

Genentech

NEWS RELEASE

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EARLY SUCCESSFUL READOUT OF TARCEVA STUDY IN A DISTINCT FORM OF LUNG CANCER

-- EURTAC is the First Phase III Study to Show Progression-Free Survival Benefit of First-Line Tarceva in a Western Population with Advanced Lung Cancer With EGFR Mutations --

SOUTH SAN FRANCISCO, Calif., MELVILLE, New York and TOKYO – January 27, 2011 – Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY) and OSI Pharmaceuticals, a wholly owned subsidiary of Astellas U.S. Holding Inc., a holding company owned by Astellas Pharma Inc., today announced that an independent data monitoring committee has recommended that the Phase III EURTAC study be stopped early because the study met its primary endpoint. At a planned interim analysis it was shown that compared to platinum-based chemotherapy, Tarceva® (erlotinib) significantly extended the time people with newly diagnosed advanced non-small cell lung cancer (NSCLC) with EGFR (epidermal growth factor receptor) activating mutations lived without their disease getting worse (progression-free survival or PFS). A preliminary safety analysis showed the safety profile was consistent with previous studies of Tarceva. Data will be submitted for presentation at a future medical meeting.

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The European Randomized Trial of Tarceva vs. Chemotherapy (EURTAC), which has been designed and sponsored by the Spanish Lung Cancer Group (SLCG) and conducted together with investigators from France and Italy, in cooperation with Roche, is the first Phase III study in a Western population with this distinct form of lung cancer. A similar study (OPTIMAL) has been carried out in an Asian population.

“The EURTAC study demonstrates that testing for EGFR activating mutations can identify people who may be candidates to receive Tarceva as their initial treatment for advanced lung cancer,” said Hal Barron, M.D., chief medical officer and head, Global Product Development, Roche. “We are encouraged by these results and look forward to discussing them with health authorities around the world.”

"We are pleased that the EURTAC study so quickly revealed Tarceva may be a viable alternative to platinum-based chemotherapy in newly diagnosed NSCLC patients with EGFR activating mutations," said Naoki Okamura, chief executive officer, OSI Pharmaceuticals. "The interim analysis of the EURTAC study reinforces the role that Tarceva may have in treating patients beyond the Asian population, which has a historically higher instance of EGFR activating mutations."

In June 2010, Roche applied to the European Medicines Agency (EMA) to extend the current label for Tarceva to include the first-line treatment of people with advanced NSCLC whose tumors harbor EGFR activating mutations. Based on the EURTAC study data, OSI and Genentech plan to discuss similar updates to the Tarceva label with the U.S. Food and Drug Administration (FDA). Roche and OSI will also collaborate

regarding submissions with other health authorities. It is estimated that as many as one in 10 (10 percent) lung cancer patients in the Western population and one in three (30 percent) Asian patients with lung cancer have NSCLC with EGFR activating mutations.

Roche Molecular Systems and OSI are collaborating on the development of a PCR-based companion diagnostic test to identify people with NSCLC that harbors EGFR activating mutations.

About the EURTAC Study

- EURTAC is a prospective, randomized, controlled Phase III trial evaluating the first-line use of Tarceva versus platinum-based chemotherapy in patients with advanced NSCLC with EGFR activating mutations.
- The primary endpoint is progression-free survival. Secondary endpoints include overall survival, one-year survival, objective response rate and safety profile.
- The platinum-based chemotherapy regimens used are cisplatin/gemcitabine; cisplatin/docetaxel; carboplatin/gemcitabine; and carboplatin/docetaxel.

About EGFR in Lung Cancer

EGFR is a protein that extends across the cell membrane. The epidermal growth factor 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 that they code for such that they have increased activity.

About Tarceva

Tarceva is a once-a-day pill that targets the EGFR pathway. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cancer cell, one of the critical growth factors in NSCLC and pancreatic cancer. The way Tarceva works to treat cancer is not fully known.

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

Tarceva is also prescribed in combination with gemcitabine for people with advanced-stage pancreatic cancer whose cancer has spread, grown, or cannot be surgically removed, and who have not received previous chemotherapy.

Tarceva is being developed and commercialized by OSI in partnership with Genentech in the United States, Chugai in Japan, and Roche in the rest of the world.

Important Safety Information For Tarceva

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.

Patients taking Tarceva plus gemcitabine were more likely to experience bleeding and clotting problems such as heart attack or stroke. Eye irritation and damage to the cornea have been reported in patients taking Tarceva. Bleeding and clotting problems, 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. Fatigue, rash, nausea, loss of appetite, and diarrhea were the most common side effects associated with Tarceva plus gemcitabine therapy in the pancreatic cancer clinical study.

For full prescribing information, please call 1-877-TARCEVA or visit <http://www.tarceva.com>.

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>.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by

discovering, developing and commercializing high-quality, novel and differentiated targeted medicines designed to extend life and improve the quality of life for patients with cancer and diabetes/obesity. Tarceva was discovered by a collaboration between OSI and a third party pharmaceutical company.

In June 2010, OSI Pharmaceuticals, Inc. became a wholly owned subsidiary of Astellas U.S. Holding, Inc., which is part of the Astellas U.S. group of companies (Astellas). For additional information about OSI, please visit <http://www.osip.com>.

Tarceva is a registered trademark of OSI Pharmaceuticals, Inc.

About The Spanish Lung Cancer Group

The SLCG is a multicenter, 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.

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