Johnson & Johnson

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Simeprevir Data in Hepatitis C Patients to be Presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD)

CORK, Ireland (Oct. 1, 2013) -- Janssen R&D Ireland (Janssen) announced that data will be presented on the investigational protease inhibitor simeprevir (TMC435) for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease at the upcoming Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), which will take place November 1 to 5 in Washington, D.C.

"Simeprevir's clinical profile has been characterized through a robust clinical development program including more than 3,700 patients," said Gaston Picchio, Disease Area Leader Hepatitis, Janssen. "The study results that will be presented at the AASLD Annual Meeting support the potential utility of simeprevir in a number of different hepatitis C patient populations."

Simeprevir was approved in Japan in September 2013 for the treatment of genotype 1 hepatitis C. In the U.S., the New Drug Application (NDA) filed by Janssen for simeprevir administered once daily in combination with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients was granted Priority Review designation by the Food and Drug Administration (FDA) in May. Simeprevir is also being studied in several interferon-free regimens using selected combinations of direct-acting antiviral agents with different mechanisms of action.

The data to be presented at the 2013 AASLD Annual Meeting include:

Poster Presentations: HCV Therapeutics: New Agents, Poster Hall, November 3, 8:00 a.m. - 5:30 p.m. (EST)

- **Simeprevir (TMC435) with peg-interferon ?-2a/ribavirin for treatment of chronic HCV genotype 1 infection in patients who relapsed after previous interferon-based therapy: Efficacy and safety in patient sub-populations in the PROMISE Phase III trial**
  - Lead Author: Xavier Forns, Hospital Clinic, Barcelona, Spain
- **Adding simeprevir to peginterferon/ribavirin for HCV shortens time with patient-reported symptoms and impairment in quality of life: Results from the simeprevir Phase III QUEST 1, QUEST 2, and PROMISE studies**
  - Lead Author: Jane A. Scott, Janssen
- **Simeprevir (TMC435) with peginterferon/ribavirin for treatment of chronic HCV genotype 1 infection in treatment-naïve patients: Efficacy in difficult-to-treat patient sub-populations in the QUEST-1 and 2 Phase III trials**
  - Lead Author: Ira M. Jacobson, Weill Cornell Medical College, New York, USA
- **Resistance analyses of HCV isolates from patients treated with simeprevir in Phase 2b/3 studies**
  - Lead Author: Oliver Lenz, Janssen
- **The relative efficacy and safety of simeprevir-based triple therapy compared to boceprevir and telaprevir in treatment naïve patients chronically infected with genotype-1 hepatitis C virus: Bayesian network meta-analyses**
  - Lead Author: Peter A. Bryden, Oxford Outcomes

Full session details and data presentation listings for the 2013 AASLD Annual Meeting can be found at http://www.aasld.org/livermeeting.

About Simeprevir
Simeprevir is an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland 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 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 in the Nordic countries. Medivir will retain marketing rights for simeprevir in these countries. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C. To date, more than 3,700 patients have been treated with simeprevir in clinical trials.

Additionally, simeprevir is being studied in combination with several direct-acting antiviral agents (DAAs) with different mechanisms of action, with and without ribavirin, as part of interferon-free regimens. These include:

- The Phase 2 COSMOS study of simeprevir and Gilead's nucleotide polymerase inhibitor sofosbuvir (GS-7977) in treatment-naïve and previous null-responder genotype 1 HCV patients, including patients with cirrhosis;
- A Phase 2 study of simeprevir and Bristol-Myers Squibb's NS5A replication complex inhibitor daclatasvir in treatment-naïve and previous null-responder genotype 1 HCV patients;
- The Phase 2 HELIX-1 study of simeprevir and Idenix's once-daily pan-genotypic NS5A inhibitor samatasvir (IDX719) in treatment-naïve genotype 1b and genotype 4 HCV patients.

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

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 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.

Media Contact: Daniel De Schryver
Mobile: +49 173 76 89 149

Media Contact: Craig Stoltz
Mobile: +1 (215) 325-3612

Investor Contact: Stan Panasewicz
Office: +1 (732) 524-2524

Investor Contact: Louise Mehrotra
Office: +1 (732) 524-6491