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Pfizer Discontinues A Phase 3 Study Of Figitumumab In Previously Treated Patients With Advanced Non-Small Cell Lung Cancer

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Findings will Contribute to Understanding and Future Study of Figitumumab

(BUSINESS WIRE)--Pfizer Inc. announced today the discontinuation of A4021018 (also known as ADVIGO 1018), a Phase 3 trial examining the effects of investigational compound figitumumab (CP-751,871) in combination with erlotinib as a second/third-line treatment in patients with previously treated advanced non-adenocarcinoma non-small cell lung cancer (NSCLC). An independent Data Safety Monitoring Committee (DSMC) recommended A4021018 be stopped after concluding that the addition of figitumumab to erlotinib is unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to erlotinib alone in the study population.

“This outcome is disappointing to us and to patients with NSCLC. Pfizer is working to thoroughly analyze all available data from the figitumumab program to better understand the compound and the IGF-1R (insulin growth factor-1 receptor) pathway,” said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer’s Oncology Business Unit. “As a pioneer in the IGF-1R field, we are committed to a thorough evaluation of figitumumab. We will carefully review our extensive clinical database and use this information to refine the figitumumab clinical program with the goal of identifying the right patient population in which to evaluate this compound.”

The Company has notified A4021018 clinical investigators and has initiated the notification procedure for all involved regulatory agencies of the discontinuation of A4021018. Investigators have been instructed to work with all of their patients in the A4021018 study on an individual basis to determine an appropriate course of action.

In December 2009, Pfizer announced the stop of A4021016 (ADVIGO 1016), a Phase 3 study examining the effects of figitumumab as first-line treatment in patients with advanced non-adenocarcinoma NSCLC, after an analysis by the DSMC showed that addition of figitumumab to carboplatin plus paclitaxel would be unlikely to meet the primary endpoint of improved overall survival compared to paclitaxel plus carboplatin alone.

Pfizer is continuing to study figitumumab in clinical trials for the potential treatment of prostate, breast and lung 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 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 March 11, 2010. Pfizer assumes no obligation to update 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, 2009 and in its reports on Form 10-Q and Form 8-K.

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