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Primary Efficacy and Safety Findings from Phase 3 Study of Janssen's Simeprevir Administered Once Daily Demonstrate Sustained Virologic Response in Treatment-Experienced Genotype 1 Chronic Hepatitis C Adult Patients

ORLANDO, Fla. (May 21, 2013) -- Janssen R&D Ireland (Janssen) today announced primary efficacy and safety results from the global Phase 3 PROMISE study demonstrating that use of the investigational protease inhibitor simeprevir (TMC435) led to sustained virologic response 12 weeks after the end of treatment (SVR12) in 79 percent of treatment-experienced genotype 1 chronic hepatitis C adult patients with compensated liver disease, including all stages of liver fibrosis, when administered once daily with pegylated interferon and ribavirin.

In the study, 37 percent of patients receiving placebo plus pegylated interferon and ribavirin achieved SVR12. In the simeprevir arm, on-treatment failure rates were 3 percent and relapse rates were 19 percent, compared to 27 percent and 48 percent in the placebo arm. All patients had previously relapsed following pegylated interferon-based therapy. The data were presented today as a later breaker oral presentation at Digestive Disease Week 2013 in Orlando, Florida based on abstract number 869b, "Simeprevir (TMC435) With Peginterferon/Ribavirin for Treatment of Chronic HCV Genotype 1 Infection in Patients Who Relapsed After Previous Interferon-Based Therapy: Results From PROMISE, a Phase III Trial."

"Hepatitis C is a complex disease and physicians need multiple treatment options to provide their patients the best possible chance at successful therapy," said Eric Lawitz, M.D., professor of medicine at University of Texas Health Science Center, Vice President, scientific and research development, The Texas Liver Institute and principal investigator of the PROMISE trial. "I'm pleased that the primary efficacy and safety results from the PROMISE study of simeprevir show sustained virologic response in patients who had relapsed following previous treatment with interferon-based regimens."

In PROMISE, patients were randomized to receive simeprevir or placebo for 12 weeks plus pegylated interferon and ribavirin for 24 or 48 weeks. In findings related to a secondary endpoint, 93 percent of patients receiving simeprevir were able to shorten therapy with pegylated interferon and ribavirin to 24 weeks as a result of meeting response-guided therapy criteria. Eighty-three percent of those patients meeting response-guided therapy criteria to stop treatment at 24 weeks achieved SVR12.

Patients enrolled in PROMISE were stratified by hepatitis C virus (HCV) genotype 1 subtype and *IL28B* genotype. SVR12 rates among patients treated with simeprevir according to *IL28B* genotype were 89 percent for the CC allele, 78 percent for the CT allele, and 65 percent for the TT allele, compared to 53 percent for the CC allele, 34 percent for the CT allele and 19 percent for the TT allele in the placebo arm. Among patients with METAVIR scores F0 to F2, 82 percent of patients treated with simeprevir and 41 percent with placebo achieved SVR12. Among patients with METAVIR scores F3 and F4, 73 percent and 74 percent of patients treated with simeprevir and 20 percent and 26 percent treated with placebo achieved SVR12, respectively. The METAVIR score is used to quantify the degree of inflammation and fibrosis of the liver and patients are scored on a five-point scale.

"Janssen is pleased to share the primary endpoint results from PROMISE with the scientific community alongside primary data from our Phase 3 QUEST-1 and QUEST-2 studies of simeprevir, which are also being presented at DDW," said Maria Beumont, M.D., medical leader for simeprevir, Janssen. "We now have robust data for simeprevir in both treatment-experienced and treatment-naïve patients that demonstrate primary efficacy and safety in patients with genotype 1 chronic hepatitis C."

The most common adverse events seen in patients receiving simeprevir versus placebo in PROMISE were fatigue (32 percent versus 42 percent), headache (32 percent versus 36 percent) and influenza-like illness (30 percent versus 20 percent), respectively. In addition, rash (19 percent versus 14 percent), itching (24 percent versus 17 percent), neutropenia (15 percent versus 17 percent), anemia (11 percent versus 6 percent), increased bilirubin (6 percent versus 2 percent), and photosensitivity conditions (4 percent versus none) were also observed. One patient in the simeprevir arm and no patients in the placebo arm discontinued treatment due to an adverse event.

Digestive Disease Week® (DDW®) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 18 - 21, 2013, at the Orange County Convention Center, Orlando, Florida. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About PROMISE
PROMISE is a global, Phase 3, randomized, double-blind, placebo-controlled clinical trial assessing the efficacy, safety and tolerability of simeprevir plus pegylated interferon and ribavirin versus pegylated interferon and ribavirin alone in adult patients with genotype 1 chronic hepatitis C with compensated liver disease, including all stages of liver fibrosis, who relapsed after previous interferon-based therapy.

In the PROMISE trial, 393 patients were randomized to receive one 150 mg capsule of simeprevir or placebo once daily plus pegylated interferon and ribavirin for 12 weeks, followed by pegylated interferon and ribavirin alone for either 12 or 36 weeks based on response-guided therapy criteria. Patients in the simeprevir arm were considered to have met response-guided therapy criteria if their HCV RNA levels were <25 IU/mL (detectable or undetectable) at week 4 and <25 IU/mL undetectable at week 12. In patients meeting response-guided therapy criteria, HCV therapy was stopped at week 24. All other patients continued treatment until week 48.

About Simeprevir
Simeprevir (TMC435) 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. New drug applications were recently submitted for simeprevir in Japan and the United States for the treatment of genotype 1 hepatitis C, and a Marketing Authorisation Application was submitted to the European Medicines Agency seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C. The U.S. FDA has granted Priority Review to the New Drug Application.

Global Phase 3 studies of simeprevir include PROMISE in adult patients who have relapsed after prior interferon-based treatment, QUEST-1 and QUEST-2 in treatment-naïve adult patients, and ATTAIN in prior null-responder adult patients. In parallel to these trials, Phase 3 studies for simeprevir are ongoing in treatment-naïve and treatment-experienced HIV-HCV co-infected patients and HCV genotype 4 patients. To date, 3,787 patients have been treated with simeprevir in clinical trials.

Simeprevir is also being studied in Phase 2 interferon-free trials with and without ribavirin in combination with:

- Janssen's non-nucleoside inhibitor TMC647055 and ritonavir in treatment-naïve genotype 1a and 1b HCV patients;
- Gilead Sciences, Inc.'s nucleotide inhibitor sofosbuvir (GS-7977) in treatment-naïve and previous null-responder genotype 1 HCV patients; and
- Bristol-Myers Squibb's NS5A replication complex inhibitor daclatasvir in treatment-naive and previous null-responder genotype 1 HCV patients.

In addition, Janssen Pharmaceuticals, Inc. has entered into a non-exclusive collaboration with Vertex Pharmaceuticals to evaluate in a Phase 2 study the safety and efficacy of an all-oral regimen of simeprevir and Vertex's investigational nucleotide analogue polymerase inhibitor VX-135 for the treatment of HCV. As a first step, Janssen Pharmaceuticals, Inc. is conducting a drug-drug interaction (DDI) study with simeprevir and VX-135. Janssen Pharmaceuticals, Inc. also has plans to initiate a Phase 2 trial of an investigational interferon-free regimen with simeprevir, TMC647055 and Idenix's IDX719, a once-daily, pan-genotypic NS5A inhibitor, with and without ribavirin.

For additional information about simeprevir clinical trials, 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 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.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 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, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new

products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; impact of business combinations; 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 Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)