

Roche to Submit Additional Data on Tamiflu for the Treatment of Influenza to the European Regulatory Authorities

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Roche and Gilead Sciences, Inc. (Nasdaq: GILD) announced today that Roche has decided to withdraw the European application for the antiviral Tamiflu (oseltamivir) for the treatment of influenza in order to have more time to submit further data. Some members of the Committee for Proprietary Medicinal Products (CPMP) raised questions, for which additional data will be available in the near future. Withdrawal of the application allows Roche the opportunity to provide this information to European regulatory authorities. The application will be resubmitted as soon as possible.

Roche is continuing to pursue regulatory approvals around the world. The first submission for the prophylaxis of influenza was recently submitted to the Food and Drug Administration (FDA) in the United States.

Tamiflu is already available for the treatment of influenza in nine countries worldwide including the United States, Canada, Switzerland and many Latin American countries based upon its demonstrated safety, efficacy and tolerability. Hundreds of thousands of sufferers were treated with Tamiflu during the last influenza season. Roche believes that Tamiflu will play an important role both in the prevention and the treatment of influenza, a disease affecting 100 million people worldwide annually, which is still not treated effectively. Treatment studies involving more than 7,000 patients with oral Tamiflu have shown a significant reduction in both duration and severity of symptoms, including fever and cough.

Tamiflu, co-developed with Gilead Sciences, USA, is a systemic treatment for influenza, designed to reach all key sites of infection in the body including the upper and lower respiratory tracts. The medication targets one of two major surface structures on the influenza virus, the neuraminidase protein. The neuraminidase is virtually the same in all common strains of influenza. If neuraminidase is inhibited, the virus is not able to infect new cells.

Gilead Sciences, Inc., headquartered in Foster City, CA is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. Gilead discovers, develops, manufactures and commercializes proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead maintains research, development or manufacturing facilities in Foster City, CA; Boulder, CO; San Dimas, CA; Cambridge, UK and Dublin, Ireland and sales and marketing organizations in United States, Europe and Australia.

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address prevention, diagnosis and treatment of diseases, thus enhancing people's well-being and quality of life.

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