New simeprevir data will be presented at The International Liver Congress 2015 of the European Association for the Study of the Liver (EASL)

Presentations include late-breaking final results from the phase III OPTIMIST trials and interim results from the phase II IMPACT trial of simeprevir

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced that new clinical data for simeprevir, the NS3/4A protease inhibitor for the treatment of hepatitis C virus (HCV) infection, will be presented by our partner Janssen Sciences Ireland UC 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.

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

A total of 12 abstracts supporting marketed and investigational therapies for HCV will be presented, including three abstracts on simeprevir accepted as late-breaking presentations.

The data to be presented at the International Liver Congress 2015 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 III, 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 III, 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 II 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 II SATURN Study.

- **Abstract 0004: Thursday 23 April, 16.45 – 17.00, Hall D**
- **Lead Author: X. Forns; 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 IIa 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

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

For further information, please contact:
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Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 12.00 CET on 8 April 2015.

About Simeprevir (OLYSIO®)
Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen Sciences Ireland UC and Medivir AB and indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Simeprevir efficacy has been established in HCV genotype 1 and HCV genotype 4 infected patients with compensated liver disease, including cirrhosis. 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 authorization held by Janssen-Cilag International NV. 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.

About Medivir
Medivir is a research based pharmaceutical company with a research focus on infectious diseases and oncology. We have a leading competence within protease inhibitor design and nucleotide/nucleoside science and we are dedicated to develop innovative pharmaceuticals that meet great unmet medical need. Our commercial organization provides a growing portfolio of specialty care pharmaceuticals on the Nordic market. Medivir is listed on the Nasdaq Stockholm Mid Cap List.