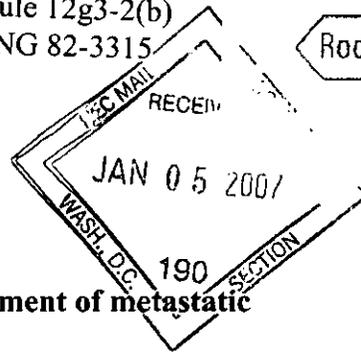


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Roche



Basel, 15 December 2006

Tarceva receives positive EU opinion for the treatment of metastatic pancreatic cancer

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Roche announced today that its oral cancer medicine Tarceva (erlotinib) has received a positive recommendation from the European Committee for Medicinal Products for Human Use (CHMP) following a re-examination of the data supporting the filing of Tarceva in metastatic pancreatic cancer. Tarceva is the first treatment in over a decade to have shown a significant survival benefit in patients with this devastating disease where the five year survival rate has not changed in decades and remains at less than five percent^{1, 2}.

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Tarceva has already been approved by the American Food and Drug Administration (FDA) in November 2005 and in a further 15 countries around the world for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine chemotherapy.

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"News of the CHMP opinion will be welcomed by pancreatic cancer patients across the EU as it widens previously limited treatment options," said Eduard Holdener, Head of Global Drug Development. "The success of Tarceva in combination with gemcitabine chemotherapy is an important step forward in the struggle against this devastating disease."

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Both the non-EU and the EU applications were based on data from the Phase III study (PA3)³ which show that treatment with Tarceva plus gemcitabine results in significantly longer survival (22 percent) compared to gemcitabine alone. In addition, a higher percentage of patients were alive at 12 months in the group treated with Tarceva plus gemcitabine, compared to those treated with chemotherapy alone (24 percent v. 19 percent).

Pancreatic cancer is the tenth most frequently occurring cancer in Europe⁴. In 2002, there were more than 78,000 new cases of pancreatic cancer diagnosed in Europe, with a death rate of approximately 82,000 people per year⁵. 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. Tarceva is the first treatment for many years to have shown a significant survival benefit in patients with pancreatic cancer.

About the PA3³ study

The results of the double-blind, placebo-controlled Phase III study conducted by the National Cancer Institute of Canada, Clinical Trials Group at Queens University and involving 569 patients showed:

- Treatment with Tarceva plus gemcitabine in patients with advanced pancreatic cancer resulted in significantly improved overall survival

- compared to gemcitabine alone (22%)
- 24% of patients receiving Tarceva plus gemcitabine were alive after one year, compared to 19% on gemcitabine alone
- Patients receiving Tarceva plus gemcitabine experienced significantly longer progression-free survival of 30%
- Tarceva plus gemcitabine was well tolerated by patients

As a result of this study, Tarceva plus gemcitabine has been approved for the treatment of advanced pancreatic cancer in 15 countries including America and Australia.

About Tarceva

Tarceva (erlotinib) is a 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.

Taken as an oral, once-daily therapy, Tarceva is the only EGFR-inhibitor to have demonstrated a survival benefit in lung cancer – a very impressive 42.5%. Currently most lung cancer patients are treated with chemotherapy which can be very debilitating due to its toxic nature. Tarceva works differently to chemotherapy by specifically targeting tumour cells, and avoids the typical side-effects of chemotherapy.

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. Tarceva has been approved by the FDA since November 2, 2005 for treatment of locally advanced, inoperable, unresectable or metastatic pancreatic cancer in combination with gemcitabine chemotherapy.

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).

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).

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For further information about:

- Genentech
- OSI Pharmaceuticals
- Cancer
- Roche in Oncology

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and only anti-angiogenic agent that has shown survival benefits in four major tumour types: colorectal, breast, lung and renal cell cancer.

A phase III trial investigating the clinical benefits of adding Avastin to Herceptin plus one of the standard chemotherapies (docetaxel) for the first-line treatment of advanced breast cancer is ongoing. In addition, based on the strong pre-clinical rationale and clinical data, the investigation of the Avastin plus Herceptin combination in the adjuvant HER2-positive breast cancer setting is in planning.

About the study with abstract # 301

The objectives of this phase II study were to evaluate the clinical efficacy of Herceptin plus Avastin in the first-line treatment of HER2-positive locally recurrent surgically unresectable, or metastatic breast cancer patients, and to evaluate the safety profile of this combination. Herceptin was administered at a dose of 4 mg/kg as loading dose then 2 mg/kg weekly plus Avastin 10 mg/kg q 2 weeks. The study is ongoing and interim data of 37 patients were presented.

Efficacy:

- Responses have been documented in 20 of 37 (~54%) evaluable patients; 1 was a complete response (confirmed by a second tumour assessment), 19 were partial responses of which 13 were confirmed
- 31/37 (~84%) patients showed a response or had stable disease at their first post-baseline tumour assessment

Safety:

- Grade III/IV drug-related adverse events: dyspnea (1 grade 3), left ventricular dysfunction (1 grade 4), hypertension (7 grade 3) and proteinuria (1 grade 3).
- Most common grade I/II adverse events: epistaxis (nose bleed) 6/0; AST increase 5/1; fatigue 1/5; headache 4/3 and hypertension 2/6
- Cardiac toxicity adverse events were observed in 13 patients: 7 grade 1, 5 grade 2, 0 grade 3 and 1 grade 4. Stringent cardiac safety surveillance will be pursued.

Pre-clinical and phase I data: In xenograft models, synergistic effects were observed when Herceptin was given in combination with Avastin. In a phase I dose-escalation study of Herceptin plus Avastin, (Pegram, et al. SABCs 2004), pharmacokinetic (PK) analysis indicated co-administration of these two humanized monoclonal antibodies did not alter the PK of either agent. Clinical responses were observed in 5 of 9 patients in the phase I, including one patient with prior disease progression on Herceptin. Overall the responses were durable with 3 patients continuing beyond 1 year on the study.

About breast cancer

Breast cancer is the most common cancer among women worldwide.^{iv} Each year more than one million new cases of breast cancer are diagnosed worldwide, and nearly 400,000 people will die of the disease annually.^v

In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumour cells. This is known as 'HER2-positivity.' High levels of HER2 are present in a particularly aggressive form of the disease which responds poorly to chemotherapy. Research shows that HER2-positivity affects approximately 20-30 percent of women with breast cancer.

About Herceptin (trastuzumab)

Herceptin is a humanised antibody, designed to target and block the function of HER2, a protein produced by a *specific gene* with cancer-causing potential. It has demonstrated efficacy in treating both early and advanced (metastatic) breast cancer. Given on its own as monotherapy as well as in combination with or following standard chemotherapy, Herceptin has been shown to improve response rates, disease-free survival and especially overall survival while maintaining quality of life in women with HER2-positive breast cancer.

Herceptin received approval for use in the European Union for advanced (metastatic) HER2-positive breast cancer in 2000 and for early HER2-positive breast cancer in 2006. In the advanced setting, Herceptin is now approved for use as a first-line therapy in combination with paclitaxel where anthracyclines are unsuitable, as first-line therapy in combination with docetaxel, and as a single agent in third-line therapy. In the early setting, Herceptin is approved for use following standard (adjuvant) chemotherapy. Herceptin is marketed in the United States by Genentech, in Japan by Chugai and internationally by Roche. Since 1998, Herceptin has been used to treat over 350,000 HER2-positive breast cancer patients worldwide.

About Avastin (bevacizumab)

Avastin is the first treatment that inhibits angiogenesis – the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissues. Avastin targets a naturally occurring protein called Vascular Endothelial Growth Factor (VEGF), a key mediator of angiogenesis, thus choking off the blood supply that is essential for the growth of the tumour and its spread throughout the body (metastasis). Avastin is the first and only anti-angiogenic agent that has shown overall and/or progression-free survival benefits in four major cancer types: colorectal, breast, lung and renal cell cancer.

In Europe, Avastin was approved in January 2005 and in the US in February 2004 for the first-line treatment of patients with metastatic colorectal cancer. It received two additional approvals in the

US: in June 2006 for the second-line treatment of patients with metastatic colorectal cancer and in October 2006 for the first-line treatment of advanced non-small cell lung cancer (NSCLC). The first filing for Avastin in Japan occurred in April 2006 for the treatment of metastatic colorectal cancer. Avastin was filed with European Health Authorities for the first-line treatment of advanced breast cancer in July 2006 and the first-line treatment of advanced NSCLC in August 2006.

Roche and Genentech are pursuing a comprehensive clinical programme investigating the use of Avastin in various tumour types (including colorectal, breast, lung, pancreatic cancer, ovarian cancer, renal cell carcinoma and others) and different settings (advanced and adjuvant i.e. post-operation). The total development programme is expected to include over 40,000 patients worldwide.

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Roche IR Contacts:

Dr. Karl Mahler
Phone: +41 (0)61 687 85 03
e-mail: karl.mahler@roche.com

Eva Schäfer-Jansen
Phone: +41 (0)61 688 66 36
e-mail: eva.schaefer-jansen@roche.com

Dianne Young
Phone: +41 (0)61 688 93 56
e-mail: dianne.young@roche.com

Dr. Zuzana Dobbie
Phone: +41 (0)61 688 80 27
e-mail: zuzana.dobbie@roche.com

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