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OLYSIO™ (simeprevir) receives marketing authorisation in the European Union for the treatment of adults with hepatitis C genotype 1 and 4 infection

Simeprevir provides a new triple therapy treatment option, as well as the first ever 12-week interferon-free and ribavirin independent treatment regimen, in combination with sofosbuvir, for appropriate patients in Europe

BEERSE, BELGIUM [May 16, 2014] Janssen-Cilag International NV today announced that its next generation protease inhibitor (PI) OLYSIO™ (simeprevir) has been granted marketing authorisation by the European Commission (EC) for the treatment of adults with genotype 1 and 4 chronic hepatitis C (CHC), in combination with other medicinal products, which includes[1]:

Patient population	Treatment	Duration
Patients with HCV genotype 1 or 4, regardless of prior treatment history and who are intolerant to or ineligible for interferon (IFN) treatment	Simeprevir + sofosbuvir, with or without ribavirin (RBV)	12 weeks
Treatment-naïve and prior relapse patients with genotype 1 or 4 with or without cirrhosis and those co-infected with human immunodeficiency virus (HIV)	Simeprevir + pegylated interferon (PegIFN) + RBV	24 weeks Treatment with simeprevir must be initiated in combination with PegIFN + RBV and administered for 12 weeks, followed by an additional 12 weeks of PegIFN + RBV
Prior non-responder patients (including partial and null responders) with HCV genotype 1 or 4 and those co-infected with HIV	Simeprevir + PegIFN + RBV	48 weeks Treatment with simeprevir must be initiated in combination with PegIFN + RBV and administered for 12 weeks, followed by an additional 36 weeks of PegIFN + RBV

This marketing authorisation represents a significant milestone in the development of new triple therapy hepatitis C (HCV) treatment options for genotype 1 and 4 patients. It also includes simeprevir as part of an all oral 12-week IFN-free direct-acting antiviral (DAA) regimen with or without RBV, in genotype 1 or 4 patients, who are intolerant to or ineligible for IFN treatment.[1]

"The EC marketing authorisation for simeprevir is a great milestone as it adds an important new treatment option for patients, demonstrating the continued role of triple therapy in the treatment of HCV. In addition, the introduction of an all oral, 12-week interferon-free treatment regimen provides a new option for sustained virologic response in HCV patients with genotypes 1 or 4 intolerant to or ineligible for interferon-based treatment," said Thomas Stark, Medical Director, Janssen EMEA.

HCV represents a major global public health concern. There are an estimated nine million people[2] living with HCV in Europe which, if untreated, can cause severe damage to the liver, including cirrhosis and hepatocellular carcinoma (HCC). HCV represents a leading cause of liver transplantation in Europe.[3] Whilst the number of patients being newly diagnosed with HCV is declining, it takes approximately 20 - 30 years for symptoms to appear, with HCV cases expecting to peak between 2030 and 2035.[4,5]

Dr Andrew Ustianowski, Chair of the British Viral Hepatitis Group and Consultant in Infectious Diseases at North Manchester General Hospital, commented: *"The treatment environment in hepatitis C infection is evolving rapidly. Simeprevir is a well-tolerated and efficacious addition to our therapies against hepatitis C, and is a very welcome development for both those with genotype 1 and those with genotype 4."*

The EC marketing authorisation for simeprevir with PegIFN + RBV is based on a clinical trial programme involving three pivotal Phase 3 studies, with over 1000 patients. The trials, QUEST-1, QUEST-2[6] and PROMISE[7], explored the use of simeprevir in combination with PegIFN + RBV in treatment-naïve patients and patients who have relapsed after prior interferon-based treatment. All three studies met their primary endpoints and demonstrated that simeprevir, in combination with PegIFN + RBV, achieves significant sustained virological response rates when compared with PegIFN + RBV alone.

The EC marketing authorisation for the combination of simeprevir and sofosbuvir also contains results from the Phase 2 study, COSMOS, in treatment-naïve patients. This was based upon prior null responder and treatment-naïve patients.[8]

Simeprevir is taken once-daily for 12 weeks, with treatment-naïve and prior-relapser patients receiving pegylated interferon and ribavirin for 24 weeks, and for 48 weeks total by those shown to be prior non-responder patients (including partial and null responders)[1]. It 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]

In March 2013, simeprevir was approved for the treatment of genotype 1 HCV in Japan, in Canada in September 2013, and the U.S. in November 2013, with the most recent approval occurring in Russia in March 2014. Following the EC marketing authorisation, it is anticipated that simeprevir will be available across a number of European Union countries, in conjunction with reimbursement, in the second half of 2014.

About Simeprevir
Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB.

Janssen is responsible for the global clinical development of simeprevir and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir AB retains marketing rights for simeprevir in these countries under the marketing authorisation held by Janssen-Cilag International NV. Simeprevir was approved for the treatment of genotype 1 hepatitis C in September 2013 in Japan, in November 2013 in Canada and the U.S., and in March 2014 in Russia.

About 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 HCV is a leading cause of liver transplantation.[2]

The World Health Organisation (WHO) and the European Association for the Study of the Liver (EASL) estimate that 150 million people worldwide were chronically infected with HCV in 2011.[9] The virus is responsible for 350,000 deaths globally[9] and 86,000 deaths in the European region each year.[10] 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.[11] 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.[12] Genotype 1 HCV is the most prevalent form of the virus worldwide[13] and one of the most challenging to treat successfully.

About Janssen Pharmaceutical Companies
The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases. Driven by our commitment to patients, Janssen develops innovative products, services and healthcare solutions to help people throughout the world.

More information can be found at www.janssen-emea.com

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.

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