Roche Submits Oral Flu Drug Tamiflu for Regulatory Approval in Europe

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Roche and Gilead Sciences, Inc. announced today that Roche has submitted Tamiflu™ (oseltamivir phosphate), the first neuraminidase inhibitor in pill form, to the European authorities (CPMP) for regulatory approval for the treatment of influenza A and B in adults and children and the prevention of influenza A and B in adolescents and adults.

In Europe, influenza can affect around one in ten of the adult population in a normal year, and this number can increase significantly during severe epidemics. Influenza is a common respiratory infection in children with around one in three children affected each year. Influenza related secondary complications are associated with excess use of antibiotics, hospitalisations and out-patient visits. In the UK last year around 20,000 people died as a result of influenza and its complications.

Tamiflu, co-developed with Gilead Sciences, Inc. (Nasdaq: GILD), is a systemic treatment for the most common strains of influenza (types A & B). The medication targets one of the two major surface structures of the influenza virus, the neuraminidase protein. The neuraminidase site is virtually the same in all common strains of influenza. Tamiflu attacks the influenza virus and stops it from spreading inside the body. Tamiflu treats the flu at its source, by attacking the virus that causes the flu, rather than simply masking the symptoms.

In its first season of availability in the United States for treatment, Tamiflu amassed more than 58 percent of the market share within the new class of antivirals called neuraminidase inhibitors, and garnered more than 30 percent of the overall influenza antiviral market.

Each year, up to 40 million Americans develop the flu, an average of about 300,000 are hospitalized, and 20,000 to 40,000 people die from influenza and its complications. The influenza virus is highly contagious and is transmitted when droplets are shed by an infected person during sneezing or coughing. A person becomes infected by breathing in these droplets. The virus then settles into the entire respiratory system, and begins replicating 24 hours before symptoms are discovered. An infected person can pass on the disease for four to five days and influenza may remain in a local area for up to six weeks.

Tamiflu is generally well tolerated. The most frequently reported adverse side effects were mild to moderate, transient nausea or vomiting. Other events reported more frequently than with placebo were bronchitis, insomnia and vertigo. Less than 1 percent of patients discontinued Tamiflu prematurely in clinical trials due to nausea or vomiting. Tamiflu is not a substitute for vaccines, which are the primary method of preventing influenza.

Serious bacterial infections may begin with influenza-like symptoms or may co-exist with or occur as complications during the course of influenza. Tamiflu has not been shown to prevent such complications.

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 commercialises 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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