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Janssen Submits New Drug Application to U.S. FDA for Simeprevir (TMC435) for Combination Treatment of Adult Patients with Genotype 1 Chronic Hepatitis C

-- Filing Based on Phase 3 Data in Treatment-Naïve and Treatment-Experienced Patients with Compensated Liver Disease --

RARITAN, N.J., March 28, 2013 /PRNewswire/ -- Janssen Research & Development, LLC (Janssen) today announced it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for simeprevir (TMC435), an investigational NS3/4A protease inhibitor, administered as a 150 mg capsule once daily with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients.

"Hepatitis C is a complicated disease and genotype 1 hepatitis C can be particularly difficult to cure. Given the complexity and diversity of the patient population, physicians need multiple options to provide their patients a chance at treatment success," said Wim Parys, Global Head of Development, Infectious Diseases and Vaccines, Janssen. "The U.S. filing represents an important step forward in bringing simeprevir to market and in helping to battle this challenging disease."

Hepatitis C virus (HCV) is a blood-borne infectious disease of the liver that affects approximately 3.2 million people in the United States. When left untreated over time, HCV can cause significant damage to the liver, including cirrhosis.

The regulatory submission for simeprevir is supported in part by data from three pivotal Phase 3 studies: QUEST-1 and QUEST-2 in treatment-naïve patients and PROMISE in patients who have relapsed after prior interferon-based treatment. In each study, participants were treated with one 150 mg simeprevir capsule once daily for 12 weeks plus pegylated interferon and ribavirin for 24 or 48 weeks. Primary efficacy data from the Phase 3 studies will be presented at an upcoming medical meeting.

About Simeprevir

Simeprevir (TMC435) is an investigational NS3/4A protease inhibitor jointly developed by Janssen and Medivir AB for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease. Simeprevir is believed to work by blocking the protease enzyme that enables the hepatitis C virus to survive and replicate in host cells.

For additional information about simeprevir clinical studies, 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, HCV can cause significant damage to the liver including cirrhosis. Additionally, hepatitis C may increase the risk of developing complications from cirrhosis, which can include liver failure.

About Janssen Research & Development, LLC

Janssen Research & Development, LLC is headquartered in Raritan, N.J. and has affiliated facilities in Europe, the United States and Asia. Janssen Research & Development is leveraging a combination of internal and external innovation to discover and develop novel medicines and solutions in five distinct therapeutic areas: Neuroscience, Oncology, Immunology, Infectious Diseases and Vaccines, and Cardiovascular and Metabolism. For more information about Janssen Research & Development, LLC visit www.janssenrnd.com.

(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 Research & Development, LLC 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; 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. Neither Janssen Research & Development, LLC nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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