(osi) pharmaceuticals

Tarceva(R) (erlotinib) Earns Approval for Lung Cancer Patients in Japan

BASEL, Switzerland & MELVILLE, N.Y.--(BUSINESS WIRE)--Oct. 22, 2007--Roche and OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that Tarceva® (erlotinib) has been approved in Japan for the treatment of patients with nonresectable, recurrent and advanced non-small cell lung cancer (NSCLC) which is aggravated following chemotherapy. The Japanese Ministry of Health approval means that lung cancer patients in Japan will now have an important new treatment, which has been demonstrated to increase overall survival and offer an improvement in quality of life. NSCLC is suffered by over one million people worldwide. It is the most common form of lung cancer and is more deadly than colon, breast, and prostate cancers combined.(1) In 2005, the number of newly diagnosed patients with NSCLC in Japan reached 85,000.(2)

Tarceva's approval in Japan is based on the submission of two Phase II studies that confirmed the safety and efficacy of Tarceva in Japanese patients, along with data from the landmark, randomized, Phase III BR.21 study which compared Tarceva to placebo in patients with advanced NSCLC after failure of at least one prior chemotherapy regimen. In this study, 31% of patients receiving Tarceva were alive at one year compared to 22% in the placebo arm and patients experienced a 42.5% improvement (6.7 months vs. 4.7 months) in the length of overall survival. In addition, significantly more patients on Tarceva had improvement in cough, pain, shortness of breath and overall physical function versus patients on placebo.(3) The BR.21 study, also published in the New England Journal of Medicine, has led to the approval of Tarceva in over 80 countries including the United States and the European Union for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

Chugai Pharmaceutical, Co., Ltd., Roche's alliance partner in Japan submitted the filing for this approval on April 14, 2006 to the Japanese Ministry of Health, Labour and Welfare. Following this formal approval, Tarceva is expected to launch in Japan by early 2008.

"Tarceva has the proven ability to prolong survival and improve quality of life in patients with the most common and deadly form of lung cancer," says William M. Burns, CEO of the Pharmaceuticals Division at Roche. "This approval in Japan underscores our commitment to ensure that eligible patients around the world will have access to this effective treatment."

"This is a huge milestone for lung cancer patients in Japan," said Gabriel Leung, President, (OSI) Oncology. "The Japanese authorities have recognized the proven benefits of Tarceva and have acted admirably to make a significant difference to local patients, caregivers and oncologists battling this devastating disease."

About Lung Cancer

According to the World Health Organization, lung cancer is the most common cancer worldwide, with 1.2 million new cases annually.(4) NSCLC accounts for almost 80 percent of all lung cancer cases.(5) In Japan specifically, the estimated incidence of lung cancer was 85,000 cases in 2005.(2)

Additional Tarceva Information

Tarceva was approved by the FDA in November 2004 and in the European Union in September 2005 as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one chemotherapy regimen. Results from two earlier large, randomized, placebo-controlled Phase III clinical trials in first-line advanced NSCLC patients showed no clinical benefit with concurrent administration of Tarceva with doublet platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

There have been infrequent reports of serious Interstitial Lung Disease (ILD)-like events, including fatalities, in patients receiving Tarceva for treatment of NSCLC, pancreatic cancer or other advanced solid tumors. In the pancreatic cancer trial, other serious adverse events associated with Tarceva plus gemcitabine and which may have included fatalities, were myocardial infarction/ischemia, cerebrovascular accident and microangiopathic hemolytic anemia with thrombocytopenia. When receiving Tarceva therapy, women should be advised against becoming pregnant or breastfeeding. Tarceva is pregnancy category D. The most common side effects in patients with NSCLC receiving Tarceva monotherapy 150 mg were rash and diarrhea. The most common side effects in patients with pancreatic cancer receiving the combination of Tarceva 100 mg plus gemcitabine were fatigue, rash, nausea, anorexia and diarrhea.

Tarceva is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, one of the factors critical to cell growth in NSCLC and other solid tumors. HER1, also known as EGFR, is a component of the HER signalling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva is designed to inhibit the tyrosine kinase activity of the HER1 signalling pathway inside the cell, which may block tumor cell growth. Tarceva is the only

HER1/EGFR-targeted therapy proven to significantly prolong survival in second-line NSCLC as a single agent.

In November 2005, the U.S. Food and Drug Administration (FDA) approved the use of Tarceva in combination with gemcitabine for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in patients who have not received previous chemotherapy. In January 2007, the European Commission granted marketing authorization for Tarceva in combination with gemcitabine for the treatment of metastatic pancreatic cancer. Tarceva is the first drug in a Phase III trial to have shown a significant improvement in overall survival when added to gemcitabine chemotherapy as an initial treatment for pancreatic cancer.

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

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolic disorders and diseases of the central nervous system. In 2006 sales by the Pharmaceuticals Division totalled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invests approximately 7 billion Swiss francs a year in R&D. Worldwide, the Group employs about 75,000 people. Additional information is available on the Internet at www.roche.com.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by discovering, developing and commercializing high-quality and novel pharmaceutical products designed to extend life and/or improve the quality of life for patients with cancer and diabetes/obesity. The Company's oncology programs are focused on developing molecular targeted therapies designed to change the paradigm of cancer care. OSI's diabetes/obesity efforts are committed to the generation of novel, targeted therapies for the treatment of type 2 diabetes and obesity. OSI's flagship product, Tarceva® (erlotinib), is the first drug discovered and developed by OSI to obtain FDA approval and the only EGFR inhibitor to have demonstrated the ability to improve survival in both non-small cell lung cancer and pancreatic cancer patients in certain settings. OSI markets Tarceva through partnerships with Genentech, Inc. in the United States and with Roche throughout the rest of the world. For additional information about OSI, please visit http://www.osip.com.

Roche Disclaimer: Cautionary statement regarding forward-looking statements

This document contains certain forward-looking statements. These forward-looking statements may be identified by words such as 'believes,' 'expects,' 'anticipates,' 'projects,' 'intends,' 'should,' 'seeks,' 'estimates,' 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this document, among others: (1) pricing and product initiatives of competitors; (2) legislative and regulatory developments and economic conditions; (3) delay or inability in obtaining regulatory approvals or bringing products to market; (4) fluctuations in currency exchange rates and general financial market conditions; (5) uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products; (6) increased government pricing pressures; (7) interruptions in production; (8) loss of or inability to obtain adequate protection for intellectual property rights; (9) litigation; (10) loss of key executives or other employees; and (11) adverse publicity and news coverage. The statement regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche's earnings or earnings per share for any current or future period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

OSI Forward-looking 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, the completion of clinical trials, the FDA review process and other governmental regulation, OSI's and its collaborators' abilities to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, the ability to effectively market products, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.

References:

1. http://www.cancer.org/docroot/CRI/content/CRI_2_2_1x_How_Many_People_Get_Non-small_Cell_Lung_Cancer.asp?sitearea

2. A. Oshima, T. Kuroishi, K. Tajima, "Cancer White Paper -Incidence/Death/Prognosis - 2004."

3. Shepherd FA, Pereira JR, Ciuleanu T, Tan EH, et al. Erlotinib in previously treated non-small-cell lung cancer. New England Journal of Medicine 2005; 353:123.

4. IARC. GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide (2002 estimates). Accessed 2007 (http://www-dep.iarc.fr/).

5. Wilking N and Jonsson B. (2005) A Pan-European comparison regarding patient access to cancer drugs, Karolinska Institute in collaboration with Stockholm School of Economics, Stockholm, Sweden.

CONTACT: Roche
Lester B. Davis, +41-61-688-2078
lester.davis@roche.com
or
OSI Pharmaceuticals, Inc.
Kathy Galante (investors/media)
631-962-2043
or
Kim Wittig (media)
631-962-2135

SOURCE: OSI Pharmaceuticals, Inc.