

## **Roche Announces New Data on Recently Approved Tamiflu™, First Pill to Treat the Most Common Strains of Influenza (A & B)**

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*1998-1999 Flu Season Data Supports Benefits of Tamiflu™ (oseltamivir phosphate) for the Treatment and Prevention of Influenza*

**Nutley, N.J. -- November 8, 1999**

Hoffmann-La Roche Inc. and Gilead Sciences, Inc. (NASDAQ:GILD), announced today results of 1998-1999 flu season clinical trial data on Roche's Tamiflu™ (oseltamivir phosphate), the first oral neuraminidase inhibitor in pill form. Tamiflu was approved by the U.S. Food and Drug Administration (FDA) on October 27, 1999 for the treatment of influenza A & B, which includes the most common strains of influenza. These results, presented at a gathering of clinical trial investigators, focus on a recently concluded treatment study involving pediatric patients. In addition, preliminary data from an ongoing Tamiflu treatment study involving elderly patients were announced, as well as results from two prophylaxis studies, in an elderly and family setting.

The FDA approved Tamiflu 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.

"The 1998-1999 flu season data reinforces the benefits that we have seen in previous clinical trials of Tamiflu," said Dr. Dominick Iacuzio, Medical Director, Hoffmann-La Roche. "The exciting findings of these studies show promise for future additional uses of the medication."

### **1998-1999 Flu Season**

#### **Treatment Studies**

A treatment study (n=695) in pediatrics, 1-12 years of age, showed the drug met the primary clinical endpoints of the study and results indicated statistically significant differences between active and placebo arms. The primary clinical endpoints included duration of influenza illness and time to return to normal health and activity. Tamiflu, administered in an oral suspension formulation, showed a 37% reduction in the duration of influenza and allowed patients to return to normal health and activity 40% faster than patients taking placebo. An additional finding was that the incidence of acute otitis media was significantly reduced, by 43%, in patients treated with Tamiflu. Tamiflu, which is not indicated for the treatment of influenza in children, was well tolerated in this study. Mild vomiting ( 14.3% vs. 8.5% in the placebo group) and diarrhea (8.8% vs. 10.5% in the placebo group) were the most common adverse events.

A preliminary analysis of safety data from ongoing treatment studies involving elderly patients (65 years of age or older) was also announced. Results indicated no overall difference in safety and tolerability in clinical trials between the elderly patients and younger adults, and no dose adjustments are required when treating these patients.

A preliminary analysis of data from ongoing treatment studies in high-risk patients also showed similar safety results. The most frequently reported adverse events in both these studies were nausea and vomiting and, to a lesser extent, bronchitis, insomnia, and vertigo. These studies are ongoing and efficacy data will be analyzed upon completion of the trials.

#### **Prophylaxis Studies**

Two prophylaxis studies, one with a long-term dosing regimen and the other with a short-term dosing regimen, show that Tamiflu was statistically significant in preventing influenza illness. In a prevention study (n=548) investigating the use of once daily Tamiflu for six weeks, the medication was shown to provide a 92% protection rate among a frail, elderly population in a residential home care setting. A six-week course of Tamiflu was well tolerated among this population, where the mean age was 81 years old. The incidence of reported adverse events was similar in both study groups, with upper gastrointestinal events reported by 15 subjects on placebo (5.5%) and 17 subjects on Tamiflu (6.1%).

The other study, a post-exposure prophylaxis trial investigating the use of Tamiflu once daily for seven days, enrolled 377

households affected by at least one index case with respiratory illness. Post-exposure prophylaxis, 75 mg once daily for seven days, protected close contacts of influenza-infected patients against influenza by 92%, and interrupted influenza transmission within households by 89%. Tamiflu was well tolerated with transient nausea being the most commonly reported event, with low incidence in both groups (Tamiflu 5.5% vs placebo 2.6%).

Use of Tamiflu should not affect the evaluation of patients for annual influenza vaccination, in accordance with the Centers for Disease Control (CDC) guidelines.

### **About Tamiflu**

Tamiflu is a systemic treatment for the most common strains of influenza (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. If neuraminidase is inhibited, the virus is not able to infect new cells. Tamiflu will be available throughout the U.S. in time for the arrival of this year's flu season.

### **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 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. For more information about Gilead, visit the company's Web site at [www.gilead.com](http://www.gilead.com).

**EDITOR'S NOTE: FOR MORE INFORMATION ON INFLUENZA AND TAMIFLU, CONSUMERS CAN LOG ONTO [WWW.TAMIFLU.COM](http://WWW.TAMIFLU.COM).**