Genentech

# NEWS RELEASE


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## TARCEVA NEARLY DOUBLED THE TIME PEOPLE WITH A GENETICALLY DISTINCT TYPE OF LUNG CANCER LIVED WITHOUT THEIR DISEASE GETTING WORSE

**SOUTH SAN FRANCISCO, Calif. – June 2, 2011 –** Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY) and Astellas Pharma US, Inc. ("Astellas"), today announced results of EURTAC, the first Phase III study with Tarceva® (erlotinib) in Western patients with a genetically distinct type of advanced non-small cell lung cancer (NSCLC). EURTAC showed that first-line Tarceva nearly doubled the time people with NSCLC with EGFR activating mutations lived without their disease getting worse compared with chemotherapy (median progression-free survival or PFS: 9.7 months compared to 5.2 months). Tarceva significantly reduced the risk of the disease getting worse by 63 percent compared with standard chemotherapy (hazard ratio=0.37, $p<0.0001$). The safety profile for Tarceva was consistent with previous studies in NSCLC. These new data are being presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) taking place in Chicago, June 3 to 7, 2011.

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The genetically distinct type of lung cancer studied in EURTAC (epidermal growth factor receptor, or EGFR, activating mutation-positive NSCLC) occurs in approximately 10 percent of lung cancer patients in the Western population and approximately 30 percent of Asian patients. Similar results were observed in another Phase III trial (OPTIMAL) conducted in Asian patients with this form of NSCLC.

“Two studies have now shown that Tarceva as a first-line therapy for EGFR mutation-positive advanced lung cancer increased the time people lived without cancer worsening compared with standard chemotherapy,” said Hal Barron, M.D., chief medical officer and head, Global Product Development, Roche. “This is an important step forward in our goal of providing personalized options for people with advanced lung cancer.”

“We are pleased with the results from the EURTAC study, which is promising for patients with this genetically distinct type of NSCLC," said Steve Ryder, president of Astellas Pharma Global Development. “The data from the EURTAC study reinforces the role that Tarceva may have in NSCLC patients with a once-a-day oral pill and a known toleration profile.”

Roche has applied to the European Medicines Agency (EMA) to extend the current EU label for Tarceva to include first-line use in people with advanced EGFR activating mutation-positive NSCLC. Discussions are ongoing with the U.S. Food and Drug Administration (FDA) regarding a submission that will include the use of a companion diagnostic test to help identify patients with activating EGFR mutations who are appropriate candidates for Tarceva.

**About the EURTAC Study**

- EURTAC (European Randomised Trial of Tarceva vs. Chemotherapy) was designed and sponsored by the Spanish Lung Cancer Group (SLCG) and conducted together with investigators from France and Italy in cooperation with Roche.
- From February 2007 to January 2011, 1,275 patients were screened for EGFR activating mutations and 174 patients were randomly assigned to receive Tarceva or platinum-based chemotherapy. The primary endpoint was investigator-assessed PFS. Secondary endpoints included response, overall survival (OS) and toxicity profiles.
- The trial was stopped at a pre-planned interim analysis because the study met its primary endpoint.
- Updated data showed that Tarceva nearly doubled median PFS compared to platinum-based chemotherapy (9.7 months compared to 5.2 months respectively) and reduced the risk of lung cancer getting worse by 63 percent (hazard ratio=0.37, $p<0.0001$; a hazard ratio of less than one indicates a decreased risk of disease progression and a p-value of less than 0.05 indicates statistical significance).
- The safety profile for Tarceva in the EURTAC study was consistent with previous studies of Tarceva in NSCLC.
- The most common adverse events with Tarceva were rash, diarrhea and liver enzyme (ALT) elevation. Serious (Grade 3 or 4) adverse events that occurred more often in patients who received Tarceva compared to those who received chemotherapy were rash, diarrhea and ALT elevation. One death related to use was reported for a patient who received Tarceva.

**About EGFR in Lung Cancer**

EGFR is a protein that extends across the cell membrane. The epidermal growth factor (EGF) binds to the part of the EGFR protein that sits on the outside of the cell. Binding leads to activation of the EGFR protein which triggers a complex signaling cascade inside the cell that leads to events including accelerated cell growth and division and development of metastases (tumor growth and spread to other parts of the body). Some NSCLC tumors have activating mutations in the EGFR gene, changing the structure of the EGFR proteins such that they have increased activity.

**About Tarceva**

Tarceva is approved for patients with advanced NSCLC whose cancer has not spread or grown after initial treatment with certain types of chemotherapy (maintenance treatment). Tarceva is also approved for patients with advanced NSCLC whose cancer has spread or grown after receiving at least one chemotherapy regimen (second-/third-line treatment). Tarceva is not meant to be used at the same time as certain types of chemotherapy for NSCLC.

**Important Safety Information for Tarceva in Advanced NSCLC**

There have been reports of serious Interstitial Lung Disease (ILD)-like events including deaths in patients taking Tarceva. Serious side effects (including deaths) in patients taking Tarceva include liver and/or kidney problems; gastrointestinal (GI) perforations (the development of a hole in the stomach, small intestine, or large intestine); and severe blistering skin reactions including cases similar to Stevens-Johnson syndrome.

Eye irritation and damage to the cornea have been reported in patients taking Tarceva. Difficulty with blood clotting, and bleeding events, including gastrointestinal

and non-gastrointestinal bleeding have been reported in clinical studies. Women should avoid becoming pregnant and avoid breastfeeding while taking Tarceva. Patients should call their doctor right away if they have these signs or symptoms: new or worsening skin rash; serious or ongoing diarrhea, nausea, loss of appetite, vomiting, or stomach pain; new or worsening shortness of breath or cough; fever; eye irritation. Rash and diarrhea were the most common side effects associated with Tarceva in the NSCLC clinical studies.

For full prescribing information on Tarceva, please visit http://www.tarceva.com.

Tarceva is a registered trademark of OSI Pharmaceuticals, LLC, a member of the Astellas global group of companies.

**About SLCG**

The Spanish Lung Cancer Group is a multi-center, multidisciplinary cooperative working group. SLCG affiliates are based in 135 centers in Spain including basic researchers, thoracic surgeons, pathologists, radiotherapists and medical oncologists. SLCG is committed to independent academic research and has included more than 10,000 patients in different studies and trials. In SLCG trials translational research and customized treatment based on genetics are the main priorities.

**About Astellas**

Astellas Pharma US, Inc., located in Deerfield, Illinois, is a U.S. affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable

pharmaceutical products. The organization is committed to becoming a global category leader in focused areas by combining outstanding R&D and marketing capabilities. In the U.S., Astellas markets products in the areas of Anti-Infectives, Cardiology, Dermatology, Neuroscience, Transplant, Oncology and Urology. For more information about Astellas Pharma US, Inc., please visit our website at http://www.astellas.us or follow us on Twitter at http://www.Twitter.com/AstellasUS.

**About Genentech**

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit http://www.gene.com.

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