Simeprevir Administered Once Daily as Part of Combination Therapy Demonstrates Sustained Virologic Response in Treatment-Naïve and Treatment-Experienced Genotype 1 Chronic Hepatitis C Adult Patients

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Janssen announced today the presentation of new data for simeprevir in genotype 1 chronic hepatitis C patients with compensated liver disease at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington, DC. These data include analyses of simeprevir in the Phase 3 QUEST-1 and QUEST-2 studies in treatment-naïve patients and the Phase 3 PROMISE study in prior relapse patients, including patients with the IL28B TT genotype and METAVIR scores of F4. This follows last week's unanimous vote by the FDA's Antiviral Drugs Advisory Committee to recommend approval of simeprevir.

Data from the Phase 2a COSMOS study of simeprevir administered once daily with Gilead's investigational nucleotide inhibitor sofosbuvir, with and without ribavirin, in genotype 1 chronic hepatitis C adult patients with compensated liver disease will also be presented during a late-breaking oral session on Monday, November 4.

Simeprevir Administered Once Daily as Part of Combination Therapy Demonstrates Sustained Virologic Response in Treatment-Naïve and Treatment-Experienced Genotype 1 Chronic Hepatitis C Adult Patients

WASHINGTON (Nov. 2, 2013) -- Janssen R&D Ireland (Janssen) today announced the presentation of new data at The Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington, DC for the investigational protease inhibitor simeprevir (TMC435) in the treatment of genotype 1 chronic hepatitis C in treatment-naïve and treatment-experienced adult patients with compensated liver disease. In analyses of the Phase 3 QUEST-1 and QUEST-2 studies in treatment-naïve patients and the Phase 3 PROMISE study in prior relapse patients, the efficacy of simeprevir was observed in hepatitis C patients, including patients with the IL28BTT genotype and METAVIR scores of F4.

"Patients with certain baseline characteristics can be more likely to fail or relapse after prior treatment," said Ira Jacobson, M.D., simeprevir clinical trial investigator, chief of the Division of Gastroenterology and Hepatology, Vincent Astor Distinguished Professor of Medicine, Weill Cornell Medical College, and attending physician, New York-Presbyterian Hospital/Weill Cornell Medical Center. "The breadth of simeprevir data presented at AASLD reinforce its potential as a treatment option for patients and will offer important guidance to physicians once simeprevir is approved."

On October 24, the U.S. Antiviral Drugs Advisory Committee of the FDA voted unanimously (19-0) to recommend approval of the new drug application filed by Janssen Research & Development, LLC for simeprevir administered once daily with pegylated interferon and

ribavirin for the treatment of genotype 1 chronic hepatitis C virus (HCV) in adult patients with compensated liver disease.

Pooled Analysis from QUEST-1 and QUEST-2 Confirms Clinical Benefit of Simeprevir in Sub-Populations of Patients (Abstract 1122)

In a pooled analysis of the Phase 3 QUEST-1 and QUEST-2 studies, 80 percent of treatment-naïve patients treated with simeprevir in combination with pegylated interferon and ribavirin achieved the primary endpoint of sustained virologic response 12 weeks after the end of treatment (SVR12) compared to 50 percent of patients treated with placebo plus pegylated interferon and ribavirin. The pooled analysis found that 61 percent of patients with the IL28B TT genotype, 60 percent of patients with a METAVIR score of F4 and 75 percent of patients with genotype 1a HCV treated with simeprevir combined with pegylated interferon and ribavirin achieved SVR12 compared to 21 percent, 34 percent and 47 percent of patients taking placebo plus pegylated interferon and ribavirin, respectively. Among patients with the genotype 1a Q80K polymorphism at baseline, 58 percent of patients treated with simeprevir combined with pegylated interferon and ribavirin achieved SVR12 compared to 52 percent of patients treated with placebo in combination with pegylated interferon and ribavirin, but the difference was not statistically significant.

Eight percent and 10 percent of patients treated with simeprevir combined with pegylated interferon and ribavirin experienced on-treatment failure and relapse, respectively, compared to 33 percent and 15 percent of patients taking placebo plus pegylated interferon and ribavirin, respectively. Three percent of patients treated with simeprevir discontinued treatment early due to an adverse event compared to two percent of patients treated with placebo.

Analysis from PROMISE Reinforces Efficacy of Simeprevir in Sub-Populations of Patients (Abstract 1092)

In the pivotal Phase 3 PROMISE study, 79 percent of treatment-experienced hepatitis C patients treated with simeprevir in combination with pegylated interferon and ribavirin who previously experienced a relapse after prior treatment with pegylated interferon-based therapy achieved the primary endpoint of SVR12 compared to 37 percent of patients treated with placebo plus pegylated interferon and ribavirin. In this sub-analysis, 65 percent of patients with the IL28B TT genotype, 74 percent of patients with a METAVIR score of F4 and 70 percent of patients with genotype 1a HCV treated with simeprevir combined with pegylated interferon and ribavirin achieved SVR12 compared to 19 percent, 26 percent and 28 percent of patients taking placebo plus pegylated interferon and ribavirin, respectively.Among patients with the genotype 1a Q80K polymorphism at baseline, 47 percent of patients treated with simeprevir combined with pegylated interferon and ribavirin achieved SVR12 compared to 30 percent of patients treated with placebo in combination with pegylated interferon and ribavirin.

The most common adverse events in patients treated with simeprevir combined with pegylated interferon and ribavirin in the first 12 weeks were fatigue, headache and influenza-like illness. Three percent and 18 percent of patients treated with simeprevir combined with pegylated interferon and ribavirin experienced on-treatment failure and relapse, respectively, compared to 27 percent and 34 percent of patients taking placebo plus pegylated interferon and ribavirin, respectively.

"We are very proud of the depth and breadth of our clinical trial program," said Gaston Picchio, Disease Area Leader Hepatitis, Janssen Research & Development. "Following last week's positive vote from the FDA's Antiviral Drugs Advisory Committee to recommend approval of simeprevir, we look forward to making simeprevir available to patients living with chronic HCV."

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 - including approximately 3.2 million people in the United States - 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 Simeprevir

Simeprevir (TMC435) is an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and its affiliated companies and Medivir AB for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including all stages of liver fibrosis. Simeprevir works by blocking the viral protease enzyme that enables the hepatitis C virus to replicate in host cells.

Janssen is responsible for the global clinical development of simeprevir and has acquired exclusive, worldwide marketing rights, except for the Nordic countries. Medivir AB will retain marketing rights for simeprevir in these Nordic countries under the marketing authorization held by Janssen-Cilag International NV. Simeprevir was approved on September 27, 2013 in Japan for the treatment of genotype 1 hepatitis C and a Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C.

Simeprevir is also being studied in several interferon-free regimens using selected combinations of direct-acting antiviral agents with different mechanisms of action. To date, more than 3,700 patients have been treated with simeprevir in clinical trials.

In October, Janssen Pharmaceuticals, Inc. acquired the investigational compound GSK2336805, an NS5a replication complex inhibitor in Phase 2 development for the treatment of chronic HCV, from an affiliate of GlaxoSmithKline plc. Since being acquired, the compound has been renamed JNJ-56914845. Janssen Pharmaceuticals plans to initiate Phase 2 studies to evaluate the use of JNJ-56914845 in interferon-free combinations with simeprevir and TMC647055, the company's non-nucleoside polymerase inhibitor, for the treatment of chronic HCV in adult patients with compensated liver disease.

For additional information about simeprevir clinical trials, please visit www.clinicaltrials.gov.

About Janssen R&D Ireland

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.janssenrnd.com for more information. #