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FDA Advisory Committee Affirms Safety of Tamiflu in Children

Nutley, NJ, November 18, 2005 – The Pediatric Advisory Committee of the U.S. Food and Drug Administration (FDA) has confirmed the safety of Tamiflu (oseltamivir phosphate) in children following a scheduled comprehensive review of data about the use of Tamiflu in children. According to Dr. Robert M. Nelson, chairman of the committee, there is “no concern at all” that Tamiflu played a role in the reported deaths of children with influenza in Japan. Dr. Nelson is an associate professor in the department of anesthesia and critical care at The Children’s Hospital of Philadelphia.

The FDA indicated that it intends to continue normal monitoring of the safety of Tamiflu for use in children, but found no basis for changing the labeling of the product for neuropsychiatric issues. Roche intends to work with the FDA to change the drug’s labeling based on adverse skin events that have occurred in a small number of patients, mostly in Japan. The FDA said it would report back to the committee in two years.

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“We welcome the outcome of the FDA advisory committee and look forward to working with the FDA and other health authorities to extend our knowledge of the use of Tamiflu and its safety profile. The positive role of Tamiflu remains unchanged,” commented William M. Burns, CEO Roche Pharma Division.

The meeting of the Pediatric Advisory Committee on November 18th was a scheduled one at which adverse events for eight medicines used in children were reviewed. Tamiflu was among the drugs reviewed because it was granted pediatric exclusivity in March 2004. Pediatric exclusivity is granted as an incentive to industry to study the use of medicines in children.

The committee heard several presentations on Tamiflu including adverse event reports, a literature review and analysis of clinical trials data.

Facts and Figures

- To date, Tamiflu has been used by about 33 million patients worldwide
- In Japan, 24.5 million patients have used Tamiflu, 11.6 million of whom were children
- 12 deaths in children aged 1 to 16 years occurred; this number of reported deaths, placed into the context of overall usage, would be a rate of 1 death per million patients treated. This is in close accordance with or lower than published rates of mortality in children infected with influenza (2 per million pediatric patients)
- Safety reporting is based on clinical trials and routine use from about 33 million patients worldwide; of these, about 13 million were children.

About Tamiflu

Tamiflu, co-developed by Gilead Sciences, Inc., based in Foster City, CA, is a systemic treatment for the most common strains of influenza (types A and B). The leading prescription oral antiviral drug, Tamiflu is indicated for treatment of type A and B influenza in patients one year and older. Tamiflu is an effective treatment, and can reduce the duration and severity of the flu when taken within two days of symptom onset. Tamiflu, a neuraminidase inhibitor, works by

attacking the influenza virus and its ability to replicate, rather than simply addressing influenza symptoms.

Tamiflu is also approved for the prevention of influenza in adults and adolescents 13 years and older. Clinical trials have shown Tamiflu is effective in preventing influenza illness when taken once daily for at least seven days. For the prevention of influenza in those 13 years or older, Tamiflu is administered following close contact with an infected individual who demonstrates characteristic symptoms of influenza, and based on knowledge that influenza is circulating in the area for 10 days, or up to six weeks for seasonal prophylaxis.

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, headache, 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.

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.

Vaccination is considered the first line of defense against influenza.

Tamiflu is available for the treatment of influenza in more than 40 countries worldwide.

For more information visit www.Tamiflu.com

About Roche – More Than a Century in the U.S. and the World

Founded in 1896 and headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is one of the world's leaders in diagnostics, the leading supplier of pharmaceuticals for cancer, as well as a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on many fronts to improve people's health and quality of life. Roche employs roughly 65,000 people in 150 countries, including approximately 15,000 in the United States.

Roche's U.S. operations celebrate their American Centennial in 2005. In another milestone this year, Roche was named in January to *Fortune* magazine's list of Best Companies to Work for in America. One of an increasingly rare breed of major healthcare companies that still bear their original name, Roche today has more than a dozen U.S. sites located in California, Colorado, Indiana, New Jersey and South Carolina, as well as in Puerto Rico. Roche has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai. Roche's Pharmaceuticals Division offers a portfolio of leading medicines in therapeutic areas including cancer, HIV/AIDS, hepatitis C, transplantation,

dermatology and influenza. Roche's Diagnostics Division supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide. For further information, visit the worldwide and U.S. websites (Global: www.roche.com and U.S.: www.roche.us).

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