

Basel, 7 November 2008

Tarceva brings new hope to patients with advanced non-small cell lung cancer **Study confirms earlier Tarceva treatment delays lung cancer progression**

Roche today announced that the SATURN (SequentiAl Tarceva in UnResectable NSCLC) study met its primary endpoint of progression free survival. The study showed that Tarceva (erlotinib), when given in first line maintenance - immediately following initial treatment with platinum-based chemotherapy - , significantly extended the time patients with advanced non-small cell lung cancer (NSCLC) lived without their cancer getting worse.

Trial investigator, Prof. F. Cappuzzo, MD, *Istituto Clinico Humanitas IRCCS, Milan, Italy*, commented: "Lung cancer patients need options to stop the rapid progress of this disease without the side effects of chemotherapy. SATURN shows that Tarceva provides this option and gives new hope to patients and their families."

"Tarceva is already proven to work in patients with advanced lung cancer whose previous treatment has failed," said William M. Burns, CEO of the Pharmaceuticals Division at Roche. "This data indicates a role for Tarceva as first-line maintenance treatment for this difficult-to-treat disease to help patients further delay the progression of their cancer."

Lung cancer is the most common cancer worldwide with 1.4 million new cases annually¹, and NSCLC accounts for almost 80 percent of all lung cancers. Extending the time patients live without their disease progressing and managing side effects are key treatment goals, so the results of the SATURN study are significant for both physicians and their patients.

The SATURN study results are being fully analyzed and will be presented at a future medical meeting. Roche will discuss with regulatory agencies the data and plans for filing of a new indication for Tarceva.

In a collaboration with OSI Pharmaceuticals and Genentech, Roche will continue an extensive development program of more than 130 clinical studies with Tarceva at earlier stages of the disease and in combination

with other treatments including Avastin to further evaluate Tarceva's life-extending benefits for patients with NSCLC lung cancer.

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 SATURN

SATURN is a multicenter, double-blind, randomized, prospective phase III study to evaluate the efficacy of Tarceva or placebo in patients with advanced, recurrent (stage IIIB) or metastatic (stage IV) non-small cell lung cancer (NSCLC) who have not progressed following first-line platinum-based chemotherapy. The study involved 889 patients from approximately 160 centers worldwide.

About Avastin

Avastin-based therapy is shown to improve overall survival in previously untreated patients with NSCLC and has the longest overall survival reported in clinical trials in that setting.

Avastin is currently licensed in combination with platinum-based chemotherapy for the first-line treatment of patients with advanced non-squamous NSCLC until disease progression. Avastin combined with chemotherapy is the standard of care for eligible patients in first-line NSCLC.

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.

Ongoing and planned phase III studies in Tarceva's development program include:

- ATLAS, a randomized phase III trial evaluating the combination of Tarceva and Avastin as a first-line maintenance treatment in patients with advanced NSCLC compared to Avastin alone
- RADIANT, a phase III trial of Tarceva in patients with NSCLC who have undergone surgery to remove EGFR-positive tumors.

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.

All trademarks used or mentioned in this release are legally protected.

Contact Information

For more information on SATURN and Tarceva or to arrange an interview with Professor Cappuzzo, please contact:

Roche Group Media Relations

Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com

- Daniel Piller (Head)
- Alexander Klauser
- Martina Rupp
- Claudia Schmitt
- Elina Ämmälä

References

1. Parkin, DM, et al. Global cancer statistics 2002. CA Cancer J Clin, 2005; 55: 74-108.