Janssen Demonstrates Continued Commitment to Combating Hepatitis C in European Patients with Data Presented at Viral Hepatitis Congress

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FRANKFURT, Germany (Oct. 10, 2014) -- Janssen R&D Ireland (Janssen) today announced the presentation of additional data for the NS3/4A protease inhibitor OLYSIO® (simeprevir) at the Viral Hepatitis Congress (VHC) in Frankfurt, Germany. The data includes new analysis of a European and Israeli Hepatitis C (HCV) patient subset within the previously presented ATTAIN Phase 3 study. Additional data presented investigates treatment considerations for a broad range of patient populations including the renal function of those treated with simeprevir as well as the prevalence of the polymorphism of Q80k in European genotype 1 (GT1) patients.

The new analysis of the Phase 3 ATTAIN study (n=763), showed sustained virological response at 12 weeks (SVR12) to be similar in European and Israeli patients compared to previous analysis of the overall patient population (GT1, null and prior responder patients).[1] Importantly these results have shown that Week 4 response rates are a good predictor of SVR12, showing that the majority of patients treated with simeprevir and pegIFN/ RBV with HCV RNA <25 IU/ml at Week 4, were likely to achieve SVR by week 12.[2]

The aim of the study was to demonstrate the non-inferiority of simeprevir versus telaprevir with pegIFN and RBV in difficult to cure HCV genotype 1-infected patients who were null or partial responders to prior pegIFN and RBV therapy. Overall, simeprevir met its primary endpoint of non-inferiority to telaprevir in treatment-experienced HCV patients and also demonstrated an improved tolerability profile, with SVR12 rates within the European cohort reported at 58 percent for the simeprevir arm and 60 percent for the telaprevir arm (compared to 54% and 55% respectively in the total patient population).[1,2]

"The new ATTAIN data presented at the Viral Hepatitis Congress adds to the breadth of data that highlights the value of simeprevir, in combination with pegylated interferon and ribavirin, as well as helping to further define patients who can benefit from this therapy," said PD Dr. med. Holger Hinrichsen, Centre for Gastroenterology and Hepatology, Kiel, Germany and investigator of the ATTAIN study. "While interferon-free regimens are a focus of industry clinical development programmes, these results demonstrate that interferon based therapies still have an important role to play within current standards of treatment."

The most common adverse events during the first 12 weeks of treatment occurred at a consistently lower frequency in the simeprevir treatment arm compared to the telaprevir treatment arm. Adverse events included: pruritus (31 percent versus 43 percent); fatigue (32 percent versus 38 percent); headache (25 percent versus 29 percent) and anemia (13 percent versus 37 percent).

Anaemia-related blood transfusions were significantly lower in the simeprevir treatment arm (0.8%) versus the telaprevir treatment arm (9.1%). Only two percent of patients in the simeprevir arm versus eight percent of patients in the telaprevir arm discontinued treatment early due to an adverse event.[2]

Breadth of data shows promise for diverse patient populations

Additional data also presented at VHC investigated the renal function in patients treated with simeprevir or placebo in combination with Peg-IFN/ribavirin (PR) in HCV genotype-1-infected, treatment-naïve patients which indicated that simeprevir has a good renal safety profile.[3] Furthermore, the post-hoc analysis of pooled efficacy data from the Phase 3 QUEST-1 and QUEST-2 studies of treatment-naïve genotype 1 HCV patients, supported the use of simeprevir in combination with PegIFN/RBV to treat HCV patients with moderate liver fibrosis.[4]

Janssen also presented an investigation of the prevalence of Q80k polymorphism in a pooled analysis of GT1 patients from telaprevir and simeprevir phase II/III clinical trials. This analysis establishes that there is a considerably lower prevalence of the Q80k polymorphism at baseline among patients infected with HCV GT1 in European countries, compared to a previous analysis in North American patients. This analysis demonstrated that within Europe, the prevalence of Q80k polymorphism varies considerably between countries, due in part to the different prevalence of GT1b (which does not contain the Q80k polymorphism) as well as the differing prevalence of Q80k in GT1a across the European region.[5]

"Hepatitis C affects a diverse patient population across a range of genotypes," said Dr. PhD Michael Schlag, Medical Affairs Director, simeprevir, Janssen EMEA. "As the Hepatitis C treatment landscape has evolved, we must look to expand our understanding of how new drugs will work for individual patients with the aim of providing tailored treatments for patients that results in improved outcomes. These additional data presented by Janssen at the Viral Hepatitis Congress demonstrates our dedication to keeping the patient at the heart of ongoing advances."

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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.[6]

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 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.[7]

The World Health Organisation (WHO) and the European Association for the Study of the Liver (EASL) estimate that 160 million people worldwide were chronically infected with HCV in 2011.[8] The virus is responsible for up to 500,000 deaths globally[9] and 86,000 deaths in the European region each year.[10] 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.[11] 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.[12] Genotype 1 HCV is the most prevalent form of the virus worldwide and one of the most challenging to treat successfully.

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.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen R&D Ireland, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

References

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