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Janssen Presents New Data Assessing OLYSIO® (Simeprevir) in Combination with Sofosbuvir in Genotype 4 Infected HCV Patients In Egypt

--OSIRIS study results presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco--

BEERSE, BELGIUM [November 16, 2015] Janssen-Cilag International NV (Janssen) today announced the preliminary results from the Phase IIa OSIRIS trial, at the Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco. The OSIRIS trial, investigating once daily OLYSIO® (simeprevir) in combination with sofosbuvir in hepatitis C virus (HCV) genotype 4 infected patients, with and without liver cirrhosis, demonstrated treatment to be safe and generally well tolerated, with Sustained Virological Response (SVR12) rates of up to 100% in patients treated for 12 weeks regardless of fibrosis stage and treatment history.[1]

"Genotype 4 is the most common HCV genotype within the Middle Eastern region and is especially prevalent in Egypt where 8%-10% of the population are infected with HCV, and almost all infections are due to genotype 4," said Professor Waked, Professor of Medicine, National Liver Institute, Egypt and lead OSIRIS study investigator. "With the majority of published research being focused on genotype 1 HCV, it's important to conduct studies such as the OSIRIS trial to aid our understanding of how best to treat genotype 4 infected patients."

The OSIRIS trial assessed genotype 4 infected patients (n=63) both treatment naïve and treatment experienced, with and without liver cirrhosis, who were treated with 150mg of simeprevir in combination with 400mg sofosbuvir once daily. Patients without liver cirrhosis were randomized to receive either 8 or 12 weeks of treatment while patients with cirrhosis were assigned to receive 12 weeks of treatment.[1]

Results demonstrated 100% SVR12 rates in patients (n=43) treated for 12 weeks, and 75% in patients (n=20) treated for 8 weeks. Out of the five patients who relapsed in the 8 week arm, all were non-responder to other therapies with IL28B non-CC genotype. The most common adverse events (≥10%) were increased lipase, pruritus, and headache. One patient reported treatment-emergent serious adverse events (pleural effusion and pulmonary hypertension;) neither considered to be related to simeprevir. There were no discontinuations due to adverse events.[1]

"The results of the OSIRIS trial presented at the Liver Meeting® show simeprevir in combination with sofosbuvir to be an effective interferon free treatment option for patients infected with genotype 4 HCV," said Isabelle Lonjon-Domanec, European Therapeutic Area Leader Infectious Diseases, Janssen Pharmaceuticals. "The Middle East and North Africa have some of the highest prevalence of HCV in the world and it's important to find treatment options that are effective in the fight against HCV in these countries."

HCV continues to be a major public health burden in Egypt, where an estimated 7.5 million people are living with the disease.[2,3] 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.

Janssen remains committed to investigating and providing effective treatment solutions for patients, particularly in the geographies where high unmet needs continue to demand attention.

For further information on simeprevir's indication in Europe, please view the European and UK summary of product characteristics: http://www.medicines.org.uk/emc/medicine/28888

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About Hepatitis C

Hepatitis C, a blood-borne infectious disease of the liver and a leading cause of chronic liver disease, is a major global public health concern. Approximately 170 million people are infected with hepatitis C worldwide[4] and 350,000 people per year die from the disease globally[5]. 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.[4]

About Janssen's HCV Clinical Development Program

The goal of the Janssen HCV clinical development program is to provide physicians with multiple treatment options in order to offer patients the best possible chance at successful therapy. Ongoing studies focus on the investigation of simeprevir in a number of different treatment combinations and HCV patient populations, including those who are difficult to cure.

Following the acquisition of Alios BioPharma by Johnson & Johnson in November 2014 the Janssen HCV pipeline also includes AL-335, a uridine based nucleotide analog in Phase 1 development, and AL-516, a guanosine-based nucleotide analog NS5B polymerase inhibitor in pre-clinical development.

In May 2015, Janssen Pharmaceuticals Inc. entered into an exclusive worldwide license and collaboration arrangement with Achillion Pharmaceuticals, Inc. to develop and commercialize one or more of Achillion's lead HCV assets which include ACH-3102, ACH-3422 and sovaprevir. A key objective of the collaboration will be to combine assets from the respective portfolios to develop a short-duration, highly effective, pan-genotypic, oral regimen for the treatment of HCV.

About Simeprevir (OLYSIO®)
Simeprevir is an NS3/4A protease inhibitor which has been developed by Janssen Sciences Ireland UC in collaboration with Medivir AB.

In November 2013, simeprevir was initially approved by the U.S. Food and Drug Administration, and in May 2014, it was granted marketing authorisation by the European Commission. Subsequent marketing authorisations have followed in several other countries around the world. Indications vary by market.

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.

About Janssen Pharmaceutical Companies of Johnson & Johnson
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-Cilag International NV is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit http://www.janssen.com for more information.

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This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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 known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen R&D Ireland and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including the uncertainty of clinical success and of obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. 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 28, 2014, including in Exhibit 99 thereto, and the company's 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. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

References

[1] OSIRIS poster, presented at the Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases, 2015.

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[3] Centres for Disease Control and Prevention. Progress Toward Prevention and Control of Hepatitis C Virus Infection — Egypt, 2001–2012. Accessed October 2015

[4] World Health Organisation, Hepatitis C. Available at: http://www.who.int/csr/disease/hepatitis/Hepc.pdf Last accessed October 2015.

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