Press Release November 4, 2013

Results from the COSMOS study with Simeprevir and Sofosbuvir in cirrhotic and non-cirrhotic HCV genotype 1 patients presented at AASLD

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced data from the interferon-free COSMOS study demonstrating safety and efficacy of the investigational protease inhibitor simeprevir (TMC435) in combination with the investigational nucleotide inhibitor sofosbuvir (GS-7977), with and without ribavirin, in genotype 1 chronic hepatitis C adult patients with compensated liver disease was presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington, D.C. during the late-breaking oral session on Monday, November 4.

"The high sustained virologic response (SVR) rates seen in genotype 1 patients with prior null response and in treatment-naïve and prior null response patients with advanced liver disease, in the COSMOS study, are highly encouraging. These difficult-to-cure patient groups are in urgent need of efficacious treatment options which today are lacking" says Charlotte Edenius, EVP Development, Medivir.

COSMOS - Study Design
COSMOS is a phase IIa, randomized, open-label study investigating the safety and efficacy of simeprevir in combination with sofosbuvir, with and without ribavirin, for either 12 or 24 weeks. The study enrolled HCV genotype 1 patients who were prior null responders to treatment with interferon and ribavirin with METAVIR F0-F2 scores (cohort 1, n=80), or treatment-naïve patients and prior null responders with METAVIR F3-F4 scores (cohort 2, n=87).

Final sustained virologic response 12 weeks after the end of treatment (SVR12) data from cohort 1 in previous null responder patients with METAVIR scores F0-F2 were presented, along with sustained virologic response 4 weeks after the end of treatment (SVR4) data from the 12 week arms of cohort 2 in treatment-naïve and previous null-responder patients with METAVIR scores F3-F4. The METAVIR score is used to quantify the degree of inflammation and fibrosis of the liver. Liver fibrosis is scored on a four-point scale.

In cohort 1, 77 percent of the patients had genotype 1a (GT1a) subtype with 50 percent of those having baseline Q80K polymorphism. Seventy percent had *IL28B* CT genotype, 24 percent had *IL28B* TT genotype and 59 percent had METAVIR score F2.

In cohort 2, 78 percent of patients had GT1a subtype with 40 percent of those having baseline Q80K polymorphism. Fifty-six percent had *IL28B* CT genotype, 23 percent had *IL28B* TT genotype, 47 percent had METAVIR score F4 (cirrhosis) and 54 percent were prior null responders.

COSMOS – Efficacy Summary
In cohort 1, the SVR12 rate was 93 percent in genotype 1 null-responder patients with METAVIR scores of F0-F2 treated with simeprevir and sofosbuvir for either 12 or 24 weeks.

In an interim analysis of cohort 2, the SVR4 rate was 100 percent in both genotype 1 treatment-naive patients and prior null-responder patients with METAVIR scores of F3-F4 treated with simeprevir and sofosbuvir for 12 weeks.

In a pooled analysis of the 12-week treatment arms in cohorts 1 and 2, SVR4 was achieved among patients treated with simeprevir and sofosbuvir with or without ribavirin, in 96 percent of patients with *IL28B* non-CC genotype, 91 and 100 percent of patients with a METAVIR score of F4, respectively, and 95 percent of prior null responders.

Medivir is a collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C. We are passionate and uncompromising in our mission to develop and commercialize innovative pharmaceuticals that improve people's health and quality of life.

All patients who completed treatment were HCV RNA undetectable at end of treatment and there were no viral breakthroughs in either cohort 1 or 2. The COSMOS study interim results show no benefit from adding ribavirin to simeprevir and sofosbuvir in this difficult to treat groups of hepatitis C patients and that 12 week treatment may confer similar clinical benefit to 24 week treatment.

Efficacy results with 150 mg simeprevir (SMV) and 400 mg sofosbuvir (SOF) once daily with or without ribavirin (RBV). Intent-to-treat (ITT) population.

Cohort 1: Prior null-responder HCV patients with METAVIR scores F0-F2				
% (n)	SMV / SOF + RBV 24-week	SMV / SOF 24-week	SMV / SOF + RBV 12-week	SMV / SOF 12-week
SVR12	79* (19/24)	93 (14/15)	96 (26/27)	93 (13/14)

*17% (4/24) non-virologic failure

Cohort 2: Prior null-responder and treatment-naïve HCV patients with METAVIR scores F3-F4**				
% (n)	SMV / SOF+ RBV Naive 12-week	SMV / SOF Naive 12-week	SMV / SOF + RBV Null response 12-week	SMV / SOF Null response 12-week
SVR4	100 (12/12)	100 (7/7)	93 (14/15)	100 (7/7)

***SVR4 data was only available for 12-week arms at time of interim analysis cut-off*

COSMOS - Summary Safety
The most common adverse events in both treatment arms were fatigue, headache, nausea and insomnia. Rash, itching, anemia and bilirubin increases occurred mainly in the ribavirin-containing arms of treatment. Four percent of patients (2/54) treated with simeprevir and sofosbuvir with ribavirin and 7 percent of patients (2/31) treated with simeprevir and sofosbuvir without ribavirin, respectively, discontinued treatment due to an adverse event in the 24 week arms, while no patients (0/82) in the 12 week arms discontinued treatment due to an adverse event at the time of this analysis.

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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 4.30 p.m. EST on 4 November 2013.

About Hepatitis C
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 – including approximately 3.2 million people in the United States – 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 Simeprevir
Simeprevir (TMC435) is an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and its affiliated companies and Medivir AB for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including all stages of liver fibrosis. Simeprevir works by blocking the viral protease enzyme that enables the hepatitis C virus to replicate in host cells.

Janssen is responsible for the global clinical development of simeprevir and has acquired exclusive, worldwide marketing rights, except for the Nordic countries. Medivir AB will retain marketing rights for simeprevir in these Nordic countries under the marketing authorization held by Janssen-Cilag International NV.

On October 24, the U.S. Antiviral Drugs Advisory Committee of the FDA voted unanimously (19-0) to recommend approval of the new drug application filed by Janssen Research & Development, LLC for simeprevir administered once daily with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C virus (HCV) in adult patients with compensated liver disease. Simeprevir was approved on September 27, 2013 in Japan for the treatment of genotype 1 hepatitis C. A Marketing Authorisation Application was submitted in April to the European Medicines Agency (EMA) by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C.

Simeprevir is also being studied in several interferon-free regimens using selected combinations of direct-acting antiviral agents with different mechanisms of action. To date, more than 43,700 patients have been treated with simeprevir in clinical trials.

In October, Janssen Pharmaceuticals, Inc. acquired the investigational compound GSK2336805, an NS5a replication complex inhibitor in phase II development for the treatment of chronic HCV, from an affiliate of GlaxoSmithKline plc. Since being acquired, the compound has been renamed JNJ-56914845. Janssen Pharmaceuticals plans to initiate phase II studies to evaluate the use of JNJ-56914845 in interferon-free combinations with simeprevir and TMC647055, the company's non-nucleoside polymerase inhibitor, for the treatment of chronic HCV in adult patients with compensated liver disease.

About Sofosbuvir
Sofosbuvir (formerly referred to as GS-7977) is a once-daily nucleotide analog polymerase inhibitor for the treatment of HCV infection being developed by Gilead Sciences, Inc. Sofosbuvir is being evaluated as part of multiple therapeutic regimens, including programs with RBV alone and in combination with peg-IFN and RBV.

About Medivir
Medivir is an emerging research-based pharmaceutical company focused on infectious diseases. Medivir has world class expertise in polymerase and protease drug targets and drug development which has resulted in a strong infectious disease R&D portfolio. The Company's key pipeline asset is simeprevir, a novel protease inhibitor for the treatment of hepatitis C that is being developed in collaboration with Janssen R&D Ireland. The company is also working with research and development in other areas, such as bone disorders and neuropathic pain. Medivir has also a broad product portfolio with prescription pharmaceuticals in the Nordics.

For more information about Medivir AB, please visit the Company's website: www.medivir.com