April 24, 2013

Janssen Submits Marketing Authorisation Application for Simeprevir (TMC435) to the European Medicines Agency for the Treatment of Adult Patients with Chronic Hepatitis C Genotype 1 or Genotype 4

Submission Based on Phase III Data in HCV Patients, Including Patients with Compensated Liver Disease

Beerse, Belgium (April 24, 2013) - Janssen-Cilag International NV (Janssen) today announced it has submitted a Marketing Authorisation Application to the European Medicines Agency seeking approval for simeprevir (TMC435).

Simeprevir is a new generation NS3/4A protease inhibitor, administered as one capsule once daily with pegylated interferon and ribavirin for the treatment of genotype 1 or genotype 4 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis), with or without HIV-1 co-infection, who are treatment naive or who have failed previous interferon therapy. Genotype 1 is the most prevalent form of hepatitis C virus (HCV) worldwide.[1-2] Simeprevir is currently in phase III development.

If approved, people living with HCV would have the option of a new generation protease inhibitor-based regimen that includes simeprevir taken once daily for 12 weeks in combination with 24 or 48 weeks of pegylated interferon and ribavirin.

"Nine million people across Europe have hepatitis C and 50 to 70% are infected with the genotype 1 virus, which can be particularly difficult to cure. Additionally, patients infected with the genotype 4 virus lack new treatment options. This filing of simeprevir in Europe represents an important step forward in the process of bringing simeprevir to market and helping to battle this challenging disease," said Wim Parys, Global Head of Development, Infectious Diseases and Vaccines, Janssen.

The regulatory submission for simeprevir is supported by primary efficacy data from three Phase III studies in patients with genotype 1 hepatitis C: QUEST-1 and QUEST-2 in treatment-naïve patients, and PROMISE in patients who have relapsed after prior interferon-based treatment. Data from a phase II and an ongoing phase III study support the use in patients with genotype 4 virus.

About Simeprevir
Simeprevir (TMC435) is a new generation NS3/4A protease inhibitor jointly developed by Janssen and Medivir AB to treat chronic hepatitis C, currently in phase III development. Simeprevir works by blocking the protease enzyme that enables the HCV to survive and replicate in host cells.

Janssen Therapeutics EMEA, a division of Janssen Pharmaceutica NV has the commercialization rights of simeprevir in EMEA. Medivir AB will commercialize the product in the Nordic countries.

For additional information about simeprevir clinical studies, please visit: https://www.clinicaltrialsregister.eu or www.clinicaltrials.gov

About Hepatitis C
Hepatitis C is a blood-borne infectious disease of the liver that affects approximately 150 million people worldwide, and causes 350,000 deaths annually.[3] In the European region alone the incidence rate is 8.7 per 100,000 and leads to 86,000 deaths annually.[4]

If left untreated, HCV can cause significant damage to the liver including cirrhosis. It is the leading cause of primary liver cancers in Europe.[1]

About Janssen
At Janssen, we are dedicated to addressing some of the most important unmet medical needs 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 Therapeutics EMEA is a division of Janssen Pharmaceutica NV, fully dedicated to HCV and simeprevir. Janssen-Cilag International NV is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssen-emea.com and www.janssentherapeutics-emea.com for more information.

References

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2. Zein NN. Clinical Significance of Hepatitis C Virus Genotypes. *Clin. Microbiol.* Rev. April 2000;13(2):223-235.
3. World Health OrganisationMedia Centre:Hepatitis C Fact Sheet No. 164; July 2012. http://www.who.int/mediacentre/factsheets/fs164/en/index.html. Last accessed April 2013.
4. World Health Organisation Region Office for Europe; What we do; Hepatitis. http://www.euro.who.int/en/what-we-do/health-topics/communicable-diseases/hepatitis. Last accessed April 2013.

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