



Press Release 22 June 2011

## TMC649128 enters Phase Ib Trial in Patients Chronically Infected with Genotype-1 Hepatitis C Virus

**Huddinge, Sweden** - Medivir AB (OMX: MVIR), the emerging research-based specialty pharmaceutical company focused on infectious diseases, today announces the start of a phase Ib clinical trial with TMC649128 intended for the treatment of chronic hepatitis C virus (HCV) infection.

TMC649128 is a nucleoside NS5B polymerase inhibitor developed in collaboration with Tibotec Pharmaceuticals. TMC649128 has demonstrated an attractive pre-clinical profile and displays *in vitro* activity across multiple HCV genotypes and a high genetic barrier to resistance. A clinical phase Ia double-blind, randomized, placebo-controlled single-ascending dose trial to assess the safety, tolerability and pharmacokinetics in healthy volunteers has now successfully been completed.

The TMC649128 phase Ib study that now is underway is a double-blind, randomized and placebo-controlled trial in genotype 1 HCV-infected patients to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of multiple ascending doses of TMC649128 given as monotherapy and in combination with pegylated interferon and ribavirin.

It is anticipated that TMC649128 will be used in combination with other HCV direct acting antiviral agents, given its high genetic barrier to resistance and antiviral activity across multiple HCV genotypes.

"We are delighted to see TMC649128, our first HCV nucleoside inhibitor, advance into clinical phase Ib studies in HCV patients", stated Bertil Samuelsson, CSO of Medivir. "The start of this phase Ib trial underscores our commitment to develop new and innovative treatments for hepatitis C infected patients. We view nucleoside inhibitors, such as TMC649128, and protease inhibitors, such as TMC435, as cornerstone components of future direct acting antiviral combinations for HCV therapy."

### For more information about Medivir, please contact;

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**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's Commitment to HCV**

Medivir and Tibotec are also jointly developing the once daily protease inhibitor TMC435 for treatment of hepatitis C virus infections (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. Medivir has a strong R&D portfolio and has recently launched its first product Xerese™/Xerclear®.

Medivir's key pipeline asset, TMC435, a protease inhibitor, is in global phase 3 clinical development for Hepatitis C and is partnered with Tibotec Pharmaceuticals.

Xerese™/Xerclear® is an innovative treatment for cold sores, which has been approved in both the US and Europe. It is partnered with GlaxoSmithKline to be sold OTC in Europe and Russia and with Meda AB in North America. 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.se](http://www.medivir.se).**