

## **New Tamiflu™ Data Shows Early Treatment Optimizes Benefit for Flu Sufferers**

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*Treatment Within 12 Hours Reduced Total Illness Duration by More Than Three Days Compared to Treatment at 48 Hours*

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Hoffmann-La Roche Inc. today announced new data on its influenza treatment Tamiflu™ (oseltamivir phosphate) that shows the drug's benefits are significantly improved when taken earlier in the course of the disease. Tamiflu, taken within the first 12 hours of symptom onset, reduced the total duration of illness by greater than three days compared to treatment at 48 hours. The study data, entitled IMPACT, was released today at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Toronto, Canada.

Tamiflu, in convenient pill form, was approved by the U.S. Food and Drug Administration (FDA) and Health Canada last year 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.

“The IMPACT study clearly shows that the sooner you recognize flu symptoms and present to a physician, the greater the benefit you'll receive from a treatment like Tamiflu,” said Fred Aoki, M.D., University of Manitoba and lead author of the IMPACT study. “It is important for patients and healthcare professionals to know when flu is in a given area, and to recognize the distinct symptoms such as sudden onset of fever, cough and body aches, in order to seek early medical attention.”

### **About Tamiflu**

The symptoms of influenza, which often begin abruptly, are a rapidly rising fever, dry cough, headache, chills, malaise, and sore throat. “Another key result of the IMPACT study is that patients are able to recognize these flu symptoms and present to the doctor within 12 hours,” said Dr. Aoki. Each flu season millions of people are affected by the debilitating flu virus.

### **About the IMPACT Study**

During the 1999-2000 influenza season, patients with sudden onset of febrile influenza illness, presenting within 48 hours, were treated with Tamiflu 75mg bid for five days. The study investigated the relationship between time of intervention and maximum treatment benefit, by treating patients as early as possible after symptom onset. The primary endpoint of the multi-center international study was duration of illness, calculated from time of onset of fever to the time of alleviation of all symptoms in the influenza-infected population. Enrolled in the study were 958 laboratory-confirmed influenza patients, 140 entered within the first six hours of symptom onset; 240 within the first 12 hours; 573 (60%) within 24 hours; and 958 (100%) within 48 hours. Tamiflu is generally well tolerated. The most common adverse events observed in the study were nausea and vomiting. The incidence of nausea was reduced when patients took the first dose with food.

The study found that there is a progressive decrease in duration of illness the earlier that Tamiflu is taken. For every 6 hours earlier that treatment of Tamiflu is administered, the total duration of illness is shortened, and starting at 48 hours there is a continuous treatment benefit at every time point in the study. For example, patients who took Tamiflu within 12 hours benefited faster than patients who started within 24 hours, and patients who took Tamiflu within 24 hours benefited faster than the 36-hour group. The total duration of illness was reduced by more than three days when Tamiflu was started within 12 hours, compared to treatment at 48 hours. Early intervention with Tamiflu optimizes its effectiveness in the treatment of influenza, confirming trends seen in previous studies.

“This study showed that people who started treatment within two days of the onset of the illness did in fact benefit from treatment with Tamiflu,” said Dr. Aoki. “We also showed that there is an increased advantage for the patient if they could start treatment earlier.”

Tamiflu, co-developed with Gilead Sciences of Foster City, California, (Nasdaq:GILD), is a systemic treatment for all common strains of influenza (types 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.

**About Hoffmann-La 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, 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.

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