



Press Release, 20 September 2012

A phase IIa interferon free combination hepatitis C trial of Simeprevir (TMC435) and TMC647055 will commence shortly

Stockholm, Sweden—Medivir AB (OMX: MVIR), announced today that simeprevir (TMC435) and TMC647055, a non-nucleoside inhibitor (NNI) will enter a phase IIa interferon free combination trial.

Simeprevir is a once daily potent HCV NS3/4A protease inhibitor in phase III clinical development for the treatment of chronic hepatitis C jointly developed by Medivir and Janssen Research & Development Ireland (Janssen). TMC647055 is a potent NNI (non-nucleoside inhibitor) of the HCV NS5B polymerase and is being developed by Janssen R&D.

“This study is in line with Medivir’s and Janssen’s strategy to evaluate different combination possibilities with simeprevir for interferon-free HCV treatments. This will broaden our understanding of simeprevir, which we believe has the necessary characteristics to potentially become a key component of future hepatitis C treatment regimens, including combination with interferon and ribavirin as well as interferon-free therapies,” comments Charlotte Edenius, Medivir’s EVP of Research and Development.

Study design

This will be an open label study in patients who are chronically infected with HCV genotype-1a or 1b to assess the efficacy, safety and tolerability of the combination. The primary endpoint in the study will be SVR12 (sustained virologic response 12 weeks after end of treatment). Simeprevir, TMC647055 and low-dose ritonavir will be co-administered once daily, with and without ribavirin.

Approximately 40 patients will be enrolled in this study, which is divided in two parts. The first part will include patients chronically infected with HCV genotype-1, who are either treatment-naive or have relapsed after prior pegylated interferon (PegIFN)/ribavirin treatment. The treatment will consist of simeprevir, TMC647055 and low-dose ritonavir, with and without ribavirin for 12 weeks.

The second part of the trial will investigate the same regimen in prior null responder patients chronically infected with HCV genotype 1a.

Additional information about this study will be posted on www.clinicaltrials.gov

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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 Research & Development Ireland

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.

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

Medivir's first product, the unique cold sore product Xerese[®]/Xerclear[®], is launched in collaboration with GlaxoSmithKline to be sold OTC under the brand name ZoviDuo in Europe, Japan and Russia.

Medivir's IPO was in 1996 and currently the company has around 180 employees.

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

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