Roche announces FDA approval of Tamiflu for the treatment of influenza in infants

First medicine approved to treat influenza in infants two weeks of age and older

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has extended the approval of Tamiflu (oseltamivir phosphate) for the treatment of acute, uncomplicated influenza to include infants two weeks of age and older. Tamiflu is prescribed by doctors to help lessen the duration and severity of influenza by blocking the virus' ability to replicate in the body.

The approval makes Tamiflu the only prescription oral antiviral medicine approved to treat people of all ages, from infants two weeks of age to elderly people. Tamiflu was first approved in the United States over 13 years ago. Approximately 30 million children worldwide over the age of one, including an estimated 6.9 million children in the United States, have received a prescription for Tamiflu.

“We are very pleased that this approval provides parents with a medicine for children as young as two weeks old, particularly because the Centers for Disease Control advises against vaccinating infants less than six months of age,” said Hal Barron, M.D., Head of Global Product Development and Chief Medical Officer for Roche.

The FDA approval is based on two open label safety and pharmacokinetic studies conducted in 136 infants less than one year of age infected with influenza, which assessed how Tamiflu was absorbed and distributed in the body and how well it was tolerated in this group. Based on these studies, a 3 mg/kg dose of Tamiflu given twice daily for five days to infants is expected to have a similar safety and efficacy profile to that observed in older children and adults. The clinical trials showed that the safety profile in patients less than one year of age was consistent with other populations.

About Tamiflu

Tamiflu, co-developed by Gilead Sciences Inc, is designed to be active against all clinically relevant influenza viruses and works by blocking the action of the neuraminidase enzyme on the surface of the virus. When
neuraminidase is inhibited, the virus is restrained from spreading to other cells in the body. Tamiflu is indicated for the treatment of acute, uncomplicated influenza caused by type A and B viruses in patients two weeks of age and older and is also indicated for preventing influenza in patients one year and older. Over 90 million people from more than 80 countries have received a prescription for Tamiflu to treat or prevent influenza, including approximately 30 million children worldwide.

**About Roche**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche’s personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: [www.roche.com](http://www.roche.com).

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**References:**

1 Tamiflu® (oseltamivir phosphate) Prescribing Information. December 21, 2012
2 Roche Data on File