASL is the leading liver association in Europe, having evolved into a major European Association with international influence, with an impressive track record in promoting research in liver disease, supporting wider education and promoting changes in European liver policy.

Contact
For more information, please contact the ILC Press Office at:

- Email: ILCpressoffice@ruderfinn.co.uk
- Telephone: +44 (0)7841 009 252

Onsite location reference

Session title: Late breaker posters
Time, date and location of session: 08:00 – 18:00, Thursday 20 April – Saturday 22 April, Hall 1
Presenter: Zobair Younossi, United States of America
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)

Author disclosures
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