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Data from the Phase III ATLAS Study Show Tarceva in Combination with Avastin as First-Line Maintenance Therapy Improved Progression-Free Survival in Advanced Lung Cancer

-- Study is Second Positive Phase III Trial of Tarceva as First-Line Maintenance Therapy --

ORLANDO, Fla., May 30, 2009 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that its U.S. partner for Tarceva(R) (erlotinib), Genentech, Inc., a wholly-owned member of the Roche Group, informed OSI of detailed results from a Genentech conducted Phase III study (ATLAS). The study met its primary endpoint by demonstrating that patients with advanced non-small cell lung cancer (NSCLC) who received Tarceva in combination with Avastin(R) (bevacizumab) as first-line maintenance treatment had a 39 percent improvement in the time they lived without the disease worsening (progression-free survival or PFS), compared with those who received Avastin plus placebo as an active control (hazard ratio=0.72; p=0.0012; a hazard ratio of less than one indicates a decreased risk of disease progression and a p-value of less than 0.05 indicates statistical significance). Adverse events were consistent with previous Avastin or Tarceva NSCLC studies, or trials evaluating the two medicines together.

Genentech also informed OSI that median PFS following four initial cycles of Avastin and chemotherapy was 4.8 months for patients who received the combination and 3.7 months for those who received Avastin plus placebo. Overall survival data are expected in the second half of 2009. In February 2009, it was announced that ATLAS was stopped early on the recommendation of an independent data safety monitoring board after a pre-planned interim analysis showed that combining Tarceva and Avastin significantly extended PFS, compared with Avastin plus placebo.

Results of the ATLAS study were featured today during a press briefing at the 45th annual meeting of the American Society of Clinical Oncology (ASCO). Full results will be presented tomorrow by Dr. Vincent Miller (Abstract #LBA8002 - Sunday, May 31, 2009, 9:30 a.m. - 9:45 a.m. EDT, West Hall E1).

Full results of the SATURN study, which showed that patients who received Tarceva alone as a maintenance treatment following initial chemotherapy had a statistically significant 41% improvement in PFS compared with placebo (hazard ratio=0.71, p-value <0.00001), will also be presented tomorrow (Abstract #8001 - Sunday, May 31, 2009, 9:15 a.m. - 9:30 a.m. EDT, West Hall E1).

Tarceva is currently approved as a treatment for patients with advanced NSCLC whose disease has progressed after one or more courses of chemotherapy and can be used in patients with either non-squamous or squamous cell NSCLC. Avastin is currently approved as first-line treatment in combination with carboplatin and paclitaxel chemotherapy for patients with locally advanced, non-squamous NSCLC. Both therapies have been shown to improve overall survival in these indications.

About ATLAS (AVF3671g)

ATLAS was a global, multicenter, randomized, double-blind, placebo-controlled study. Patients in the study were treated with Avastin plus four cycles of platinum-based chemotherapy. If the cancer did not progress and patients did not experience significant toxicity, patients (n=743) were then randomized to receive Avastin plus either Tarceva or placebo until progression. PFS, as assessed by investigators, was defined as the length of time from randomization to disease progression or death from any cause.

Severe (Grade 3 to 4) adverse events were observed in 44 percent of patients receiving Avastin plus Tarceva and 30 percent of patients in the Avastin only arm. The most common Grade 3 to 4 adverse events that occurred in 5 percent or more of patients treated with Avastin plus Tarceva compared with patients in the Avastin only arm were rash (10.4 percent vs. 0.5 percent), diarrhea (9.3 percent vs. 0.8 percent), high blood pressure (5.4 percent vs. 5.7 percent) and fatigue (5.4 percent vs. 2.2 percent). There were eight deaths associated with adverse events in the group of patients treated with Avastin plus Tarceva, compared with four in the Avastin plus placebo group.

The ATLAS study was funded by Genentech and Roche. Under terms of the Tripartite Agreement between OSI, Genentech and Roche, OSI may be required to make certain retrospective funding payments for the ATLAS study depending upon, amongst other things, potential submission of data to regulatory authorities or the inclusion of data from the ATLAS study in the Tarceva label.

About Lung Cancer

According to the American Cancer Society (ACS), lung cancer is the single largest cause of cancer death among men and women in the U.S. and approximately 160,000 Americans will die from the disease in 2009. NSCLC is the most common type of lung cancer.

Most people with lung cancer are diagnosed with advanced stage disease that cannot be surgically removed or has spread to other parts of the body. The majority of people with advanced lung cancer survive less than one year.

About Tarceva

Tarceva is indicated as a single agent for patients with advanced NSCLC whose disease has progressed after one or more courses of chemotherapy. Results from two multicenter, placebo-controlled, randomized Phase III trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy (carboplatin/paclitaxel or gemcitabine/cisplatin) and its use is not recommended in that setting.

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, 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 non-small cell lung cancer clinical study.

For Tarceva full prescribing information, please 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 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.

SOURCE: OSI Pharmaceuticals, Inc.

OSI Pharmaceuticals, Inc.
Kathy Galante (investors/media), 516-924-5989
or
Kim Wittig (media), 917-699-5093
Director
or
Burns McClellan, Inc. (representing OSI)
Kathy Nugent (media), 205-401-0260