Pfizer Presents Phase 2 Data Showing Investigational Therapy PD-0332991 Plus Letrozole Significantly Improved Progression Free Survival Compared With Letrozole Alone In Patients With ER Positive, HER2 Negative Advanced Breast Cancer

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Randomized Phase 3 Study Evaluating CDK 4 and 6 Inhibitor, PD-0332991, Planned for 2013

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(BUSINESS WIRE)--Pfizer Inc. today announced randomized Phase 2 data that showed PD-0332991 (PD-991) in combination with letrozole significantly extended progression free survival (PFS) compared with letrozole alone in post-menopausal patients with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) locally advanced or metastatic breast cancer. For patients treated with the combination of PD-991 plus letrozole, median PFS was 26.1 months, a statistically significant improvement compared to the median PFS in women who received letrozole alone, which was 7.5 months (HR=0.37 [95% CI: 0.21, 0.63]; P <0.001). These data were presented today and featured in a press conference at the 2012 CTRC-AACR San Antonio Breast

Cancer Symposium (Abstract #S1-6).

“These results are especially important because of the magnitude of clinical effect observed and the fact that PD-991 represents a potential first-in-class compound. Based on these positive Phase 2 data, Pfizer is planning to open a randomized Phase 3 study of PD-991 in this patient population in 2013,” said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer’s Oncology Business Unit. “We are working with regulatory authorities to advance the development of this promising compound in the most expeditious and responsible way.”

Breast cancer is the most commonly diagnosed cancer1 and the leading cause of cancer death among women worldwide.2 Estrogen receptor positive, HER2- breast cancer represents approximately 60 percent of all cases of breast cancer.3 Despite currently available treatments, survival rates for advanced or metastatic breast cancer remain low.4

About the Phase 2 Program

The focus of Phase 2 evaluation of PD-991 was to measure the clinical activity of PD-991 in combination with letrozole versus letrozole alone in post-menopausal women with ER+, HER2- locally advanced or metastatic breast cancer. In Part 1, 66 patients were enrolled. Preliminary results were presented in May 2012 at the IMPAKT Breast Cancer Conference in Brussels, Belgium, and showed statistically significant improvement in median PFS in the PD-991 plus letrozole arm versus the letrozole arm. Part 2 enrolled 99 additional patients whose tumors were selected for presence of biomarkers: cyclin D1 amplification and/or p16 loss. The results presented here at SABCS reflect the combined interim data analysis of parts 1 and 2 of the Phase 2 evaluation.

In patients with measurable disease, the objective response rate was 45 percent for those women who received PD-991 plus letrozole versus 31 percent for those who received letrozole alone. The clinical benefit rate (defined as complete response plus partial response plus stable disease for ≥24 weeks) was 70 percent versus 44 percent, respectively. The differences observed in the objective response rate and clinical benefit rate were statistically significant. The most frequently reported treatment-related Grade 3/4 adverse events (AEs) in patients who received the combination therapy were neutropenia, leucopenia, anemia and fatigue.

Both Part 1 and Part 2 of this Phase 2 evaluation are ongoing but no longer enrolling new patients. Final efficacy and safety data are expected to be presented at a future medical congress.

“In demonstrating very strong efficacy and a manageable tolerability profile, these new data represent a potential major advancement in breast cancer clinical research and our continued efforts to identify new medicines that target patients most likely to have an optimal response,” said Dr. Richard S. Finn, Associate Professor of Medicine, Revlon/UCLA Women’s Cancer Research Program at Jonsson Comprehensive Cancer Center, UCLA, and lead investigator of the Phase 2 trial. “The oncology community is looking forward to the further evaluation of PD-991 in the planned Phase 3 trial and very interested in the potential for this novel CDK 4 and 6 inhibitor to improve the treatment landscape for patients with advanced breast cancer.”

About PD-991

PD-991 is an investigational, oral and selective inhibitor of the CDK 4 and 6 kinases. CDK 4 and 6 are two closely related kinases that enable tumor cell progression during phase G1 to phase S in the cell cycle. This progression is necessary for DNA replication and cell division. Inhibition of CDK 4 and 6 has been shown to prevent the deactivation of retinoblastoma, a tumor suppressor protein, and interfere with tumor cell progression. In pre-clinical studies, PD-991 was shown to be an inhibitor of cell growth and a suppressor of DNA replication by preventing cells from entering S phase.

In addition to breast cancer, PD-991 is currently being evaluated through Pfizer-sponsored and investigator-initiated research in other cancers, including liposarcoma, non-small cell lung cancer, liver cancer, ovarian cancer, glioblastoma, refractory solid tumors, multiple myeloma, and mantle cell lymphoma.

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 of biologics and small molecules, 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. 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 each patient at the right time. For more information, please visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of December 5, 2012. 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 that involves substantial risks and uncertainties about PD-991, an investigational therapy, including a potential indication for advanced breast cancer and various other potential indications and the anticipated commencement of a Phase 3 study in advanced breast cancer in 2013. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates, regulatory submission and approval dates, and launch dates; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any such potential indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such potential 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, 2011 and in its reports on Form 10-Q and Form 8-K.

1 World Health Organization. Breast Cancer Burden. Available at: http://www.who.int/cancer/detection/breastcancer/en/index1.html. Accessed November 15, 2012.

2 World Health Organization. Cancer. Available at: http://www.who.int/mediacentre/factsheets/fs297/en/. Accessed November 15, 2012.

3 Decision Resources. Event Driven Pharmacor Report. 2012.

4 Miles, David. When HER2 is not the target: advances in the treatment of HER2-negative metastatic breast cancer. Breast Cancer Research 2009 August; 11(4).

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