Genentech Contacts:
Media: Holli Dickson (650) 467-6800
Advocacy: Jen Mills (650) 467-6722
Investors: Thomas Kudsk Larsen (650) 467-2016
Karl Mahler 011 41 61 687 8503

Astellas Contacts:
Media: Jenny Kite (224) 205-5405

FDA APPROVES TARCEVA (ERLOTINIB) TABLETS AND COBAS EGFR MUTATION TEST FOR SPECIFIC TYPE OF LUNG CANCER

-- Tarceva is the First Personalized Medicine Approved for the Initial Treatment of People with EGFR Mutation-Positive Advanced Non-Small Cell Lung Cancer in the United States --

SOUTH SAN FRANCISCO, Calif. and NORTHBROOK, Ill. – May 14, 2013 – Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY) and Astellas Pharma US, Inc. ("Astellas"), a U.S. subsidiary of Tokyo-based Astellas Pharma Inc. (Tokyo: 4503), today announced that the U.S. Food and Drug Administration (FDA) has approved Tarceva® (erlotinib) tablets for the initial (first-line) treatment of people with metastatic non-small cell lung cancer (NSCLC) whose tumors have certain epidermal growth factor receptor (EGFR) activating mutations as detected by an FDA-approved test. The FDA also approved the cobas® EGFR Mutation Test, which was developed by Roche and validated in the pivotal EURTAC study. In the study, treatment with Tarceva demonstrated that patients lived longer without their disease getting worse (median progression-free survival [PFS] 10.4 months vs. 5.2 months; HR=0.34; p<0.001 [95 percent CI 0.23 to 0.49]) compared to chemotherapy. The safety profile for Tarceva in the EURTAC study was consistent with previous

studies of Tarceva in NSCLC.

“Ten to 30 percent of people worldwide with lung cancer have tumors that test positive for certain EGFR mutations,” said Hal Barron, M.D., chief medical officer and head, Genentech Global Product Development. “People with this type of lung cancer now have the option to use a personalized medicine as their initial treatment to help them live longer without their disease worsening.”

“With this approval, more patients across all lines of therapy have access to Tarceva,” said Sef Kurstjens, M.D., chief medical officer, Astellas Pharma Inc. “This new indication is emblematic of Astellas’ commitment to continue our development efforts in lung cancer and precision medicine.”

“Increasingly, doctors and patients rely on diagnostics to help guide personalized treatment decisions. The approval of the cobas EGFR Mutation Test highlights the importance of sensitive, accurate tests that can be conducted in time to inform crucial treatment decisions,” said Paul Brown, head of Roche Molecular Diagnostics. “At Roche, we have a deep commitment to providing personalized healthcare options and are currently developing companion diagnostics for more than half of the medicines in our pipeline.”

In the United States, Tarceva is already approved, irrespective of histology or biomarker status for people with advanced-stage 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-stage NSCLC whose cancer 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

certain types of chemotherapy for advanced NSCLC.

This latest FDA approval for Tarceva is based on the results of the Phase III EURTAC study, which evaluated the first-line use of Tarceva versus platinum-based chemotherapy in people with EGFR-activating mutation-positive advanced NSCLC. Tumor shrinkage (response rate) was observed in 65 percent of patients treated with Tarceva and 16 percent of patients treated with chemotherapy. The most frequent (greater than or equal to 30 percent) adverse events in Tarceva-treated patients were diarrhea, weakness, rash, cough, shortness of breath and decreased appetite. The most frequent Grade 3-4 reactions in Tarceva-treated patients were rash and diarrhea.

About the EURTAC Study

- EURTAC (European Randomized Trial of Tarceva versus Chemotherapy) was designed and sponsored by the Spanish Lung Cancer Group (SLCG) and conducted in Spain, France and Italy in cooperation with Roche.
- The cobas EGFR Mutation Test was used to confirm people with mutations (exon 19 deletion or exon 21 [L858R] substitution) in the EGFR gene.
- From February 2007 to January 2011, 174 patients mostly of European descent were randomly assigned to receive Tarceva or platinum-based chemotherapy. The primary endpoint was investigator-assessed PFS.
- Randomization was stratified by certain EGFR mutations and ECOG performance status (0 vs. 1 vs. 2).
- The safety profile for Tarceva in the EURTAC study was consistent with previous studies of Tarceva in NSCLC.
- The most frequent (greater than or equal to 30 percent) adverse events in Tarceva-treated patients were diarrhea, weakness, rash, cough, shortness of breath and

decreased appetite. The most frequent Grade 3-4 reactions in Tarceva-treated patients were rash and diarrhea.

About Lung Cancer

According to the American Cancer Society, it is estimated that more than 228,000 Americans will be diagnosed with lung cancer in 2013, and NSCLC accounts for 85 percent of all lung cancers. It is estimated that approximately 60 percent of lung cancer diagnoses are made when the disease is in the advanced stages.

About EGFR in Lung Cancer

EGFR is a protein that extends across the cell surface. 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 cobas EGFR Mutation Test

The cobas EGFR Mutation Test is a real-time, polymerase chain reaction-based diagnostic test for the qualitative detection and identification of exon 19 deletion or exon 21 (L858R) substitution mutations in the EGFR gene in DNA derived from formalin-fixed, paraffin-embedded tumor (FFPET) tissue from NSCLC patients. The test is intended to be used to identify patients with advanced NSCLC whose tumors harbor these certain types of mutations.

About Genentech Access Solutions

Genentech is committed to people having access to our medicines. Genentech Access Solutions is a team of more than 350 Genentech employees who help those who need our medicines. Our knowledgeable and experienced specialists can help patients and medical practices navigate the access and reimbursement process and provide assistance to eligible patients in the United States who do not have insurance coverage or who cannot afford their out-of-pocket co-pay costs. For more information, please visit http://www.Genentech-Access.com.

About Tarceva

Tarceva is a once-daily, oral non-chemotherapy medicine for the treatment of advanced or metastatic NSCLC. It has been shown to inhibit EGFR, a protein involved in the growth and development of cancers. Tarceva is a trademark of OSI Pharmaceuticals, LLC, Farmingdale, NY, USA, an affiliate of Astellas Pharma US, Inc. In the United States, Tarceva is jointly marketed by Astellas and Genentech, a member of the Roche Group.

Tarceva Indications in NSCLC

First-Line, Maintenance Therapy, and Second- or Third-Line Therapy in Advanced Non-Small Cell Lung Cancer (NSCLC):

- Tarceva is prescribed as initial treatment for patients with NSCLC, whose cancer has spread to other parts of the body, that has certain types of Epidermal Growth Factor Receptor (EGFR) mutations. (First-line treatment)
- Tarceva is prescribed for patients with advanced-stage non-small cell lung cancer (NSCLC) whose cancer has not spread or grown after initial treatment with certain types of chemotherapy. (Maintenance treatment)

- Tarceva is prescribed for patients with advanced-stage (NSCLC) whose cancer has spread or grown after receiving at least 1 chemotherapy regimen. (Second/Third-line treatment)

Limitations of Use

- Tarceva is not meant to be used at the same time as certain types of chemotherapy for advanced NSCLC.
- For Initial treatment with NSCLC whose cancer has not spread to other parts of the body, it is not known if Tarceva is safe and effective in other EGFR mutations.

Important Safety Information

The following serious adverse reactions, which may include deaths, were reported in patients taking Tarceva: Interstitial Lung Disease (ILD)-like events; Liver and/or kidney problems; Gastrointestinal (GI) perforations (the development of a hole in the stomach, small intestine, or large intestine); Serious skin conditions; Bleeding and clotting problems (Heart attack or stroke); Eye disorders (eye irritation and damage to the cornea); Bleeding events when taking warfarin or non-steroidal anti-inflammatory drugs (NSAIDs); Pregnancy (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: Serious or ongoing diarrhea, nausea, loss of appetite, or vomiting; New or worsening shortness of breath or cough; Eye irritation; New or worsening skin rash, blistering or skin peeling; Any changes in smoking habits.

The most common, but less serious side effects include:

First-line NSCLC treatment: Diarrhea, weakness, rash, cough, shortness of breath, and loss of appetite.

Maintenance/Second- or Third-Line NSCLC treatment: Rash and diarrhea.

Report side effects to the FDA at (800) FDA-1088 or http://www.fda.gov/medwatch.

Patients and caregivers may also report side effects to Genentech at (888) 835-2555.

For full prescribing information, please call (877) TARCEVA or visit http://www.tarceva.com.

About Astellas

Astellas Pharma US, Inc., located in Northbrook, 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 oncology, and has several oncology products on the market and compounds in development. Astellas is proud to be an award recipient of the CEO Gold Standard Accreditation from the CEO Roundtable on Cancer. For more information on Astellas Pharma Inc., please visit our website at http://www.astellas.us.

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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