Week 24 Interim Results From Phase 2b PILLAR Study to be Presented as Late-breaker at AASLD

Data show high antiviral activity, safety and tolerability comparable to placebo

[Boston, MA. Saturday 30th October 2010] - Tibotec Pharmaceuticals (Tibotec) today will present the results of a Week-24 planned interim analysis of the phase 2 response-guided PILLAR study in treatment-naïve patients with chronic genotype 1 hepatitis C virus (HCV) as part of a late-breaker oral presentation at the 61st Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston, MA., USA.

The results showed that in the four TMC435 treatment groups between 79 and 86 percent of patients were able to stop all therapy at Week-24, according to the response criteria defined in the study protocol. There were no relevant differences for adverse events between TMC435 treatment groups and placebo. TMC435, a hepatitis C protease inhibitor, dosed once daily (q.d.) is being developed jointly by Tibotec Pharmaceuticals and Medivir.

The PILLAR study [**P**rotease **I**nhibitor TMC435 trial assessing the optima**L** dose and duration as once dai**L**y **A**nti-viral **R**egimen] (TMC435-C205; NCT00882908) is an ongoing, five-arm, global phase 2b randomized, double-blind, placebo controlled study in 386 treatment-naive patients. TMC435 was administered in doses of 75mg or 150mg q.d. for either 12 weeks or 24 weeks in combination with 24 weeks of peg-interferon and ribavirin (PR). Patients in the placebo arm receive 24 weeks of placebo plus peg-interferon and ribavirin followed by 24 additional weeks of peg-interferon and ribavirin treatment. The primary endpoint of the study is sustained virologic response at Week-72 (SVR24). The PILLAR study is being conducted in 13 countries in Europe, North America, and Australasia.

Patients receiving TMC435 were allowed to stop all treatment at week 24 when a) HCV RNA levels < 25 IU/mL at week 4 and b) HCV RNA < 25 IU/mL levels at weeks 12, 16 and 20. Patients who did not meet the above response-guided criteria continued with peg-interferon and ribavirin until Week-48. TMC435 demonstrated potent antiviral activity, at week 4 (rapid virologic response (RVR)) and at week 12 (complete early virologic response (cEVR)) HCV RNA was undetectable (<25IU/ml) for the majority of patients. The viral breakthrough rate was 4.9 percent in the TMC435 treatment groups.

"Chronic infection with HCV is a leading cause of cirrhosis, liver cancer, and liver transplantation worldwide" said Dr Michael W. Fried M.D., lead clinical investigator and Professor of Medicine, Director of Hepatology, University of North Carolina at Chapel Hill. "We are extremely encouraged by these data for TMC435."

The goal of HCV treatment is to achieve SVR24, which means the virus remains undetectable in patients' blood six months after they have finished treatment. Patients who achieve SVR are considered cured. The current standard of care for HCV, pegylated interferon combined with ribavirin, may cause debilitating side effects[1] and cures only about half of patients starting therapy for the first time.[1]

The most common adverse events were headache and fatigue, 46 percent and 42 percent in the TMC435 groups and 51 percent and 47 percent in the placebo group respectively. There were no clinically significant differences in frequency of rash, anemia or gastrointestinal events between the TMC435 groups and placebo. Most AEs were mild to moderate in severity. AEs leading to treatment discontinuation were reported in 7.1 percent of patients in TMC435 arms and 7.8 percent in placebo arm.

In laboratory parameters, significant decreases in transaminases (ALT and AST) were observed in all treatment groups. Small and transient bilirubin elevations (direct and indirect) were seen in the TMC435 150mg dose groups.

"With a strong heritage in virology, Tibotec is committed to improving the lives of those impacted by HCV through the development of innovative new treatment regimens," said Greg Fanning PhD, head of hepatitis C research and development at Tibotec. "TMC435 is an important component of our growing HCV pipeline and we are encouraged by the results of the interim analysis presented at the AASLD meeting."

TMC435 is also being studied in HCV genotype-1 treatment-experienced patients who have failed treatment with peg-interferon and ribavirin. The ASPIRE study (Antiviral STAT-C Protease Inhibitor Regimen in Experienced patients; TMC435-C206; NCT00980330) is an ongoing global phase 2b randomized, double-blind, placebo controlled study in 463 patients.

In addition to the late-breaker oral presentation described above, data on TMC435 has been presented in 4 posters at AASLD:

278. "In vitro studies investigating the mechanism of interaction between TMC435 and hepatic transporters." M.T. Huisman
812. "Virologic analysis of genotype-1-infected patients treated with once-daily TMC435 during the Optimal Protease inhibitor Enhancement of Response to Therapy (OPERA)-1 study." O. Lenz
895. "A Phase IIa, open-label study to assess the antiviral activity of TMC435 monotherapy in patients infected with HCV genotypes 2-6." C. Moreno
1873. "Pharmacokinetic-pharmacodynamic analyses of TMC435 in patients infected with Hepatitis C Virus (HCV) genotypes 2 to 6." V. Sekar

About HCV

HCV is a blood-borne infectious disease that affects the liver.[1] With an estimated 170 million people infected worldwide1 and three to four million people newly infected each year[2], HCV puts a significant burden on patients and society. Chronic infection with HCV can lead to liver cancer and other serious and fatal liver diseases, and is the most common cause of liver transplant worldwide[3]. Discovering and developing new treatments is very important to improving the standard of care for the millions of people living with this disease.

About Tibotec Pharmaceuticals

Tibotec Pharmaceuticals is a global pharmaceutical and research development company. The Company's main research and development facilities are in Beerse, Belgium with offices in Titusville, NJ and Cork, Ireland. Tibotec is dedicated to the discovery and development of innovative HIV/AIDS and hepatitis C drugs, and anti-infectives for diseases of high unmet medical need. Tibotec Pharmaceuticals is a subsidiary of Johnson & Johnson.

---

[1] World Health Organization (2002). Hepatitis C. Retrieved October 26, 2010 from http://www.who.int/csr/disease/hepatitis/Hepc.pdf

[2] Hepatitis C: Global Prevalence. Weekly Epidemiological Record. 1997;72 : 341-8. Retrieved October 26, 2010 from http://www.who.int/docstore/wer/pdf/1997/wer7246.pdf.

[3] Roche B, Samuel D., Villejuif, France. Risk factors for hepatitis C recurrence after liver transplantation. J Viral Hepat. 2007 Nov;14. Suppl 1:89-96.