Two phase III trials evaluating once-daily Simeprevir and Sofosbuvir in hepatitis C infected patients have been initiated

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announces that two phase III trials are recruiting patients to examine the efficacy and safety of the NS3/4A protease inhibitor simeprevir in combination with the nucleotide inhibitor sofosbuvir for the treatment of chronic genotype 1 hepatitis C virus (HCV) infection in treatment-naïve and treatment-experienced patients with and without cirrhosis.

"Positive safety and efficacy results have previously been demonstrated in genotype 1 HCV infected patients with the interferon- and ribavirin free combination of simeprevir and sofosbuvir in the phase II COSMOS study. The OPTIMIST trials aim to further consolidate these data and to explore a shorter treatment duration of eight weeks to potentially further simplify this promising treatment option," says Charlotte Edenius, EVP Development, Medivir AB

Study design
OPTIMIST-1
The first trial, called OPTIMIST-1 or TMC435HPC3017, is a phase III, open-label, randomized study investigating the efficacy and safety of simeprevir 150 mg in combination with sofosbuvir 400 mg.
The combination will be administered once daily for 8 or 12 weeks in chronic HCV genotype 1 infected patients without cirrhosis who are HCV treatment naïve or treatment experienced. This study will enroll approximately 300 patients in the U.S. and Canada.

OPTIMIST-2
The second trial, called OPTIMIST-2 or TMC435HPC3018, is a phase III, open-label, single-arm study investigating the efficacy and safety of simeprevir 150 mg in combination with sofosbuvir 400 mg.
The combination will be administered once daily for 12 weeks in HCV genotype 1 infected patients with cirrhosis who are HCV treatment naïve or treatment experienced. This study will enroll approximately 100 patients in the U.S. and Canada.

Ribavirin will not be administered in the OPTIMIST trials. The primary efficacy endpoint in each study is the proportion of patients achieving sustained virologic response 12 weeks after the end of treatment (SVR12).

For additional information, including inclusion and exclusion criteria for these trials, please visit *www.clinicaltrials.gov*

COSMOS study
The combination of simeprevir and sofosbuvir was previously evaluated in the phase II COSMOS trial.
The final cohort 1 study results (SVR12) in patients without fibrosis or cirrhosis (METAVIR score of F0-2) and the interim cohort 2 study results (SVR4) in patients with fibrosis or cirrhosis (METAVIR score of F3-4) from the COSMOS study were presented at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting 2013 in Washington, D.C.

Final cohort 2 results (SVR12) have been accepted for presentation at the European Association for the Study of the Liver (EASL) International Liver Congress 2014 on April 12.

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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 13.00 CET on 2 April 2014.

About Simeprevir
Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB and indicated for the treatment chronic hepatitis C infection in combination with pegylated interferon and ribavirin in HCV genotype 1 and 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 will retain marketing rights for simeprevir in these countries under the marketing authorization held by Janssen-Cilag International NV. The treatment was approved for the treatment of genotype 1 hepatitis C in September 2013 in Japan and in November 2013 in Canada and the U.S. and in March 2014 in Russia. The Committee for Medicinal Products for Human Use (CHMP) recently recommended Marketing Authorisation in the European Union for the use of Simeprevir in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adult patients. An approval is expected during Q2-2014.

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.