



October 7, 2013

Simeprevir Data from COSMOS study in Hepatitis C Patients Accepted as Late-Breaking Presentation at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD)

CORK, Ireland (Oct. 7, 2013) -- Data from the Phase 2a COSMOS study (**Combination Of Simeprevir and Sofosbuvir in HCV genotype 1 infected patients**) of the investigational protease inhibitor simeprevir (TMC435) administered once daily with Gilead Sciences Inc.'s investigational nucleotide inhibitor sofosbuvir (GS-7977), with and without ribavirin, in genotype 1 chronic hepatitis C adult patients with compensated liver disease has been accepted as a late-breaking oral presentation at the upcoming Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). AASLD will take place November 1 to 5 in Washington, D.C.

The COSMOS data will be presented during the late-breaking oral session on Monday, November 4, 2:45-4:30 p.m. (EST) in Hall E:

- **SVR results of a once-daily regimen of simeprevir (TMC435) plus sofosbuvir (GS-7977) with or without ribavirin in cirrhotic and non-cirrhotic HCV genotype 1 treatment-naïve and prior null responder patients: The COSMOS study**
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Additional simeprevir data are scheduled for presentation at the 2013 AASLD Annual Meeting on Sunday, November 3 and were [announced](#) on October 1. 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 and genotype 4 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.

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. 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.

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.

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.

(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.)