**Press Release 13 December 2012**

# Medivir announces initiation of the second cohort of the interferon-free phase II study combining Simeprevir and sofosbuvir for hepatitis C treatment

**Stockholm, Sweden—Medivir AB (OMX: MVIR),** announced today the initiation of cohort 2 in the interferon-free phase II trial combining simeprevir with sofosbuvir (GS7977) based on a safety and efficacy planned interim analysis of cohort 1 including prior null responder HCV genotype 1 infected patients without advanced hepatic fibrosis. Data from the cohort 1 study will be presented at a scientific conference during H1-2013.

**Study design**
Simeprevir, a NS3/4A protease inhibitor is being studied with sofosbuvir, a nucleotide NS5B polymerase inhibitor, in a phase IIa, randomized, open-label study to investigate the efficacy and safety of 12 or 24 weeks of simeprevir (150 mg QD) and sofosbuvir (400 mg QD) with or without ribavirin (RBV) in HCV genotype 1 (GT1) patients.

Cohort 1 included a total of 80 HCV GT1 prior null responders to PegIFN/RBV therapy with METAVIR score F0-F2.

Cohort 2 (90 patients) will include both HCV GT1 treatment naïve and prior null responders to PegIFN/RBV patients with advanced hepatic fibrosis (METAVIR score F3 or F4). Patient screening for cohort 2 was recently initiated.

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**About Simeprevir (TMC435)**
Simeprevir is a once-daily potent investigational hepatitis C protease inhibitor in late phase III clinical development being jointly developed by Medivir AB and Janssen R&D Ireland to treat chronic hepatitis C virus infections. Simeprevir is being investigated in combination with PegIFN/RBV in phase III trials and is also being evaluated with direct-acting antiviral (DAA) agents in three other phase II interferon free combinations both with and without ribavirin (RBV).

Global phase III studies of simeprevir include QUEST-1 and QUEST-2 in treatment naïve patients, PROMISE in patients who have relapsed after prior IFN-based treatment and ATTAIN in treatment experienced patients. In parallel to these trials, phase III studies for simeprevir are ongoing in both treatment naïve and treatment experienced HIV-HCV co-infected patients, HCV genotype 4 infected patients and in Japanese HCV genotype 1 patients.

The phase II interferon-free combinations of simeprevir, include:

- Simeprevir in combination with Gilead Sciences' sofosbuvir (GS7977) in hepatitis C genotype 1 treatment-naïve or prior null responder patients.
- Simeprevir in combination with BMS's, daclatasvir in hepatitis C genotype 1 treatment-naïve or prior null responder 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.*

- Simeprevir in combination with Janssen's TMC647055 and low dose ritonavir in hepatitis C genotype 1 treatment-naïve, prior relapser or null responder patients
- Simeprevir in combination with Vertex's VX-135 in hepatitis C genotype 1 treatment-naïve patients.

**For additional information about Simeprevir please see www.clinicaltrials.gov**

**About Hepatitis C**
Hepatitis C is a blood-borne infectious disease of the liver and is a leading cause of chronic liver disease and liver transplants. The World Health Organization estimates that nearly 170 million people worldwide, approximately 3% of the world's population, are infected with hepatitis C virus (HCV). The CDC (Centers for Disease Control and Prevention) has reported that more than three million people in the United States are chronically infected with HCV.

**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 (TMC435), a novel protease inhibitor in phase III clinical development for hepatitis C that is being developed in collaboration with Janssen R&D Ireland.

In June 2011, Medivir acquired the specialty pharmaceutical company BioPhausia and today Medivir has a broad product portfolio with prescription pharmaceuticals in the Nordics.

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