Press Release 18 February 2011

The phase 3 program for TMC435 in treatment-naïve patients and patients who have relapsed after prior interferon-based treatment has now started

Huddinge, Sweden - Medivir AB (OMX: MVIR), the emerging research-based specialty pharmaceutical company focused on infectious diseases, notes that its development partner, Tibotec Pharmaceuticals, announced today that the global phase 3 studies with TMC435 in treatment-naïve patients and patients who have relapsed after prior SOC treatment have started.

Phase 3 Program in brief:

- TMC435-C208 or QUEST-1 includes approximately 375 treatment-naïve patients
- TMC435-C216 or QUEST-2 includes approximately 375 treatment-naïve patients
- TMC435-C3007 or PROMISE includes approximately 375 who have relapsed after prior interferon-based treatment

Medivir's CEO, Ron Long, comments - "This is a momentous and important step for both the project and for Medivir as a company. It is impressive to see Tibotec's diligence and enterprise in developing TMC435 in a time-effective and thorough fashion."

The phase 3 milestone of Euro 5 million flagged in February 2010 will now be recognized as income in the first quarter 2011.

For additional information, please contact

Medivir (www.medivir.se)
Rein Piir, CFO & VP Investor Relations — Mobile: +46 708 537 292
M:Communications — Medivir@mcomgroup.com
Europe: Mary-Jane Elliott/ Amber Bielecka /Nick Francis — +44(0)20 7920 2330
USA: Roland Tomforde — +1 212 897 5497

Tibotec released today the following statement:

Cork, Ireland, February 17, 2011 – Tibotec Pharmaceuticals announced today that two global, registrational phase 3 trials are recruiting patients to examine TMC435, its investigational hepatitis C protease inhibitor, in treatment-naïve adults with chronic genotype 1 hepatitis C virus (HCV). A third global phase 3 trial is being conducted in genotype 1 HCV patients who have experienced a viral relapse after prior interferon-based treatment.

Approximately 3.2 million people in the U.S. live with chronic hepatitis C disease and more than 170 million people have the disease globally.[i,ii] The response-guided trials will compare the efficacy, safety and tolerability of TMC435 given as a single 150 mg oral tablet once daily for 12 weeks versus placebo; each patient also will be treated with a background regimen of peginterferon and ribavirin for 24 or 48 weeks.

"TMC435 is an important component of our growing HCV pipeline said Brian Woodfall M.D., Vice President of Global Clinical Development at Tibotec". "The initiation of the TMC435 phase 3 clinical trial program reinforces our commitment to develop innovative new treatment options that may decrease the duration of treatment for patients with chronic hepatitis C infection."

Three global studies
The first global, phase 3, double-blind, randomized study, known as TMC435-C208 or QUEST-1 (**Q**D dosing of TMC435 of previo**U**sly untreated G**E**notype 1 patien**T**s-1), will evaluate a single TMC435 once-daily oral tablet (150 mg) versus placebo in treatment-naïve HCV patients. Both groups will also receive peginterferon alfa-2a (Pegasys®) and ribavirin (Copegus®) as part of their treatment.

The second global, phase 3, double-blind, randomized study, known as TMC435-C216 or QUEST-2 (**Q**D dosing of TMC435 of previo**U**sly untreated G**E**notype 1 patien**T**s-2), also will evaluate a single TMC435 once-daily oral tablet (150 mg) versus placebo in treatment-naïve HCV patients. However, patients in this trial will either receive peginterferon alfa-2a (Pegasys®) and ribavirin (Copegus®) or peginterferon alfa-2b (PegIntron®) and ribavirin (Rebetol®) as part of their treatment.

A third global, phase 3, double-blind randomized study, known as TMC435-C3007 or PROMISE (**PRO**tease inhibitor T**M**C435 **I**n Patient**S** who have previously r**E**lapsed on IFN/RBV), will evaluate a single TMC435 once-daily oral tablet (150 mg) verses placebo in HCV patients who experienced viral relapse after previous interferon-based therapy. Both groups will receive peginterferon alfa-2a (Pegasys®) and ribavirin (Copegus®). The complete treatment duration for all three trials will be 24 or 48 weeks, depending on patient response.

In parallel to these trials phase 3 studies for TMC435 have also recently been launched in Japan.

Centers and inclusion criteria's
The studies will be conducted at more than 160 sites in 24 countries, including the U.S. and countries throughout Europe, and together seek to enroll approximately 1,125 HCV genotype 1 infected patients who are treatment-naïve or have experienced a relapse after previous interferon-based HCV therapy. To be eligible, patients must have chronic hepatitis C infection, and must have had a liver biopsy within three years of the screening visit. For those patients who have not had a liver biopsy in the three years prior to the study, one will be performed before the baseline visit. In addition, eligible patients need to have completed a recent ultrasound with no findings suspicious of hepatocellular carcinoma (HCC). Patients with signs of hepatic decompensation, liver disease of any non-HCV etiology, co-infection with hepatitis B or HIV-1 and 2 or a history of malignancy within 5 years of the screening visits are ineligible for the study.

Patients in QUEST-1 and QUEST-2 trials must not have received any prior treatment for hepatitis C, and patients in the PROMISE trial must have previously received at least 24 weeks of (peg)interferon-based therapy, along with documented negative HCV RNA at last on-treatment measurement, and have relapsed (detectable HCV RNA) within one year of last taking medication.
The primary endpoint of the studies is to assess whether TMC435 is superior to placebo in achieving sustained virologic reponse (SVR), defined as HCV RNA <25 IU/ml undetectable, 24 weeks after the planned end of treatment (SVR 24), with the final analysis being performed after the last patient reaches week 72 of the study. Secondary endpoints include superiority of TMC435 versus placebo at 12 weeks (SVR 12), after planned end of treatment and at week 72 of the study. Evaluations of viral breakthroughs, relapse rates in treatment groups, safety and tolerability also will be assessed.

[1]Centers for Disease Control and Prevention (CDC). "Hepatitis C FAQs for the Public." June 9, 2009. Available at http://www.cdc.gov/hepatitis/C/cFAQ.htm#. Last accessed February 4, 2011.

[1] Afdhal, N.H. "The Natural History of Hepatitis C." *Seminars in Liver Disease*. 2004. 24 (2): 3-8. Available at http://www.ncbi.nlm.nih.gov/pubmed/15346240. Last accessed February 4, 2011.

About TMC435 in other clinical studies
TMC435 is a once-daily (q.d.) protease inhibitor drug jointly developed by Medivir and Tibotec Pharmaceuticals, to treat chronic hepatitis C virus infections.

In parallel to the recent start of the global phase 3-studies, TMC435 is currently in a follow up phase in three phase 2b clinical trials (TMC435-C205, TMC435-C206 and TMC435-C215) in G1 treatment-naïve and in G1 patients that failed previous IFN-based treatment. More safety and efficacy data from the phase 2b trials will be presented at scientific meetings later in 2011.

For additional information for these studies, 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 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. 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, recently entered global phase 3 development for the treatment of 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 on Medivir, please see the company website: www.medivir.se