Press Release 30 May 2013

An all-oral combination phase II study of Simeprevir and Samatasvir (IDX719) for the treatment of hepatitis C virus infection initiated

- **Phase II HELIX-1 trial is first hepatitis C clinical study to commence through collaboration agreement between Janssen Pharmaceuticals Inc. and Idenix Pharmaceuticals Inc.**

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced that Idenix Pharmaceuticals Inc. has initiated a phase II clinical trial, called HELIX-1, evaluating an all-oral, direct-acting antiviral (DAA) HCV combination regimen of simeprevir, a once-daily protease inhibitor jointly developed by Medivir and Janssen R&D Ireland and samatasvir (IDX719), Idenix's once-daily pan-genotypic NS5A inhibitor.

"Hepatitis C is a complex disease and there is a need for multiple treatment options. Future hepatitis C treatment will be interferon free and will consist of two to three direct acting antivirals (DAAs). We are pleased and looking forward to having simeprevir evaluated in this two-direct-acting antiviral phase II study", said Charlotte Edenius, EVP Development, Medivir AB.

About the HELIX trial
The HELIX-1 trial is a 12-week, randomized, double-blind, parallel group study evaluating the safety and tolerability of simeprevir and samatasvir in addition to antiviral activity endpoints, with a target enrollment of 90 treatment-naïve, non-cirrhotic, genotype 1b or 4 HCV-infected patients.

Patients will be randomized equally across three treatment arms, receiving 50, 100, or 150 mg samatasvir once-daily for 12 weeks in combination with 150mg simeprevir plus ribavirin.

The HELIX-1 trial is the first study in HCV-infected patients to commence under a non-exclusive collaboration agreement signed between Janssen and Idenix in January 2013. A second trial (HELIX-2) of simeprevir, samatasvir and TMC647055, a once-daily non-nucleoside polymerase inhibitor boosted with low-dose ritonavir being developed by Janssen, is expected to commence in the second half of 2013.

For more information please contact:
Rein Piir, EVP Corporate Affairs & IR
Mobile: +46 708 537 292

About Simeprevir
Simeprevir is an investigational NS3/4A protease inhibitor jointly developed by Medivir AB and Janssen R&D Ireland 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 protease enzyme that enables the hepatitis C virus to replicate in host cells.

New drug applications were recently submitted for simeprevir in Japan and the United States for the treatment of genotype 1 hepatitis C, and a Marketing Authorisation Application was submitted to the European Medicines Agency seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C. The U.S. FDA has granted Priority Review to the New Drug Application.

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.

Global phase III studies of simeprevir include PROMISE in adult patients who have relapsed after prior interferon-based treatment, QUEST-1 and QUEST-2 in treatment-naïve adult patients, and ATTAIN in prior null-responder adult 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 in treatment-naive and previous null-responder genotype 1 HCV patients.

In addition, Janssen Pharmaceuticals, Inc. 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 Pharmaceuticals, Inc. is conducting a drug-drug interaction (DDI) study with simeprevir and VX-135.

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

About Samatasvir (IDX719)
Samatasvir is an NS5A inhibitor with low picomolar, pan-genotypic antiviral activity in vitro. To date, samatasvir has been safe and well-tolerated after single and multiple doses of up to 150 mg in healthy volunteers for up to 14 days duration and up to 100 mg in HCV-infected patients for up to 3 days duration. There have been no treatment-emergent serious adverse events reported in the program. Samatasvir has demonstrated potent pan-genotypic antiviral activity in HCV-infected patients with mean maximal viral load reductions up to approximately 4.0 log10 IU/mL across HCV genotypes 1-4 in a proof-of-concept, three-day monotherapy study. For information about Idenix, please refer to www.idenix.com.

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 virus worldwide, and about 350,000 people per year die from the disease. 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 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 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