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Vertex Pharmaceuticals and Mitsubishi Tanabe Pharma Corporation Amend Agreement to Develop and Commercialize Telaprevir in Asia

-- Vertex to receive $105 million from Mitsubishi following signing, plus the potential for additional milestones upon commercialization ---- Phase 3 registration program for telaprevir in Japan expected to complete enrollment in the third quarter of 2009 --

CAMBRIDGE, Mass., Jul 30, 2009 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) and Mitsubishi Tanabe Pharma Corporation today amended their agreement for the development and commercialization of telaprevir for the treatment of hepatitis C virus (HCV) infection in Japan and other countries in the Far East. Telaprevir is an HCV protease inhibitor currently in Phase 3 clinical trials in Japan, as well as in the United States and in Europe. Under the terms of the amended agreement, Vertex will receive $105 million following signing, and will be eligible to receive further milestones upon approval and commercialization in Japan.

The previous agreement signed in 2004 between Vertex and Mitsubishi Tanabe provided certain development and commercial rights to telaprevir as a potential monotherapy for the treatment of Hepatitis C. The amended agreement announced today provides a fully-paid license to commercialize telaprevir as part of a combination regimen with interferon and ribavirin to treat hepatitis C in Japan and the Far East. Vertex retains exclusive development and commercial rights to telaprevir in North America. Janssen Pharmaceutica, an affiliate of Johnson & Johnson, holds development and commercial rights to telaprevir in Europe, South America, Australia, and the Middle East.

"This amendment recognizes the value of telaprevir-based combination therapy as a potential major advance in the treatment of hepatitis C in Japan and Asian countries, aligning the telaprevir development program on a global basis," said Kurt Graves, Vertex Executive Vice President, Chief Commercial Officer and Head of Corporate Development. "Moreover, following this amendment, the cash received strengthens our corporate financial position during an important period of investment and growth as we advance two Phase 3 programs in hepatitis C and cystic fibrosis."

Terms of the Agreement

Under the amended development and commercialization agreement, Mitsubishi Tanabe will receive a license in its territory for telaprevir-based combination therapy with interferon and ribavirin, as well as rights to manufacture telaprevir for sale in its territory. Mitsubishi Tanabe will pay Vertex $105 million upon signing. In addition, the parties have reached other commercial agreements in the amendment, including potential bonus milestone payments in lieu of royalties, that if realized would range between $15 million and $65 million.

Status of Telaprevir Phase 3 Registration Program in Japan

Mitsubishi Tanabe is conducting Phase 3 registration studies with telaprevir in combination with pegylated interferon and ribavirin in Japan in approximately 300 treatment-naïve and treatment-failure genotype 1 hepatitis C patients. The registration program is expected to be fully enrolled sometime in the third quarter of 2009, and sustained viral response (SVR) data from these studies is expected to be available in 2010. SVR is the goal of hepatitis C therapy, and is defined as the absence of detectable virus in the blood 24 weeks after the completion of treatment.

About Telaprevir and Vertex's HCV Development Portfolio

Telaprevir (VX-950) is an investigational oral inhibitor of HCV protease, an enzyme essential for viral replication, and is one of the most advanced investigational antiviral agents in development that specifically targets HCV. Telaprevir is being evaluated as part of a global Phase 3 registration program in more than 2,200 treatment-naïve and treatment-failure patients.

Vertex retains commercial rights to telaprevir in North America. Vertex and Tibotec are collaborating to develop and commercialize telaprevir in Europe, South America, Australia, the Middle East and other countries. Vertex is collaborating with Mitsubishi Tanabe Pharma to develop and commercialize telaprevir in Japan and the Far East.

Vertex is also developing VX-222 (formerly VCH-222), an oral inhibitor of the HCV NS5B polymerase. HCV polymerase

inhibitors represent an additional class of drug candidates that are aimed at inhibiting viral replication.

About Hepatitis C

Hepatitis C is an infectious disease caused by the hepatitis C virus. There are an estimated 170 million people chronically infected with HCV globally, and 3 to 4 million new infections occur each year. The United States Centers for Disease Control (CDC) estimate that approximately 4.1 million people in the U.S. have been infected with HCV, and 3.2 million of these people have chronic infection, making it the most common chronic blood-borne infection in the country. Approximately 50 percent - or 2 million people - in the US living with HCV remain undiagnosed and untreated.

The burden of liver disease associated with HCV infection is increasing, and current therapies typically provide sustained benefit in less than half of patients with genotype 1 HCV, the most common strain of the virus. As many as 250,000 patients in the United States have received at least one course of treatment with peg-interferon and ribavirin but have not achieved an SVR. Patients who have failed interferon-based treatment typically have few or no available treatment options, and are at risk for progressive liver disease. In a recent study, the risk of liver failure, cancer or death following unsuccessful HCV treatment was 23% after 4 years, and 43% after 8 years. (1).

(1) Veldt et al, "Sustained virologic response and clinical outcomes in patients with chronic hepatitis C and advanced fibrosis," Annals of Internal Medicine, 20 November 2007; 147: 677-684.

About Vertex

Vertex Pharmaceuticals Incorporated is a global biotechnology company committed to the discovery and development of breakthrough small molecule drugs for serious diseases. The Company's strategy is to commercialize its products both independently and in collaboration with major pharmaceutical companies. Vertex's product pipeline is focused on viral diseases, cystic fibrosis, inflammation, autoimmune diseases, cancer and pain. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

Lexivais a registered trademark of the GlaxoSmithKline group of companies.

Special Note Regarding Forward-looking Statements

This press release contains forward-looking statements, including statements that (i) the parties have reached other commercial agreements in the amendment, including potential bonus milestone payments in lieu of royalties, that if realized would range between $15 million and $65 million and (ii) Mitsubishi Tanabe expects that patient enrollment in its studies will be complete sometime in the third quarter of 2009, with SVR data available in 2010. While the Company believes the forward-looking statements contained in this press release are accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. Those risks and uncertainties include, among other things, that the outcomes for Mitsubishi Tanabe's planned clinical trials of telaprevir may not be favorable, that regulatory authorities may require supplemental clinical trials in order to support marketing approval of telaprevir in Japan, that clinical trial enrollment may be more difficult or slower than currently anticipated, that the conditions required for Vertex to realize the additional milestone payments may not be realized, and other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through the Company's website at www.vrtx.com. We disclaim any obligation to update the information contained in this press release as new information becomes available.

Vertex's press releases are available at www.vrtx.com.

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