



NEWS RELEASE

Janssen Highlights Hepatitis C Virus Development Program at The International Liver Congress® 2015 of the European Association for the Study of the Liver (EASL)

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CORK, Ireland (8 April 2015) - Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), today announced that clinical data for simeprevir, its NS3/4A protease inhibitor for the treatment of hepatitis C virus (HCV) infection, will be presented at The International Liver Congress® 2015 of the European Association for the Study of the Liver (EASL) taking place in Vienna from April 22-26. Early-stage data on the investigational nucleotide analog polymerase inhibitors AL-335 and AL-516, which were recently obtained through Janssen's acquisition of Alios BioPharma, will also be presented.

Several key presentations will report on the efficacy and tolerability of simeprevir in interferon-free combination regimens in Phase 2, Phase 3 and real-world clinical settings.

"Hepatitis C remains a serious health problem. The breadth of data we are presenting at The International Liver Congress® reinforces our commitment to reducing the significant burden of this infectious disease around the world," said Gaston Picchio, hepatitis disease area leader, Janssen. "Janssen has an extensive and ongoing clinical trial program for hepatitis C, including confirmatory and new exploratory studies, and we look forward to sharing these results. We remain focused on investigating alternative and more immediate treatment options for patients with a high unmet need."

A total of 14 company-sponsored abstracts supporting Janssen's marketed and investigational therapies for HCV

will be presented, including three abstracts on simeprevir accepted as late-breaking presentations. The scope and rigor of these data underscore Janssen's commitment to being a positive catalyst in the fight against this serious public health threat.

"These data highlight the strength of our commitment to advancing research in the area of viral hepatitis," said Lawrence M. Blatt, PhD, global head therapeutics, Janssen Infectious Diseases and Vaccines, and president and chief executive officer of Alios BioPharma. "We are delighted to present additional data for simeprevir in combination with other currently available therapeutic options alongside early-stage data for our nucleotide portfolio."

Studies on Janssen's HCV portfolio to be presented at The International Liver Congress 2015^{#8482} include:

Late-Breaking Poster Presentations

All posters will be displayed electronically from Thursday 23 April, 07:30 to Saturday 25 April, 20:00 in Hall B.

- A Phase 3, randomised, open-label study to evaluate the efficacy and safety of 12 and 8 weeks of simeprevir (SMV) plus sofosbuvir (SOF) in treatment-naïve and -experienced patients with chronic HCV genotype 1 infection without cirrhosis: The OPTIMIST-1 study
 - Abstract LP14
 - Lead Author: P. Kwo; Division of Gastroenterology and Hepatology, Department of Medicine, Indiana University, Indianapolis, IN, USA
- A Phase 3, open-label, single-arm study to evaluate the efficacy and safety of 12 weeks of simeprevir (SMV) plus sofosbuvir (SOF) in treatment-naïve or -experienced patients with chronic HCV genotype 1 infection and cirrhosis: The OPTIMIST-2 study
 - Abstract LP04
 - Lead Author: E. Lawitz; Texas Liver Institute, University of Texas Health Science Center, San Antonio, TX, USA
- Simeprevir (SMV) plus daclatasvir (DCV) and sofosbuvir (SOF) in treatment-naïve and -experienced patients with chronic hepatitis C virus genotype 1 or 4 infection and decompensated liver disease: Interim results from the Phase 2 IMPACT study
 - Abstract LP07
 - Lead Author: E. Lawitz; Texas Liver Institute, University of Texas Health Science Center, San Antonio, TX, USA

Oral Presentations

- On-treatment virologic response and tolerability of simeprevir, daclatasvir and ribavirin in patients with recurrent hepatitis C virus genotype 1b infection after orthotopic liver transplantation (OLT): Interim data from the Phase 2 SATURN Study
 - Abstract 0004: Thursday 23 April, 16.45 - 17.00, Hall D
 - Lead Author: X. Fornis; Liver Unit, Hospital Clinic, Barcelona, Spain

Poster Presentations

All posters will be displayed electronically from Thursday 23 April, 07:30 to Saturday 25 April, 20:00 in Hall B.

- Significant drug-drug interaction between simeprevir and cyclosporine A but not tacrolimus in patients with recurrent chronic HCV infection after orthotopic liver transplantation: The SATURN study
 - Abstract P0834
 - Lead Author: S. Ouwerkerk-Mahadevan; Janssen Research & Development, Beerse, Belgium
- Deep sequencing analyses in HCV genotype 1-infected patients treated with simeprevir plus sofosbuvir with/without ribavirin in the COSMOS study
 - Abstract P0780
 - Lead Author: B. Fevery; Janssen Infectious Diseases BVBA, Beerse, Belgium
- Effectiveness of simeprevir (SMV)-containing regimens among patients with chronic hepatitis c virus (HCV) in various U.S. practice settings: Interim analysis of the SONET study
 - Abstract P0826
 - Lead Author: I. Alam; Austin Hepatitis Center, Austin, TX, USA.
- Study protocol for a partly randomised, open-label Phase 2a trial of once-daily simeprevir combined with sofosbuvir for the treatment of HCV genotype 4-infected patients with or without cirrhosis (OSIRIS)
 - Abstract P1346
 - Lead Author: M. El Raziky, Departments of Pediatrics, Cairo University, Cairo, Egypt
- Baseline factors associated with increased SVR rates in 123 treatment-naïve chronic HCV genotype 1 patients treated with a shortened 12-week simeprevir plus pegylated interferon and ribavirin regimen: A multivariate analysis
 - Abstract P0792
 - Lead Author: T Asselah, Beaujon Hospital, University of Paris, France.
- Clinical characteristics and outcomes of chronic hepatitis C (CHC) patients treated with newer direct-acting antiviral (DAA)-based regimens from a large U.S. payer perspective

- Abstract P0852
- Lead Author: N. Tandon; Janssen Scientific Affairs, LLC , Titusville, NJ , USA
- A descriptive analysis of a real-world population with chronic hepatitis C (CHC) treated with simeprevir (SMV)- and/or sofosbuvir (SOF)-based regimens: Findings from a U.S. payer database
 - Abstract P0827
 - Lead Author: J.B. Forlenza; Janssen Scientific Affairs, LLC , Titusville, NJ , USA
- Real world effectiveness and cost of simeprevir- and/or sofosbuvir-based HCV treatments: \$175,000 per SVR12
 - Abstract P0881
 - Lead Author: K. Bichoupan; Division of Liver Diseases, Icahn School of Medicine at the Mount Sinai Medical Center, New York, NY, USA

Alios BioPharma Poster Presentations

- Derisking the potential for mitochondrial toxicity of nucleoside analogs
 - Abstract P0679
 - Lead author: Z. Jin; Alios BioPharma, San Francisco, CA, USA
- Preclinical characterization of AL-335, a potent uridine based nucleoside polymerase inhibitor for the treatment of chronic hepatitis C
 - Abstract P0682
 - Lead Author: H. Tan; Alios BioPharma, San Francisco, CA, USA

Full session details and data presentation listings for The International Liver Congress 2015 can be found at <http://www.ilc-congress.eu>.

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 and 350,000 people per year die from the disease globally. 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.

About Janssen's HCV 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 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 express intent of targeting critical steps of the hepatitis C virus 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 approved by the U.S. Food & 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.

INDICATIONS

OLYSIO® (simeprevir) is a hepatitis C virus (HCV) NS3/4A protease inhibitor indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection as a component of a combination antiviral treatment regimen.

Limitations of Use

- OLYSIO® monotherapy is not recommended.
- OLYSIO® efficacy in combination with peginterferon alfa (Peg-IFN-alfa) and ribavirin (RBV) is substantially reduced in patients infected with HCV genotype 1a with an NS3 Q80K polymorphism at baseline compared to patients infected with hepatitis C virus (HCV) genotype 1a without the Q80K polymorphism. Screening patients with HCV genotype 1a infection for the presence of virus with the NS3 Q80K polymorphism at baseline is strongly recommended. Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.

- OLYSIO® is not recommended in patients with severe hepatic impairment (Child-Pugh Class C) due to substantial increases in simeprevir exposures, which have been associated with increased frequency of adverse reactions.
- OLYSIO® is not recommended in patients who have previously failed therapy with a treatment regimen that included OLYSIO® or other HCV protease inhibitors.

IMPORTANT SAFETY INFORMATION

Contraindications

- There are no specific contraindications to OLYSIO®. However, as OLYSIO® should always be administered in combination with other antiviral drugs for the treatment of CHC infection, prescribers should consult the complete prescribing information for these drugs for a description of contraindications.

Warnings and Precautions

- Risk of Serious Adverse Reactions Associated With Combination Treatment: OLYSIO® should be used in combination with other antiviral drugs for the treatment of CHC infection. Therefore, consult the prescribing information for these drugs before starting therapy with OLYSIO®.
- Photosensitivity: Photosensitivity reactions have been observed with OLYSIO® combination therapy. Serious photosensitivity reactions resulting in hospitalization have been observed with OLYSIO® in combination with Peg-IFN-alfa and RBV. Photosensitivity reactions occurred most frequently in the first 4 weeks of treatment, but can occur at any time during treatment. Photosensitivity may present as an exaggerated sunburn reaction, usually affecting areas exposed to light (typically the face, "V" area of the neck, extensor surfaces of the forearms, and dorsa of the hands). Manifestations may include burning, erythema, exudation, blistering, and edema.

Use sun protective measures and limit sun exposure during treatment with OLYSIO®. Avoid use of tanning devices during treatment with OLYSIO®. Discontinuation of OLYSIO® should be considered if a photosensitivity reaction occurs and patients should be monitored until the reaction has resolved. If a decision is made to continue OLYSIO® in the setting of a photosensitivity reaction, expert consultation is advised.

- Rash: Rash has been observed with OLYSIO® combination therapy. Rash occurred most frequently in the first 4 weeks of treatment, but can occur at any time during treatment. Severe rash and rash requiring discontinuation of OLYSIO® have been reported in subjects receiving OLYSIO® in combination with Peg-IFN-

alfa and RBV. Most of the rash events in OLYSIO®-treated patients were of mild or moderate severity. Patients with mild to moderate rashes should be followed for possible progression of rash, including the development of mucosal signs (e.g., oral lesions, conjunctivitis) or systemic symptoms. If the rash becomes severe, OLYSIO® should be discontinued. Patients should be monitored until the rash has resolved.

- **Sulfa Allergy:** OLYSIO® contains a sulfonamide moiety. In subjects with a history of sulfa allergy (n=16), no increased incidence of rash or photosensitivity reactions has been observed. However, there are insufficient data to exclude an association between sulfa allergy and the frequency or severity of adverse reactions observed with the use of OLYSIO®.
- **Risk of Adverse Reactions or Reduced Therapeutic Effect Due to Drug Interactions:** Co-administration of OLYSIO® with substances that are moderate or strong inducers or inhibitors of cytochrome P450 3A (CYP3A) is not recommended as this may lead to significantly lower or higher exposure of simeprevir, respectively, which may result in reduced therapeutic effect or adverse reactions.

Adverse Reactions

- **Use with Peg-IFN-alfa and RBV:** Adverse reactions (all grades, at least 3% higher frequency) for OLYSIO® with Peg-IFN-alfa and RBV vs. Peg-IFN-alfa and RBV alone in the first 12 weeks were rash (including photosensitivity) (28% vs. 20%), pruritus (22% vs. 15%), nausea (22% vs. 18%), myalgia (16% vs. 13%), and dyspnea (12% vs. 8%).
- **Use with sofosbuvir:** The most common (> 10%) adverse reactions reported during 12 weeks treatment with OLYSIO® in combination with sofosbuvir without RBV were fatigue (25%), headache (21%), nausea (21%), insomnia (14%) and pruritus (11%). Rash and photosensitivity were reported in 11% and 7% of subjects, respectively. During 24 weeks treatment with OLYSIO® in combination with sofosbuvir, dizziness (16%), and diarrhea (16%) were also commonly reported.

Use in Specific Populations

- **Pregnancy Category C:** Adequate and well controlled trials with OLYSIO® have not been conducted in pregnant women. OLYSIO® should be used during pregnancy only if the potential benefit justifies the potential risk. Female patients of childbearing potential should use an effective contraceptive method.
- **Race:** Patients of East Asian ancestry exhibit higher simeprevir exposures. In clinical trials, higher simeprevir exposures have been associated with increased frequency of adverse reactions, including rash and

photosensitivity. There are insufficient safety data to recommend an appropriate dose for patients of East Asian ancestry. The potential risks and benefits of OLYSIO® should be carefully considered prior to use in patients of East Asian ancestry.

- Renal Impairment: No dose adjustment of OLYSIO® is required in patients with mild, moderate or severe renal impairment. The safety and efficacy of OLYSIO® have not been studied in HCV-infected patients with severe renal impairment (creatinine clearance below 30 mL/min) or end-stage renal disease, including patients requiring dialysis. Simeprevir is highly protein-bound; therefore, dialysis is unlikely to result in significant removal of simeprevir.
- Hepatic Impairment: No dose adjustment of OLYSIO® is required in patients with mild hepatic impairment (Child-Pugh Class A). The safety and efficacy of OLYSIO® have not been studied in HCV-infected patients with moderate or severe hepatic impairment (Child-Pugh Class B or C). No dosage recommendation can be given for patients with moderate hepatic impairment (Child-Pugh Class B) due to modest increases in simeprevir exposures. OLYSIO® is not recommended for patients with severe hepatic impairment (Child-Pugh Class C) due to substantially higher simeprevir exposures.

In clinical trials, higher simeprevir exposures have been associated with increased frequency of adverse reactions, including rash and photosensitivity. The potential risks and benefits of OLYSIO® should be carefully considered prior to use in patients with moderate hepatic impairment. The combination of OLYSIO® with Peg-IFN-alfa and RBV is contraindicated in patients with decompensated cirrhosis (moderate or severe hepatic impairment).

- Other HCV Genotypes: The safety and efficacy of OLYSIO® have not been established in patients infected with other HCV genotypes.
- Liver Transplantation: The safety and efficacy of OLYSIO® have not been studied in liver transplant patients.

Not a complete list of Uses in Specific Populations.

Consult the PI for Peg-IFN-alfa and RBV or sofosbuvir before starting therapy with OLYSIO®. Safety information related to these drugs also applies to their use in OLYSIO® combination treatment.

Please see **full Prescribing Information** and **Patient Information** for more details.

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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