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FDA Extends Review Period for Tarceva Application for First-Line Maintenance Use in Advanced Non-Small Cell Lung Cancer

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif., Jan 15, 2010 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) and Genentech, Inc., a wholly owned member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), announced today that the U.S. Food and Drug Administration (FDA) has extended the review period for the supplemental New Drug Application (sNDA) for Tarceva(R) (erlotinib) as a first-line maintenance therapy in advanced non-small cell lung cancer (NSCLC) by an additional 90 days. The extension follows OSI's submission of further data in support of the application. The original Prescription Drug User Fee Act (PDUFA) date was January 18, 2010. The companies now anticipate FDA action on the sNDA by April 18, 2010.

OSI and Genentech will work closely with the FDA during this extended review period.

About SATURN

SATURN was an international, placebo-controlled, randomized, double-blinded, Phase III study that enrolled 889 patients with advanced NSCLC at approximately 160 sites worldwide. Patients were treated with four cycles of standard first-line platinum-based chemotherapy and then randomized to Tarceva or placebo if the cancer did not progress. The co-primary endpoints were progression-free survival (PFS) in all patients and PFS in patients whose tumors over-expressed the epidermal growth factor receptor (EGFR) as assessed by Immunohistochemistry (IHC). PFS was defined as the length of time from randomization to disease progression or death from any cause. Secondary endpoints included overall survival, safety and an evaluation of exploratory biomarkers.

About Lung Cancer

According to the American Cancer Society, lung cancer is the leading cause of cancer death in the United States. It is estimated approximately 159,000 Americans died from the disease in 2009. Most people are diagnosed with advanced stage disease and only 15 percent survive five years. NSCLC is the most common type of lung cancer.

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. Tarceva is indicated as a monotherapy for people with locally advanced or metastatic NSCLC whose disease has progressed after one or more courses of chemotherapy. Tarceva is not intended to be used at the same time as chemotherapy for NSCLC.

Tarceva is also indicated in combination with gemcitabine chemotherapy for the first-line treatment of people with locally advanced pancreatic cancer, pancreatic cancer that cannot be surgically removed or pancreatic cancer that has spread to distant body organs.

Tarceva Safety

There have been infrequent 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. 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 study. 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 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. For additional information about OSI, please visit http://www.osip.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 wholly owned member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit http://www.gene.com.

OSI Safe Harbor Statement

This news release contains forward-looking statements. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made.Factors that might cause such a difference include, among others, OSI's and its collaborators' abilities to effectively market and sell Tarceva and to expand the approved indications for Tarceva, OSI's ability to protect its intellectual property rights, safety concerns regarding Tarceva,competition to Tarceva and OSI's drug candidatesfrom other biotechnology andpharmaceutical companies, the completion of clinical trials, the effects of FDA and other governmental regulation, including pricing controls,OSI's ability to successfully develop and commercialize drug candidates, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.

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