

FDA Approves Tarceva(R) in Combination with Gemcitabine Chemotherapy for Treatment of Locally Advanced, Inoperable or Metastatic Pancreatic Cancer; Tarceva Now Approved for Advanced Non-Small Cell Lung Cancer and Pancreatic Cancer

MELVILLE, N.Y. and SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 2, 2005--OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) and Genentech, Inc. (NYSE: DNA) announced today that the U.S. Food and Drug Administration (FDA) approved Tarceva® (erlotinib) in combination with gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy. 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 initial treatment for pancreatic cancer. Tarceva is a once-daily oral tablet already approved for use in patients with non-small cell lung cancer (NSCLC) whose disease has progressed after one or more courses of chemotherapy. OSI also announced that Roche, its international partner for Tarceva, has submitted a Marketing Authorization Application (MAA) to the European Health Authorities for Tarceva for the treatment of pancreatic cancer.

"Improvements in therapy in advanced pancreatic cancer have been very difficult to come by. As a molecularly targeted agent, erlotinib has been shown to add a survival benefit when combined with gemcitabine for patients facing pancreatic cancer," said Dr. Malcolm Moore, study chair and medical oncologist at Princess Margaret Hospital in Toronto, Canada, and Chair of the Gastrointestinal Disease Site, NCIC Clinical Trials Group. "Erlotinib represents a notable step forward for patients and healthcare providers in a disease with a very poor prognosis."

Pancreatic cancer has the highest one-year mortality rate of any cancer. The average life expectancy for a patient diagnosed with metastatic pancreatic cancer is three to six months, according to The Pancreatic Cancer Action Network (PanCAN), a national patient advocacy organization for the pancreatic cancer community.

"We welcome the approval of Tarceva as part of a combination therapy with gemcitabine for pancreatic cancer patients," said Julie Fleshman, president and CEO of PanCAN. "The disease is incredibly deadly with most patients not surviving past one year. For years, treatments for pancreatic cancer have lagged behind other cancers so the availability of Tarceva means patients now have more treatment options as they make informed decisions."

The FDA based its approval decision for Tarceva on results from a randomized double-blind,

placebo-controlled Phase III clinical study of Tarceva, in combination with gemcitabine chemotherapy in patients with unresectable locally advanced or metastatic pancreatic cancer. The study met its primary endpoint of improving overall survival. Compared to gemcitabine plus placebo, those patients receiving gemcitabine plus Tarceva 100 mg/day demonstrated a statistically significant (23 percent) improvement in overall survival (hazard ratio = 0.81; $p = 0.028$). After one year, 24 percent of patients receiving Tarceva plus gemcitabine were alive compared to 19 percent of patients receiving gemcitabine plus placebo. A statistically significant improvement in progression-free survival (hazard ratio = 0.76; $p = 0.006$) also was demonstrated. Although no difference in tumor response was observed (8.6 percent in patients receiving Tarceva plus gemcitabine versus 7.9 percent in the gemcitabine plus placebo arm), the disease control rate (complete response + partial response + stable disease) was significantly improved (59 percent in patients receiving Tarceva plus gemcitabine versus 49 percent in the gemcitabine plus placebo arm, $p = 0.036$). The global study was conducted by the National Cancer Institute of Canada in collaboration with OSI Pharmaceuticals.

"Tarceva is the first FDA approved therapy in nine years to demonstrate an improvement in overall survival and we are pleased that pancreatic cancer patients now have a new treatment option with a proven survival benefit," said Gabe Leung, President of (OSI) Oncology at OSI Pharmaceuticals. "In addition, the submission of Tarceva for pancreatic cancer in the European Union underscores the commitment of the OSI/Genentech/Roche alliance to make Tarceva available to cancer patients around the world as soon as possible."

"Advanced pancreatic cancer and non-small cell lung cancer are two of the most difficult-to-treat cancers, and Tarceva, which targets the EGFR/HER1 pathway, has now been shown to increase survival in both these cancers," stated Hal Barron, M.D., Genentech's senior vice president, development and chief medical officer. "We continue to study Tarceva in other cancers and in combination with other therapies."

Tarceva Safety

Tarceva has a well-established safety profile. In the Phase III study in pancreatic cancer, the most common adverse events reported were fatigue, rash, nausea, anorexia and diarrhea. Rash was reported in 69 percent of patients who received Tarceva

plus gemcitabine and in 30 percent of patients who received gemcitabine plus placebo. Diarrhea was reported in 48 percent of patients who received Tarceva plus gemcitabine and in 36 percent of patients who received gemcitabine plus placebo. Two percent of the patients discontinued Tarceva because of rash and 2 percent because of diarrhea. In addition, severe and potential fatal adverse events included interstitial lung disease-like complications, myocardial infarction or ischemia, cerebrovascular accident, and microangiopathic hemolytic anemia with thrombocytopenia.

About Pancreatic Cancer

According to the World Health Organization, more than 216,000 people worldwide are diagnosed each year with pancreatic cancer. The American Cancer Society predicts that in 2005 about 32,180 people in the United States will be diagnosed with pancreatic cancer and about 31,800 will die of the disease. Although pancreatic cancer accounts for 2 percent of new cancer cases in the United States, it is the fourth leading cause of all cancer deaths. Most pancreatic tumors originate in the exocrine duct cells or in the cells that produce digestive enzymes (acinar cells). Called adenocarcinomas, these tumors account for nearly 95 percent of pancreatic cancers.

About Tarceva

Tarceva is an oral tablet currently approved for use in non-small cell lung cancer (NSCLC) for those patients whose disease has progressed after one or more courses of chemotherapy and in combination with gemcitabine for the treatment of locally advanced or metastatic pancreatic cancer in patients who have not received previous chemotherapy. Tarceva is a small molecule designed to target the human epidermal growth factor receptor 1 (EGFR/HER1) pathway, which is one of the factors critical to cell growth in a number of different cancer types. EGFR/HER1 is a component of the HER signaling 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 signaling pathway inside the cell, which may block tumor cell growth. Tarceva is the only EGFR therapy to show in a Phase III trial improved survival for advanced NSCLC patients. Additional early-stage trials of Tarceva are being conducted in other solid tumors. For Tarceva full prescribing information, please call 1-877-TARCEVA or visit <http://www.tarceva.com>.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicines and changing lives" by discovering, developing and commercializing high-quality and novel pharmaceutical products that extend life or improve the quality of life for cancer and diabetes patients worldwide. The company operates through two business teams, (OSI) Oncology and (OSI) Prosidion. (OSI) Oncology is focused on developing molecular targeted therapies designed to change the paradigm of cancer care. (OSI) Prosidion is 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. OSI markets Tarceva through collaborations with Genentech, Inc. in the U.S. and with Roche throughout the rest of the world. For additional information about OSI, please visit <http://www.osip.com>.

In addition to Tarceva, (OSI) Oncology exclusively markets Novantrone® (mitoxantrone concentrate for injection) for its approved oncology indications and markets Gelclair® Bioadherent Oral Gel for the relief of pain associated with oral mucositis. The research and development pipeline consists of novel molecularly targeted anti-cancer agents focused on signal transduction pathways involved in cell proliferation, apoptosis and angiogenesis. The most advanced of these programs, targeting the co-inhibition of c-kit and VEGFR, has two candidates in development.

About Genentech BioOncology

Genentech is committed to changing the way cancer is treated by establishing a broad oncology portfolio of innovative, targeted therapies with the goal of improving patients' lives. The company is the leading provider of anti-tumor therapeutics in the United States. Genentech is leading clinical development programs for Rituxan® (Rituximab), Herceptin® (Trastuzumab), Avastin® (bevacizumab) and Tarceva® (erlotinib), and markets all four products in the United States alone (Avastin and Herceptin), with Biogen Idec Inc. (Rituxan), or with OSI Pharmaceuticals (Tarceva). Genentech has licensed Rituxan, Herceptin, and Avastin, and OSI Pharmaceuticals has licensed Tarceva to Roche for sale by the Roche Group outside of the United States.

The company has a robust pipeline of potential oncology therapies with a focus on four key areas: angiogenesis, apoptosis (i.e., programmed cell death), the HER pathway, and B-cell biology. Potential oncology therapies directed at the HER pathway include a therapeutic antibody currently in Phase II trials. Also in early development are a small molecule directed at the hedgehog pathway, a soluble human protein targeting apoptosis, and a humanized anti-CD20 antibody for hematology/oncology indications.

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutics for significant unmet medical needs. A considerable number of the currently approved biotechnology products originated from

or are based on Genentech science. Genentech manufactures and commercializes multiple biotechnology products directly in the United States and licenses several additional products to other companies. The company has headquarters in South San Francisco, Calif., and is traded on the New York Stock Exchange under the symbol DNA. For additional information about the company, please visit <http://www.gene.com>.

For full prescribing information, including Boxed Warnings for Avastin, Rituxan, and Herceptin, or for Tarceva full prescribing information, please call 800-821-8590 or visit www.gene.com.

Regarding OSI

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.

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