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Avastin and Tarceva in combination significantly improves the time patients with advanced lung cancer can live without their disease worsening

Roche today announced interim results from a phase III study (ATLAS) in patients with advanced non small cell lung cancer (NSCLC). The study was stopped early because of the significance of the interim data. The results showed that Tarceva (erlotinib) plus Avastin (bevacizumab) given as first line maintenance treatment following initial therapy with Avastin plus chemotherapy extends the time patients live without their disease getting worse (progression free survival) compared to maintenance therapy with Avastin plus placebo. The results will be welcome news for patients and their physicians as extending the time patients live without their disease advancing is a key treatment aim in lung cancer. Most people with lung cancer are diagnosed with advanced stage disease and die within 12 months of diagnosis¹.

“ATLAS is the second study to show that people with lung cancer who took the daily pill Tarceva following initial treatment lived longer without their cancer getting worse” said William M. Burns, CEO Division Roche Pharmaceuticals. “ The results build on the strong data currently available for Avastin in first line treatment and Tarceva in second line therapy, and offer a new option to help extend the time these patients live without their disease progressing.”

A preliminary safety analysis showed adverse events were consistent with previous Avastin or Tarceva studies, as well as trials evaluating the two medicines together, and no new safety signals were observed.

Avastin and Tarceva are already available for the treatment of patients with advanced lung cancer in the US and Europe. Avastin used first line is proven to deliver the longest survival times for patients while Tarceva has a proven record as second and third line treatment for advanced lung cancer. In addition, the SATURN study showed that Tarceva when given in first line maintenance – immediately following initial treatment with platinum based chemotherapy – significantly extended the time patients with NSCLC lived without their cancer getting worse compared to placebo.

Data from the ATLAS study will be submitted for presentation to a forthcoming medical meeting. Roche plans to discuss these data with the regulatory authorities to determine next steps.

About ATLAS (AVF3671g)

ATLAS is a global, multicentre, randomised, double blind, placebo controlled study that enrolled 1,157 patients with locally advanced, recurrent or metastatic NSCLC. Patients were initially given first line treatment of four cycles of Avastin in combination with investigators' choice of multiple chemotherapy regimens (carboplatin/gemcitabine, carboplatin/paclitaxel, carboplatin/docetaxel, cisplatin/vinorelbine, cisplatin/docetaxel or cisplatin/gemcitabine). If their cancer did not progress and they did not experience significant toxicity, patients were then randomised (n=768) to receive maintenance therapy with Avastin plus Tarceva or Avastin plus placebo until disease progression. The study's primary efficacy endpoint was post-chemotherapy PFS, defined as the length of time from randomisation to either disease progression or death on study treatment. Secondary endpoints included overall survival, incidence of all and serious adverse events, and incidence of treatment discontinuation.

About lung cancer

Lung cancer is the single biggest cancer killer in Europe, claiming 334,800 lives in 2006². Unfortunately, the majority of NSCLC cases are still diagnosed at an advanced stage 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 5% of people with advanced NSCLC survive for five years after diagnosis and most die within 12 months¹.

About Avastin

Avastin is a novel medicine that inhibits the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissues. Avastin received its first license in 2004 in the US and 2005 in the European Union for first line treatment for patients with metastatic colorectal cancer and received approval for first line treatment for patients with advanced NSCLC in 2006 in the US and 2007 in Europe. In Europe Avastin is currently used to treat patients with four cancer types (breast cancer, lung cancer, colorectal cancer and renal cell cancer), which collectively cause nearly 3 million deaths each year. There are more than 450 ongoing clinical trials investigating the use of Avastin in over 30 tumour types with the hope that Avastin's full potential can be realised for people with cancer all over the world. Avastin has changed the way cancer is being treated and has already helped more than 350,000 people with cancer live longer and more productive lives.

About Tarceva

Tarceva is the first and only epidermal growth factor receptor (EGFR) oral targeted agent in second line with a proven and significant survival and symptom benefit in a broad range of patients with advanced lung cancer without the toxic side effects of chemotherapy. Tarceva has been approved in the EU since September 2005 and in the US since November 2004 for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

Furthermore Tarceva in combination with chemotherapy is the first treatment in over a decade to have shown a significant survival benefit in treating patients with pancreatic cancer. It is approved in the US in combination with gemcitabine for the first line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer and in the EU for treatment of metastatic pancreatic cancer. Since its initial launch three years ago, Tarceva has been used to treat more than 200,000 patients and has been approved in over 80 countries 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 the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in *in vitro* diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 80,000 people. Additional information is available on the internet at www.roche.com

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Additional information

About Roche: www.roche.com

The Newsmarket: www.thenewsmarket.com (video clips about Avastin and Tarceva in broadcast standard, free of charge)

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