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October 19, 2004 -- Nutley N.J.

## HHS CITES TAMIFLU® IN NEW ANTIVIRAL GUIDELINES FOR PREVENTING, TREATING INFLUENZA

*-- Antivirals to Play Greater Role with Vaccine Shortage --*

The U.S. Department of Health and Human Services (HHS) today announced new guidelines to address the use of antivirals, such as Tamiflu® (oseltamivir phosphate), in the prevention and treatment of influenza. Tamiflu, developed by Roche, is the only prescription antiviral medication that can treat both the A and B influenza flu strains in patients one year and older who have been symptomatic for no more than two days and prevent influenza in patients 13 years and older. Roche has approximately four million treatment courses of Tamiflu available by prescription in the U.S. for 2004–2005 flu season -- three times the amount consumed during last year's season.

"It is clear that antivirals will play an even larger role in preventing and treating influenza this season, in light of the vaccine shortage this year," said George B. Abercrombie, president and CEO, Hoffmann-La Roche Inc. "Roche recently expanded its production capabilities of Tamiflu to ensure sufficient quantities for the upcoming flu season. We are working closely with the government to ensure adequate supply of Tamiflu and plan to bring manufacturing capabilities to the U.S. in preparation for next flu season."

Tamiflu also plays a critical role in pandemic planning. In the U.S. Department of Health and Human Services (HHS) draft "Pandemic Influenza Preparedness and Response Plan" issued in August, Tamiflu is highlighted as an antiviral drug being stockpiled by the U.S. government as part of its preparation for a potential influenza pandemic. Roche is continuing to work in cooperation with HHS agencies to address and prepare for a potential flu pandemic in the U.S.

Tamiflu is also an effective treatment and can reduce the duration and severity of the flu when taken within two days of symptom onset. Tamiflu is also approved for the prevention of influenza in adults and adolescents 13 years and older. Clinical trials have also shown Tamiflu to be up to 92 percent effective in preventing influenza illness when taken once daily for at least seven days.

Frequently reported adverse events include nausea and vomiting.

### **Children, Elderly at Greatest Risk**

A study published in the September 15, 2004 issue of the *Journal of the American Medical Association* found that more than 200,000 people are hospitalized each year because of flu-related illnesses, far more than the 114,000 annual hospitalizations previously estimated. Flu complications are more severe in people over 50 and the highest rates of hospitalizations are found in people over 85. The study also found that children under five are hospitalized at higher rates than those in the 50-64 age group. According to the CDC, an average of 36,000 people in the United States die from influenza each year.

### **Tracking the Spread of the Flu**

FluSTAR™ (System for Tracking and Reporting Flu) is a surveillance system that provides timely and reliable reporting of flu activity on a regional and nationwide basis. It enhances the ability of physicians to diagnose influenza illness, thus allowing appropriate and timely prescribing of antiviral therapy. The surveillance program was co-developed by Roche and Surveillance Data, Inc. (SDI) who operates the system. This flu season, physicians and patients can log on to [www.flustar.com](http://www.flustar.com) to determine the location and spread of influenza in local areas across the country.

### **About Tamiflu**

Tamiflu, co-developed by Gilead Sciences, Inc., is a systemic treatment for the most common strains of influenza (types A and 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 the most common strains of influenza, types A and B. Tamiflu attacks the influenza virus and is thought to work by stopping it from spreading inside the body. Tamiflu treats flu at its source, by attacking the virus that causes the flu, rather than simply masking symptoms.

Tamiflu is generally well tolerated. In treatment studies in adults, the most frequently reported adverse events were mild-to-moderate transient nausea and vomiting. Other events reported more frequently than with placebo were bronchitis, insomnia and vertigo. In prophylaxis studies in patients aged 13 and older, adverse events were qualitatively similar to those seen in the treatment studies despite a longer duration of dosing. Events reported more frequently in subjects receiving Tamiflu compared to subjects receiving placebo in prophylaxis studies included nausea, vomiting, diarrhea, abdominal pain, dizziness, insomnia, vertigo and fatigue.

In pediatric treatment studies, the most frequently reported adverse event was vomiting. Other events reported more frequently by pediatric patients treated with Tamiflu included abdominal pain, epistaxis, ear disorder and conjunctivitis. These events generally occurred once and resolved despite continued dosing.

Efficacy of Tamiflu in the treatment of subjects with chronic cardiac disease and/or respiratory disease has not been established. Safety and efficacy of repeated treatment or prophylaxis courses have not been studied.

Tamiflu was approved by the U.S. Food and Drug Administration (FDA) for the treatment of uncomplicated acute illness due to influenza infection in adults in October 1999. The FDA granted marketing approval for the prevention of naturally occurring influenza A and B in adults and adolescents 13 years and older in November 2000. The FDA granted marketing approval of the oral suspension for use in the treatment of influenza A and B in children one year and older in December 2000. Tamiflu oral suspension is used for pediatric patients one year and older or adult patients who cannot swallow a capsule. Tamiflu is the first and only liquid suspension to treat influenza A and B.

Tamiflu is available for the treatment of influenza in more than 40 countries worldwide. For more information visit [www.Tamiflu.com](http://www.Tamiflu.com)

### **About Roche**

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 and diagnostics. 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: dermatology; genitourinary disease; infectious diseases, including influenza; inflammation, including arthritis and osteoporosis; metabolic diseases, including obesity and diabetes; neurology; oncology; transplantation; vascular diseases; and virology, including HIV/AIDS and hepatitis C.

For more information on the Roche pharmaceuticals business in the United States, visit the company's web site at: <http://www.rocheusa.com>

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**Contact:** Terence Hurley  
(973) 562-2882  
[mailto:terence\\_j.hurley@roche.com](mailto:terence_j.hurley@roche.com)