Pfizer’s Palbociclib (PD-0332991) Receives Food And Drug Administration Breakthrough Therapy Designation For Potential Treatment Of Patients With Breast Cancer

Tuesday, April 09, 2013 - 06:30pm

"We appreciate the opportunity that Breakthrough Therapy designation provides to work closely with the FDA on the development of palbociclib"

(BUSINESS WIRE)--Pfizer Inc. announced today its investigational compound palbociclib (PD-0332991), an oral and selective inhibitor of cyclin dependent kinases (CDK) 4 and 6, has received Breakthrough Therapy designation by the United States Food and Drug Administration (FDA) for the potential treatment of patients with breast cancer.

Enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA), Breakthrough Therapy designation is intended to expedite the development and review of a potential new medicine if it is “intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.” 1 The Breakthrough Therapy designation is distinct from the FDA’s other mechanisms to expedite drug development and review.2

“We appreciate the opportunity that Breakthrough Therapy designation provides to work closely with the FDA on the development of palbociclib,” said Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for Pfizer’s Oncology business unit. “Palbociclib is one example of Pfizer’s commitment to identifying and

translating innovative science into meaningful new treatment options for cancer patients."

Pfizer will continue to work with the FDA to better understand the implications of Breakthrough Therapy designation on the palbociclib development program and to generate evidence needed to support a potential regulatory submission. The FDA's requirements for a potential submission have not yet been defined.

Pfizer has initiated a randomized, multi-center, double-blind Phase 3 study (known as Study 1008) evaluating palbociclib in combination with letrozole versus letrozole alone as a first-line treatment for post-menopausal patients with ER+, HER2- locally advanced or metastatic breast cancer. Study 1008 is currently open and enrolling.3

The Breakthrough Therapy designation was based on preliminary Phase 2 data in this patient population. Interim data presented at the 2012 CTRC-AACR San Antonio Breast Cancer Symposium showed that women treated with the combination of palbociclib plus letrozole achieved a statistically significant improvement in median progression free survival (PFS) compared to women who received letrozole alone (26.1 months and 7.5 months, respectively).4

Breast cancer is the most commonly diagnosed cancer in women5 and the leading cause of cancer death among women worldwide.6 Among post-menopausal patients with advanced or metastatic breast cancer, ER+, HER2- is the largest molecular subgroup, representing approximately 60 percent of cases.7 Despite currently available treatments, survival rates for advanced or metastatic breast cancer remain low.8

About Palbociclib

Palbociclib is an investigational, oral and selective inhibitor of cyclin dependent kinases (CDK) 4 and 6. 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 susceptibility gene protein, a tumor suppressor protein, and interfere with tumor cell progression. In pre-clinical studies, palbociclib 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, palbociclib is currently being evaluated through Pfizer-sponsored and investigator-initiated research in other cancers. For more information on ongoing clinical trials of palbociclib, please visit www.clinicaltrials.gov.

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 April 10, 2013. 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 palbociclib, an investigational therapy for the potential treatment of advanced breast cancer and various other types of cancer, 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, including the ability to meet anticipated clinical trial commencement and completion dates, regulatory submission and approval dates, and launch dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data or additional analyses of existing clinical data. It is important to note that any potential regulatory submissions and potential regulatory approvals for any such potential indications for palbociclib will depend on final analyses of clinical trial data; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any such potential indications for palbociclib as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any 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, 2012 and in its reports on Form 10-Q and Form 8-K.

1 U.S. Food and Drug Administration Safety and Innovation Act. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf. Accessed April 4, 2013.

2 U.S. Food and Drug Administration Frequently Asked Questions: Breakthrough Therapies. Available at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/S Accessed April 8, 2013.

3 Clinicaltrials.gov. A Study of PD-0332991 + Letrozole vs. Letrozole For 1st Line Treatment Of Postmenopausal Women With ER+/HER2- Advanced Breast Cancer. Available at: http://clinicaltrials.gov/ct2/show/NCT01740427?term=0332991+and+pfizer&rank=2 . Accessed March 28, 2013.

4 Finn, Richard. Results of a randomized phase 2 study of PD 0332991, a cyclin-dependent kinase (CDK) 4/6 inhibitor, in combination with letrozole vs letrozole alone for first-line treatment of ER+/HER2- advanced breast cancer (BC). Abstract. Publication Number S1-6. 2012 San Antonio Breast Cancer treatment of ER+/HER2- advanced breast cancer (BC). Abstract. Publication Number S1-6. 2012 San Antonio Breast Cancer Symposium (SABCS), San Antonio, Texas.

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

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

7 Decision Resources. Event Driven Pharmacor Report. 2012.

8 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).

Pfizer Inc. Media: Victoria Davis, (484) 865-5194 Investors: Suzanne Harnett, (212) 733-8009