

Basel, 20 November 2000

Roche granted new Tamiflu indication for the prevention of influenza in the U.S.

Roche and Gilead Sciences, Inc., today announced that the U.S. Food and Drug Administration (FDA) has granted marketing approval for a prevention indication for its influenza antiviral Tamiflu (oseltamivir phosphate). Tamiflu received approval in the U.S. in October 1999 for the treatment of influenza in adults. Tamiflu will be available this influenza season in the U.S. for the prevention of influenza A & B in adults and adolescents 13 years and older.

The results of several clinical studies show that Tamiflu is up to 92 % effective in preventing influenza illness in adolescents, adults and the elderly when taken once daily. The studies examined Tamiflu's ability to prevent the development of flu in three different settings: households, communities and residential nursing homes. Tamiflu is the first antiviral pill that can safely protect people who are in close contact with someone who has the flu.

The studies

The indication is supported by findings from three separate Phase III randomized, double-blind, placebo-controlled clinical trials involving 3,434 healthy patients (adolescents, adults and the elderly). The prophylaxis studies examined the drug's preventative capabilities in a household setting where family members were exposed to the virus, during a community outbreak and during outbreaks within residential nursing home settings.

Post-Exposure Trial

In one trial of over 950 patients, 75mg of Tamiflu taken once daily for seven days reduced the incidence of influenza by 92 % (from 12% in placebo group to 1% in Tamiflu group) in adults and adolescents who were in contact with a household member infected with the flu.

Community Outbreak and Nursing Home Outbreak Trials

Tamiflu was shown to reduce the incidence of laboratory confirmed influenza by 76 % (from 4.8% in placebo group to 1.2% in Tamiflu group) in healthy adults during a community outbreak and by 92% (from 4.4% in placebo group to 0.4% in Tamiflu group) in the elderly in residential nursing home settings. In total 1,480 people received 75mg of Tamiflu taken once daily for up to 42 days. In these studies, Tamiflu reduced the incidence of influenza among the participants, many of whom were not vaccinated. In the residential nursing home trial, the protection level of Tamiflu was demonstrated among elderly participants, 80 % of whom had been vaccinated, suggesting that the benefits of Tamiflu complement those of vaccination. Tamiflu also reduced the incidence of influenza-associated bronchitis, pneumonia and sinusitis by 86 %.

Tamiflu, taken for prevention of influenza, is not a replacement for vaccines but for people who aren't vaccinated, in cases where the vaccine does not match the influenza strain of the season, or for high-risk patients who might need additional protection, Tamiflu can provide an added means of preventing influenza illness.

Influenza's Impact in the U.S.

Each year, up to 40 million Americans develop the flu, resulting in an annual cost of \$14.6 billion in physician visits, lost productivity and lost wages. In addition, nearly 300,000 people are hospitalized, and 20,000 to 40,000 die from influenza and its complications. The risks for hospitalization and death from influenza are higher among people aged 65 or older, and those people with underlying high-risk medical conditions.

Tamiflu

Tamiflu, co-developed by Gilead Sciences Inc., California, USA, 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.

In its first U.S. season, under its current treatment application, Tamiflu has gained more than 58 % of the market share within the new class of antivirals known as neuraminidase inhibitors. In studies with more than 8,000 patients oral Tamiflu demonstrated a good efficacy, safety and tolerability profile.

The prevention indication is pending in a number of other markets around the world including Canada. As well as the U.S. Tamiflu is available for the treatment of influenza in a number of countries world-wide including Canada, Switzerland and many Latin American countries. Hundreds of thousands of sufferers were treated with Tamiflu during the last influenza season. An application for the use in children 1 year and older has been filed in the United States, where it will receive expedited review.

Roche and Gilead

Gilead Sciences, Inc. (NASDAQ:GILD), 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. Gilead discovers, develops, manufactures and commercialises 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; Cambridge, UK and Dublin, Ireland and sales and marketing organisations in the United States, Europe and Australia.

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well-being and quality of life. Roche has approximately 63,900 employees and sells its products in over 170 countries. The Roche Group posted sales of 20.3 billion Swiss francs in the first nine months of 2000. In the first half of 2000 the company's net income amounted to 3 billion Swiss francs. It invested 1.9 billion Swiss francs in research and development.

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