



October 24, 2013

## **FDA Advisory Committee Recommends Approval of Simeprevir for Combination Treatment of Genotype 1 Chronic Hepatitis C in Adult Patients**

RARITAN, N.J. (October 24, 2013) -- Janssen Research & Development, LLC (Janssen) announced today that the Antiviral Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted unanimously (19 to 0) to recommend approval of the investigational protease inhibitor simeprevir (TMC435) administered once daily as a 150 mg capsule with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis. The Advisory Committee recommended the approval of simeprevir based on analyses of data from clinical trials in patients who are treatment naïve or who have failed previous interferon-based therapy.

"We are pleased with the positive recommendation from the Advisory Committee for simeprevir and appreciate the rigorous review of our data," said Katia Boven, M.D., Medical Department Head, Infectious Diseases and Vaccines, Janssen. "It is our hope that the FDA will consider this recommendation and, upon completion of its review process, make simeprevir available to patients with genotype 1 chronic hepatitis C."

The FDA granted a Priority Review designation in May to the New Drug Application (NDA) filed by Janssen for simeprevir. Recommendations and findings from the Advisory Committee are based in part on efficacy and safety data from an extensive clinical development program for simeprevir and will be considered by the FDA in its review of the NDA for simeprevir, but the FDA is not required to follow them.

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 - as well as data from the Phase 2b ASPIRE study in prior non-responder patients. Janssen R&D Ireland presented data from the QUEST-1 and QUEST-2 studies earlier this year at the 48<sup>th</sup> Annual Meeting of the European Association for the Study of the Liver (EASL) in Amsterdam, The Netherlands, and presented data from PROMISE at Digestive Disease Week 2013 (DDW) in Orlando, Florida. Data from ASPIRE were presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in 2012.

### **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 Simeprevir**

Simeprevir (TMC435) is an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and its affiliated companies and Medivir AB for the treatment of genotype 1 and genotype 4 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis. 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 in the Nordic countries. Medivir AB will retain marketing rights for simeprevir in Nordic countries under the marketing authorization held by Janssen-Cilag International NV. Simeprevir was approved on September 27, 2013 in Japan for the treatment of genotype 1 hepatitis C and a Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) by Janssen-Cilag International NV 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.

For additional information about simeprevir clinical trials, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **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](http://www.janssenrnd.com).

Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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