Press Release 23 April 2013

New data from Simeprevir phase III studies Quest 1 and 2 in hepatitis C patients will be presented at EASL 23-28 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 genotype 1 hepatitis C patients.

These primary efficacy and safety results from two global phase III studies demonstrate that use of the investigational protease inhibitor simeprevir led to sustained virologic response 12 weeks after the end of treatment (SVR12) in 80 and 81 percent, respectively, of treatment-naïve genotype 1 chronic hepatitis C adult patients with compensated liver disease, when administered once daily with pegylated interferon and ribavirin. In both studies, 50 percent of patients receiving pegylated interferon and ribavirin alone achieved SVR12.

The data will be presented this week at The International Liver Congress 2013 of the European Association for the Study of the Liver (EASL) in Amsterdam, The Netherlands. The QUEST-1 and QUEST-2 data will also be discussed in an official EASL press conference on April 24 at 11:00 a.m. CEST.

"We are very happy about the robust high cure rates and the very good safety profile of simeprevir as demonstrated in the QUEST 1 and 2 studies both also including patients with severe liver disease and other characteristics that are predictors of more difficult to cure patients", said Charlotte Edenius, EVP Development, Medivir AB. " These data together with the data from a third phase III study in relapser patients (PROMISE study) form the basis for the regulatory filings which were recently submitted in both Japan and US while the EU submission is expected in the near future."

In QUEST-1 and QUEST-2, patients were randomized to receive simeprevir or placebo for 12 weeks plus pegylated interferon and ribavirin for 24 or 36 weeks. In findings related to a secondary endpoint, 85 (QUEST-1) and 91 percent (QUEST-2) of patients receiving simeprevir were able to shorten therapy with pegylated interferon and ribavirin to 24 weeks due to meeting response-guided therapy (RGT) criteria. Of those patients meeting RGT criteria to stop treatment at 24 weeks, 91 percent (QUEST-1) and 86 percent of patients (QUEST-2) achieved SVR12.

"These data represent new and important improvements infor the future treatment of genotype 1 hepatitis C patients", said Maris Hartmanis, Medivir's CEO.

Patients enrolled in QUEST-1 and QUEST-2 were stratified by HCV genotype 1 subtype and IL28B genotype. In QUEST-1, among patients treated with simeprevir, SVR12 rates according to IL28B genotype were 94 percent (CC), 76 percent (CT), and 65 percent (TT). In QUEST-2, in the simeprevir arm, SVR12 rates according to IL28B genotype were 96 percent (CC), 80 percent (CT), and 58 percent (TT). Among patients with METAVIR scores F3 and F4, 70 percent of patients treated with simeprevir in QUEST-1 and 66 percent of patients treated with simeprevir in QUEST-2 achieved SVR12. Among patients with METAVIR scores F0 to F2, 83 percent of patients treated with simeprevir in QUEST-1 and 85 percent of patients treated with simeprevir in QUEST-2 achieved SVR12. The METAVIR score is used to quantify the degree of inflammation and fibrosis of the liver and patients are scored on a four-point scale.

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.

The most common adverse events seen in patients receiving simeprevir in QUEST-1 were fatigue (42 percent versus 41 percent for placebo), itch (26 percent versus 16 percent for placebo), and headache (33 percent versus 39 percent for placebo). The most common adverse events seen in patients receiving simeprevir in QUEST-2 were fatigue (37 percent versus 42 percent for placebo), itch (25 percent versus 25 percent for placebo), headache (39 percent versus 37 percent for placebo), fever (31 percent versus 40 percent for placebo), and influenza-like illness (26 percent versus 26 percent for placebo). In QUEST-1, in both the simeprevir and placebo arms, 3 percent of patients discontinued treatment due to an adverse event. In QUEST-2, 2 percent of patients in the simeprevir arm and 1 percent of patients in the placebo arm discontinued treatment due to an adverse event.

About QUEST-1 and QUEST-2
QUEST-1 and QUEST-2 are global, phase III, randomized, double-blind, placebo controlled clinical trials assessing the efficacy, safety and tolerability of simeprevir plus pegylated interferon and ribavirin versus pegylated interferon and ribavirin alone in treatment-naïve adult patients with genotype 1 chronic hepatitis C with compensated liver disease.

In the QUEST-1 and QUEST-2 trials, 394 and 391 patients, respectively, were randomized to receive one 150 mg capsule of simeprevir or placebo once daily plus pegylated interferon and ribavirin for 12 weeks, followed by pegylated interferon and ribavirin alone for either 12 or 36 weeks based on RGT criteria. Patients in the simeprevir arm were considered to have met RGT criteria if their HCV RNA levels were <25 IU/mL (detectable or undetectable) at week 4 and <25 IU/mL undetectable at week 12. In patients meeting RGT criteria, HCV therapy was stopped at week 24. All other patients continued treatment until week 48.

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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-naive 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