Press Release 22 February 2011

Medivir Announces positive Phase 2b 48-week (SVR24) Interim Results of TMC435 in Treatment-naïve 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, announces today further positive results from the phase 2b PILLAR (C205) study of TMC435 in treatment-naïve patients with hepatitis C virus (HCV) genotype-1.

- ***TMC435 was safe and well tolerated with no clinically relevant differences in adverse events between treatment groups and standard of care (SoC).***
- ***In the TMC435 treatment groups 83% of patients were able to stop all therapy at week 24***
- ***Potent and consistent antiviral efficacy was demonstrated with SVR24 rates of up to 84%***

"We are very pleased by both the efficacy and safety shown by TMC435 in this 48-Week interim analysis. With the additional features of once daily dosing, TMC435 also has a more convenient and competitive dosing regimen" stated Bertil Samuelsson, CSO of Medivir. "The recently published start of three global phase 3 clinical trials is an important milestone in the continued development of TMC435. We are now looking forward to the 48-week interim data from the phase 2b trial C206 (ASPIRE) in treatment-experienced patients during Q2 2011."

The 48-week interim results from the 5-arm phase 2b response guided PILLAR study in 386 treatment-naïve patients showed further consistent high antiviral activity, and the good safety and tolerability previously demonstrated was confirmed. The 24-week (EOT) interim results were presented at the AASLD conference in Boston, MA, in November 2010

Study design
In the PILLAR study, 75mg or 150mg TMC435 was given for either 12 or 24 weeks in combination with 24 weeks of ribavirin and pegIFNalpha-2A, the current standard of care (SoC). Patients in the TMC435 arms stopped all treatment at week 24 if certain predefined response-guided criteria were met. In the TMC435 treatment groups 83% of patients were able to stop all therapy at week 24. Patients who did not meet the above response-guided criteria continued with SoC until week 48 as did the placebo group.

Evaluation criteria
A protocol-defined interim analysis was performed when all patients completed their Week 48 visit or discontinued earlier. Final SVR4 and SVR24 data were available for 98% (303/309; n/N) and 93% (288/309; n/N) of TMC435 treated patients, respectively. SVR24 is determined 24 weeks after the planned end of treatment (EoT) and was therefore not yet available for the patients in the placebo group and for some of those in the TMC435 group who received 48 weeks

of treatment. SVR4, which is determined 4 weeks after the planned EoT, was available for 77% (59/77; n/M) of the patients in the placebo group

Results - Efficacy
Potent and sustained antiviral efficacy was demonstrated in the SVR4 and SVR24 rates with no major differences between TMC435 doses or length of triple therapy. At week 4 after cessation of treatment 87.2%, 86.5%, 84.9% and 88.5% of patients taking TMC435 and Peg-IFN/RBV (SoC) achieved undetectable HCV RNA levels. At week 24 after cessation of treatment 83.6%, 76.1%, 83.1% and 84.4% of patients taking TMC435 and Peg-IFN/RBV (SoC) achieved undetectable HCV RNA levels, i.e. SVR24. At week 4 after cessation of treatment 71.2% in the placebo SoC group had achieved undetectable HCV RNA levels.

The results are derived from an intent-to-treat (ITT) analysis of the patient population who took at least one dose of the study medication and who reached the criteria for stopping all treatment at 24 weeks (83%).

Sustained Virological Response 4 and 24 Weeks after Planned End of Treatment (EoT);					
% (n/N)	**TMC435 12PR24 75mg q.d. N=78**	**TMC435 24PR24 75mg q.d. N=75**	**TMC435 12PR24 150mg q.d. N=77**	**TMC435 24PR24 150mg q.d. N=79**	**Placebo N=77**
SVR4	**87.2 (68/78)**	**86.5 (64/74)**	**84.9 (62/73)**	**88.5 (69/78)**	**71.2 (42/59)**
SVR24	**83.6 (61/73)**	**76.1 (51/67)**	**83.1 (59/71)**	**84.4 (65/77)**	**N/A**

* < 25 log10 IU/mL undetectable
q.d.: once daily, PR: pegIFNalpha-2A and ribavirin,
SVR4 and SVR24: patients with undetectable HCV RNA 4 and 24 weeks after planned EoT, respectively.
N/A: Patients in the control arm continue SoC until Week 48 and SVR24 data was not available

Results – Safety and Tolerability
TMC435 was generally safe and well tolerated and overall incidence of adverse events (AEs) was similar across treatment groups. AEs leading to discontinuation of TMC435 or placebo treatment were reported in 7.8% of the placebo subjects and in 7.1% of the TMC435 treated subjects. In the safety analyses, special attention was given to the following AEs of interest: hepatobiliary AEs, pruritus, rash, anemia, and cardiac events. For each category of AEs of interest; the incidence was similar between TMC435 and placebo.

In laboratory parameters, there were no clinically relevant differences between any TMC435 groups and placebo except for mild on treatment reversible bilirubin elevations (total, direct and indirect) in the 150 mg TMC435 arm, which were normalized after TMC435 dosing was completed. There were no meaningful differences between treatment groups for any of the other laboratory parameters. Significant and rapid decreases in transaminases (ALT and AST) were observed in all TMC435 treatment groups.

For additional information, please contact

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Conference Call For Analysts and Investors:
There will be a conference call today, February 22 2011, for investors and sell-side analysts at 09:00 (EDT) / 14:00 (GMT) / 15:00 (CET) with the management team of Medivir to discuss this announcement. To dial-in to the conference call please use the following numbers:

Participant Telephone Numbers:	+1 718 354 1385	USA
	+46 (0)8 5352 6408	Sweden
	+44 (0)20 7806 1951	UK
Confirmation Code:	6641746	

Alternatively, please contact Lindsey Neville at M:Communications on Tel: +44 (0) 207 920 2333, Email: Neville@mcomgroup.com.

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.

The clinical phase 3 program started recently including

- 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

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.

A phase 3 program for TMC435 has also recently been launched in Japan.

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