

Basel, 13 July 2009

New data from phase III SATURN study shows Tarceva improves overall survival when used immediately after initial chemotherapy in patients with advanced lung cancer

Roche announced today that SATURN, a pivotal Phase III study, met a key secondary endpoint of extending overall survival in patients with advanced non-small cell lung cancer (NSCLC) who received Tarceva (erlotinib) immediately after their initial chemotherapy. A statistically significant improvement in overall survival was seen in the pre-planned final analysis of the total patient population in the study. The new data will be presented during the 13th World Conference on Lung Cancer to be held July 31 – August 4, 2009 in San Francisco.

Treating patients immediately following first-line chemotherapy versus waiting for the cancer to grow or spread before giving additional treatment represents a new approach in advanced NSCLC.

“This study has now not only confirmed that immediate treatment with Tarceva after initial chemotherapy delayed the progression of disease, but also importantly helped patients in the study live longer,” said Professor Federico Cappuzzo, M.D., Istituto Clinico Humanitas IRCCS, Milan and principal investigator of the SATURN study. “This is good news for doctors and their patients since advanced lung cancer is one of the most challenging cancers to treat and is often associated with a very short life-expectancy.”

Commenting on the study, William M. Burns, CEO Division Roche Pharmaceuticals said, “This is the second set of data from large studies that has shown Tarceva helps patients with advanced lung cancer to live longer. These results confirm that Tarceva has an important role to play in improving the lives of patients earlier in the management of this devastating disease.”

Tarceva is already a well established treatment in second-line management of advanced NSCLC after the failure of chemotherapy and is proven to extend survival for a broad range of patients in this setting.¹ Most recently presentation of the SATURN primary endpoint data analysis at ASCO 2009 showed that patients who received treatment with Tarceva immediately after initial chemotherapy if their cancer had not

progressed had a 41% improvement in the length of time they lived without their disease getting worse compared to placebo.²

Roche and OSI, its US collaborator for Tarceva, will use the overall survival data to support their European and US applications for use of Tarceva as a first-line maintenance treatment for patients with advanced NSCLC. These applications were made to the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) in March 2009 and are based on the pivotal Phase III SATURN trial.

Lung cancer is the most common cancer worldwide with 1.5 million new cases annually³ and NSCLC accounts for almost 85 percent of all lung cancers⁴. NSCLC progresses rapidly; less than 5% of advanced NSCLC patients survive for five years⁴. Extending the time patients live and managing side effects are key treatment goals.

About SATURN

A global multicentre, double blind, randomised, prospective phase III study to evaluate the efficacy of Tarceva or placebo in patients with advanced, recurrent or metastatic NSCLC who had not progressed following first line platinum-based chemotherapy. The study involved more than 880 patients from approximately 160 centres; 438 received Tarceva and 451 placebo.

- The study met its primary endpoint demonstrating a statistically significant extension of the time patients live without their disease worsening; there was a 41% increase compared with placebo (hazard ratio= 0.71. p-value <0.0001).
- Overall survival was a secondary end-point in the study.
- Adverse events in the SATURN study were consistent with previous Tarceva studies and no new safety signals were observed.

About Tarceva

Tarceva is different from conventional chemotherapies and has been shown to potently inhibit EGFR. It is the first and 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 side effects associated with 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 250,000 patients and has been approved in over 80 countries worldwide.

About Roche

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Note to Editors

Recently announced results from the phase III ATLAS study supported findings in the SATURN study.⁵ ATLAS showed that combined treatment with Avastin (bevacizumab) and Tarceva, immediately following initial therapy with Avastin plus chemotherapy was highly effective and significantly delayed disease progression for patients with advanced NSCLC, without the need for chemotherapy.

References

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- ¹ Shepherd FA et al. N Engl J Med 2005; 353:123-132.
 - ² Cappuzzo F et al. Abstract 8001 presented at ASCO 2009 Annual Meeting, Orlando, US.
 - ³ Garcia M et al. Global Cancer Facts & Figures. Atlanta, GA: American Cancer Society, 2007.
 - ⁴ Allen J et al. J Natl Compr Canc Netw 2008; 6(3): 285-93.
 - ⁵ Miller V et al. Abstract LBA8002 presented at ASCO 2009 Annual Meeting, Orlando, US.