

Media Release

Furnished under Rule 12g3-2(b)
ROCHE HOLDING 82-3315



PROCESSED

JAN 05 2006

THOMSON
FINANCIAL

Basel, 22 Dezember 2005



05013656



U.S. Food and Drug Administration extends prophylaxis indication for Tamiflu to children between 1 to 12 years of age

SUPPL

Roche announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application (sNDA) extending the prophylaxis (prevention) indication for Tamiflu (oseltamivir phosphate) to include children ages one through 12. The leading prescription antiviral medication for prevention and treatment of influenza, Tamiflu was previously approved for prophylaxis in adolescents (age 13 years and older) and adults. Tamiflu is also the only antiviral medication indicated for the treatment of influenza type A or type B infection in patients one year and older, and is available in both capsule and liquid suspension formulations.

William M. Burns, CEO Division Roche Pharma, said: "Very young children are particularly vulnerable during any outbreak of influenza. The approval of Tamiflu in this indication enables doctors to have a safe and effective medicine at hand to help prevent young children from getting influenza. The data which the submission was based on confirms the importance of Tamiflu in the management of influenza".

When administered within 48 hours of exposure, clinical data show that prophylaxis with Tamiflu reduced the incidence of flu from 17 percent (18/106) in the group not receiving Tamiflu to 3 percent (3/95) in the group receiving prophylaxis. The dosing for the new indication is 30 mg to 60 mg once daily (dependant on body weight) for a duration of 10 days. Therapy should begin within two days of exposure, following close contact with an infected individual.

The sNDA was filed based on results from a subset of pediatric patients in a clinical study where Tamiflu was used for the management of influenza in households. The study, which included

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more than 1,000 patients (including adults and children), showed that post-exposure prophylaxis is effective in preventing secondary spread of influenza infection and illness in households and that the protective efficacy of Tamiflu was the same in children aged one through 12 as the whole population.

Tamiflu gained a positive opinion in Europe and Switzerland for prevention of influenza in children 1 to 12 years last week.

Flu's Impact on Children

Influenza is particularly dangerous for the most vulnerable in society and this includes young children and infants. Children younger than two years old are as likely as those over age 65 to be hospitalized because of influenza. It is estimated that children are three times more likely to get sick with the flu – on average, one in 10 adults is affected by influenza annually, compared with one in three children. Therefore, prevention of influenza in children can have a significant impact on the spread of influenza in the household and the whole community.

About Tamiflu

Tamiflu delivers:

- 38 percent reduction in the severity of symptoms
- 67 percent reduction in secondary complications such as bronchitis, pneumonia and sinusitis in otherwise healthy individuals
- 97 percent reduction in the duration of influenza illness
- Tamiflu is shown to provide up to 89 percent overall protective efficacy against clinical influenza in adults and adolescents who had been in close contact with influenza-infected patients

In children, treatment with Tamiflu delivers:

- 36 percent reduction in the severity and duration of influenza symptoms
- 44 percent reduced incidence of associated otitis media as compared to standard care

Tamiflu was invented by Gilead Sciences and licensed to Roche in 1996. Roche and Gilead partnered on clinical development, with Roche leading efforts to produce, register and bring the product to the markets. Under the terms of the companies' agreement, amended in November 2005, Gilead participates with Roche in the consideration of sub-licenses for the pandemic supply of Tamiflu in resource-limited countries. To ensure broader access to Tamiflu for all patients in

need, Gilead has agreed to waive its right to full royalty payments for product sold under these sub-licenses.

Pandemic Stockpiling

The World Health Organization (WHO) advises that stockpiling antivirals in advance is presently the only way to ensure that sufficient supplies are available in the event of a pandemic. Roche has been working closely with WHO and national governments to ensure governments are aware of the importance of stockpiling antivirals in the event of a pandemic situation. Roche has received and fulfilled pandemic orders for Tamiflu from around 50 countries worldwide. The magnitude of these orders varies with some countries, France, Finland, Iceland, Ireland, Luxembourg, Netherlands, New Zealand, Norway, Switzerland and UK stockpiling or intending to stockpile adequate Tamiflu to cover 20-40% of their population. To meet this demand Roche has already significantly expanded its Tamiflu production capacity several times, and will continue to take action, both on its own and with several partners, to increase production capacity to assist governments with their pandemic preparedness.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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Additional information

- Roche Health-Kiosk, Influenza: www.health-kiosk.ch/start_grip.htm
- About Tamiflu: www.roche.com/med_mbtamiflu05e.pdf
- About influenza: www.roche.com/med_mbinfluenza05e.pdf
- WHO: Global influenza programme: www.who.int/csr/disease/influenza/en/

-WHO: Avian flu: www.who.int/mediacentre/factsheets/fs274/en/

Roche Group Media Office

Telephone: +41 61 688 8888 / Email: basel.mediaoffice@roche.com

- Baschi Dürr
- Alexander Klauser
- Daniel Piller (Head Roche Group Media Office)
- Katja Prowald (Head Science Communications)
- Martina Rupp