



Final Data from the Phase 2 COSMOS Study of Janssen's Once-Daily Simeprevir in Combination with Sofosbuvir Presented at The International Liver Congress™ 2014 of the European Association for the Study of the Liver (EASL)

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Additional Studies Presented in Genotype 1 and Genotype 4 Hepatitis C Patient Subgroups Underscore Benefit of Simeprevir-based Treatment Regimens

LONDON (April 12, 2014) -- Janssen R&D Ireland (Janssen) today announced positive new data from the clinical development program of the protease inhibitor simeprevir, including final data from cohort 2 of the Phase 2 COSMOS study of simeprevir administered once daily with Gilead Sciences, Inc.'s nucleotide inhibitor sofosbuvir, with and without ribavirin, in adult patients chronically infected with genotype 1 hepatitis C virus (HCV) and advanced fibrosis, including cirrhosis. The final data, along with an additional analysis from COSMOS cohort 1 and new subgroup analyses of Phase 3 data in genotype 1 and genotype 4 HCV patients, were presented at The International Liver Congress™ 2014 of the European Association for the Study of the Liver (EASL) in London.

Final Phase 2 Data from the Interferon-free COSMOS Study

Cohort 2

Final results from cohort 2 of the Phase 2 COSMOS study demonstrated that 93 percent of patients with genotype 1 HCV and advanced liver fibrosis (METAVIR scores F3 and F4) who were treated with simeprevir and sofosbuvir for 12 weeks achieved sustained virologic response 12 weeks after the end of treatment (SVR12). The addition of ribavirin did not improve SVR rates and consistent responses for both treatment arms were seen across HCV genotype subgroups after 12 weeks.



The most common adverse events reported during the study were fatigue, headache, nausea, anemia, pruritus, dizziness, rash and photosensitivity. One patient discontinued treatment due to adverse events.

Cohort 1

Previously presented data from cohort 1 demonstrated that 93 percent and 96 percent of patients with METAVIR F0-F2 scores treated with simeprevir and sofosbuvir with or without ribavirin, respectively, for 12 weeks achieved SVR12.



In genotype 1a patients with the Q80K polymorphism at baseline, 89 percent and 83 percent achieved SVR12 after 12 weeks of treatment with and without ribavirin, respectively. Rapid virologic response (RVR, defined as undetectable HCV RNA at Week 4 of treatment) was not found to be predictive of achieving SVR. In patients receiving simeprevir and sofosbuvir alone for 12 weeks, 93 percent achieved SVR, while 57 percent achieved RVR. The most common adverse events in both treatment arms were fatigue, headache, nausea and insomnia. Two patients discontinued treatment due to adverse events.

"The combination of simeprevir and sofosbuvir demonstrated efficacy, including in patients with more advanced liver fibrosis," said Eric Lawitz, M.D., simeprevir clinical trial investigator, Medical Director at The Texas Liver Institute and Professor of Medicine at University of Texas Health Science Center. "I look forward to seeing the results of the recently announced Phase 3 OPTIMIST trials, which will further evaluate simeprevir and sofosbuvir without interferon or ribavirin."

Phase 3 Efficacy Data in Patients with Genotype 4 Hepatitis C

Results from the Phase 3 RESTORE trial of simeprevir in combination with pegylated interferon and ribavirin in HCV genotype 4 treatment-naïve and treatment-experienced patients demonstrated that overall 65 percent of patients achieved SVR12, including 83 percent of treatment-naïve patients, 86 percent of prior relapsers, 60 percent of prior partial responders, and 40 percent of prior null responders. Among patients with genotype 4a and 4d HCV, 69 percent and 52 percent achieved SVR12, respectively.

In patients with the *IL28B* CT and TT genotypes, 66 percent and 60 percent achieved SVR12, respectively. Among patients with more severe liver fibrosis characterized by a METAVIR score of F3 or F4, 67 percent and 47 percent achieved SVR12, respectively. The most frequent adverse events included influenza-like illness, asthenia (weakness) and fatigue. Genotype 4 HCV is considered particularly difficult to cure and currently only limited treatment options are available.

Subgroup Analyses of Patients from Phase 3 Studies of Simeprevir

Analyses of pooled efficacy data from the QUEST-1 and QUEST-2 studies found 87 percent of European patients treated with simeprevir in combination with pegylated interferon and ribavirin achieved SVR12 compared to 80 percent in the overall study population. In an analysis from the PROMISE study, 88 percent of European patients treated with simeprevir in combination with pegylated interferon and ribavirin achieved SVR12 compared to 79 percent in the overall study population.

The efficacy of simeprevir in combination with pegylated interferon and ribavirin was also observed among European patients with baseline characteristics typically considered more difficult to cure. In QUEST-1 and QUEST-2, 71 percent of patients with METAVIR F4 scores, 86 percent of

patients with the *IL28B* CT genotype, 69 percent of patients with the *IL28B* TT genotype and 64 percent of genotype 1a patients with the Q80K polymorphism at baseline achieved SVR12 in the simeprevir arm, compared to 25 percent, 44 percent, 31 percent and 50 percent of patients in the placebo arm, respectively. In PROMISE, 85 percent of patients with METAVIR F4 scores, 88 percent of patients with the *IL28B* CT genotype, 77 percent of patients with the *IL28B* TT genotype and 75 percent of genotype 1a patients with the Q80K polymorphism at baseline achieved SVR12 in the simeprevir arm, compared to 30 percent, 41 percent, 18 percent and 57 percent of patients treated in the placebo arm, respectively.

"The data presented at The International Liver Congress™ 2014 further reinforce the benefit of simeprevir-based treatment across diverse patient populations, including European patients," said Gaston Picchio, Hepatitis Disease Area Leader, Janssen Research & Development. "Following the recent positive opinion for simeprevir from the Committee for Medicinal Products for Human Use in the European Union, we look forward to bringing simeprevir to patients in Europe in the near future."

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 in combination with pegylated interferon and ribavirin in HCV genotype 1 infected patients with compensated liver disease, including cirrhosis.

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 pegylated interferon and ribavirin 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., and in March 2014 in Russia. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April 2013 by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C and the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending Marketing Authorisation in the European Union for the use of simeprevir in combination with other medicinal products for the treatment of chronic HCV. This application is under review by the EMA.

About Hepatitis C

Hepatitis C, a blood-borne infectious disease of the liver and a leading cause of chronic liver disease, is the focus of a rapidly evolving treatment landscape. Approximately 150 million people are infected with hepatitis C worldwide and 350,000 people per year die from the disease globally. When left untreated, hepatitis C can cause significant damage to the liver including cirrhosis. Additionally, hepatitis C may increase the risk of developing complications from cirrhosis, which may include liver failure.

About Janssen Pharmaceutical Companies

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen R&D Ireland is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit <http://www.janssenrmd.com> for more information.

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