Press Release 2 November 2011

Medivir Announces Final Results from TMC435 Phase IIb ASPIRE (C206) Study

TMC435-Based Therapy Significantly Improved Viral Cure Rates in Patients Who Failed Prior Treatment for Hepatitis C

- ASPIRE: All TMC435 subgroups achieved substantially higher viral cure rates (SVR24) compared with control group (pegylated interferon and ribavirin alone): 85% vs. 37% in prior relapsers, 75% vs. 9% in prior partial responders and 51% vs. 19% in prior null responders –

- Once daily TMC435 was generally safe and well tolerated at all doses and treatment durations -

Medivir AB (OMX: MVIR), a research-based speciality pharmaceutical company focused on infectious diseases, today announces final results from the ASPIRE study. This phase IIb study evaluated TMC435 once daily in addition to pegylated interferon (PegIFN) and ribavirin (RBV) in patients with genotype-1 chronic hepatitis C whose prior treatment with PegIFN and RBV was unsuccessful either because they relapsed, had a partial response or had a null response.

Data from the ASPIRE study showed that patients in each of these subgroups who were treated with TMC435-based combination therapy achieved superior rates of sustained virologic response (viral cure) compared with those retreated with PegIFN and RBV alone.

Charlotte Edenius, Executive VP Research and Development, of Medivir commented, "We are extremely pleased with the final results from the ASPIRE study showing high viral cure rates and a favourable safety and tolerability profile in these difficult to treat genotype-1 hepatitis C patients whose prior treatment was unsuccessful. These results may provide new optimism for people who have failed on previous therapy, including those with advanced liver disease. We are highly committed to the broad and rapid development of TMC435 and global pivotal phase III clinical trials are currently well underway"

ASPIRE (C206) – Design
TMC435, a potent, once-daily, oral hepatitis C virus protease inhibitor, is being developed by Tibotec jointly with Medivir. The randomized, placebo-controlled, double-blind ASPIRE study evaluates the effect of TMC435 in combination with pegylated-interferon and ribavirin in 462 patients infected with genotype-1 hepatitis C virus who have failed prior treatment with PegIFN/RBV. The primary endpoint was proportion of patients with undetectable HCV RNA 24 weeks after the planned end of treatment (SVR24).

The study includes patients who have relapsed, achieved partial response, or achieved no response (null responders) to PegIFN/RBV treatment. 62 percent (287/462) of patients had advanced liver disease, periportal or septal fibrosis or cirrhosis (scarring of the liver) upon study entry (Metavir score F2-F4).

Patients were equally randomized to one of seven different treatment arms, six TMC435 treatment arms and one placebo arm. TMC435 was administered once daily at a dose of either 100 mg or 150 mg given for either 12, 24, or 48 weeks in combination with 48 weeks of PegIFN/RBV. The results are based on the intent-to-treat (ITT), population which included all randomized patients who took at least one dose of the study medication.

Results - Efficacy

In this final analysis, all subgroups of treatment-experienced patients who failed previous PegIFN and RBV treatment, achieved substantially higher virologic response rates following treatment with TMC435-containing regimen at all doses and durations, compared with PegIFN and RBV alone.
Regardless of treatment duration all TMC435 treatment arms showed significantly improved effect on SVR24 versus PegIFN/RBV alone.

Sustained Virologic Response (SVR24) Rates in TMC435 Dose Groups (150 mg q.d.) vs Placebo						
% (n/N)		TMC435 **12**PR48 N=66	TMC435 **24**PR48 N=68	TMC435 **48**PR48 N=65	**All TMC435** PR48 N=199	**Placebo** PR48 N=66
Relapsers	**SVR24**	76.9 (20/26)	88.9 (24/27)	88.5 (23/26)	84.8 (67/79)	37.0 (10/27)
Partial Responders	**SVR24**	65.2 (15/23)	75.0 (18/24)	86.4 (19/22)	75.3 (52/69)	8.7 (2/23)
Null Responders	**SVR24**	52.9 (9/17)	41.2 (7/17)	58.8 (10/17)	51.0 (26/51)	18.8 (3/16)

q.d.: once daily; PR: pegIFNalpha-2A and ribavirin; EoT: End of Treatment,
SVR24: patients with undetectable HCV RNA (<25 IU/mL Undetectable) 24 weeks after planned EoT. All TMC435 groups: p<0.001 vs placebo.
Prior Relapser: undetectable HCV RNA at EoT and detectable within 24 weeks of follow-up
Prior Partial Responders: more than 2 log reduction in HCV RNA at W12 but not achieving undetectable at EoT
Prior Null Responders: less than 2 log reduction in HCV RNA at W12

Results – Safety and Tolerability

TMC435 was generally safe and well tolerated and overall incidence of adverse events (AEs) was similar across treatment groups. Most of the AEs were grade 1 or 2 in severity. Serious AEs (SAEs) were reported in 6.1% subjects in the placebo and in 7.8% of the patients treated with TMC435. AEs leading to treatment discontinuation were reported in 4.5% of the placebo patients and in 7.8% of the TMC435 treated patients. Patients in the TMC435 ASPIRE treatment groups had overall longer treatment duration than patients in the placebo group due to a higher frequency of early discontinuation in the placebo group due to treatment failures (i.e. reaching viral stopping rules). The most common AEs during the treatment period were headache, fatigue, pruritus and influenza-like illness. Incidence was similar across treatment groups and the level of AEs and frequency were consistent with the prior phase IIb (PILLAR) study in treatment-naïve hepatitis C patients of TMC435.

In the safety analyses, special attention was given to the following AEs of interest: hepatobiliary AEs, pruritus, rash and anemia. Most AEs of interest were grade 1 or 2 in severity and infrequently led to treatment discontinuation. For each category of AEs of interest the incidence was similar for the TMC435 treatment arms and control arm.

Mild and reversible increases in bilirubin (total, direct and indirect) were observed in TMC435 dose groups with no differences between 100 mg and 150 mg. There were no meaningful differences between treatment groups for any of the other laboratory parameters. There were no clinically significant findings on vital signs. Mean alanine aminotransferase (ALT) levels decreased in all treatment groups.

DRAGON (C215) – Update on recently published results
The final data from the phase II Dragon study in Japan was recently published at the Japan Digestive Disease Week meeting, 20-23 October 2011 in Fukuoka, Japan. The DRAGON study is a phase II randomized, open-label, response-guided study to evaluate the efficacy, safety, and pharmacokinetics of TMC435 plus PegIFN/RBV in 92 Japanese treatment-naïve patients infected with HCV genotype-1. Addition of once daily TMC435 (100 mg) to PegIFN/RBV increased the viral cure rate (SVR24) from 46% in the PegIFN/RBV only group to 82% (32/39) in the TMC435 100mg groups. In these groups, 87% of patients were eligible to complete all treatment at Week 24 if preset criteria on virologic response were met. TMC435 was generally safe and well tolerated with no apparent difference in the safety profile between TMC435 treatment groups and the control group (PegIFN/RBV only).

About TMC435
TMC435 is a highly potent and selective once-daily (q.d.) investigational drug that is being jointly developed by Tibotec Pharmaceuticals and Medivir to treat chronic hepatitis C virus infections.

TMC435 has received "Fast Track" designation by the U.S. Food and Drug Administration ("FDA") for the treatment of chronic hepatitis C (CHC) genotype-1 infection. This is based on TMC435's potential to address unmet medical needs in the treatment of chronic HCV infection. TMC435 is currently being developed in three global phase III studies, QUEST-1 and QUEST-2 in treatment-naïve patients and PROMISE in patients who have relapsed after prior interferon-based treatment. In parallel with these trials, phase III studies for TMC435 in Japan, in both treatment naive and treatment experienced hepatitis C genotype-1 infected patients, are ongoing.

For additional information from these studies, please see www.medivir.com and www.clinicaltrials.gov

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Conference call for analysts and investors:
There will be a conference call today, 2 November 2011, for investors and analysts at 11.00 (EDT) / 15.00 (GMT) / 16.00 (CET) to discuss the data. To dial-in to the conference call please use the following numbers:

Participant telephone numbers:	Sweden	+46 (0)200 884 518
	Europe	+44 (0)1452 569 335
	USA	+1 866 655 1591
Please quote participant code		23849230
Soundbyte replay access numbers:	Sweden	+46 (0)200 899 157
	Europe	+44 (0)1452 55 00 00
	USA	+1 866 247 4222
Replay access code:		23849230#

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 that is in phase III clinical development for hepatitis C and is partnered with Tibotec Pharmaceuticals.

In June 2011, Medivir acquired the specialty pharmaceutical company BioPhausia to ensure timely commercialization 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 February 2011. Xerese®/Xerclear®, which has been approved in both the US and Europe is partnered 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.