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Medivir Announces Phase 2b 24-week Interim Results of TMC435 in Treatment-naïve Patients Chronically Infected with Genotype-1 Hepatitis C Virus

Potent and consistent antiviral efficacy was demonstrated at 24-week end-of-treatment and in interim SVR4 and SVR12 results. There were no clinically relevant differences between TMC435 treatment groups and placebo for adverse events.

Medivir announced today 24-week end-of-treatment interim results from the 5-arm phase 2b response guided PILLAR study in 386 treatment-naïve patients with hepatitis C virus (HCV) genotype-1 (TMC435-C205).

TMC435 is a protease inhibitor jointly developed by Medivir and Tibotec Pharmaceuticals, dosed as one pill once daily (q.d.) to treat hepatitis C virus infections (HCV).

In the PILLAR study, 75mg or 150mg TMC435 was given for either 12 weeks or 24 weeks in combination with 24 weeks of ribavirin and pegIFNalpha-2A, the current standard of care (SOC). Patients stopped all treatment at week 24 when HCV RNA levels at week 4 were < 25 log10 IU/mL detectable or undetectable and HCV RNA levels at week 12, week 16 and week 20 were < 25 log10 IU/mL undetectable. Patients who did not meet the above response-guided criteria continued with SOC until week 48. The results showed that in the TMC435 treatment groups 83% of patients were able to stop all therapy at Week 24.

Potent and consistent antiviral efficacy was demonstrated at 24-week end-of-treatment and in interim SVR4 and SVR12 rates with no major differences between TMC435 doses or length of triple therapy. 92% of patients taking TMC435 and Peg-IFN/RBV (SoC) achieved undetectable HCV RNA levels at week 4 and 92% at week 12 after cessation of treatment, i.e. SVR4 and SVR12. SVR4 and SVR12 data were available for 82% and 42% of the TMC435-treated patients respectively who had stopped all therapy before or at Week 24 and had completed the follow-up visits. Both the viral breakthrough rate (4.9%) and relapse rate (1.6%) were low in the TMC435 treatment groups.

TMC435 was generally safe and well tolerated with no relevant differences in adverse events (AEs) between placebo and TMC435 treatment groups. Most AEs were mild to moderate in severity and the discontinuation rate due to AEs was low and not different from placebo.

When looking at particular adverse events of interest, the incidence of rash, pruritis, GI side effects and anemia were similar in TMC435 groups and placebo and were generally mild to moderate in nature. Use of erythropoetin-stimulating agents (ESAs) was not allowed during the trial.

In laboratory parameters, there were no clinically relevant differences between any TMC435 groups and placebo except for mild bilirubin elevations. Significant decreases in transaminases (ALT and AST) were observed in all treatment groups.

Further safety and efficacy data will be presented at future scientific meetings later in 2010.

"We are extremely encouraged and excited by the efficacy and safety demonstrating that TMC435 is truly a second-generation HCV protease inhibitor," stated Bertil Samuelsson, CSO of Medivir. "We also are looking forward to the top-line data coming up from the phase 2b trial C206 (ASPIRE) in treatment-experienced patients later this year as well as start of phase 3 clinical trials in treatment-naïve patients early next year."

Frequency of Undetectable* HCV RNA Levels During and After Treatment					
Treatment week **N (%)**	**TMC12PR24 75mg q.d.** **N=78**	**TMC24PR24 75mg q.d.** **N=75**	**TMC12PR24 150mg q.d.** **N=77**	**TMC24PR24 150mg q.d.** **N=79**	**SoC** **N=77**
Week-24, EoT* **	67/73 (92%)	65/67 (97%)	68/74 (92%)	73/78 (94%)	4/18 (22%)**
Follow-up at Week-4 and Week-12 after EoT					
SVR4	59/65 (91%)	56/60 (93%)	57/61 (93%)	63/68 (93%)	NA****
SVR12	32/33 (97%)	27/29 (93%)	32/36 (89%)	29/32 (91%)	NA

* < 25 log10 IU/mL undetectable
** End of treatment
***EoT: End of Treatment
**** Patients in the control arm continue SoC till Week 48 and SVR data are not available
q.d.: once daily, PR: pegIFNalpha-2A and ribavirin, SVR4: undetectable HCV RNA at EoT & undetectable HCV RNA 4 weeks after planned EoT, SVR12: undetectable HCV RNA at EoT & undetectable HCV RNA 12 weeks after planned EoT

About TMC435 clinical trial programs
TMC435 is a protease inhibitor jointly developed by Medivir and Tibotec Pharmaceuticals to treat hepatitis C virus infections (HCV).

TMC435 is currently being developed 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. Safety and efficacy data from the phase 2b trials will be presented at scientific meetings later in 2010.

TMC435-C205 is a global phase 2b study in 386 genotype-1 treatment-naïve patients. It is a once daily treatment of TMC435 with different doses and durations given in addition to standard of care treatment, consisting of ribavirin and pegIFNalpha-2A.

TMC435-C215 is a Japan phase 2b study in 92 genotype-1 treatment-naïve patients. It is a once daily treatment of TMC435 with different doses and durations given in addition to standard of care treatment, consisting of ribavirin and pegIFNalpha-2A.

TMC435-C206 is a global phase 2b study in 463 genotype-1 treatment-experienced patients. It is a once daily treatment of TMC435 in with different doses of given in addition to standard of care treatment, consisting of ribavirin and pegIFNalpha-2A.

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.

Invitation to a Press Conference
Medivir will host a teleconference today at 15:00 (Central European summer time) focusing on the phase 2b 24-week interim results.

To participate in the teleconference, please call +46 8 619 75 30 using the participant code 195272#.

For additional information, please contact
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For more information on Medivir, please see the company website: www.medivir.se