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FDA ACCEPTS SUPPLEMENTAL NEW DRUG APPLICATION FOR TARCEVA® (ERLOTINIB) TABLETS FOR GENETICALLY DISTINCT FORM OF ADVANCED LUNG CANCER

– The Tarceva application has been granted priority review –

NORTHBROOK, Ill. – January 16, 2013 – 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 accepted for filing a supplemental New Drug Application (sNDA) for Tarceva® (erlotinib) for first-line use in people with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) activating mutations. The application has been granted Priority Review status, and an FDA decision is expected in the second quarter of 2013. A pre-market approval (PMA) application for a companion diagnostic, the cobas® EGFR Mutation Test developed by Roche Molecular Diagnostics, has also been submitted to the FDA.

"We are pleased the FDA granted an expedited six-month review of our application because lung cancer is one of the most common and deadly cancers," said Stephen Eck, M.D., Ph.D., vice president, head of Medical Oncology, Astellas Pharma Global Development, Inc. "We are proud of Tarceva's already approved indications for the maintenance and relapsed advanced NSCLC settings. If approved, people with a genetically distinct form of lung cancer could have a potential new personalized medicine for use as a first-line treatment."

It is estimated that as many as one in 10 (10 percent) people in Western populations with lung cancer and three in 10 (30 percent) Asian people with lung cancer have EGFR activating mutations.

The sNDA submission is based on results of the international EURTAC trial, a prospective, randomized, controlled Phase 3 trial evaluating the first-line use of Tarceva versus platinum-based chemotherapy in patients with EGFR activating mutation-positive advanced NSCLC.

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 in Spain, France and Italy in cooperation with Roche.
- From February 2007 to January 2011, 174 predominantly Caucasian patients were randomly assigned to receive Tarceva or platinum-based chemotherapy. The primary endpoint was investigator-assessed progression-free survival (PFS).

About Lung Cancer

In 2012, it was estimated that more than 226,000 Americans would be diagnosed with lung cancer, 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 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
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); severe blistering skin reactions including cases similar to Stevens-Johnson syndrome; and bleeding events including GI and non-GI bleeding when taking warfarin or non-steroidal anti-inflammatory drugs (NSAIDs). Eye irritation and damage to the cornea have been reported in patients taking Tarceva. 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; or eye irritation. Rash and diarrhea were the most common side effects associated with Tarceva in the advanced NSCLC clinical studies.

Report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch.
Patients and caregivers may also report side effects to Genentech at (888) 835-2555.

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

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.

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 www.astellas.us.

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