JAMA Study Reveals Roche's Tamiflu™ Effective In Protecting People Exposed to Influenza

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Tamiflu™ (oseltamivir phosphate) is the only antiviral approved for the prevention of influenza in adults and the treatment of flu, in pill or liquid form, in adults and children 1 year and older

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According to a study published in today's issue of the Journal of the American Medical Association (JAMA), Tamiflu™ (oseltamivir phosphate) has been shown to be effective in protecting people in a close-contact setting, like households and colleges, from getting the flu when in contact with someone already infected with the disease. The study results demonstrate that Tamiflu™, when taken once daily for seven days, can significantly reduce the spread of influenza to people exposed to the virus, thus preventing an outbreak.

When one household member develops influenza, others in the household are at heightened risk of being infected. In this post-exposure study of more than 950 patients, Tamiflu, when taken within two days of symptom onset in the index case, had an overall protection rate of 89 percent against clinical influenza in individuals.

STUDY DESIGN AND FINDINGS

"The influenza virus is easily spread between people. Tamiflu has been shown in several clinical settings to be highly effective in protecting against influenza illness, and is well tolerated when taken once daily," said Arnold S. Monto, M.D., University of Michigan School of Public Health and author of the post-exposure study. "The protection rate observed is exciting because it shows that Tamiflu can provide immediate protection for people who have been exposed to the virus through interaction with someone infected with influenza."

Co-developed by Hoffmann-La Roche Inc. and Gilead Sciences, Inc. (NASDAQ:GILD), Tamiflu received government approval in October 1999 for the treatment of uncomplicated acute illness due to influenza infection in adults. In November 2000, the U.S. Food and Drug Administration (FDA) approved Tamiflu for the prevention of naturally occurring influenza in adults and adolescents 13 years and older. Last December Roche received marketing approval for the treatment of acute illness due to influenza in children 1 year and older. Tamiflu is now available in a liquid suspension for children and adults who cannot swallow a capsule, particularly the elderly, including residents of nursing homes and long term care facilities.

"Last year, Tamiflu was shown to be safe and effective in treating patients who contracted the influenza virus. This year, Tamiflu has an added benefit for physicians and their patients," said Michael Hassman, D.O., Comprehensive Clinical Research and co-author of the study. "If you have been exposed to the flu see your health care provider within two days, because we now have an additional option that can also be used to protect people who are in close contact with someone who has the flu."

The study investigated the efficacy of Tamiflu (oseltamivir phosphate) in preventing the spread of influenza in adults and adolescents in contact with a household member infected with the flu. Households were defined as family groups, groups of students or young adults. The randomized, double-blind, placebo-controlled study included 955 adults and adolescents aged 12 years and older. Study participants included 377 patients with flu-like illness, of which 163 had confirmed influenza. Of the 955 contacts, 415 lived with an influenza positive patient.

ABOUT INFLUENZA

The study found that individuals who lived with a flu-positive patient had a reduction in the incidence of influenza from 12.6% in the placebo group to 1.4% in the Tamiflu group (a difference of 89%). Viral shedding was also inhibited in household members taking Tamiflu. In addition, both influenza types A and B were circulating during the study, with nearly half of infected index cases having laboratory evidence of infection with influenza B.

"Flu is arriving late this season, and surveillance systems, like FluSTAR™, are reporting an increase in flu B isolates this year over last," said Hassman. "That is why it is important for patients to receive an antiviral, like Tamiflu, that treats and prevents both influenza A and B."

Tamiflu is generally well tolerated. In clinical trials, the adverse events were qualitatively similar to those seen in treatment studies, despite the longer duration of treatment, and no clinically relevant differences in safety profile were seen in the elderly patients compared to the younger population. The most frequently reported adverse events were nausea, vomiting, diarrhea and headache.

Tamiflu is not a substitute for a flu vaccination. You should continue to get a flu vaccination every year, according to your health care professional's advice. Serious bacterial infections may begin with influenza-like symptoms or may co-exist with or occur as complications during the course of influenza. Tamiflu has not been shown to prevent such complications.

These findings are significant because during flu season the influenza virus is easily spread between household members. Study participant Robert Stone notes that Tamiflu was able to protect his family from the flu, whereas in the past the disease spread through the whole family. "My son was very sick with the flu. He had a high fever, chills, and body aches. I was certain that the rest of the family was going to get sick, so we enrolled in the Tamiflu study. I was surprised how well Tamiflu worked; my wife, our two daughters, and I all remained healthy. It is comforting to know that there was something out there to prevent us from the misery that my son went through with the flu."

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 influenza virus is highly contagious and is transmitted when droplets are shed by an infected person during sneezing or coughing. A person becomes infected by breathing in these droplets. The virus then settles into the entire respiratory system, and begins replicating 24 hours before symptoms are discovered. An infected person can pass on the disease for four to five days and influenza may remain in a local area for up to six weeks.

ABOUT TAMIFLU
Tamiflu is a systemic treatment for the most 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. Tamiflu attacks the influenza virus and stops it from spreading inside the body. Tamiflu treats the flu at its source, by attacking the virus that causes the flu, rather than simply masking the symptoms.

In its first season of availability for treatment, Tamiflu 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.

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.

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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