Press Release 30 September 2011

Medivir Announces Acceptance of Four TMC435 Abstracts for Presentation at the AASLD Meeting

~ Including a Late-breaking Oral Presentation of final analysis of the TMC435 phase 2b PILLAR study ~

Medivir AB (OMX: MVIR), a research-based speciality pharmaceutical company focused on infectious diseases, today announces that four abstracts related to its once daily (QD), oral investigational hepatitis C drug TMC435 have been accepted for presentation at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), taking place from November 4-8 in San Francisco, USA.

The abstracts have been published today and can be accessed on the AASLD website **http://www.aasld.org**. In accordance with the AASLD embargo policy, information from the abstracts and the accepted titles only are provided below. TMC435, an investigational hepatitis C NS3/4A protease inhibitor, is being jointly developed by Medivir and Tibotec Pharmaceuticals.

At the AASLD meeting, in a Late Breaker Oral Presentation, the final analysis, including SVR24 data, from the phase 2b PILLAR study of TMC435 will be presented. In this study, treatment-naive patients infected with HCV genotype 1 (G1) were dosed once daily for 24 or 48 weeks with 75mg or 150mg of TMC435 in combination with peginterferon α-2a (PegIFN) and ribavirin (RBV). A 24 week duration was assigned if HCV RNA levels were <25 IU/mL detectable or undetectable at Week 4 and <25 IU/mL undetectable at Weeks 12, 16, and 20. In the control arm patients were treated for 48 weeks with PegIFN/RBV only. The primary endpoint of the study was sustained virologic response (SVR) at Week 72.

Significantly higher response rates were observed with TMC435 compared to control.

Response, n/N (%)	**TMC435 12W P/R RGT**	**TMC435 24W P/R RGT**	**TMC435 12W P/R RGT**	**TMC435 24W P/R RGT**	**Placebo/P/R 48W**
	75 mg		**150 mg**		
	N=78	**N=75**	**N=77**	**N=79**	**N=77**
RVR[1]	59/78(75.6)	51/75(68.0)	58/77 (75.3)	59/79(74.7)	4/77 (5.2)
EOT[2]	72/78(92.3)	73/75(97.3)	71/77(92.2)	74/79(93.7)	61/77(79.2)
SVR24[3]	64/78(82.1)*	56/75(74.7)	62/77(80.5)*	68/79(86.1)**	50/77(64.9)
SVR W72[4]	63/78(80.8)*	53/75(70.7)	60/77(77.9)*	67/79(84.8)**	50/77(64.9)
Viral relapse	8/72 (11.1)	14/72(19.4)	6/69 (8.7)	6/75 (8.0)	11/62(17.7)

HCV RNA <25 IU/mL undetectable at: [1]Week 4 (rapid virologic response); [2]End of treatment; [3]24 weeks after planned end of treatment; [4]Week 72
**p<0.05, **p<0.005, significant difference vs control (closed testing procedure), other SVR differences not significant; P/R, peginterferon α-2a/ribavirin; RGT, response guided therapy*

In TMC435 arms, 79-86% of patients were eligible to complete treatment at Week 24. The incidence of discontinuations, adverse events (AEs, including rash, anemia and neutropenia) and serious AEs were similar in the TMC435 and control arms. Mild, transient increases in direct and indirect bilirubin, not associated with increases in other hepatic parameters, were observed with TMC435 150 mg.

TMC435 150 mg QD for 12 weeks is being pursued in the ongoing global phase 3 trials. Additionally, there will be three poster presentations at the 2011 AASLD meeting.

The titles for the accepted Abstracts are as follows:

Late Breaker Oral Presentation: Monday 7 Nov. 3:45pm:

- **LB-5.** "TMC435 in combination with peginterferon and ribavirin in treatment-naïve HCV genotype 1 patients: Final analysis of the PILLAR Phase IIb study." *M. Fried; M. Buti; G. J. Dore; R. Flisiak; P. Ferenci; I. M. Jacobson; P. Marcellin; M. P. Manns; I. Nikitin; F. Poordad; M. Sherman; S. Zeuzem; O. Lenz; M. Peeters; V. Sekar; G. De Smedt*

Poster Presentations**:**

- **1329**. "TMC435 in combination with peginterferon alpha-2a/ribavirin in treatment-naïve patients infected with HCV genotype 1: virology analysis of the PILLAR study". *O. Lenz; B. Fevery; L. Vijgen; J. Verbeeck ; M. Peeters; M. Beumont; M. W. Fried; G. Picchio*
- **1354**. "The pharmacokinetic interaction between the investigational HCV NS3/4A protease inhibitor TMC435 and escitalopram". *M. Beumont-Mauviel; A. Simion; G. De Smedt; K. Spittaels; M. Peeters; V. Sekar*
- **1353**. "The pharmacokinetic interaction between the investigational NS3-4A HCV protease inhibitor TMC435 and methadone". *M. Beumont-Mauviel; G. . De Smedt; M. Peeters; S. H. Akuma; V. Sekar*

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About TMC435
TMC435 is a highly potent, selective, safe once-daily (QD) investigational drug jointly developed by Tibotec Pharmaceuticals to treat chronic hepatitis C virus infection. TMC435 is being developed both in combination with PegIFN/RBV and in combination with Direct-Acting Antiviral (DAA) agents in an all oral, IFN free regimen, with or without ribavirin (RBV).

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.

For additional information from these studies, please see **www.medivir.com** and **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 World Health Organization 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 is in phase 3 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**