

Basel, 6 October 2008

Roche announces topline outcomes for Avastin-Tarceva combination study in advanced lung cancer

Phase III data shows evidence of potential benefit for patients with advanced lung cancer

Roche today announced topline results from the phase III BeTa Lung study investigating the addition of Avastin (bevacizumab) to Tarceva (erlotinib) compared with Tarceva alone for the second-line treatment of patients with advanced non-small cell lung cancer (NSCLC), the most common form of lung cancer. The primary endpoint, a significant increase in overall survival with the Avastin- Tarceva combination compared with Tarceva alone, was not met with the median survival being similar in both arms of the study. Further analyses, including post-progression therapy, are being conducted to explore the potential impact on the overall survival endpoint.

However, the study showed improvements in secondary efficacy endpoints. There was clear evidence of an increase in time patients lived without their disease getting worse (progression-free survival) as well as of response rate when Avastin was added to Tarceva compared to Tarceva alone.

No new safety signals for Avastin or Tarceva were reported, and the adverse events were similar to those observed in previous NSCLC clinical trials. Roche is further analysing the study results and the data will be submitted for presentation at the 2008 Chicago Multidisciplinary Symposium in Thoracic Oncology in Chicago, Ill., November 13-15.

“Advanced lung cancer has a very poor prognosis and is an extremely difficult-to-treat disease. We are encouraged to see that the combination of Avastin and Tarceva showed evidence of clinical activity for the patients,” said William M. Burns, CEO of Roche’s Pharmaceuticals Division. “The results of the study do not affect the approved indications of Avastin or Tarceva in advanced lung cancer. Roche remains committed to the development of innovative treatments for NSCLC.”

Both Avastin and Tarceva are already available for the treatment of patients with advanced NSCLC in the US and Europe. Avastin used first-line in combination with platinum-based chemotherapy is proven to deliver

the longest survival times for previously untreated patients while Tarceva in second-line was the first targeted therapy to significantly improve survival in previously treated patients.

The evidence of clinical activity with the combination of Avastin and Tarceva in the BeTa Lung trial is encouraging for the ongoing trials evaluating this chemotherapy-free combination in the first-line setting. A second study (ATLAS) is evaluating the combination of Avastin and Tarceva as first-line maintenance therapy for advanced lung cancer patients whose disease has not progressed following initial treatment with Avastin in combination with chemotherapy. Results are expected in the first half of 2009.

About BeTa Lung

BeTa Lung is a multi-centre, placebo-controlled, randomised, double-blind phase III study investigating the addition of Avastin to Tarceva compared with Tarceva alone for the second-line treatment of patients with advanced NSCLC. A total of 636 patients were randomised to receive either Avastin in combination with Tarceva or Tarceva in combination with placebo. The primary endpoint was overall survival.

Median survival in patients treated with Tarceva and placebo was 9.2 months. This exceeded the median survival in the Tarceva registration study, BR.21, that included patients treated in the second- and third-line settings. These results continue to support the role of Tarceva as an important treatment option for advanced lung cancer patients.

About Lung Cancer

Lung cancer is the single biggest cancer killer in Europe, claiming 334,800 lives in 2006. 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 five percent of people with advanced NSCLC survive for five years after diagnosis and most die within twelve months.

About Avastin

Data from the comprehensive Avastin cancer clinical development programme have resulted in approvals in advanced colorectal, breast, lung, and kidney cancer:

- February 2004 (US) and January 2005 (EU) – first-line treatment in patients with metastatic colorectal cancer (CRC)
- June 2006 (US) – second-line treatment in patients with metastatic CRC

- October 2006 (US) and August 2007 (EU) – first-line treatment in patients with advanced non-small cell lung cancer (NSCLC)
- March 2007 (EU) – first-line treatment in patients with metastatic breast cancer
- April 2007 (Japan) – treatment in patients with recurrent or advanced CRC
- December 2007 (EU) – first-line treatment in patients with advanced RCC
- January 2008 (EU) – first and later-line treatment in patients with mCRC in combination with any chemotherapy

About Tarceva

Tarceva is the only 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 delivers effectiveness comparable to chemotherapy and significantly improves overall quality of life. In the landmark registration study BR.21, more patients on Tarceva had improvement in cough, pain, shortness of breath and overall physical function versus patients on placebo. In addition Tarceva does not induce the distressing side-effects associated with chemotherapy, such as nausea and vomiting. Tarceva is also more convenient as patients can take a tablet once a day at home rather than receive intravenous treatments in a hospital.

Tarceva has been approved in the European Union 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 286,000 patients and has been approved in 92 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

- Video clips about Avastin and Tarceva in broadcast standard, free of charge: www.thenewsmarket.com

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