

## **Roche Submits Tamiflu for Regulatory Approval in Japan; First Oral Neuraminidase Inhibitor for the Treatment and Prevention of Influenza**

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Roche and Gilead Sciences, Inc. (Nasdaq: GILD) announced today that Roche has submitted Tamiflu (oseltamivir phosphate) to the Japanese Ministry for Health and Welfare (MHW) for regulatory approval for A and B influenza virus infection in adults; this includes both treatment and prophylaxis. Japan provides a significant marketing opportunity for Tamiflu. Roche anticipates that Tamiflu will play an important role in the management of influenza in Japan.

The application in Japan is supported by clinical trial data demonstrating that Tamiflu is effective in the treatment and prevention of influenza infection. Treatment studies with oral Tamiflu have shown a significant reduction in both the duration and severity of symptoms, including fever and cough, allowing people to return to their normal lives more quickly. Prevention studies have shown that Tamiflu significantly reduces the incidence of influenza during a community outbreak.

In Japan, influenza can affect between 5 to 10 percent of the population in a normal year, and this number can increase significantly during severe epidemics. Over a three-month period in 1999, more than 1,200 people died in Japan as a result of influenza and its complications. Sufferers are predominantly prescribed a combination of antibiotics, cough and cold preparations and anti-pyretics in an effort to fight the disease.

Tamiflu is already available for the treatment of influenza in a number of countries worldwide including the United States, Canada, Switzerland and many Latin American countries. Hundreds of thousands of sufferers were treated with Tamiflu during the last influenza season. Applications for the prophylaxis indication have recently been filed in the United States, where it will receive expedited review, and Canada. In addition, an application for the use in children 1 year and older has been filed in the United States, where it will also receive expedited review.

Tamiflu, co-developed with Gilead Sciences, Inc., is a systemic treatment for all common strains of influenza (Types A and B). The medication targets one of two major surface structures on the influenza virus, the neuraminidase protein. The neuraminidase protein 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, USA, 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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