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New Pfizer Data Presented on CP-751,871 across Non-Small Cell Lung Cancer and Ewing's Sarcoma

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ADVIGO CP-751,871 Global Phase III Clinical Trial Program Initiated (ADVancing IGF-1R in Oncology)

(BUSINESS WIRE)--Pfizer announced today results from several clinical trials further describing the activity of its investigational compound CP-751,871 in non-small cell lung cancer (NSCLC) and Ewing's Sarcoma, both diseases with high unmet medical need. The three oral presentations and one poster discussion underscore that the insulin-like growth factor receptor (IGF-1R) is increasingly recognized by the medical community as a relevant target for investigation in cancer research. The results were presented at the 44th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL.

Updated Response Data from the 1002 NSCLC Trial

Updated study results from a Phase II, randomized, non-comparative study showed 54 percent of patients with Stage III/IV treatment-naïve NSCLC receiving the combination CP-751,871 plus carboplatin and paclitaxel (n=97) experienced objective responses. The response rate observed for patients treated with carboplatin and paclitaxel alone was 41 percent.

Of note, 78 percent of a subset of patients with squamous cell carcinoma (n=23) and 57 percent of a subset of patients with adenocarcinoma (n=28) receiving 20 mg/kg of CP-751,871 plus carboplatin and paclitaxel experienced objective responses. Response rates were 46 percent and 25 percent, respectively, for squamous cell (n=13) and adenocarcinoma patients (n=20) receiving carboplatin and paclitaxel alone. No response advantage with CP-751,871 was seen in a subset of patients with undifferentiated tumors (Not otherwise specified, NOS).

"Patients with advanced NSCLC typically face a poor prognosis and we need to develop new strategies and new treatment combinations to improve their survival," said lead investigator Daniel Karp, M.D., director of the M.D. Anderson Cancer Center Clinical and Translational Research Center (CTRC). "The updated study results add to our growing understanding of the potential safety and efficacy of CP-751,871. In this trial, increasing the dose to 20 mg/kg in Stage 2 of the trial resulted in an increased overall response rate in all differentiated histologies, including adenocarcinoma, non-adenocarcinoma, and particularly in squamous histologies, which we consider to be of interest for future study."

Dr. Karp also presented progression-free survival (PFS) results from the study. At the dose level of 20 mg/kg, the observed progression-free survival was 5 months in the CP-751,871 plus carboplatin/paclitaxel arm and 4 months in the carboplatin/paclitaxel only arm. The highest observed PFS was in the group of patients with squamous histologies (5.6 months in the CP-751,871 plus carboplatin/paclitaxel arm and 4.3 months in the carboplatin/paclitaxel only arm) corresponding to the patients that demonstrated the highest response rates. PFS was defined as either the length of time before the cancer progressed or death.

In this study, CP-751,871 was generally well tolerated. The most common Grade 3 or 4 side effects reported were hyperglycemia (increased blood sugar) (20 percent) and neutropenia (30 percent).

Correlative Science Study Results Support Karp Data

This abstract summarized ancillary studies conducted to investigate the molecular make up of lung tumors and its relevance to anti-IGF-IR therapy. Members of the IGF-IR pathway appear to be expressed differentially across lung tumor histologies which may help to explain the differential activity of CP-751,871 across these histologies. Tumor differentiation also appears to play a role. Data were also presented demonstrating that EGFR inhibition sensitizes tumors to CP-751,871 treatment.

“These results help us to understand better how CP-751,871 works, provide support for our phase III trial strategy and underscore Pfizer’s commitment to bring science and innovation to the forefront of drug development,” said Antonio Gualberto, M.D., Ph.D., Global Clinical Lead for the CP-751,871 program, Pfizer Global Research and Development.

ADVIGO Phase III Registration Program (ADVancing IGF-IR in Oncology)

Based on these data, Pfizer has initiated a large global Phase III clinical trial program for CP-751,871 in NSCLC, including some studies with patients with non-adenocarcinoma (ADVIGO 1016, ADVIGO 1018). The program includes trials for patients who are newly diagnosed and for those who have already been treated with other therapies.

Pfizer has made a major commitment to CP-751,871 and has invested significant resources in the Phase III program, which will include more than 2,000 patients around the world.

For more information on the ADVIGO registration program please visit, http://PfizerCancerTrials.com.

Preliminary Data Presented on CP-751,871 in Sarcoma

Phase I data presented at ASCO showed single agent CP-751,871 was generally well-tolerated in patients with relapsed or refractory sarcoma (n=22), including Ewing’s sarcoma (n=9). A response of stable disease or better was seen in 12 out of 20 evaluable patients, including one confirmed partial response in a 12-year-old patient with Ewing’s sarcoma, the second most common malignant bone tumor in young patients and the most deadly bone tumor.

CP-751,871 was generally well tolerated in patients with relapsed or refractory sarcoma. Grade 3 or 4 treatment-related side effects reported included Grade 4 uric acid increase (n=1) and Grade 3 bilateral deep-vein thrombosis (n=1).

About CP-751,871

CP-751,871, a fully human IgG2 monoclonal antibody, is a highly specific inhibitor of the IGF-1R pathway. It is believed that through this inhibition, CP-751,871 blocks one of the key signaling pathways in cancer cells that lead to uncontrolled growth and survival of tumor cells.

Pfizer recently initiated a global Phase III clinical trial registration program for CP-751,871 in non-adenocarcinoma NSCLC. In addition, Pfizer is studying CP-751,871 in clinical trials for the treatment of many other cancers, including prostate, breast and colon cancers and Ewing’s sarcoma. To date, more than 500 patients have participated in CP-751,871 clinical trials in multiple tumor types.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of treatments and currently has 22 innovative compounds in clinical development across four platforms. By leveraging the strength of our resources and scientific talent, Pfizer Oncology strives to discover and develop novel treatment options to improve the outlook for oncology patients. Pfizer currently devotes more than 22 percent of its total R&D budget to the field of oncology, investing annually in worldwide research initiatives. We also partner with healthcare providers, governments and local communities around the world to provide better quality healthcare and health system support.

For more information on the above information, please visit http://www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of June 2, 2008. 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 a product candidate, CP-751,871, 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 candidate 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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