Palbociclib Expanded Access Program Now Open To Eligible U.S. Patients With HR+, HER2- Advanced Breast Cancer

Thursday, August 21, 2014 - 04:00am

Pfizer Inc. today announced that the company has initiated a multi-center, open-label expanded access program (EAP) in the United States for the investigational CDK 4/6 inhibitor, palbociclib. Through the program, palbociclib is being made available for use in combination with letrozole for post-menopausal women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer for whom letrozole is considered appropriate therapy. Healthcare professionals and patients can learn more about the palbociclib EAP by visiting www.clinicaltrials.gov (trial number: NCT02142868).

Under its expanded access programs, the U.S. Food and Drug Administration (FDA) works with companies to allow access to investigational therapies to patients with serious or life-threatening illnesses who do not otherwise qualify for participation in a clinical trial and for whom there are no comparable or satisfactory alternate therapies.

“Palbociclib is being evaluated as a potential new treatment for women with HR+, HER2- advanced breast cancer, who represent the largest subgroup of women with this disease,” said Dr. Mace Rothenberg, senior vice president, Clinical Development and Medical Affairs, and chief medical officer, Pfizer Oncology. “As announced this week, we have completed the submission of a New Drug Application for palbociclib in the U.S.

based on the results of our Phase 2, PALOMA-1 study. With recruitment of new patients to our Phase 3 PALOMA-2 and PALOMA-3 trials now complete, Pfizer is initiating the Palbociclib Expanded Access Program. This program will provide a mechanism by which eligible women who may benefit from treatment with palbociclib can gain access to this investigational therapy at this time."

About the Palbociclib EAP

The palbociclib EAP is a U.S.-only, single-arm, open label study for post-menopausal women with HR+, HER2- advanced breast cancer. Women enrolled to the study will receive palbociclib for use in combination with letrozole, and therefore must be deemed appropriate for letrozole therapy. Additional enrollment criteria are available at www.clinicaltrials.gov (trial number: NCT02142868).

U.S.-based health care professionals seeking more information about the palbociclib EAP can call 1-800-420-6755 or e-mail Palbociclib-EAP@parexel.com for further details.

Patients who are interested in enrolling to the palbociclib EAP should speak with their physician to understand if palbociclib is an appropriate treatment option.

Palbociclib is an investigational therapy and is not approved for any indication in any markets.

More information and Frequently Asked Questions

About Palbociclib

Palbociclib is an investigational oral targeted agent that selectively inhibits cyclin-dependent kinases (CDKs) 4 and 6 to regain cell cycle control and block tumor cell proliferation.[1]

Loss of cell cycle control is a hallmark of cancer and CDK 4/6 are overactivated in numerous cancers, leading to loss of proliferative control.[2],[3] CDK 4/6 are key regulators of the cell cycle that trigger cellular progression from growth phase (G1) into phases associated with DNA replication (S).[4],[5] CDK 4/6, whose increased activity is frequent in estrogen receptor-positive (ER+) breast cancer (BC), are key downstream targets of ER signaling in ER+ BC.[6],[7] Preclinical data suggest that dual inhibition of CDK 4/6 and ER signaling is synergistic and has been shown to stop growth of ER+ BC cell lines in the G1 phase.

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.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than

150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of August 21, 2014. 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, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Forward-looking statements include those about palbociclib's potential benefits and the potential indication for the treatment of postmenopausal women with ER+, HER2- advanced breast cancer who have not received previous systemic treatment for their advanced disease (the "Potential Indication"). 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 and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when the FDA will accept the New Drug Application (the "NDA") submitted for palbociclib; whether the PALOMA-2 Phase 3 trial of palbociclib for the Potential Indication will demonstrate a statistically significant improvement in progression-free survival and whether the other Phase 3 trials of palbociclib will meet their primary endpoints; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any other jurisdictions for the Potential Indication or in any jurisdictions for any other potential indications for palbociclib; whether and when the NDA or any such other applications may be approved by the FDA or other regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by the FDA and other regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of the Potential Indication or any other 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, 2013 and in its subsequent reports on

Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

# # # # #

[1] Clinicaltrials.gov. Study of Letrozole with or without PD 0332991 for the first-line treatment of hormone-receptor positive advanced breast cancer. Available here: http://www.clinicaltrials.gov/ct2/show/NCT00721409?term=PD+0332991&rank=10. Accessed August 19, 2014.

2 Shapiro GI. Cyclin-dependent kinase pathways as targets for cancer treatment. J Clin Oncol. 2006;24(11):1770-1783.

3 Weinberg RA. The Biology of Cancer. New York, NY. Garland Science; 2013.

4 Hirama T and H. Phillip Koeffler. Role of the Cyclin-Dependent Kinase Inhibitors in the Development of Cancer. *Blood*. 1995; 86: 841-854.

5 Fry D et al. Specific Inhibition of cyclin-dependent kinase 4/6 by PD 0332991 and associated antitumor activity in human tumor xenografts. *Molecular Cancer Therapeutics.* 2004; 3: 1427-1437.

6 Finn RS et al. PD 0332991, a selective cyclin D kinase 4/6 inhibitor, preferentially inhibits proliferation of luminal estrogen receptor-positive human breast cancer cell lines in vitro. *Breast Cancer Res.* 2009;11(5):R77.

[7] Lamb R, Lehn S, Rogerson L, Clarke RB, Landberg G. Cell cycle regulators cyclin D1 and CDK4/6 have estrogen receptor-dependent divergent functions in breast cancer migration and stem cell-like activity. Cell Cycle. 2013;12(15):2384-2394.

Media Contact: Sally Beatty (212) 733-6566 Investor Contact: Ryan Crowe (212) 733-8160