Pfizer Discontinues Global Phase III Trial of Axitinib for Futility in Advanced Pancreatic Cancer

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(BUSINESS WIRE)--Pfizer Inc announced today the discontinuation of a Phase III study of its investigational agent axitinib for the treatment of advanced pancreatic cancer. Based on an interim analysis, an independent Data Safety Monitoring Board (DSMB) found no evidence of improvement in the primary endpoint of survival in patients treated with axitinib and gemcitabine, compared to gemcitabine alone, the current standard of care for patients with advanced pancreatic cancer.

“These results were disappointing, given the trend towards prolonged survival seen in a Phase II study of axitinib in this extremely difficult-to-treat patient population,” said Mace L. Rothenberg, M.D., senior vice president, clinical development and medical affairs, Pfizer’s Oncology Business Unit. “However, we remain steadfastly committed to continued investigation of axitinib in renal cell carcinoma where it is currently in Phase III for 2nd line treatment.”

The Company has notified all clinical trial investigators involved in the study and regulatory agencies of these interim findings and recommends patients discontinue treatment with axitinib. Pfizer encourages investigators to determine the best course of action for their patients. The full data set from this study is being analyzed and more details will be presented at an upcoming medical meeting.

Pancreatic cancer is the fourth leading cause of cancer deaths in the United States. In the past 20 years, there have been only 2 widely approved treatments, with many other drugs failing in Phase III trials.

“We have a robust pipeline of compounds in clinical development and will determine if one or more of those compounds can move forward in pancreatic cancer,” said Dr. Rothenberg. “We also are continuing to evaluate axitinib in Phase II trials in other tumor types, including advanced non-small cell lung cancer and colorectal cancer,” said Dr. Rothenberg.

Axitinib is an oral and selective inhibitor of VEGF receptors 1, 2 and 3. 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 http://www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of January 30, 2009. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about axitinib, 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, 2007 and in its reports on Form 10-Q and Form 8-K.

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