

FDA Advisory Committee Recommends Against Approving Tarceva for First-Line Maintenance Use in Advanced Non-Small Cell Lung Cancer

GAITHERSBURG, Md., Dec 16, 2009 (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) Oncologic Drugs Advisory Committee (ODAC) voted 12 to one recommending against approval of the daily pill Tarceva^(R) (erlotinib) for first-line maintenance use in people with advanced or metastatic non-small cell lung cancer (NSCLC) whose cancer has not progressed (grown or spread) following first-line treatment with platinum-based chemotherapy. The FDA is not bound by the recommendations of its advisory committees and the agency is expected to make a decision whether to approve Tarceva for this use by January 18, 2010.

"We are disappointed with the Committee's recommendation and will work diligently to respond to the issues that arose today as quickly as possible," said Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We continue to believe that having an oral, well-tolerated treatment option that can maintain the initial benefit from cytotoxic chemotherapy would be an important advance in treating advanced lung cancer and will explore further with regulatory agencies how best to pursue this outcome."

"We continue to hope Tarceva may be an option that could help more people with advanced non-small cell lung cancer live longer without the disease getting worse," said Hal Barron, M.D., executive vice president, Global Development and chief medical officer, Genentech. "We will work closely with OSI to carefully review and address the Committee's comments."

The ODAC recommendation was based on a review of data from the pivotal Phase III SATURN study which showed a statistically significant improvement in both progression-free survival (PFS) and overall survival (OS) with Tarceva compared to placebo in the NSCLC maintenance setting. There were no new or unexpected safety signals in the study and adverse events were consistent with those previously reported for Tarceva in NSCLC.

- People who received Tarceva had a 41 percent improvement in the likelihood of living without the disease getting worse (PFS, the primary endpoint) compared to placebo (hazard ratio=0.71, 29 percent reduction in the risk of cancer progression or death, $p<0.0001$; median PFS 12.3 weeks vs. 11.1 weeks).
- People whose tumors over-expressed the epidermal growth factor receptor (EGFR) as assessed by Immunohistochemistry (IHC) who received Tarceva had a 45 percent improvement in PFS compared to placebo (the co-primary endpoint; hazard ratio=0.69, 31 percent reduction in the risk of cancer progression or death, $p<0.0001$; median PFS 12.3 weeks vs. 11.1 weeks).
- OS, a key secondary endpoint, was also significantly improved by 23 percent with Tarceva compared to placebo (hazard ratio=0.81, 19 percent reduction in the risk of death, $p=0.0088$; median OS 12.0 months vs. 11.0 months).
- The most commonly reported adverse events in patients who received Tarceva were rash (49 percent) and diarrhea (20 percent). Grade 3 rash and diarrhea were experienced by six percent and two percent of patients, respectively. There were no cases of Grade 4 rash or diarrhea.

About SATURN

SATURN was an international, placebo-controlled, randomized, double-blind, 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 PFS in all patients and PFS in patients whose tumors over-expressed EGFR as assessed by IHC. PFS was defined as the length of time from randomization to disease progression or death from any cause. Secondary endpoints included OS, 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. In 2009, approximately 159,000 Americans will die from the disease. 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 patients 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.

In pancreatic cancer, Tarceva is indicated in combination with gemcitabine chemotherapy for the first-line treatment of patients 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>.

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 candidates from other biotechnology and pharmaceutical 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.

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=6122682&lang=en>

SOURCE: OSI Pharmaceuticals, Inc. and Genentech, Inc.

OSI Pharmaceuticals, Inc.

Media/Investor:

Kathy Galante, 631-962-2043

or

Media:

Kim Wittig, 631-962-2135

or

Genentech, Inc.

Media:

Charlotte Arnold, 650-467-6800

or

Advocacy:

Kristin Olson, 650-467-9219

or

Investor:

Susan Morris, 650-225-6334

or

Karl Mahler, 011 41 61 687 85 03

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