Press Release 18 November 2010

Medivir Announces Positive 24-week Interim Data of TMC435 from the ASPIRE Study (C206)

~ Once daily novel therapy in treatment-experienced Hepatitis C patients ~

Highlights of the study:

TMC435 added to standard of care:

- increased the response rates and antiviral efficacy, which progressed through to week 24.
- increased the number of patients with undetectable Hepatitis C Virus (HCV) levels through week 4, 12 and 24
- was safe and well tolerated

Huddinge, Sweden - Medivir AB (OMX: MVIR), the emerging research-based specialty pharmaceutical company focused on infectious diseases announces today positive top-line 24-week interim data from the Phase 2b ASPIRE (C206) study of TMC435 in treatment-experienced hepatitis C patients. The results demonstrate the potent and consistent antiviral efficacy of TMC435 in patients who had failed earlier treatment with peg-IFN and ribavarin (standard of care), as well as an safety and adverse event profile for TMC435 that is consistent with what we have previously reported in the phase 2b PILLAR C205 study. TMC435, a hepatitis C protease inhibitor, dosed once daily (q.d.) is being developed jointly by Tibotec Pharmaceuticals and Medivir.

The ASPIRE study evaluates the effect of TMC435 in combination with standard of care in 462 patients infected with the difficult to treat genotype-1 hepatitis C virus who had undergone and failed prior treatment with standard of care. The study includes patients that have relapsed, achieved partial response, or achieved no response (null responders) to treatment with standard of care.
TMC435 was administered once daily at a dose of either 100 mg or 150mg given for either 12, 24, or 48 weeks in combination with standard of care. Standard of care treatment was continued until the study completion at week 48.

Overview of the ASPIRE (C206) Week 24 Interim Study Results
The week 24 interim analysis was performed when all patients completed 24 weeks of treatment or discontinued earlier. An Intention-to-Treat, ITT, analysis was performed including all patients who took at least one dose of TMC435.
In the interim analysis patients treated with TMC435 and standard of care demonstrated high response rates and antiviral efficacy in all patient groups up to and including week 4, 12 and 24.
In the relapser group 81%, 92% and 94% of patients taking TMC435 and Peg-IFN and RBV achieved undetectable HCV RNA levels at week 4, week 12 and week 24 respectively. For the partial responder group 62%, 84% and 86% achieved undetectable HCV RNA levels at week 4, week 12 and week 24 respectively.

The null responder group also demonstrated significant response rates with 38%, 64% and 78% of patients taking TMC435 and Peg-IFN and RBV achieving undetectable HCV RNA levels at week 4, week 12 and week 24 respectively. All patients continue on active treatment up until week 48.

In the table below the TMC435 data pooled and all data are taken into account at the specific time point.

An Intention-to-Treat analysis of Virologic Response: HCV RNA<25IU/mL undetectable

(%)	Relapser*		Partial responder**		Null responder**	
	TMC435 N = 158	Placebo N = 27	TMC435 N = 138	Placebo N = 23	TMC435 N = 100	Placebo N = 16
RVR WEEK 4	81	4	62	0	38	0
cEVR WEEK 12	92	31	84	10	64	21
WEEK 24	94	83	86	19	78	44

*Relapser: undetectable at EOT but detectable within 24 weeks of Follow-up
**Partial response: >2 log reduction at Week 12 but not achieving undetectable at EOT
***Null response: <2 log reduction in HCV RNA at Week 12

Safety and Tolerabillty
An Intention-to-Treat analysis was performed including all patients who took at least one dose of TMC435. TMC435 was generally safe and well tolerated and the results were consistent with the previously reported phase 2b PILLAR C205 study. Significant decreases in transaminases (ALT and AST) were observed in all TMC435 treatment groups. The two most frequently reported AEs were fatigue and headache, with comparable results shown from the placebo group.

%	All TMC435 N = 396	Placebo N = 66
Fatigue	41	42
Headache	33	33

Commenting on the results, Ron Long, CEO of Medivir said, "We are extremely encouraged and excited by the pronounced efficacy and advantageous safety of TMC435 in these difficult-to-treat patients that are in a great need of new and improved treatment options. We are now looking forward to the next important development milestone for TMC435, the start of phase 3 clinical trials in treatment-naïve patients in early 2011."

Conference call
A conference call will take place at 15:00 (GMT) / 16:00 (CET) / 10:00 (EST) to discuss the Phase 2b TMC435 ASPIRE (C206) data announced today.

Please dial: UK: +44 (0)20 7906 8535, Sweden Access Number: +46 (0)85 063 9549 or US Access Number: +1 703 865 2821, no passcode is required. A seven day replay of the conference call can be accessed via: UK: +44 (0)20 3364 5943, Sweden: +46 (0) 20 089 6353, US: +1 866 286 6997, please quote the passcode 281259#.

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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 phase 2b 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 GSK to be sold OTC in Europe and Russia and with Meda 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.

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 TMC435 clinical trial programs
TMC435 is a once daily protease inhibitor jointly developed by Medivir and Tibotec Pharmaceuticals to treat hepatitis C virus infections. TMC435 is currently being studied 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. TMC435 is planned to enter phase 3 studies early 2011.

PILLAR Study (TMC435-C205)
TMC435-C205 is an ongoing randomized double-blind global phase 2b study in 386 genotype-1 treatment-naïve patients. It evaluates once daily treatment of TMC435 with different doses and durations given in addition to standard of care treatment, consisting of ribavirin and pegIFNalpha-2A. Week 24 interim results were presented as a late-breaker oral presentation at AASLD 61st Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston, MA., USA.

ASPIRE Study (TMC435-C206)
TMC435-C206 is an ongoing randomized double-blind global phase 2b study in 462 genotype-1 treatment-experienced patients. It evaluates once daily treatment of TMC435 in with different doses of given in addition to standard of care treatment, consisting of ribavirin and pegIFNalpha-2A.

DRAGON Study (TMC435-C215)
TMC435-C215 is an ongoing Japanese phase 2b study in 92 genotype-1 treatment-naïve patients. It evaluates once daily treatment of TMC435 with different doses and durations given in addition to standard of care treatment, consisting of ribavirin and pegIFNalpha-2A.

Opera-2 (TMC435-C202)
TMC435-C202 is a completed phase 2a study in treatment-naïve genotype 2 to 6 HCV patients. It is a once daily treatment of TMC435 during seven days, at 200 mg. Subsequently, patients could continue with SoC treatment consisting of pegylated interferon and ribavirin upon agreement with the study doctor.