Tibotec Presents Interim Findings for TMC435, an Investigational Genotype 1 Hepatitis C Treatment, at the AASLD Liver Meeting 2008

Nearly 90 percent of patients achieve undetectable viral load in Phase IIa trial within 28 days of combined treatment with standard of care

San Francisco, CA (November 1, 2008) - New clinical data show antiviral activity of TMC435, an investigational protease inhibitor (PI) being developed by Tibotec BVBA for the treatment of chronic hepatitis C virus (HCV) infection. Tibotec will present findings from three TMC435 studies, including a late-breaker poster on the proof-of-principle phase IIa trial, OPERA-1 (TMC435-C201), at the American Association for the Study of Liver Disease's (AASLD) Liver Meeting 2008 in San Francisco.

The current standard of care treatment for HCV infection, pegylated interferon (Peg-IFN) combined with ribavirin (RBV), is effective in 30 to 50 percent of patients infected with chronic genotype 1 HCV infection, the most common type in the United States.[1] The development of new therapies and strategies for treating HCV, particularly the introduction of direct antivirals, may offer patients a new option with shorter treatment duration.[2,3]

TMC435 Phase IIa Study Results
In interim findings from the first 28 days of treatment for the first cohort of fifty (50) treatment naive HCV+, genotype 1, patients (once daily dose of 25 mg or 75 mg TMC435 versus placebo), both doses showed dose-dependent antiviral activity. TMC435 was administered in combination with PegIFNalpha-2a/RBV (triple therapy) for 28 days or as monotherapy for seven days and, thereafter, in combination with PegIFNalpha-2a/RBV (triple therapy) for three weeks. There were neither serious adverse events, nor grade 3 or 4 adverse events, related to TMC435 or any safety-related treatment discontinuations during this 28 day treatment period.

The most common adverse events associated with TMC435 were nausea, diarrhea, and headache. There were no clinically relevant changes in laboratory parameters, ECGs, or vital signs. Steady-state plasma trough levels of TMC435 25 mg and 75 mg represented ~10 and >30-fold excess above the HCV replicon EC50 value, respectively.

Mean reductions of HCV RNA from baseline to day seven with TMC435 alone and in triple therapy were 2.63 and 3.47 log10 IU/mL, respectively, in the 25 mg arm, and 3.43 and 4.55 log10 IU/mL in the 75 mg arm. In the 75 mg four-week triple therapy arm, no viral breakthrough was observed; 9/9 patients achieved HCV RNA below lower limit of quantification (<25 IU/mL) and 8/9 patients achieved undetectable HCV RNA (<10 IU/mL) at day 28 (RVR=89 percent).

"These data provide important information about an emerging new approach to treating HCV," said Professor and Chairman Michael Manns, Hannover Medical School, Germany. "The discovery and development of new treatments is critical to improving the standard of care for the millions of people living with this disease."

As a global virology leader committed to patient care, Tibotec uses innovative science and expertise to research, develop, and manufacture, drugs for medical conditions with an unmet need. The company has successfully launched two antiviral medications for the treatment of HIV and is now building a portfolio of novel antiviral therapies for HCV with the goal of becoming a prominent leader in the treatment of this infectious disease.

TMC435 was discovered through a drug discovery collaboration between Medivir and Tibotec. Tibotec has the right to develop and commercialize the compound throughout the world, excluding the Nordic countries. In addition to TMC435, Tibotec has another PI in phase III development for the treatment of chronic HCV infection.

"Tibotec is committed to evaluating the safety and efficacy of TMC435 in clinical studies to determine its potential use in people with HCV," said Roger Pomerantz, M.D., president of Tibotec Research and Development. "This is an important step in our mission of addressing treatment challenges of infectious diseases, including HCV, HIV and tuberculosis."

About the Phase IIa Study
Investigators in five European countries assessed the antiviral activity, safety, and pharmacokinetics of two once-daily regimens of TMC435 (25 mg or 75 mg TMC435 versus placebo) in fifty HCV genotype 1 treatment-naive patients in an ongoing double-blind, placebo-controlled phase IIa trial. Patients were randomized to receive either seven days of monotherapy with TMC435 or placebo followed by 21 days of triple therapy with TMC435 or placebo, plus PegIFNalpha-2a (180 mcg once weekly) and RBV (1000-1200 mg daily); or, 28 days of triple therapy with TMC435 or placebo, plus PegIFNalpha-2a and RBV. After day 28, patients continue on PegIFNalpha-2a/RBV alone for a total of 24 or 48 weeks at the discretion of the investigator.

TMC435 data from other studies will also be presented at the AASLD Liver Meeting.

About HCV
According to the Centers for Disease Control and Prevention (CDC), about 3.2 million people in the United States are infected with chronic HCV and 19,000 people are newly infected each year. [4] Chronic infection with HCV can lead to cirrhosis and liver cancer, and is the most common cause of liver transplant in the United States. [4,5]

About Tibotec BVBA
Tibotec BVBA is a global pharmaceutical and research development company. The company's main research and development facilities are in Mechelen, Belgium with offices in Yardley, Pa. 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.

Forward Looking Statement
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Tibotec BVBA's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2006. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Tibotec BVBA or Johnson & Johnson. Tibotec BVBA does not undertake to update any forward-looking statements as a result of new information or future events or developments.

Tibotec is a member of the Johnson & Johnson family of companies.

[1] Centers for Disease Control and Prevention (CDC). Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. 1998. http://www.cdc.gov/mmwr/preview/mmwrhtml/00055154.htm.

[2] Relapse to prior therapy is the most important factor for the retreatment response in patients with chronic hepatitis C virus infection. Liver Int. 2007 Sep;27(7):954-9. Sagir A, Heintges T, Akyazi Z, Oette M, Erhardt A, Haussinger D. Klinik fur Gastroenterologie, Hepatologie und Infektiologie, Universitatsklinik Dusseldorf, Dusseldorf, Germany. sagir@med.uni-duesseldorf.de

[3] Antiviral Research. Volume 71, Issues 2-3, September 2006, Pages 363-371. Special Issue To Honour Professor Erik De Clercq

[4] Centers for Disease Control and Prevention (CDC). FAQs for Health Professionals. Revised July 2008. http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section1.

[5] Risk factors for hepatitis C recurrence after liver transplantation. J Viral Hepat. 2007 Nov;14 Suppl 1:89-96. Roche B, Samuel D. Assistance Publique-Hopitaux de Paris, Hopital Paul Brousse, Centre Hepato-Biliaire; and INSERM, Unite 785; and Universite Paris-Sud, UMR-S 785, Villejuif, France.