Data from Simeprevir in hepatitis C patients will be presented at EASL during 24-28 April in Amsterdam

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announces that data will be presented on the investigational protease inhibitor simeprevir (TMC435) for the treatment of hepatitis C at The International Liver Congress 2013 of the European Association for the Study of the Liver (EASL), which will take place April 24 to 28 in Amsterdam, The Netherlands. These data presentations will include primary efficacy and safety results from the phase III QUEST-1 study of simeprevir administered once daily in combination with pegylated interferon and ribavirin in treatment-naive genotype 1 chronic hepatitis C patients.

Simeprevir is an investigational NS3/4A protease inhibitor, administered as a 150 mg capsule once daily in combination with pegylated interferon and ribavirin jointly developed by Medivir and Janssen Pharmaceuticals, Inc. (Janssen).

Janssen recently submitted new drug applications in Japan and the United States for simeprevir administered once daily in combination with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients. We anticipate a submission of simeprevir for regulatory authorization in the EU in the first half of 2013.

Simeprevir is also being studied in combination with pegylated interferon and ribavirin for the treatment of genotype 4 HCV infection and in several interferon-free regimens using selected combinations of direct-acting antiviral agents with different mechanisms of action.

Additional simeprevir data from the QUEST-2 study have been accepted by The International Liver Congress, but are subject to EASL’s embargo policy until April 23. The data to be presented at The International Liver Congress 2013 include:

**Simeprevir (TMC435) with peginterferon/ribavirin for chronic HCV genotype-1 infection in treatment-naive patients: results from QUEST-1, a phase III trial**
- Available Thursday, April 25 – Saturday, April 27

**Pharmacokinetics of simeprevir (TMC435) in volunteers with moderate or severe hepatic impairment**
- Available Friday, April 26

**Improved SVR with simeprevir (TMC435) associated with reduced time with patient-reported fatigue in treatment-naive, HCV-infected patients in the PILLAR phase Ib trial**
- Available Friday, April 26

**Adding simeprevir (TMC435) to pegylated interferon/ribavirin does not increase patient reported fatigue in treatment-experienced patients with chronic HCV infection: results from the ASPIRE trial**
- Available Friday, April 26

**Combination therapy of TMC647055 with simeprevir (TMC435) in genotype 1 HCV patients**

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 lives.
Full session details and data presentation listings for The International Liver Congress 2013 can be found at http://www.easl.eu.

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About Simeprevir
Simeprevir is an investigational NS3/4A protease inhibitor jointly developed by Janssen and Medivir AB for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease. Janssen recently announced the submission of new drug applications for simeprevir in Japan and the United States for the treatment of genotype 1 hepatitis C.

Global phase III studies of simeprevir include QUEST-1 and QUEST-2 in treatment-naïve patients, PROMISE in patients who have relapsed after prior interferon-based treatment and ATTAIN in null-responder patients. In parallel to these trials, phase III studies for simeprevir are ongoing in treatment-naïve and treatment-experienced HIV-HCV co-infected patients and HCV genotype 4 patients. Simeprevir is also being studied in phase II interferon-free trials with and without ribavirin in combination with:

- Janssen’s non-nucleoside inhibitor TMC647055 and ritonavir in treatment-naïve genotype 1a and 1b HCV patients;
- Gilead Sciences, Inc.’s nucleotide inhibitor sofosbuvir (GS-7977) in treatment-naïve and previous null-responder genotype 1 HCV patients; and
- Bristol-Myers Squibb’s NS5A replication complex inhibitor daclatasvir (BMS-790052) in treatment-naïve and previous null-responder genotype 1 HCV patients.

In addition, Janssen has entered into a non-exclusive collaboration with Vertex Pharmaceuticals to evaluate in a phase II study the safety and efficacy of an all-oral regimen of simeprevir and Vertex’s investigational nucleotide analogue polymerase inhibitor VX-135 for the treatment of HCV. As a first step, Janssen Pharmaceutical Inc. will conduct a drug-drug interaction (DDI) study with simeprevir and VX-135. Janssen also has plans to initiate a phase II trial of an investigational interferon-free regimen with simeprevir, TMC647055 and Idenix’s IDX719, a once-daily, pan-genotypic NS5A inhibitor, with and without ribavirin.

For additional information about simeprevir clinical trials, please visit www.clinicaltrials.gov.

About Hepatitis C
Hepatitis C, a blood-borne infectious disease of the liver and a leading cause of chronic liver disease and liver transplants, is a rapidly evolving treatment area with a clear need for innovative treatments. Approximately 150 million people are infected with hepatitis C worldwide, and 350,000 people per year die from the disease.

About Medivir AB
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 in late phase III clinical development for hepatitis C that is being developed in collaboration with Janssen R&D Ireland. 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