

First Approval of Roche's Tamiflu™, a New Flu Treatment

September 24, 1999 6:24 PM ET

Nutley, NJ -- September 24, 1999

Hoffmann-La Roche Inc. and Gilead Sciences, Inc. (NASDAQ: GILD), announced today that Roche's Tamiflu™ (oseltamivir phosphate) was approved by the Swiss Regulatory Authority (Interkantonale Kontrollstelle für Heilmittel) for the treatment of influenza. Tamiflu, the first neuraminidase inhibitor in a convenient pill form, is designed to treat all common strains of influenza and to reduce both the duration of illness and the severity of symptoms. Tamiflu will be available by prescription beginning October 1st in Switzerland. U.S. and Canadian regulatory authorities have granted Tamiflu priority review status, and a decision is expected in the United States in time for this year's flu season. Other regulatory approvals for Tamiflu are pending worldwide.

During influenza infection, millions of uncontrolled replicating flu viruses infect the ear, nose, throat and the chest, creating discomfort for the infected individual. Tamiflu is an innovative flu treatment that is designed to stop the virus from multiplying and spreading throughout the body. Tamiflu, when taken at the onset of flu symptoms (fever, cough, headache, sore throat, nasal congestion, fatigue and muscle aches), twice daily for five days, has been shown to stop the replication and spread of the influenza virus. Tamiflu reaches all key sites of infection within the body, inhibiting further spread of the virus.

Tamiflu, co-developed with Gilead Sciences, has been studied in more than 7,000 patients worldwide. Data involving 1,348 patients from trials conducted in the United States, Europe, Canada and China were presented to regulatory authorities for the treatment of influenza. In a U.S. clinical trial, Tamiflu reduced the duration of illness by 30 percent and severity of symptoms by 40 percent, including fever, cough, aches and pains. In addition, Tamiflu alleviated secondary flu complications treated with antibiotics, such as bronchitis and sinusitis, by approximately 50 percent in previously healthy adults. During five days of treatment for acute influenza, Tamiflu was well tolerated, with only some patients reporting transient, mostly mild nausea or vomiting.

"Availability of Tamiflu for the 1999/2000 flu season will help reduce patient misery and suffering from influenza, a potentially life threatening infection," said Franz B. Humer, Chief Executive Officer and Head of Roche's Pharmaceutical Division. "Tamiflu is a major advance in the treatment of influenza. Tamiflu, an oral flu treatment, will help with patient compliance and ease of use, especially when patients feel miserable." Humer continued: "The launch of this innovative compound further signifies Roche's commitment in reducing human suffering caused by viral diseases."

Influenza – The Disease

Influenza is a contagious viral illness that affects the whole body and is considerably more serious than the common cold. It occurs during the winter months in regional outbreaks, usually lasting 6-8 weeks. The illness, which comes on suddenly with symptoms, such as fever, muscle aches and generalized weakness, headache, sore throat, and dry cough, can progress to complications in the upper and lower respiratory tracts causing secondary complications such as sinusitis, bronchitis, pneumonia and otitis media.

In the United States, Europe and Japan, more than 100 million people are infected with the flu each year. In the United States, influenza affects as many as 40 million Americans, killing 20,000 to 40,000 of them each year and causing 300,000 hospitalizations. Influenza costs the United States an average 14.6 billion USD in direct and indirect costs each year.

Roche, dedicated to improving influenza management, will present additional Tamiflu clinical trial data at the 39th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in San Francisco, on September 27.

Roche and Gilead

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, NJ, 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 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.