Roche's Oral Flu Drug Tamiflu™ Gets Approval in Japan

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Roche and Gilead Sciences, Inc. (Nasdaq: GILD) announced today that Roche has received regulatory approval for Tamiflu™ (oseltamivir phosphate), the first neuraminidase inhibitor available in pill form, from the Japanese Ministry for Health and Welfare (MHW), for the treatment of influenza A and B virus infection in adults.

In Japan, influenza can affect between 5 to 10 percent of its 125 million inhabitants 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. With Tamiflu, influenza sufferers in Japan will now have an effective oral drug to help them fight all common strains of influenza (types A & B).

The application in Japan, which received priority review, was supported by clinical trial data demonstrating that Tamiflu is effective in the treatment of influenza infection. Tamiflu is indicated for the treatment of uncomplicated acute illness due to influenza infection in adults who have been symptomatic for no more than two days. The recommended oral dose of Tamiflu is 75 mg twice daily for five days.

Tamiflu, in convenient pill form, was approved by the U.S. Food and Drug Administration (FDA) in October 1999 for the treatment of uncomplicated influenza in adults. In its first season of availability in the U.S., Tamiflu, the number one prescribed antiviral treatment for influenza, has 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.

Two Phase III double-blinded, placebo-controlled clinical trials of Tamiflu were conducted; one in the U.S. and the other in international sites. The two studies enrolled a total of 849 influenza-infected patients, 18-65 years of age. In both statistically significant studies at the recommended dose, there was a 1.3 day (30%) reduction in the median time to improvement in patients receiving Tamiflu compared to patients receiving placebo.

Tamiflu is generally well tolerated. The most frequently reported adverse events were mild to moderate, transient nausea or vomiting. Other events reported more frequently than with placebo were bronchitis, insomnia and vertigo. Less than 1% 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.

About Tamiflu
Tamiflu is already marketed for the treatment of influenza in 30 countries world-wide including the United States, Canada, Switzerland and many Latin American countries. Tamiflu was approved in the U.S. on November 17, 2000 for a prophylaxis indication in adolescents and adults, making it the first influenza antiviral approved for both the treatment and prevention of all common strains of influenza (types A & B) in the U.S.

Tamiflu co-developed with Gilead Sciences of Foster City, California, is a systemic treatment for all common strains of influenza (types A & B) and is available in a convenient pill form.

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. If neuraminidase is inhibited, the virus is not able to infect new cells.

About Hoffmann-La Roche and Gilead Sciences
Hoffmann-La Roche Inc. (Roche), based in Nutley, N.J., is the U.S. prescription drug unit of the Roche Group, a leading research-based health care enterprise that ranks among the world’s leaders in pharmaceuticals, diagnostics and vitamins. Roche

discovers, develops, manufactures and markets numerous important prescription drugs that enhance people's health, well-being and quality of life. Among the company's areas of therapeutic interest are: virology, including HIV/AIDS and hepatitis C; infectious diseases, including influenza; cardiology; neurology; oncology; transplantation; dermatology; and metabolic diseases, including obesity and diabetes.

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 the United States, Europe and Australia.

For more information on the Roche pharmaceuticals business in the United States, visit the company's web site at: http://www.rocheusa.com. To learn about influenza surveillance and to find out if flu is in your area, log onto http://www.flustar.com.

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