

# Media Statement

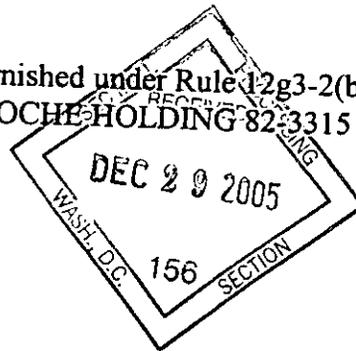
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## Roche grants Tamiflu sub-license to India's Hetero Drugs to make flu medicine for India and developing countries

Roche today announced that it has granted a sub-license to the Indian company Hetero Drugs for the production of oseltamivir (Tamiflu), as part of continued efforts to increase and speed up availability of the medicine for influenza pandemic planning world wide. The agreement with Hetero is focused on providing oseltamivir for government pandemic use and will have an immediate effect on the availability in India and developing countries – both directly and through further agreements with local companies.

David Reddy, Roche's Pandemic Taskforce Leader, commented: "As a result of a period of intense production planning, we are pleased to announce the partnership with Hetero Drugs as the latest step in our scale-up efforts to meet the needs of governments in preparing for the potential public health threat posed by avian influenza. This is another demonstration of Roche's commitment to working as a collaborative and responsible partner with governments and the World Health Organization (WHO) to assist in pandemic planning".

Whilst Roche remains on schedule to meet the current orders received from over 50 governments, the collaboration with Hetero will enhance the supply of oseltamivir in some of the world's poorest countries, resulting in earlier than anticipated delivery timelines and more capacity for further orders. Hetero is the first company that was identified to be able to speed up agreed delivery timelines in the first half of 2006. Following two and a half years of work, Hetero recently received approval to manufacture the medicine, have demonstrated that they meet the criteria which Roche defined in terms of technical ability, capacity and the speed of bringing that capacity on stream.

F. Hoffmann-La Roche Ltd.

CH-4070 Basel

Corporate Communications

Tel. 061 - 888 88 88

Fax 061 - 888 27 75

<http://www.roche.com>

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With this agreement, Hetero is respecting Roche's and Gilead's intellectual property on Tamiflu in India. The medicine would never have been invented without strong patent systems in place. The recognition of intellectual property in India through this partnership with Hetero therefore is very significant as it respects the new Indian Patent legislation which came into effect on January 1, 2005.

#### **About pandemic planning**

Roche has been working with many governments over the last few years to determine their needs for stockpiling of Tamiflu and has received and/or fulfilled orders from around 50 countries. Roche has also pledged to donate 3 million treatments to the WHO for use where an influenza pandemic may start. This amount, based on mathematical modeling, could contain or stop the spread of a potential pandemic at the source of the outbreak.

#### **Tamiflu (oseltamivir)**

Tamiflu is designed to be active against all clinically relevant influenza viruses and key international research groups have demonstrated, using animal models of influenza that Tamiflu is effective against the avian H5N1 strain circulating in the Far East.<sup>3</sup>

It works by blocking the action of the neuraminidase (NAI) enzyme on the surface of the virus. When neuraminidase is inhibited, the virus is not able to spread to and infect other cells in the body.

#### **Tamiflu delivers:**

- 38 percent reduction in the severity of symptoms<sup>1</sup>
- 67 percent reduction in secondary complications such as bronchitis, pneumonia and sinusitis in otherwise healthy individuals<sup>2</sup>
- 37 percent reduction in the duration of influenza illness<sup>5,3</sup>
- Tamiflu was 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<sup>4</sup>

#### **In children, Tamiflu delivers:**

- 36 percent reduction in the severity and duration of influenza symptoms<sup>5</sup>
- 44 percent reduced incidence of associated otitis media as compared to standard care<sup>6</sup>

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.

#### **Avian Influenza and Pandemics**

Most avian influenza viruses are not infectious to humans, but, should an avian and a human influenza virus co-infect a human or a pig, the virus strains can join, mutate and create a completely new virus, which may be transmissible from animals to humans, and from humans to humans. Such a strain would be entirely new in composition, so vaccines developed and administered to date to protect humans during seasonal epidemics, would be ineffective against this new strain, leaving the population vulnerable to infection. Experts believe the next influenza pandemic could result from such a mutation of virus strains.

#### **World Health Organisation**

The WHO has recommended as part of its Pandemic Preparedness Plan that countries establish stockpiles of antiviral treatments such as Tamiflu, which are effective against all strains of the influenza virus. The Pandemic Preparedness Plan, along with details of the countries that have implemented national plans, can be viewed at:

[http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_CSR\\_EDC\\_99\\_1/en/](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_EDC_99_1/en/)

#### **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.

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#### Additional information

- About Hetero: [www.heterodrugs.com](http://www.heterodrugs.com)
- Roche Health Kiosk, Influenza: [www.health-kiosk.ch/start\\_grip.htm](http://www.health-kiosk.ch/start_grip.htm)
- About Tamiflu: [www.roche.com/med\\_mbtamiflu05e.pdf](http://www.roche.com/med_mbtamiflu05e.pdf)
- About influenza: [www.roche.com/med\\_mbinfluenza05e.pdf](http://www.roche.com/med_mbinfluenza05e.pdf)
- WHO: Global influenza programme: [www.who.int/csr/disease/influenza/en/](http://www.who.int/csr/disease/influenza/en/)
- WHO: Avian flu: [www.who.int/mediacentre/factsheets/fs195/en/](http://www.who.int/mediacentre/factsheets/fs195/en/)

#### Roche Group Media Office

Phone: +41-61-688 8888 / e-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

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

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1 Treanor JJ et al. Efficacy and safety of the oral neuraminidase inhibitor oseltamivir in treating acute influenza: a randomized, controlled trial. *JAMA* 2000;283: 1016-24

2 Kaiser et al. Impact of Oseltamivir treatment on influenza-related lower respiratory tract complications and hospitalisations. *Arch Intern Med.* 163:1667-1672 (2003)

3 Nicholson KG et al. Efficacy and safety of oseltamivir in treatment of acute influenza: a randomised controlled trial. *Lancet* 2000; 355:1845-1850

4 Welliver R. W. et al. Effectiveness of oseltamivir in preventing influenza in household contacts: a randomized controlled trial. *JAMA*, 2001 Feb 14; 285(6): 748-754

5 Whitely RJ, Hayden FG et al; Oral oseltamivir treatment of influenza in children, *Pediatr Infect Dis J* 2000; 20: 122-133

6 Roche data on file, 2003