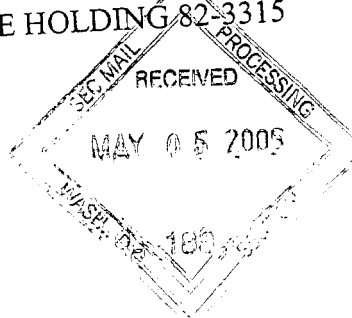


# Media Release



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Basel, 02 May 2005

# SUPPL

## Tarceva: supplemental new drug application filed in the US for treatment of pancreatic cancer

Roche, OSI Pharmaceuticals and Genentech announced today that a supplemental New Drug Application (sNDA) has been submitted to the U.S. Food and Drug Administration (FDA) for use of Tarceva (erlotinib) in combination with chemotherapy for the first-line treatment of patients with advanced or metastatic pancreatic cancer, one of the most difficult to treat cancers.

Tarceva, an oral tablet, is the first drug and the only EGFR-targeted treatment shown to prolong survival in a phase III trial (PA3) when added to standard of care (gemcitabine) for the treatment of patients with previously untreated advanced pancreatic cancer. Tarceva was approved by the FDA in November 2004, and obtained approval in Switzerland in March 2005, for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. It has been filed for the treatment of advanced NSCLC in the EU for regulatory approval in August 2004.

"The impressive results from the pivotal study that support this submission are very encouraging" said William M. Burns, CEO Division Roche Pharma. "We are confident that the clear survival benefit demonstrated by Tarceva in pancreatic and lung cancer patients reinforces the potential of this medicine in other cancer types. We look forward to discussing and filing this data with the EU regulatory authorities."

Pancreatic cancer is the fourth leading cause of all cancer deaths worldwide<sup>1</sup> and is the tenth most frequently occurring cancer in Europe<sup>2</sup>. In 2002, there were more than 78,000 new cases of pancreatic cancer diagnosed in Europe.<sup>3</sup> Pancreatic cancer is difficult to treat, as it is often resistant to chemotherapy and radiotherapy, and tends to spread quickly to other parts of the body, leading to its high mortality and short life expectancy.<sup>4</sup>

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#### About the PA3 study

The sNDA filing is based on a pivotal phase III multi-center, randomised, double-blind, placebo-controlled trial evaluating Tarceva in 569 patients with locally advanced or metastatic pancreatic cancer.

The study demonstrated a statistically significant 23.5 percent improvement in overall survival for patients receiving Tarceva plus gemcitabine compared to patients receiving gemcitabine plus placebo (hazard ratio = 0.81, p-value = 0.025). Twenty-four percent of patients receiving Tarceva plus gemcitabine were alive after one year compared to 17 percent of patients receiving gemcitabine plus placebo. So patients taking Tarceva improved their chances of being alive after one year from 1 in 5 to 1 in 4. Median survival in the Tarceva plus gemcitabine arm was 6.4 months compared to 5.9 months in the gemcitabine plus placebo arm. An exploratory analysis of survival by pre-treatment characteristics also showed that patients with metastatic disease and patients with poor performance status derived a significant survival benefit. Progression-free survival in the Tarceva plus gemcitabine arm also was significantly improved (hazard ratio = 0.76, p-value = 0.003), although there was virtually no difference in tumour response (9 percent in patients receiving Tarceva plus gemcitabine versus 8 percent in the gemcitabine plus placebo arm). The full data analysis has been presented at the Second Annual Gastrointestinal Cancers Symposium in Hollywood, Fla. in January this year.

The analysis of safety data did not reveal any unexpected safety signals beyond that seen in previous studies of Tarceva in both monotherapy and combination settings.

#### 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 currently being evaluated in an extensive clinical development program by a global alliance among OSI Pharmaceuticals, Genentech, and Roche. Chugai is pursuing its development and regulatory approval for the Japanese market. In the United States, Tarceva is jointly marketed by Genentech and OSI Pharmaceuticals.

## 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](http://www.roche.com)).

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## References:

1. [www.pancreas.org](http://www.pancreas.org)
2. [www.startoncology.net](http://www.startoncology.net)
3. Ferlay J et al. GLOBOCAN 2002: Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No. 5, Version 2.0, Lyon; IARC Press 2004
4. [www.cancerhelp.org.uk](http://www.cancerhelp.org.uk)

## Further information:

- Genentech: [www.gene.com](http://www.gene.com)
- OSI Pharmaceuticals: [www.osip.com](http://www.osip.com)
- Cancer: [www.health-kiosk.ch](http://www.health-kiosk.ch)
- Roche in oncology: [www.roche.com/pages/downloads/company/pdf/mbononcology05a\\_b.pdf](http://www.roche.com/pages/downloads/company/pdf/mbononcology05a_b.pdf)

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## Group News



Basel, 2 May 2005

### **FDA clears Roche's new Accu-Chek Aviva blood glucose meter**

Accu-Chek Aviva combines dependability and ease of use to help in the management of diabetes

Roche Diagnostics announced today that it has received U.S. Food and Drug Administration (FDA) 510K clearance for the Accu-Chek Aviva meter, its newest blood glucose meter for the management of diabetes. The meter will be available for consumers in the US later this year.

"The new Accu-Chek Aviva meter has a strong combination of features paired with the dependability and ease of use that our customers have come to expect from Accu-Chek products," said Heino von Prondzynski, CEO Division Roche Diagnostics and Member of Roche's Corporate Executive Committee. "As the world's leader in diabetes care products and services, we are dedicated to making products that will fit into the lifestyles of our customers. The Accu-Chek Aviva meter offers people with diabetes a meter that makes testing simple and convenient, and underscores our commitment of creating solutions for easier diabetes management."

Since consistent blood glucose monitoring is critical for maintaining a healthy lifestyle, the new Accu-Chek Aviva meter is part of a broad portfolio of diabetes management tools developed by Roche Diagnostics to meet the diverse needs of people with diabetes. These tools include the blood glucose monitoring portfolio of Accu-Chek Compact, Accu-Chek Advantage, Accu-Chek Active and Accu-Chek Complete meters, as well as the Accu-Chek MultiClix lancet device and Accu-Chek SoftClix lancet device, which helps minimize testing pain. In addition, Accu-Chek diabetes management software also is available for convenient data entry and storage. Further information is available on the Internet ([www.accu-chek.com](http://www.accu-chek.com)).

#### **About Roche**

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**Additional information**

- Roche Diagnostics: [www.roche-diagnostics.com](http://www.roche-diagnostics.com)