



Press Release 13 March 2012

Medivir announces new studies in phase III program for TMC435

- Study in previous non-responder Hepatitis C genotype-1 infected patients
- Study in Hepatitis C genotype-4 infected patients

Huddinge, Sweden – MedivirAB (OMX: MVIR) a research based specialty pharmaceutical company focused on infectious diseases announces that its oral, once daily investigational protease inhibitor TMC435, developed by Janssen Pharmaceuticals for the treatment of Hepatitis C virus (HCV), has commenced patient dosing and started screening in two new phase III clinical trials, HPC3001 and HPC3011, respectively.

HPC3001

HPC3001 is a phase III efficacy, safety and tolerability study comparing TMC435 versus telaprevir, each in combination with Pegylated Interferon α -2a (PegINF) and ribavirin (RBV), in hepatitis C genotype-1 infected patients who were null or partial responders to prior PegINF/RBV therapy. The study which is a randomized, double-blind, double-dummy, two-arm study is targeted to enroll 744 patients.

The aim of the study is to demonstrate the efficacy of TMC435 based therapy compared to the approved telaprevir regimen in this difficult to treat population.

Patients will receive TMC435 150 mg once daily or telaprevir 750 mg administered every eight hours (q8h) in combination with PegINF/RBV for 12 weeks followed by 36 weeks of PegINF/RBV alone. The primary endpoint of the study is sustained virological response at 12 weeks (SVR12).

HPC3011

HPC3011 is an open label, single arm phase III trial to explore the efficacy, safety and tolerability of TMC435 150 mg once daily, in combination with PegINF/RBV in 100 treatment naïve or treatment experienced, Hepatitis C genotype-4 infected patients.

Current standard of care treatment for chronic HCV genotype-4 infection consists of 48 weeks of PegINF/RBV with a large proportion of patients do not achieve SVR with this treatment regimen.

All subjects will receive 12 weeks triple therapy of TMC435 150 mg once daily and PegINF/RBV, followed by PegINF/RBV alone. The duration of total treatment is response guided in treatment naïve and prior relapser subjects and patients are eligible to stop all treatment at week 24 if predefined response-guided criteria are met. Subjects with cirrhosis will receive 48 weeks of therapy, irrespective of on-treatment virologic response and treatment history. The primary endpoint in the study is SVR12.

TMC435 - Ongoing global phase III program in brief:

- TMC435-C208 or QUEST-1 in 375 treatment-naïve genotype-1 patients
- TMC435-C216 or QUEST-2 in 375 treatment-naïve genotype-1 patients
- TMC435-C3007 or PROMISE in 375 genotype-1 patients who have relapsed after prior interferon-based treatment
- Phase III program in Japan, includes 417 genotype-1 treatment naïve and treatment experienced patients

Charlotte Edenius, Executive VP Research and Development, of Medivir commented,

"We are extremely pleased to expand the phase III program with these two new trials as we continue development of TMC435 for broad patient populations. The 744 patient HPC3001 study is aimed at

further confirming the positive findings of the ASPIRE phase IIb trial in genotype-1 non-responder patient populations and in the HPC3011 study, the genotype-4 activity of TMC435 is being investigated.”

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About TMC435

TMC435 is an investigational HCV protease inhibitor in late phase III clinical development. It is an efficacious, safe and well-tolerated once-daily (q.d.) drug jointly developed by Janssen Pharmaceuticals to treat chronic hepatitis C virus infections.

TMC435 is in phase III clinical development in combination with PegIFN/RBV but is also being evaluated with Direct-acting Antiviral (DAA) agents in interferon-free combinations both with and without ribavirin (RBV).

For additional information please visit www.medivir.com and 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 WHO estimates that nearly 180 million people worldwide, or approximately 3% of the world's population, are infected with hepatitis C virus (HCV). The CDC has reported that almost three million people in the United States are chronically infected with HCV.

About Medivir

Medivir is an emerging research-based specialty pharmaceutical company focused on the development of high-value treatments for 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 TMC435, a novel protease inhibitor in phase III clinical development for hepatitis C that is being developed in collaboration with Janssen Pharmaceuticals.

In June 2011, Medivir acquired the specialty pharmaceutical company BioPhausia to ensure timely commercialisation of TMC435 in the Nordic markets, once approved.

Medivir's first product, the unique cold sore product Xerese[®]/Xerclear[®], was launched on the US market in 2011. Xerese[®]/Xerclear[®], which has been approved in both the US and Europe, is being launched in collaboration with GlaxoSmithKline to be sold OTC in Europe, Japan and Russia. Rights in North America, Canada and Mexico were sold to Meda AB in June 2011. Medivir has retained the Rx rights for Xerclear[®] in Sweden and Finland.

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