



NEWS RELEASE

## Janssen to Unveil New Hepatitis B and C Data at The International Liver Congress™ 2016 of the European Association for the Study of the Liver (EASL)

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CORK, Ireland, March 30, 2016 /PRNewswire/ --

Includes several late breaking and oral presentations from across R&D pipeline

Highlights potential of R&D pipeline to deliver several new hepatitis B and C regimens

Janssen Sciences Ireland UC and certain Janssen affiliates\* today announced it will present thirteen abstracts featuring new data on an investigational regimen for treatment of hepatitis B virus (HBV) and approved and investigational regimens for the treatment of hepatitis C virus (HCV) at the upcoming International Liver Congress™ of the European Association for the Study of the Liver (EASL 2016). The data to be presented is a reflection of the Janssen Pharmaceutical Companies' ongoing commitment to make hepatitis history by contributing through our research efforts to the elimination of viral hepatitis as a global public health concern.

(Logo: <http://photos.prnewswire.com/prnh/20140324/NY88746LOGO> )

"Despite recent advances, the global impact of viral hepatitis remains far reaching with significant unmet needs yet to be addressed. We have come a long way in developing cures for hepatitis C, but further innovation is needed to deliver one treatment suitable for all patient types," said Lawrence M. Blatt, PhD, Global Therapeutic Area Head Infectious Diseases and Vaccines, Janssen Research & Development, LLC. "Chronic hepatitis B is a potentially fatal



liver disease that requires life-long treatment. There remains no known cure which represents an unmet medical need and we are excited by the opportunity to fully leverage our expertise in this critical disease area in order to bring potentially new treatments to patients".

Data from Janssen's hepatitis B and C portfolio includes a late breaking abstract on **NVR 3-778**, a potentially first-in-drug-class HBV capsid assembly inhibitor in treatment-naïve HBeAG--positive patients, which is also to be featured as part of the official congress press programme.

Late breaking data for the Phase 3 PLUTO trial with Janssen's protease inhibitor, **simeprevir** plus sofosbuvir for patients with HCV genotype 4 infection will also be presented. Alongside this, several other Phase 2 and 3 studies which evaluate the efficacy and tolerability for simeprevir in a range of adult patients with varying stages of chronic hepatitis C will be presented.

Further data on several early-stage investigational regimens in chronic hepatitis C, including new data on Janssen's nucleotide polymerase inhibitor, **AL-335**, which is currently in a Phase 2a study (NCT02569710) in combination with odalasvir (also called ACHN-3102) and simeprevir, along with Phase 1 data for its nucleotide polymerase inhibitor, **JNJ-54257099** will be presented.

Below is a full list of the data to be presented at the International Liver Congress&#8482 2016. Full poster and oral presentation details can be accessed via the congress website at:

**<https://events.easl.eu/EventProgramme/ILC2016/POSTER.aspx>** :

## Abstracts in Hepatitis C

### Simeprevir

- LBP516: Simeprevir plus sofosbuvir for hepatitis C virus genotype 4 infection: a Phase 3, open-label study

Late-breaking poster presentation, Thursday 14 April at 08:00 and Saturday 16 April at 18:00

Lead Author: María Buti, Hospital Vall d'Hebron and Centro de Investigacion Biomedica en Red en Enfermedades Hepaticas y Digestivas (CIBERehad), Barcelona

- SAT-264: Pharmacokinetic interactions between simeprevir and ledipasvir in treatment-naïve hepatitis C virus genotype 1-infected patients without cirrhosis treated with a simeprevir/sofosbuvir/ledipasvir regimen

Poster presentation, Saturday 16 April, 08:00 - 18:00, Hall 8.1

Lead Author: S. Bourgeois, Department of Internal Medicine, ZNA Ster, Antwerp

- THU-215: Deep sequencing results from the Phase 2 IMPACT study of simeprevir in combination with daclatasvir and sofosbuvir in treatment-naïve and -experienced patients with chronic hepatitis C virus genotype 1 or 4 infection and decompensated liver disease

Poster presentation, Thursday 14 April, 08:00 - 18:00, Hall 8.1

Lead Author: C. Sarrazin, Johann Wolfgang Goethe University Medical Center, Frankfurt am Main, Germany

- THU-214: Consistent simeprevir resistance profile in hepatitis C virus genotype 1-infected patients failing simeprevir interferon-free compared with interferon-containing regimens

Poster presentation, Thursday 14 April, 08:00 - 18:00, Hall 8.1

Lead Author: B. Fevery Janssen Infectious Diseases BVBA, Beerse, Belgium

- SAT-167: Effectiveness of simeprevir-containing regimens among patients with chronic hepatitis C virus in various US practice settings: The SONET study

Poster presentation, Saturday 16 April, 08:00 - 18:00, Hall 8.1 Lead Author: I. Alam, Austin Hepatitis Center, Austin, TX, USA

- FRI-457: Efficacy and safety of simeprevir and sofosbuvir with and without ribavirin for 12 weeks in subjects with recurrent genotype 1 hepatitis C post-orthotopic liver transplant: The GALAXY study

Poster presentation, Friday 15 April, 08:00 - 18:00, Hall 8.1

Lead Author: J.G. O'Leary, Baylor University Medical Center, Dallas, TX, USA

- SAT-130: Efficacy and tolerability of simeprevir and daclatasvir for 12 or 24 weeks in HCV genotype 1b-infected treatment-naïve patients with advanced fibrosis or compensated cirrhosis

Poster presentation, Saturday 16 April, 08:00 - 18:00, Hall 8.1 Lead Author: C. Hézode, Department of Hepatology and Gastroenterology, H&#8482pital Henri Mondor, Université Paris-Est, France

- SAT-162: Effectiveness of simeprevir treatment for hepatitis C in real practice: preliminary results from the STILy Italian observational study

Poster presentation, Saturday 16 April, 08:00 - 18:00, Hall 8.1

Lead Author: G.B Gaeta, Seconda Universita di Napoli, Napoli

- SAT-212: Safety of simeprevir-based treatment for hepatitis C in real practice: preliminary results from the STIly observational study

Poster presentation, Saturday 16 April, 08:00 - 18:00, Hall 8.1

Lead Author: M. Colombo, Ospedale Maggiore Policlinico, Milano

JNJ-54257099

- THU-261: Preclinical characterization of JNJ-54257099 - a potent uridine-based nucleotide polymerase inhibitor in Phase I clinical development for the treatment of chronic hepatitis C

Poster presentation, Thursday 14 April, 08:00 - 18:00, Hall 8.1

Lead Author: L. Tambuyzer, Janssen Infectious Diseases, BVBA, Beerse, Belgium

AL-335

- THU-228: AL-335, A once-daily pangenotypic nucleotide HCV polymerase inhibitor, demonstrates potent antiviral activity over 7 days in treatment-naïve genotype 1-4 patients

Poster presentation, Thursday 14 April, 08:00 - 18:00, Hall 8.1

Lead Author: E. Berliba, Internal Medicine, State Medical University "N. Testemitanu", Chisinau, Republic of Moldova

- THU-226: Pan-genotypic evaluation of AL-335, a clinical stage uridine analogue inhibitor of hepatitis C virus polymerase

Poster presentation, Thursday 14 April, 08:00 - 18:00, Hall 8.1

Lead Author: J. Deval\*

## Abstracts in Hepatitis B

NVR 3-778

- LBO6: NVR 3-778, a first-in-class HBV core inhibitor, alone and in combination with peginterferon (PEGIFN), in treatment-naïve HBeAG-positive patients: Early reductions in HBV DNA and HBeAG

Oral presentation is under embargo until Saturday 16 April, 07:00 CET

Lead Author: Man-Fung Yuen\*\*

\* Alios BioPharma, Inc. and Novira Therapeutics Inc. Both part of the Janssen Pharmaceutical Companies

\*\*Full session details and data presentation listings for The International Liver Congress 2016 can be found at <http://www.ilc-congress.eu>.

## Janssen in Viral Hepatitis

At Janssen, our commitment is to make hepatitis history by contributing to the elimination of viral hepatitis as a global public health concern. Leveraging our vast research and development experience in viral diseases, we have co-developed two approved treatments for chronic hepatitis C (telaprevir, simeprevir) and are striving to bring forth further transformational medical innovations for chronic hepatitis B and C to improve the lives of all those affected by viral hepatitis.

We are developing a new combination regimen in hepatitis C which has the potential to treat and cure a broad range of people living with this disease. And seek to overcome the treatment challenges in hepatitis B, such as the requirement for people to require lifelong therapy, with the aim of developing a functional cure.

With goals like this, there's no time to waste. That is why we partner with organizations around the world, connecting our own expertise with that of others. Because, only together we can Make Hepatitis History.

## About Hepatitis

Hepatitis C, a blood-borne infectious disease of the liver and a leading cause of chronic liver disease, is the focus of a rapidly evolving treatment landscape. Approximately 150 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. Similarly, chronic hepatitis B (HBV) causes approximately 650,000 deaths worldwide from cirrhosis and liver cancer, with approximately 60 percent of hepatocellular carcinoma attributed to hepatitis B infection. Current recommended therapies are unable to cure the infection, requiring most people to continue treatment for life.

## About Janssen Pharmaceutical Companies of Johnson & Johnson

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. For more information, visit <http://www.janssen.com> or follow @JanssenGlobal.

## Cautions Concerning Forward-Looking Statements

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 Sciences Ireland UC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success; 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 January 3, 2016, 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 <http://www.sec.gov>, <http://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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