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Phase 2 COSMOS Study Results Published in The Lancet Demonstrate Efficacy and Safety of Janssen's Once-Daily Simeprevir in All Oral 12-Week Combination with Sofosbuvir for Genotype 1 Chronic Hepatitis C

Study evaluated interferon-free combination in treatment-naïve and prior null-responder patients with all stages of liver fibrosis, including cirrhosis

CORK, Ireland (July 28, 2014) -- Results from the Phase 2 COSMOS (**C**ombination **O**f **S**i**M**eprevir and s**O**fosbuvir in HCV genotype 1 infected patient**S**) clinical study were published July 28 in *The Lancet*, demonstrating that 92 percent of genotype 1 chronic hepatitis C virus (HCV) adult patients treated with Janssen R&D Ireland's (Janssen) simeprevir, an NS3/4A protease inhibitor, in combination with sofosbuvir, achieved sustained virologic response 12 weeks after the end of treatment (SVR12), including those patients with compensated cirrhosis and prior null response to treatment with pegylated interferon (PegIFN) and ribavirin (RBV).

According to findings from the study, the all-oral 12-week, interferon-free treatment regimen with simeprevir and sofosbuvir resulted in consistent SVR12 rates regardless of degree of fibrosis, and was an effective and well-tolerated therapeutic regimen in both treatment-naïve and prior null-responder patients.

"The publication of results from the COSMOS study in *The Lancet* on World Hepatitis Day underscores the significance of these data to the hepatitis C community," said Eric Lawitz, M.D., Principal Investigator of the COSMOS study, Medical Director at The Texas Liver Institute, and Professor of Medicine at University of Texas Health Science Center. "These data demonstrate that the all-oral, interferon-free combination of simeprevir and sofosbuvir offers a highly effective 12-week treatment option for patients, including prior null-responders and those with advanced fibrosis who are considered difficult to cure."

The open-label, randomised Phase 2 COSMOS study investigated the efficacy and safety of 12 or 24 weeks of simeprevir (150 mg once daily) with sofosbuvir (400 mg once daily) without or with RBV in HCV genotype 1 chronically infected patients with compensated liver disease. The study included two cohorts: Cohort 1 included null-responder patients with no to moderate liver fibrosis (defined as METAVIR F0 to F2 scores) and Cohort 2 included treatment-naïve and prior null-responder patients with advanced fibrosis, including cirrhosis (defined as METAVIR F3 to F4 scores).[i]

PHGB/HEP/0714/0009
Date of preparation: July 2014

In Cohort 1 (N=80), 93 percent and 96 percent of genotype 1 HCV patients with no to moderate liver fibrosis who were prior null responders to PegIFN + RBV treated with simeprevir and sofosbuvir for 12 weeks without or with RBV, respectively, achieved SVR12. Additionally, in Cohort 2 (N=87), 93 percent of treatment-naïve and prior null-responder patients with genotype 1 HCV and advanced liver fibrosis treated with simeprevir and sofosbuvir for 12 weeks without or with RBV, respectively, achieved SVR12.[i]

In the COSMOS trial, the most common (> 10 percent) adverse events reported during treatment with simeprevir in combination with sofosbuvir without and with RBV were fatigue (31 percent), headache (20 percent), and nausea (16 percent).

“The publication of the COSMOS study results represents the first peer-reviewed report describing the use of simeprevir in combination with other direct-acting antiviral agents in an all-oral interferon-free regimen,” said Gaston Picchio, Hepatitis Disease Area Leader, Janssen Research & Development. “This has been included as part of the European marketing authorisation earlier this year and we are further discussing these results with other authorities around the world to better inform the treatment of hepatitis C patients.”

Based on the findings from the COSMOS study, in April 2014, Janssen announced initiation of the Phase 3 OPTIMIST-1 and OPTIMIST-2 trials examining the safety and efficacy of simeprevir and sofosbuvir without interferon or RBV for the treatment of chronic genotype 1 HCV infection. For more information please visit www.clinicaltrials.gov.

Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor developed by Gilead Sciences, Inc.

About Hepatitis C

Hepatitis C (HCV) is a major global public health concern. It is a serious and complex blood-borne virus which manifests itself through complications of the liver. If left untreated, it can cause significant and potentially fatal damage to the liver including cirrhosis, leading to eventual transplantation. In Europe, HCV is a leading cause of liver transplantation.[ii]

The World Health Organisation (WHO) and the European Association for the Study of the Liver (EASL) estimate that 150 million people worldwide were chronically infected with HCV in 2011.[iii] The virus is responsible for 350,000 deaths globally[iii] and 86,000 deaths in the European region each year.[iv] As the disease is often asymptomatic in its early stages it can be difficult to diagnose and treat. Up to 90 percent of those with HCV do not clear the virus without treatment and become chronically infected.[v] The WHO estimates that 20 percent of people with HCV will develop cirrhosis and, of those, up to 20 percent may progress to liver cancer.[vi] Genotype 1 HCV is the most prevalent form of the virus worldwide[vii] and one of the most challenging to treat successfully.

About Simeprevir

Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB and indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Simeprevir efficacy has been established in HCV genotype 1 and 4 infected patients with compensated liver disease, including cirrhosis.[viii]

Janssen is responsible for the global clinical development of simeprevir and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir AB retains marketing rights for simeprevir in these countries under the marketing authorization held by Janssen-Cilag International NV. Simeprevir was approved for the treatment of chronic hepatitis C

infection as part of an antiviral treatment regimen in combination with PegIFN + RBV in genotype 1 infected adults with compensated liver disease, including cirrhosis in September 2013 in Japan, in November 2013 in Canada and the U.S., in March 2014 in Russia, and in July 2014 in Mexico and Australia. In May 2014 simeprevir was granted marketing authorization by the European Commission (EC) for the treatment of adult patients with genotype 1 or genotype 4 chronic HCV.

About Janssen Pharmaceutical Companies

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases. Driven by our commitment to patients, Janssen develops innovative products, services and healthcare solutions to help people throughout the world.

Janssen believes to effectively fight hepatitis C, a serious commitment is required from all stakeholders to improve the healthcare infrastructure across the continuum of care, increase awareness, provide education and ensure access to effective treatment for people living with hepatitis C. Janssen is working around the world to be a positive catalyst in the fight towards eradication of this deadly disease and serious public health problem.

More information can be found at www.janssen.com.

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