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OSI Pharmaceuticals Announces That "RADIANT", an International Phase III Tarceva Adjuvant Trial in Non-Small Cell Lung Cancer, Completes Enrollment

MELVILLE, N.Y., Apr 26, 2010 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that it has completed enrollment in the RADIANT study, a Phase III clinical trial testing Tarceva® (erlotinib) as an adjuvant therapy in patients with Stage IB-IIIA non-small cell lung cancer (NSCLC) who have undergone surgery and have EGFR-positive tumors. RADIANT is an international, randomized, double-blinded, placebo-controlled Phase III study that has reached its enrollment goal of 945 patients. The primary objective of the study is to determine whether the targeted therapy Tarceva prolongs disease-free survival when given as an adjuvant therapy. This is defined as a cancer treatment that is given after the primary treatment, which is typically surgery or surgery and chemotherapy in this group of NSCLC patients, to lower the risk of the cancer coming back.

"We believe an oral therapy like Tarceva can be a valuable addition to the treatment paradigm by extending the disease-free survival of patients with Stage Ib-IIIa NSCLC," said Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "The study has received considerable interest from both investigators and patients and we look forward to the potential for interim results in 2012 and final results in 2013-2014."

About RADIANT

RADIANT is being conducted at approximately 240 sites in the United States, Canada, Western and Eastern Europe, Asia Pacific and Argentina. The study enrolled patients with surgically removed Stage IB-IIIA NSCLC who have EGFR-positive tumors, as expressed by immunohistochemistry (IHC) and/or fluorescence in-situ hybridization (FISH), and who had completed up to four cycles of standard adjuvant platinum-based chemotherapy or were chemotherapy naive. Patients were randomized 2:1 to receive either Tarceva 150 mg or placebo once daily for two years.

The primary objective of RADIANT is to evaluate the effectiveness of adjuvant therapy with Tarceva in prolonging disease-free survival. Secondary objectives of the study include comparing overall survival between study arms, evaluating the safety of adjuvant Tarceva therapy, and exploring the predictive value of EGFR-related biomarkers that may be associated with clinical outcomes following treatment with Tarceva.

About Lung Cancer

Lung cancer is the most common cancer worldwide with 1.5 million new cases annually and NSCLC accounts for almost 85% of all lung cancers. NSCLC progresses rapidly; less than 5% of advanced NSCLC patients survive for five years.

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 patients with advanced-stage NSCLC whose cancer has not grown or spread after initial treatment with certain types of chemotherapy. Tarceva is also prescribed for people with advanced-stage NSCLC whose cancer has grown or spread after receiving at least one chemotherapy regimen. Tarceva is not meant to be used at the same time as certain types of chemotherapy for NSCLC. In pancreatic cancer, Tarceva in combination with gemcitabine is prescribed for patients with advanced-stage pancreatic cancer whose cancer has spread, grown, or cannot be surgically removed, and who have not received previous chemotherapy.

Tarceva Safety

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. Difficulty with blood clotting, and bleeding events, 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 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.

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.

SOURCE: OSI Pharmaceuticals, Inc.

OSI Pharmaceuticals, Inc.
Kathy Galante (investors/media)
Senior Director
631-962-2043
or
Kim Wittig (media)
Director
631-962-2135
or
Media:
Joele Frank, Wilkinson Brimmer Katcher
Joele Frank/Andy Brimmer/Eric Brielmann
212-355-4449
or
Investors:
Burns McClellan
Lisa Burns
212-213-0006