

# Media Release



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Basel, 19 April 2006



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## Rapid response stockpile of Tamiflu now ready and available to the World Health Organisation (WHO)

3 million treatment courses ready to be shipped to site of influenza pandemic outbreak

Roche announced today that the "Rapid Response Stockpile" of Tamiflu is now assembled and available to the WHO upon request. A symbolic "handover" event has taken place today between Franz B. Humer, Chairman and CEO of Roche, and Lee Jong-Wook, Director General, WHO. The agreement in which Roche committed to reserve for donation to the WHO a "Rapid Response Stockpile" of 3 million treatment courses (30 million capsules) of the influenza antiviral Tamiflu (oseltamivir) for the use by the WHO was signed on August 22nd 2005. The aim is to contain an emerging outbreak of a novel and potentially pandemic strain of influenza and to slow or prevent its national and international spread. Roche will deliver the required stockpile to an international airport of the WHO's choosing.

As of 2.30pm CET, pictures / downloads of the event will be available at (link inactive until then):  
<http://www.roche.com/pages/downloads/photos/060419/>

Roche has been in discussions with governments as early as 1997 regarding pandemic preparedness and in the last few years, has supplied Tamiflu to over 65 governments around the world for pandemic stockpiling. Clearly, anti-viral medicines like Tamiflu are an important component of any pandemic preparedness plan. To meet this demand, by working with third parties, Roche has substantially increased the production of Tamiflu and are in a position to produce 400 million treatments annually by the end of this year. In addition, sub-licensing agreements have been granted to companies in China and India for production of oseltamivir.

During discussions with governments, it became clear that developing nations were the least prepared in terms of antiviral stockpiling. Subsequent discussions between Roche and WHO led

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to the concept of a rapid response stockpile of 3 million treatments, 1.5 million treatments being stored in Kaiseraugst and 1.5 million treatments stored in Nutley, US. The idea of such stock is to use the medicine as a fire blanket, to contain a pandemic where it starts.

Under a separate agreement, Roche has also donated a further two million treatment courses to WHO for use in those developing countries which are most likely to be affected by avian influenza in humans and are unable to afford the drug. These treatment courses can be used by WHO according to its assessment of the situation, and will be available for delivery at the end of the year.

#### About Tamiflu (oseltamivir)

Tamiflu is designed to be active against all clinically relevant influenza viruses and 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.

#### Roche and Gilead

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 oseltamivir. 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.

#### 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 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 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](http://www.roche.com)).

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#### Additional information

- 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/avian\\_influenza/en/](http://www.who.int/mediacentre/factsheets/avian_influenza/en/)

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#### References

- <sup>1</sup> Govorkova E.A and Webster R.G. Evaluation of oseltamivir in lethal H5N1 in vivo model. Presented 20 January, 2006 at The First Pandemic of the 21<sup>st</sup> century – a central role for antivirals conference, London.
- <sup>2</sup> Yen et al. Duration and Dosage of Oseltamivir Treatment of H5N1 (A/Vietnam/1203/04) influenza virus infection in mice. *Journal of Infectious Diseases*, 2005.
- <sup>3</sup> 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.
- <sup>4</sup> Kaiser et al. Impact of Oseltamivir treatment on influenza-related lower respiratory tract complications and hospitalisations. *Arch Intern Med*. 163:1667-1672 (2003).
- <sup>5</sup> Nicholson KG et al. Efficacy and safety of oseltamivir in treatment of acute influenza: a randomised controlled trial. *Lancet* 2000; 355:1845–1850.
- <sup>6</sup> 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.
- <sup>7</sup> Whitley RJ, Hayden FG et al; Oral oseltamivir treatment of influenza in children, *Pediatr Infect Dis J* 2000; 20: 122-133.
- <sup>8</sup> Roche data on file, 2003.

# Investor Update



Basel, 18 April 2006

## Chugai files NDA for Tarceva in advanced or recurrent non-small cell lung cancer

Roche announced today that Chugai Pharmaceutical Co., Ltd. has filed a New Drug Application (NDA) with the Japanese Ministry of Health, Labour and Welfare (MHLW) for Tarceva (erlotinib) in patients with advanced or recurrent non-small cell lung cancer (NSCLC). In Japan the incidence of lung cancer is about 85,000<sup>1</sup>.

Taken as an oral, once-daily therapy, Tarceva is the only EGFR-inhibitor to have demonstrated improvement in survival by an impressive 42.5%<sup>2</sup>. Moreover, Tarceva improves disease symptoms and quality of life for patients suffering from NSCLC.

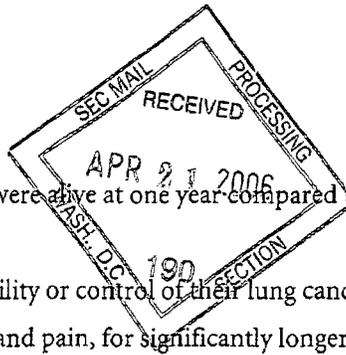
### Major data used for filing

Tarceva is filed in Japan based on local Phase II along with the pivotal Phase III clinical trial, BR.21. The local phase II study in NSCLC patients who failed prior chemotherapy regimen including platinum treatment demonstrated anti-tumor effect and tolerability of Tarceva in the Japanese population. According to the lead investigator, data from this study will be submitted to an upcoming medical meeting.

The pivotal phase III study, BR.21, (published in the *New England Journal of Medicine* (NEJM)) was conducted by the National Cancer Institute of Canada Clinical Trials Group based at Queen's University, in collaboration with OSI Pharmaceuticals, Roche and Genentech, with the participation of 86 sites from 17 countries around the world. This Phase III study (NCIC-CTG BR.21) involved 731 patients with advanced NSCLC whose cancers had progressed after first- or second-line chemotherapy. The study compared patients receiving Tarceva monotherapy with placebo.

The key study results were:

- Treatment with Tarceva in patients with advanced NSCLC resulted in significantly longer survival compared to placebo, a 42.5% improvement (6.7 months vs. 4.7 months).



- 31% of patients receiving Tarceva were alive at one year compared to 22% in the placebo arm.
- Patients receiving Tarceva had stability or control of their lung cancer-related symptoms such as cough, shortness of breath and pain, for significantly longer.
- Patients also had a superior quality of life and improved physical function compared to those on placebo.
- The benefits of Tarceva were shown in a broad spectrum of patients.

Tarceva is approved for treatment of locally advanced or metastatic NSCLC in EU and US and has been launched in this indication in more than 50 countries all over the world. Moreover, Tarceva is approved in US and filed in EU for first-line treatment of advanced pancreatic cancer.

<sup>1</sup>A. Oshima, T. Kuroishi, K. Tajima, Cancer White Paper – Incidence/Death/Prognosis-2004

<sup>2</sup>F. Shepherd, J. Rodrigues Pereira, T. Ciuleanu, et al. Erlotinib in Previously Treated Non-Small Cell Lung Cancer, A Trial of the National Cancer Institute of Canada Clinical Trials Group. *N Engl J Med* 2005;353:123-32.

#### About Tarceva

Tarceva is an investigational small molecule that targets the human epidermal growth factor receptor (HER1) pathway. HER1, also known as EGFR, is a key component of this signalling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva blocks tumour cell growth by inhibiting the tyrosine kinase activity of the HER1 signalling pathway inside the cell.

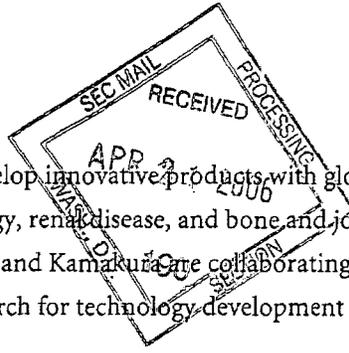
Tarceva is approved in the US and across the European Union for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. Furthermore, Tarceva is approved in US and filed in European Union for first-line treatment of patients with advanced pancreatic cancer.

Tarceva is currently being evaluated in an extensive clinical development programme by a global alliance among OSI Pharmaceuticals, Genentech, and Roche, focussing on earlier stages of NSCLC. Additionally, Tarceva is being studied in combination with Avastin in NSCLC. Trials are also being conducted with Tarceva in other solid tumours, such as ovarian, bronchioloalveolar (BAC), colorectal, pancreatic, head and neck and glioma (brain). Chugai is pursuing its development and regulatory approval for the Japanese market.

#### About Chugai

Chugai Pharmaceutical, based in Tokyo, specializes in prescription pharmaceuticals and ranked 4th in the domestic market in 2005.

Since the start of the strategic alliance with Roche in October 2002, Chugai is actively involved in prescription pharmaceutical R&D activities in Japan and abroad as an important member of the



Roche Group. Specifically, Chugai is working to develop innovative products with global applications, focusing on the disease areas of oncology, renal disease, and bone and joint. In Japan, Chugai's research facilities in Fuji Gotenba and Kamakura are collaborating to develop new pharmaceuticals and Ukima is conducting research for technology development for industrial production.

Overseas, Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

**About Roche**

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