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***Janssen receives positive CHMP opinion for simeprevir in the treatment of adults with chronic hepatitis C in the European Union***

**BEERSE, BELGIUM [March 21, 2014]** Janssen R&D Ireland (Janssen) today announced that 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 hepatitis C (CHC) in adult patients.[1]

Simeprevir is a new generation, NS3/4A protease inhibitor administered as a once daily 150 mg capsule with pegylated interferon (pegIFN) and ribavirin (RBV) offering proven efficacy across a range of different hepatitis C virus (HCV) patient types.[2]

The CHMP opinion was based on positive and consistent results from three pivotal Phase 3 studies in patients with genotype 1 HCV: QUEST-1 and QUEST-2 in treatment-naïve patients and PROMISE in patients who have relapsed after prior interferon-based treatment. The studies involved over 1000 patients. QUEST-1 and QUEST-2 included 785 treatment-naïve patients with genotype 1 chronic HCV infection. PROMISE included 393 relapser patients with genotype 1 chronic HCV infection. All three studies met their primary end points and demonstrated simeprevir, in combination with pegIFN and RBV, achieves superior cure rates when compared with PegIFN and RBV alone, in treatment naïve and prior-relapser patients.[2,3]

Simeprevir is generally well tolerated, with the most common adverse events reported in clinical trials (incidence ≥ 5%) including nausea, rash, pruritus, dyspnoea, blood bilirubin increase and photosensitivity reaction.[1]

HCV is a major health problem in the European Union, where nine million people are living with the disease. Treatment of HCV is complex because of the unpredictable course of the infection and the heterogeneous population of patients it affects. Treatment efficacy is also highly dependent on the genotype of the virus.[4]

*"The CHMP positive opinion for simeprevir brings us another step closer to delivering an innovative therapy for patients suffering from this devastating disease. Simeprevir offers a potentially new treatment option and therefore renewed hope to people living with HCV,"*

said Brian Woodfall, Head of Development & Global Medical Affairs, Infectious Diseases/Vaccines, Janssen.

A CHMP positive opinion is the last step prior to the European Commission potentially granting Marketing Authorisation to a medicinal product. It does not guarantee approval. A final decision on simeprevir by the European Commission is anticipated during the second quarter of 2014.

**-ENDS-**

**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 genotype 1 HCV 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 will retain marketing rights for simeprevir in these countries under the marketing authorisation held by Janssen-Cilag International NV. The treatment was approved for the treatment of genotype 1 HCV 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 HCV. This application is under review by the EMA.

**About hepatitis C**
Hepatitis C (HCV) is a major global public health concern. It is a serious and complex blood-borne virus which manifests itself through complications of the liver. If left untreated, it can cause significant and potentially fatal damage to the liver including cirrhosis, leading to eventual transplantation. In Europe it is a leading cause of liver transplantation.[5]

The World Health Organisation (WHO) and the European Association for the Study of the Liver (EASL) estimate that 160 million people worldwide were chronically infected with HCV in 2011.[4] The virus is responsible for 350,000 deaths globally[6] and 86,000 deaths in the European region each year.[7] As the disease is often asymptomatic in its early stages it can be difficult to diagnose and treat. Up to 90 percent of those with HCV do not clear the virus without treatment and become chronically infected.[8] The WHO estimates that 20 percent of people with HCV will develop cirrhosis and, of those, up to 20 percent may progress to liver cancer.[9] Genotype 1 HCV is the most prevalent form of the virus worldwide[10] and one of the most challenging to treat successfully.

**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.

**Janssen Forward Looking Statement**

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 and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations; competition, including 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; general industry conditions including 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 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. Neither Janssen nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

**References**


[1] Committee for Medicinal Products for Human Use (CHMP) report. Available from http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/002777/WC500163524.pdf Accessed March 2014.

[2] Forns X et al. Simeprevir with Peginterferon and Ribavirin Leads to High Rates of SVR in Patients with HCV Genotype 1 Who Relapsed After Previous Therapy: a Phase 3 Trial. Gastroenterology. 2014 Mar 3. pii: S0016-5085(14)00293-5. doi: 10.1053/j.gastro. 2014.02.051. [Epub ahead of print]

[3] Jacobson I et al. The QUEST 1 and 2 studies, abstract presented at the 64th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD).

[4] European Association for the Study of the Liver. EASL Clinical Practice Guidelines: Management of hepatitis C virus infection. *Journal of Hepatology*. 2011:55,245-264.

[5] European Association for the Study of the Liver. EASL The Burden of Liver Disease in Europe. Available from http://www.easl.eu/assets/application/files/54ae845caec619f_file.pdf. Accessed March 2014.

[6] World Health Organisation. Hepatitis C. Fact sheet N. 164. Available at: http://www.who.int/mediacentre/factsheets/fs164/en/. Accessed March 2014.

[7] Muhlberger M et al. HCV-related burden of disease in Europe: a systematic assessment of incidence, prevalence, morbidity, and mortality. *BMC Public Health* 2009:9,34.

[8] World Health Organisations (WHO). "Hepatitis C: About HCV Infection." Available at: www.who.int/csr/disease/hepatitis/whocdscsrlyo2003/en/index3.html Accessed March 2014.

[9] World Health Organisation. Hepatitis C. Available at: http://www.who.int/csr/disease/hepatitis/Hepc.pdf. Accessed March 2014

[10] Zein NN. Clinical Significance of Hepatitis C Virus Genotypes. *Clin. Microbiol.* Rev. April 2000:13(2),223-235.