NEWS RELEASE

Janssen Announces SVR12 Rates with Twelve Weeks of Treatment with All-Oral, Once-Daily Regimen of Simeprevir ▼ Plus Sofosbuvir ▼ in Genotype 1 HCV Patients With and Without Cirrhosis

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- Data from OPTIMIST-1 and OPTIMIST-2 Trials Showing SVR12 Rates of 97 Percent and 84 Percent to be Presented at The International Liver Congress™ 2015 of the European Association for the Study of the Liver -

- SVR12 Rates of up to 100 Percent Achieved Among Subgroups in Both Trials -

CORK, Ireland--(BUSINESS WIRE)-- Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), today announced results for its hepatitis C treatment simeprevir at The International Liver Congress™ 2015 of the European Association for the Study of the Liver (EASL) in Vienna. Late-breaking results from the Phase 3 OPTIMIST-1 and OPTIMIST-2 trials highlight the clinical outcomes of simeprevir in an all-oral combination regimen in a wide range of patients with hepatitis C virus (HCV) infection.

"The new data for simeprevir presented at The International Liver Congress™ confirms its efficacy when combined with sofosbuvir in an all-oral, ribavirin-free regimen for HCV patients, including those who are treatment-naïve and treatment-experienced, both with and without cirrhosis," said Gaston Picchio, hepatitis disease area leader, Janssen. "These data further demonstrate the role of simeprevir within the HCV treatment landscape, as it provides patients with an important therapeutic option."

The results from the OPTIMIST-1 and OPTIMIST-2 trials are the first Phase 3 data to be presented on simeprevir in combination with sofosbuvir (SMV/SOF) in patients with genotype 1 chronic HCV infection, both with and without cirrhosis. Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor developed by Gilead Sciences, Inc.

OPTIMIST-1[1]

- OPTIMIST-1 is a Phase 3, randomised, open-label trial to investigate the efficacy and safety of the all-oral regimen of SMV/SOF among treatment-naïve and treatment-experienced genotype 1 chronic HCV-infected patients without cirrhosis. The primary objective was to show superior sustained virologic response (SVR) at 12 weeks after treatment (SVR12) with 12 and eight weeks of treatment with SMV/SOF versus a historical control (patients previously treated with approved regimens containing a direct-acting antiviral, pegylated interferon and ribavirin).
- Ninety-seven (97) percent of patients treated with SMV/SOF for 12 weeks (n=150/155) achieved SVR12, which was superior to the SVR12 rate of 87 percent among the historical control.
    - SVR12 rates of 100 percent were seen among patients with IL28B CC genotype (n=43/43) and those with baseline NS5A and NS3 Q80K polymorphisms (n=9/9).
- Patients treated with eight weeks of SMV/SOF achieved an SVR12 rate of 83 percent (n=128/155), which was not superior to the SVR12 rate of 83 percent in the historical control.
    - High SVR12 rates were seen among patients with baseline HCV RNA &#60 4 million IU/mL (96 percent; n=46/48), IL28B CC genotype (93 percent; n=38/41), patients with genotype 1b HCV infection (92 percent; n=36/39) and patients without baseline NS5A and Q80K polymorphisms (89 percent; n=78/88).
- The most frequently reported adverse events in the 12-week and eight-week treatment arms were headache (14 and 17 percent, respectively), fatigue (12 and 15 percent, respectively) and nausea (15 and 9 percent, respectively).

OPTIMIST-2[2]

- OPTIMIST-2 is a Phase 3, open-label, single-arm trial to investigate the efficacy and safety of SMV/SOF in treatment-naïve and treatment-experienced genotype 1 chronic HCV-infected patients with cirrhosis. The primary objective was to show superior SVR12 with 12 weeks of treatment with SMV/SOF versus a historical control.
- Twelve (12) weeks of treatment with SMV/SOF resulted in SVR12 rates of 84 percent (n=86/103), which was superior to the SVR12 rate of 70 percent in the historical control.
- Higher SVR12 rates were seen in patients with baseline NS5A polymorphisms with or without NS3 Q80K polymorphisms (100 percent; n=13/13), patients with albumin ≥4 g/dL (94 percent; n=47/50) and treatment-naïve patients (88 percent; n=44/50).
- The most common adverse events were fatigue (20 percent), headache (20 percent) and nausea (11 percent).

"Chronic HCV infection is a leading cause of cirrhosis, and once it is developed, these patients can be very difficult to cure. The results of the OPTIMIST-2 study demonstrate the safety and efficacy of the all-oral regimen of simeprevir and sofosbuvir for genotype 1 chronic HCV patients with cirrhosis," said Eric Lawitz, M.D., Texas Liver Institute, principal investigator of the OPTIMIST-2 study.

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[3] and 350,000 people per year die from the disease globally[4] with 86,000 deaths in the European region each year.[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.[3]

About Janssen's HCV Development Programme

The goal of the Janssen hepatitis C virus (HCV) clinical development programme 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 the NS3/4A protease inhibitor simeprevir in a number of different treatment combinations and HCV patient populations, including those who are difficult to cure.

Janssen's HCV pipeline also includes JNJ-56914845, an investigational NS5A replication complex inhibitor currently in Phase 2 studies, and following the acquisition of Alios BioPharma by Johnson & Johnson in November 2014, 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.

These compounds are being developed with the intent of targeting critical steps of the HCV replication cycle.

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 R&D Ireland is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit **http://www.janssenrnd.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.

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References

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[1] A Phase 3, randomised, open-label study to evaluate the efficacy and safety of 12 and 8 weeks of treatment with simeprevir plus sofosbuvir in treatment-naïve and -experienced patients with chronic HCV genotype 1 infection

without cirrhosis: The OPTIMIST-1 study. Presented at The International Liver Congress™ 2015.

[2] A Phase 3, open-label, single-arm study to evaluate the efficacy and safety of 12 weeks of simeprevir plus sofosbuvir in treatment-naïve or -experienced patients with chronic hepatitis c virus genotype 1 infection and cirrhosis: The OPTIMIST-2 study. Presented at The International Liver Congress™ 2015.

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

[4]World Health Organisation. Hepatitis C. Fact sheet N. 164. Available at: **http://www.who.int/mediacentre/factsheets/fs164/en/**. Last accessed April 2015.

[5] 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.

Janssen
Media Contact: Ronan Collins (Global)
Mobile: +47 488 425 00
or
Media Contact: Hans Vanavermaete (EMEA)
Mobile: +32 478 447278
or
Investor Contact: Lesley Fishman
Office: +1 (732) 524 2524
or
Investor Contact: Louise Mehrotra
Office: +1 (732) 524 6491

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