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New Data Show Pfizer's Axitinib Prolonged Overall Survival in Advanced Pancreatic Cancer When Combined with Standard of Care Chemotherapy

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Phase II Data Examining Efficacy of Axitinib as Single-Agent and in Combination with Chemotherapies Across a Number of Tumor Types Also Presented at ASCO

(BUSINESS WIRE)--Pfizer announced today that axitinib (AG-013736), an investigational oral, selective inhibitor of VEGFR 1, 2,3 (vascular endothelial growth factor receptors 1, 2, 3) combined with gemcitabine showed a trend towards prolonged overall survival (OS) in patients with advanced pancreatic cancer, compared with gemcitabine alone, according to preliminary data from a randomized Phase II trial**.**

These data were presented at the 43rd American Society of Clinical Oncology (ASCO) Annual Meeting this week, along with results from several other Phase II studies evaluating the efficacy and safety of axitinib in metastatic refractory thyroid, renal cell, non-small cell lung (NSCLC) and breast cancer.

“Pancreatic cancer continues to be one of the most life-threatening and difficult-to-treat solid tumors,” said lead study investigator Jean-Philippe Spano, MD, PhD, Hospital La Piti-Salpetriere. “Seeing an agent with this level of activity and tolerability at this stage in development is encouraging news for patients. These findings suggest that axitinib has anti-tumor activity in advanced pancreatic cancer and provide the basis for a Phase III program to further evaluate the potential benefits of this agent in pancreatic cancer patients.”

Advanced Pancreatic Cancer

Results from a randomized Phase II study of 103 previously untreated patients with advanced pancreatic cancer demonstrated median overall survival with axitinib in combination with gemcitabine of 6.9 months compared with 5.6 months with gemcitabine alone. Axitinib combined with gemcitabine reduced the risk of death - by 26 percent compared to gemcitabine alone (HR=0.74; CI 0.427 - 1.284).

Advanced Refractory Thyroid Cancer

The anti-tumor effects of single-agent axitinib in advanced refractory thyroid cancer were demonstrated in a single-arm, multi-center Phase II study of 60 patients who were iodine-refractory, or not suitable candidates for iodine treatment. This showed an objective response rate with axitinib of 30 percent. 72 percent of patients received a clinical benefit, meaning a partial response or stable disease was observed (partial response 30 percent and 42 percent with stable disease ?16 weeks). Treatment duration range was 6-744 days, with 24 patients currently still on treatment.

A global trial of axitinib in advanced refractory thyroid cancer patients, who have become resistant to a commonly used chemotherapy, is ongoing.

Metastatic Breast Cancer

A randomized, double-blind, placebo-controlled Phase II study found that axitinib combined with the chemotherapy docetaxel, demonstrated an acceptable safety profile and anti-tumor activity in the first-line treatment of metastatic breast cancer.

A total of 168 patients were randomized to receive docetaxel plus axitinib (AG) or docetaxel (DOC) plus placebo (PL). The median time to tumor progression (TTP) was 8.2 months in the AG + DOC arm versus 7 months in the DOC + PL arm (P=0.052). The objective response rate (ORR) was 40 percent for AG + DOC arm and 23 percent for DOC + PL arm (P=0.038).

Advanced Renal Cell Carcinoma (RCC)

A multicenter, open-label, Phase II study investigated axitinib in RCC patients with advanced RCC who were resistant to multi-kinase therapy. The study found that axitinib demonstrated anti-tumor activity in advanced RCC.

Of the 62 patients in the study, partial response was observed in 13 patients (21 percent) and 21 patients experienced stable disease (34 percent). Median Progression Free Survival (PFS) was 7.4 months.

Data from an open-label multi-center Phase II study of single-agent axitinib in non-small cell lung cancer were also presented this week.

“Pfizer is committed to delivering new and innovative options to patients living with cancer,” said Charles Baum, MD PhD, head of oncology development at Pfizer. “These exciting data contribute to an emerging body of research indicating the benefit that oral selective inhibitors of VEGF receptors, like axitinib, may provide to patients. We have plans to further explore axitinib in advanced pancreatic cancer as part of a Phase III program and are continuing to evaluate axitinib across multiple other tumor types.”

The most common adverse events in trials of axitinib as a single agent included fatigue, proteinurea, stomatitis/mucositis, hypertension and diarrhea. When studied in combination with myelosuppressive chemotherapies, the most common adverse events included neutropenia, diarrhea, fatigue, stomatitis and hypertension. The complete adverse event profile of axitinib is not yet known.

About Axitinib

Axitinib is an oral, selective inhibitor of VEGFR 1, 2, 3 (vascular endothelial growth factor receptors 1, 2 and 3), which has been shown to induce tumor regression as a single-agent and in combination with chemotherapy. Inhibiting VEGF binding plays a key role in anti-angiogenesis – or blocking blood vessel formation which starves tumors of the blood and nutrients needed for growth.

Axitinib is an investigational agent and has not yet been approved by the U.S. Food and Drug Administration or other global regulatory agencies.

For more information on Pfizer Oncology please visit www.pfizer.com.

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future events or developments.

This release contains forward-looking information about a product in development, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product in development as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and in its reports on Form 10-Q and Form 8-K.

Pfizer Vanessa Aristide, 212-733-3784