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Pfizer Announces Positive Top-Line Results From PALOMA-1 Evaluating Palbociclib Plus Letrozole in Women with Advanced Breast Cancer

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Clinical Benefit Demonstrated For Potential First-in-Class CDK 4 and 6 Inhibitor

Pfizer Inc. (NYSE: PFE) today announced that the randomized Phase 2 trial [PALOMA-1] of palbociclib achieved its primary endpoint by demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) for the combination of palbociclib and letrozole compared with letrozole alone in post-menopausal women with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) locally advanced or newly diagnosed metastatic breast cancer.

“We are delighted with the final data, which suggest the potential for palbociclib to transform the standard of care for post-menopausal women with ER+ and HER2- advanced breast cancer. This is encouraging information for these women, who represent approximately 60 percent of the advanced breast cancer population,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. “We will discuss these results with the FDA and other regulatory authorities to determine next steps, with the goal of bringing a much-needed new medicine to patients.”

Adverse events observed for the palbociclib arm were consistent with the known adverse event profile for this combination. Detailed efficacy and safety data from PALOMA-1 will be submitted for presentation at the American Association for Cancer Research (AACR) Annual Meeting 2014 scheduled for April 5-9th in San Diego.

Palbociclib received Breakthrough Therapy designation by the United States Food and Drug Administration (FDA) in April 2013, for the initial treatment of women with advanced or metastatic ER+, HER2- breast cancer. This designation was based on interim data from the PALOMA-1 trial. A randomized, global Phase 3 trial (PALOMA-2) in this patient population is currently enrolling patients.

About PALOMA-1
PALOMA-1 (also known as Study 1003) is a Phase 2 trial designed to assess the PFS of palbociclib (125 mg once daily for three out of four weeks in repeated cycles) in combination with letrozole versus letrozole alone (2.5 mg once daily on a continuous regimen) in post-menopausal women with ER+, HER2- advanced breast cancer. PFS is comprised of time from randomization to time of disease progression or death from any cause. PALOMA-1 was conducted in collaboration with the Jonsson Cancer Center’s Revlon/UCLA Women’s Cancer Research Program. PALOMA-1 is a multi-center trial with 101 global sites participating.

Palbociclib Development Program in ER+, HER2- Breast Cancer
Pfizer has worked closely with investigators and international breast cancer experts to establish a robust development program for palbociclib in ER+, HER2- breast cancer across stages and treatment settings.

Pfizer has initiated two Phase 3 studies of palbociclib in advanced/metastatic breast cancer. PALOMA-2 (also known as Study 1008) is a randomized (2:1), multi-center, double blind Phase 3 study that evaluates palbociclib in combination with letrozole versus letrozole plus placebo as first-line treatment for post-menopausal patients with ER+, HER2- advanced breast cancer. PALOMA-3 (also known as Study 1023) is a randomized (2:1), multi-center, double blind Phase 3 study that evaluates palbociclib in combination with fulvestrant versus fulvestrant plus placebo in women with hormone receptor-positive (HR+), HER2- metastatic breast cancer whose disease has progressed after prior endocrine therapy.

Additional, investigator-led studies of palbociclib in advanced/metastatic breast cancer and in early breast cancer are open and enrolling patients, including PENELOPE-B, a randomized (1:1), double blind, placebo-controlled Phase 3 study comparing palbociclib plus standard endocrine therapy to placebo plus standard endocrine therapy in patients with HR+, HER2-normal (also known as HER2-) early-stage breast cancer with certain features that suggest an increased risk for recurrence after completing pre-operative chemotherapy followed by surgery. This international study is sponsored by the German Breast Group (GBG).

For more information on these and other ongoing clinical trials of palbociclib, please visit www.clinicaltrials.gov.

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.

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. , 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). , 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. , 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.
Palbociclib is not approved for any indication in any markets.

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 February 3. 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 palbociclib, an investigational therapy, including potential indications and potential commercialization. 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 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 PALOMA-2 will demonstrate a statistically

significant improvement in progression-free survival; 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 jurisdictions for any potential indications for palbociclib; whether and when any such applications may be approved by regulatory authorities, as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such indications; and competitive developments.

A further description of risks and uncertainties can be found under the heading “Risk Factors” in Pfizer’s Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012 and in its subsequent reports on Form 10-Q and Form 8-K.

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