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Medivir: Week 24 Interim Results from TMC435 Hepatitis C Phase 2b ASPIRE Study presented at EASL

Results show potent antiviral efficacy of once daily 150 mg TMC435 in hepatitis C patients who have failed earlier treatment, especially in prior null responders, and excellent safety and tolerability

Huddinge, Sweden - Medivir AB (OMX: MVIR), the emerging research-based specialty pharmaceutical company focused on infectious diseases, announces that their partner, Tibotec has presented the results of a planned Week 24 interim analysis of the phase 2b ASPIRE study for TMC435 in treatment experienced hepatitis C patients in a late-breaker session at the 46th Annual meeting of the European Association for the Study of the Liver (EASL), Berlin, Germany.

Treatment experienced patients are known to be the most difficult to treat hepatitis C patient group.

TMC435 is a potent, once-daily, oral hepatitis C virus protease inhibitor which recently entered clinical phase 3 studies. The study enrolled patients chronically infected with genotype-1 hepatitis C virus (HCV) that had previously failed treatment with standard of care therapy (peginterferon and ribavirin). TMC435 is being jointly developed by Medivir and its partner Tibotec.

In this Week 24 interim analysis, treatment-experienced patients who failed peginterferon and ribavirin treatment achieved significantly greater virologic response rates following treatment with TMC435-containing regimen at all doses, compared with placebo. Results demonstrated that the TMC435 150 mg dose group showed the highest response, particularly in prior null responders. In this 150 mg dose group, HCV RNA levels were undetectable at week 24 for between 82% and 91% of the patients. Results also showed that there was no statistically relevant difference in safety and tolerability between the TMC435 and placebo treated groups.

Ron Long, CEO of Medivir, commented: "We are delighted that these strong results are to be presented at such a prestigious scientific conference as EASL. TMC435 continues to demonstrate why Medivir are so confident that hepatitis C treatment can be significantly changed by a more convenient, once daily protease inhibitor especially for treatment experienced patients. These data and the recent start of phase 3 clinical studies for TMC435, represent an exciting stage in Medivir's development as a significant player in the infectious disease market."

On-treatment response rates are shown below.

	TMC12/P R48 100mg (N=66)	TMC24/P R48 100mg (N=65)	TMC48/P R48 100mg (N=66)	TMC12/P R48 150mg (N=66)	TMC24/P R48 150mg (N=68)	TMC48/P R48 150mg (N=65)	Pbo48/P R48 (N=66)
HCV RNA <25 IU/mL undetectable, % (u/N)							
Overall population Week 4 (RVR)	67,7 (44/65) ***	59,4 (38/64) ***	53,8 (35/65) ***	63,1 (41/65) ***	70,8 (46/65) ***	66,2 (43/65) ***	1,5 (1/65)
Prior null responders	33,3 (5/15)	50,0 (8/16)	25,0 (4/16)	35,3 (6/17)	41,2 (7/17)	41,2 (7/17)	0,0 (0/16)
Prior partial responders	65,2 (15/23)	40,9 (9/22)	60,9 (14/23)	65,2 (15/23)	69,6 (16/23)	68,2 (15/22)	0,0 (0/23)
Prior relapser	88,9 (24/27)	80,8 (21/26)	65,4 (17/26)	80,0 (20/25)	92,0 (23/25)	80,8 (21/26)	3,8 (1/26)
Overall population Week 24	87,1 (54/62) ***	84,5 (49/58) ***	85,2 (52/61) ***	85,7 (54/63) ***	90,8 (59/65) ***	90,3 (56/62) ***	51,9 (28/54)
Prior null responders	71,4 (10/14)	83,3 (10/12)	68,8 (11/16)	70,6 (12/17)	81,3 (13/16)	93,3 (14/15)	44,4 (4/9)
Prior partial responders	86,6 (19/22)	80,0 (16/20)	85,7 (18/21)	86,4 (19/22)	90,9 (20/22)	86,4 (19/22)	19,0 (4/21)
Prior relapser	96,2 (25/26)	88,5 (23/26)	95,8 (23/24)	95,8 (23/24)	96,3 (26/27)	92,0 (23/25)	83,3 (20/24)

*** Statistically significant difference versus placebo, p<0,001

The ASPIRE study evaluates the effect of TMC435 in combination with standard of care (SoC) in 462 patients infected with the difficult to treat genotype-1 hepatitis C virus who had undergone and failed prior treatment with (SoC). 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.

As well as the late-breaker ASPIRE data presented, a further three presentations will be made at EASL on TMC435. These include:

Oral presentation: *Impact of IL28b genotype and pretreatment serum IP-10 in treatment-naïve genotype-1 HCV patients treated with TMC435 in combination with peginterferon-2a and ribavirin in PILLAR study*, J. Aerssens, which found that during 24 weeks of treatment, IL28B genotype and serum IP-10 were predictive of response in patients receiving standard of care (peginterferon and ribavirin) but had limited predictive value in patients treated with both TMC435 and peginterferon and ribavirin, therefore suggesting that TMC435, a potent, once daily oral protease inhibitor, may overcome the negative consequences of unfavourable host genotype encountered with pegIFN/RBV.

Poster presentation No.472: *Pharmacokinetics of TMC435 in subjects with moderate hepatic impairment*, V. Sekar, which found that no TMC435 dose adjustment was necessary for patients with moderate liver impairment.

Poster presentation No.1221: *Treatment outcome and resistance analysis in HCV genotype 1 patients previously exposed to TMC435 monotherapy and re-treated with TMC435 in combination with pegifna 2a/ribavirin*, O. Lenz, which found that viral variants in patients who had received TMC435 as a monotherapy were no longer detected over time and successful treatment after prior exposure to TMC435 with emergence of resistance variants was possible in 3/5 patients who had failed interferon-based therapy.

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.

Three clinical phase 3 response guided studies were recently initiated:

- 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

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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 protease inhibitor which has recently entered phase 3 clinical development for hepatitis C and is partnered with Tibotec Pharmaceuticals.

Medivir is also marketing its first product, the unique cold sore product Xerese™/Xerclear® which has recently been launched on the US market. Xerese™/Xerclear®, which is also approved in Europe, is partnered with GlaxoSmithKline to be sold OTC in Europe, Japan and Russia and with Meda AB in North America, Canada and Mexico. 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.