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Janssen Initiates Phase 3 OPTIMIST Trials of Once-Daily Simeprevir in Combination with Once-Daily Sofosbuvir for the Treatment of Genotype 1 Chronic Hepatitis C

OPTIMIST represents the first Phase 3 studies of the two treatments in a regimen without interferon and ribavirin

CORK, Ireland (April 2, 2014) -- Janssen R&D Ireland (Janssen) announced today that two Phase 3 trials are recruiting patients to examine the efficacy and safety of the NS3/4A protease inhibitor simeprevir in combination with the nucleotide inhibitor sofosbuvir for the treatment of chronic genotype 1 hepatitis C virus (HCV) infection in treatment-naïve and treatment-experienced patients with and without cirrhosis. Simeprevir is approved in the U.S., Canada, Japan and Russia for the treatment of genotype 1 HCV as part of an antiviral treatment regimen in combination with pegylated interferon and ribavirin and the Committee for Medicinal Products for Human Use 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. The combination of simeprevir and sofosbuvir was previously evaluated in the Phase 2 COSMOS trial.

"The combination of simeprevir and sofosbuvir with and without ribavirin demonstrated efficacy and safety in treatment-naïve and treatment-experienced patients, including those with cirrhosis, in the Phase 2 COSMOS study," said Gaston Picchio, Hepatitis Disease Area Leader, Janssen. "The initiation of these Phase 3 clinical trials is the latest fulfillment of Janssen's commitment to investigate the utility of simeprevir for patients with chronic hepatitis C infection."

The first trial, known as OPTIMIST-1 (**Op**timal **T**reatment w**i**th a si**m**eprev**i**r and **s**ofosbuvir **T**herapy) or TMC435HPC3017, is a Phase 3, multicenter, open-label, randomized study investigating the efficacy and safety of simeprevir 150 mg in combination with sofosbuvir 400 mg. The combination will be administered once daily for 8 or 12 weeks in chronic HCV genotype 1 infected patients without cirrhosis who are HCV treatment naïve or treatment experienced. The second trial, known as OPTIMIST-2 or TMC435HPC3018, is a Phase 3, multicenter, open-label, single-arm study investigating the efficacy and safety of simeprevir 150 mg in combination with sofosbuvir 400 mg. The combination will be administered once daily for 12 weeks in HCV genotype 1 infected patients with cirrhosis who are HCV treatment naïve or treatment experienced. Ribavirin will not be administered in the OPTIMIST trials.

The primary efficacy endpoint in each study is the proportion of patients achieving sustained virologic response 12 weeks after the end of treatment (SVR12). The studies will seek to enroll approximately 400 patients in the U.S. and Canada.

The final cohort 1 study results (SVR12) and the interim cohort 2 study results (SVR4) from the COSMOS study were presented as a late-breaker abstract at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting 2013 in Washington, D.C. Final cohort 2 results (SVR12) have been accepted for presentation at the International Liver Congress 2014™ of the European Association for the Study of the Liver (EASL) on April 12. For additional information, including inclusion and exclusion criteria for these trials, please visit www.clinicaltrials.gov.

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 genotype 1 hepatitis C in September 2013 in Japan and in November 2013 in Canada and the U.S. 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.janssenrnd.com for more information.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product research and 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen R&D Ireland and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainties inherent in research and development, including the ability to carry out the clinical trials as planned, the possibility of unfavorable clinical trial results and challenges in 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; and general industry conditions including trends toward health care cost containment. 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 our 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.)