Roche Receives FDA Approval Of TAMIFLU™, First Pill To Treat The Most Common Strains Of Influenza (A&B)

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TAMIFLU™ (oseltamivir phosphate) Decreases Duration of Flu Symptoms

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Hoffmann-La Roche Inc. and Gilead Sciences, Inc. (NASDAQ:GILD), announced today that Roche's TAMIFLU™ (oseltamivir phosphate) has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of influenza A&B, which includes all common strains of influenza. TAMIFLU, the first neuraminidase inhibitor in pill form, will be available nationwide in time for the arrival of this year's flu season.

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.

Unlike over-the-counter medications that only mask the symptoms of influenza, TAMIFLU is an antiviral agent that, based on in vitro data, targets the actual influenza virus and stops it from replicating from cell to cell.

About TAMIFLU

Co-developed with Gilead Sciences, TAMIFLU is a systemic treatment for influenza. The medication, part of a new class of drugs called neuraminidase inhibitors, 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 effectively replicate and spread to other cells.

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. Patients participating in the trials were required to self-assess the influenza-associated symptoms as 'none', 'mild', 'moderate' or 'severe'. Time to improvement was calculated from the time of treatment initiation to the time when all symptoms (fever, nasal congestion, sore throat, cough, aches, fatigue, headaches, chills, and sweats) were assessed as 'none' or 'mild'.

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. The most frequently reported adverse events in these studies in patients taking TAMIFLU were nausea and vomiting and, to a lesser extent, bronchitis, insomnia, and vertigo. These events were generally mild to moderate and transient. Less than 1% of patients discontinued prematurely from clinical trials due to nausea and vomiting. TAMIFLU may be taken with or without food. However, when taken with food, tolerability may be enhanced in some patients.

Elderly Patients

In an ongoing study of otherwise healthy elderly patients, 65 years of age and older, given the recommended dose of TAMIFLU, there was a reduction in the duration of flu in patients receiving TAMIFLU similar to that seen in younger adults. Also, no overall difference in safety was observed in clinical trials between the elderly patients and younger adults, and no dose adjustments are required when treating these populations.

"The timing of the FDA's approval for TAMIFLU is ideal," said Dr. Dominick Iacuzio, Medical Director, Hoffmann–La Roche. "The early arrival of the 1999-2000 flu season means many Americans may be caught short in taking preventive measures, such as receiving their flu vaccination. This early outbreak, coupled with predictions of a severe flu season, makes TAMIFLU a welcome treatment alternative to managing the misery of the flu."

In clinical studies, TAMIFLU showed no interference with the antibody response to the influenza infection. Use of TAMIFLU should not effect the evaluation of patients for annual influenza vaccination, in accordance with the Centers for Disease Control (CDC) guidelines.

“One of the advantages of TAMIFLU is that it is administered orally, which makes it not only convenient, but allows the drug to be distributed throughout the body, reaching all key sites of infection, including the upper and lower respiratory tracts,” said Dr. Frederick Hayden, a lead investigator in the TAMIFLU studies and the Stuart S. Richardson Professor of Clinical Virology in Internal Medicine and Professor of Internal Medicine and Pathology at the University of Virginia School of Medicine.

Influenza’s Impact

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 risks for hospitalization and death from influenza are higher among persons aged 65 or older, and persons at any age with underlying high risk medical conditions. The economic impact is high as well, costing the United States an annual $14.6 billion in physician visits, lost productivity, and lost wages.

About Hoffmann-La Roche and Gilead Sciences

Hoffmann-La Roche Inc. is a leading research-intensive pharmaceutical company that discovers, develops, manufactures and markets numerous important prescription drugs that improve, prolong and save the lives of patients with serious illnesses. 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.

The Company provides a wide range of medications in the United States through its marketing and sales subsidiary, Roche Laboratories Inc. Headquartered in Nutley, N.J., both companies are members of the Basel, Switzerland-based Roche Group, a global leader in health care with principal businesses in pharmaceuticals, diagnostics, vitamins, and fragrances and flavors. For more information on Roche Pharmaceuticals in the United States, visit the company’s web site at: http://www.rocheusa.com

Gilead Sciences, headquartered in Foster City, CA, is an independent biopharmaceutical company that seeks to provide accelerated treatment solutions for patients and the people who care for them. The Company 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, and Cambridge, UK, and sales and marketing organizations in the United States, Europe and Australia. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.

EDITOR’S NOTE: FOR MORE INFORMATION ON INFLUENZA AND TAMIFLU, CONSUMERS CAN LOG ONTO WWW.TAMIFLU.COM.