Pfizer Discontinues A Phase 3 Trial Of Figitumumab In Non-Small Cell Lung Cancer (NSCLC) For Futility

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A href="http://www.businesswire.com" >BUSINESS WIRE)--Pfizer Inc. announced today the discontinuation of A4021016 (also known as ADVIGO 1016), a Phase 3 trial examining the effects of investigational compound figitumumab (CP-751,871) as first-line treatment in patients with advanced non-adenocarcinoma non-small cell lung cancer (NSCLC) due to the study meeting predefined boundaries for early termination.

An analysis by an independent Data Safety Monitoring Committee (DSMC) showed that the addition of figitumumab to paclitaxel plus carboplatin would be unlikely to meet the primary endpoint of improving overall survival compared to paclitaxel plus carboplatin alone. This discontinuation follows a halt in new patient enrollment to A4021016 in September 2009 when the DSMC observed an apparent imbalance of certain serious adverse events between the treatment arms with more events, including fatalities, occurring in patients who were randomized to receive figitumumab.

"While these findings are disappointing, Pfizer is committed to using information gained from this study to refine the design of future trials of figitumumab in non-small cell lung cancer," said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer's Oncology Business Unit. "We are hopeful that we will be able to identify a subset of patients who may have derived benefit from the addition of figitumumab to chemotherapy. If this can be done, then future trials will focus on this group of patients in our efforts to deliver this drug to the right patient."

The Phase 3 study was initiated based on robust findings from a Phase 2 study that identified patients of squamous cell histology, the most common form of non-adenocarcinoma and a disease with a high unmet medical need, as those who could potentially benefit most from figitumumab treatment.

The Company has notified A4021016 clinical investigators and has initiated the notification procedure for all involved regulatory agencies of the discontinuation of A4021016. Investigators have been instructed to work with all of their patients in the A4021016 study on an individual basis to determine an appropriate course of action.

A4021016 is part of a global Phase 3 clinical trial program, called ADVIGO (ADVancing IGF-1R in Oncology), which is studying figitumumab in patients with NSCLC. The program also includes A4021018 (also known as ADVIGO 1018), an ongoing study in patients with refractory advanced non-adenocarcinoma NSCLC that is evaluating figitumumab with erlotinib compared to erlotinib alone. A4021017 (also known as ADVIGO 1017), is a Phase 3 trial that will evaluate figitumumab in combination with another chemotherapy regimen - cisplatin and gemcitabine - as 1st-line treatment of advanced NSCLC. This trial is still in the planning stage and will incorporate lessons learned from ADVIGO 1016 into the final design.

“While the clinical development of first-in-class agents in oncology is challenging, Pfizer is determined to provide lung cancer patients with novel, safe and effective therapeutic agents. We remain strongly committed to the figitumumab clinical development program in NSCLC, in addition to other cancers where treatment options are desperately needed,” said Garry Nicholson, senior vice president, general manager of the Oncology Business Unit.

In addition to NSCLC, Pfizer is studying figitumumab in clinical trials for the potential treatment of other cancers, including prostate and breast cancers, and Ewing’s sarcoma.

About Non-Small Cell Lung Cancer

Lung cancer is the most common cancer worldwide. NSCLC accounts for about 85 percent of lung cancer cases and 25 to 30 percent are of squamous histology. Nearly 60 percent of NSCLC patients are diagnosed late with Stage IIIB/IV advanced disease. Despite recent advances, NSCLC remains difficult to treat, particularly in the metastatic setting.

About Figitumumab (CP-751,871)

Figitumumab, an investigational fully human monoclonal antibody, is a highly specific inhibitor of the insulin growth factor-1 receptor (IGF-1R) pathway. The IGF-1R pathway is thought to be one of the fundamental signaling pathways that leads to uncontrolled growth and survival of tumor cells, and may represent a resistance mechanism against EGFR inhibitors and other anti-cancer therapies.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers, including breast, lung, prostate, sarcoma, melanoma, and various hematologic cancers. Pfizer Oncology has more than 25 biologics and small molecules in clinical development and more than 200 clinical trials underway.

By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for the right patient at the right time.

For more information please visit www.Pfizer.com.

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DISCLOSURE NOTICE: The information contained in this release is as of December 29, 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 potential indications for figitumumab, including their 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 any such indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such indications; 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, 2008 and in its reports on Form 10-Q and Form 8-K.

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