

Media Release



06016061

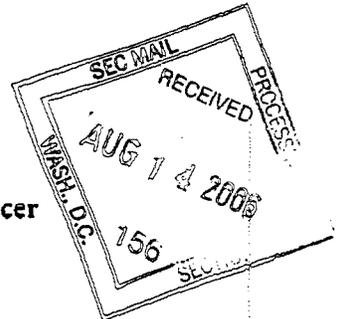
Furnished under Rule 12g3-2(b)
ROCHE HOLDING 82-3315

Basel, 8 August 2006

PROCESSED

AUG 17 2006

**THOMSON
FINANCIAL**



Avastin filed in Europe for treatment of most common form of lung cancer
First medicine to extend survival of previously untreated patients beyond one year

Roche announced today that it has submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for the use of its innovative cancer medicine Avastin in addition to platinum-based chemotherapy for the first-line treatment of the most common form of lung cancer - non-small cell lung cancer (NSCLC) in patients with a certain cell type. The filing is based on data from the pivotal US (E4599) trial which showed a strong survival benefit for patients treated with Avastin plus chemotherapy compared to chemotherapy alone, as well as preliminary data from the ongoing AVAiL trial.

SUPPL

This signals new reason for hope in Europe, where lung cancer claims more than 900 lives per day, making it the leading cause of cancer-related deaths.¹ Few effective treatment options exist. Avastin was submitted in April in the US for NSCLC with histology other than predominant squamous cell and is currently undergoing priority review.

Avastin is the first biological therapy to show survival benefit in people with previously untreated non-small cell lung cancer," said Eduard Holdener, Head Global Drug Development. "Providing patients with novel treatment options to help them fight their disease is a priority for Roche, so we are very pleased to take the next step in making Avastin available to patients with this particularly devastating form of cancer".

After colorectal and breast cancer, lung cancer is the third type of cancer in which the anti-angiogenic agent Avastin has demonstrated significant survival benefit. 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 in combination with IV 5-FU-based chemotherapy. It received another approval in the US in June 2006 as a second-line treatment for patients with metastatic

Handwritten signature/initials

colorectal cancer in combination with IV 5-FU-based chemotherapy. The first filing for Avastin in Japan occurred in April 2006 for the treatment of advanced colorectal cancer. More recently, Avastin was filed for the treatment of women with advanced breast cancer in the EU in July 2006, which followed the US May 2006 filing of Avastin in combination with taxane chemotherapy for patients who have not previously received chemotherapy for their locally recurrent or metastatic breast cancer.

About the pivotal (E4599) study

The EU filing of Avastin in NSCLC is based on impressive data from the randomised, controlled, multicenter Phase III study E4599. These study results have been accepted for publication in the *New England Journal of Medicine*.

The results of the E4599 study of 878 patients with locally advanced, metastatic or recurrent NSCLC with histology other than predominant squamous cell show that:

- Patients treated with Avastin plus paclitaxel and carboplatin chemotherapy had a 20 percent reduction in the risk of death at any time of the study conduct, compared to patients receiving chemotherapy alone.
- Median survival of patients treated with Avastin at a dose of 15mg/kg every three weeks plus chemotherapy was 12.3 months, compared to 10.3 months for patients treated with chemotherapy alone³
- Median time patients lived without their disease advancing ("progression free survival") was increased by 33%: 6.4 months for patients treated with Avastin plus chemotherapy, compared to 4.8 months for patients treated with chemotherapy alone
- Response rate in patients with measurable disease was 29 percent in the group receiving Avastin plus chemotherapy, compared to 13 percent in the group receiving chemotherapy alone
- Pulmonary haemorrhage (haemoptysis) cases were observed in 2.3% of the patients receiving Avastin plus chemotherapy

About AVAiL

AVAiL is a randomised, controlled, multicenter international Phase III trial planning to enrol 1,050 patients with previously untreated advanced non-squamous NSCLC with histology other than predominant squamous cell to explore two doses of Avastin (7.5 or 15 mg/kg every 3 weeks) in combination with a platinum doublet (gemcitabine/cisplatin) chemotherapy. The primary objective of the study is to demonstrate superiority in progression-free survival of both Avastin containing treatment arms versus control.

Preliminary data from AVAiL was submitted for regulatory purposes only to support the EU filing. The study blind has not been broken and final AVAiL data are expected in 2007. Only then will conclusions be drawn on the efficacy of the two doses of Avastin used in AVAiL.

About Lung Cancer

Lung cancer accounts for 1 in 3 and 1 in 4 cancer-related deaths in men and women, respectively. NSCLC is the most common form of the disease and accounts for more than 80 percent of all lung cancers, with histology other than predominant squamous cell as the most common subtype accounting for approximately 60 percent of NSCLC cases. Sadly, the majority of NSCLC cases are diagnosed at an advanced stage² when the cancer is inoperable or has already spread to another part of the body. In spite of the use of chemotherapy as the first-line treatment option, less than five percent of people with advanced NSCLC survive for five years after diagnosis and most die within twelve months².

About Avastin

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 VEGF (Vascular Endothelial Growth Factor), 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).

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 ie post-operation). The total development programme is expected to include over 40,000 patients worldwide.

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).

All trademarks used or mentioned in this release are protected by law.

Additional information

- Lung Cancer: www.roche.com/med_mbackerlungcancer.pdf
- Roche in Oncology: www.roche.com/med_mboncology06a.pdf
- Roche Health Kiosk, Cancer: www.health-kiosk.ch/start_krebs

Roche Group Media Office

Telephone: +41 61 688 8888 / Email: basel.mediaoffice@roche.com

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

References

1. Boyle P and Ferlay J. Cancer incidence and mortality in Europe, 2004. *Ann Oncol*: 16; 481-488, 2005.
2. Wilking N and Jonsson B. A Pan-European comparison regarding patient access to cancer drugs. Karolinska Institute in collaboration with Stockholm School of Economics, Stockholm, Sweden, 2005.
3. Sandler AB, Gray R, Bhramar J, et al. Randomized phase II/III Trial of paclitaxel (P) plus carboplatin (C) with or without bevacizumab (NSC # 704865) in patients with advanced non-squamous non-small cell lung cancer (NSCLC): An Eastern Cooperative Oncology Group (ECOG) Trial – E4599. ASCO 2005, Abstract LBA4.