Pfizer Announces PALOMA-3 Trial For IBRANCE® (Palbociclib) Stopped Early Due To Efficacy Seen In Patients With HR+, HER2- Metastatic Breast Cancer Whose Disease Has Progressed Following Endocrine Therapy

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Phase 3 Top-Line Results Show IBRANCE in Combination with Fulvestrant Meets Progression-Free Survival (PFS) Primary Endpoint

Pfizer Inc. (NYSE:PFE) today announced that the Phase 3 PALOMA-3 trial for IBRANCE® (palbociclib) met its primary endpoint of demonstrating an improvement in progression-free survival (PFS) for the combination of IBRANCE plus fulvestrant compared with fulvestrant plus placebo in women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer following disease progression during or after endocrine therapy. The study was stopped early due to efficacy based on an assessment by an independent Data Monitoring Committee (DMC). These are the first randomized Phase 3 trial results for IBRANCE, a new anti-cancer medicine with the novel mechanism of cyclin-dependent kinase 4/6 (CDK 4/6) inhibition.

“The results of this trial are especially important because they help us understand the potential of IBRANCE to improve outcomes in patients with this difficult to treat cancer. We’re gratified to be able to stop the trial early and are engaging in discussions with

health authorities regarding a regulatory path forward," said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology.

The adverse events observed with IBRANCE in combination with fulvestrant in PALOMA-3 were generally consistent with their respective known adverse event profiles. Detailed efficacy and safety results from PALOMA-3 will be submitted for presentation at the American Society of Clinical Oncology (ASCO) 2015 Annual Meeting.

IBRANCE was approved by the U.S. Food and Drug Administration (FDA) in February 2015 as a first-line treatment for women with advanced or metastatic estrogen receptor positive, human epidermal growth factor receptor 2 negative (ER+/HER2-) breast cancer. IBRANCE® (palbociclib), in combination with letrozole, is indicated for the treatment of postmenopausal women with ER+/HER2- advanced breast cancer as initial endocrine-based therapy for their metastatic disease.i This indication is approved under accelerated approval based on PFS.i Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The confirmatory Phase 3 trial, PALOMA-2, is fully enrolled. IBRANCE is not approved for the use being investigated in PALOMA-3 or for any indication in any market outside the U.S.

The full prescribing information for IBRANCE can be found at www.IBRANCE.com.

Important IBRANCE (palbociclib) Safety Information from the U.S. Prescribing Information

Neutropenia: Neutropenia is frequently reported with IBRANCE therapy. In the randomized phase II study, Grade 3 (57%) or 4 (5%) decreased neutrophil counts were reported in patients receiving IBRANCE plus letrozole. Febrile neutropenia can occur.

Monitor complete blood count prior to starting IBRANCE and at the beginning of each cycle, as well as Day 14 of the first two cycles, and as clinically indicated. For patients who experience Grade 3 neutropenia, consider repeating the complete blood count monitoring 1 week later. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Infections: Infections have been reported at a higher rate in patients treated with IBRANCE plus letrozole (55%) compared with letrozole alone (34%). Grade 3 or 4 infections occurred in 5% of patients treated with IBRANCE plus letrozole vs no patients treated with letrozole alone. Monitor patients for signs and symptoms of infection and treat as medically appropriate.

Pulmonary embolism (PE): PE has been reported at a higher rate in patients treated with IBRANCE plus letrozole (5%) compared with no cases in patients treated with letrozole alone. Monitor patients for signs and symptoms of PE and treat as medically appropriate.

Pregnancy and lactation: Based on the mechanism of action, IBRANCE can cause fetal harm. Advise females with reproductive potential to use effective contraception during therapy with IBRANCE and for at least 2 weeks after the last dose. Advise females to contact their healthcare provider if they become pregnant or if pregnancy is suspected during treatment with IBRANCE. Advise women not to breastfeed while on IBRANCE therapy because of the potential for serious adverse reactions in nursing infants from IBRANCE.

Additional hematologic abnormalities: Decreases in hemoglobin (83% vs 40%), leukocytes (95% vs 26%), lymphocytes (81% vs 35%), and platelets (61% vs 16%) occurred at a higher rate in patients treated with IBRANCE plus letrozole vs letrozole alone.

Adverse reactions: The most common all causality adverse reactions (≥10%) of any grade reported in patients treated with IBRANCE plus letrozole vs letrozole alone in the phase II study included neutropenia (75% vs 5%), leukopenia (43% vs 3%), fatigue (41% vs 23%), anemia (35% vs 7%), upper respiratory infection (31% vs 18%), nausea (25% vs 13%), stomatitis (25% vs 7%), alopecia (22% vs 3%), diarrhea (21% vs 10%), thrombocytopenia (17% vs 1%), decreased appetite (16% vs 7%), vomiting (15% vs 4%), asthenia (13% vs 4%), peripheral neuropathy (13% vs 5%), and epistaxis (11% vs 1%).

Grade 3/4 adverse reactions reported (≥10%) occurring at a higher incidence in the IBRANCE plus letrozole vs letrozole alone group include neutropenia (54% vs 1%) and leukopenia (19% vs 0%). The most frequently reported serious adverse events in patients receiving IBRANCE were pulmonary embolism (4%) and diarrhea (2%).

General dosing information: The recommended dose of IBRANCE is 125 mg taken orally once daily for 21 days followed by 7 days off treatment in 28-day cycles. IBRANCE should be taken with food and in combination with letrozole 2.5 mg once daily continuously.

Patients should be encouraged to take their dose at approximately the same time each day.

Capsules should be swallowed whole. No capsule should be ingested if it is broken, cracked, or otherwise not intact. If a patient vomits or misses a dose, an additional dose should not be taken that day. The next prescribed dose should be taken at the usual

time.

Management of some adverse reactions may require temporary dose interruption/delay and/or dose reduction, or permanent discontinuation. Dose modification of IBRANCE is recommended based on individual safety and tolerability.

Drug interactions: Avoid concurrent use of strong CYP3A inhibitors. If patients must be administered a strong CYP3A inhibitor, reduce the IBRANCE dose to 75 mg/day. If the strong inhibitor is discontinued, increase the IBRANCE dose (after 3-5 half-lives of the inhibitor) to the dose used prior to the initiation of the strong CYP3A inhibitor. Grapefruit or grapefruit juice may increase plasma concentrations of IBRANCE and should be avoided.

Avoid concomitant use of strong and moderate CYP3A inducers. The dose of the sensitive CYP3A substrates with a narrow therapeutic index may need to be reduced as IBRANCE may increase their exposure.

Hepatic and renal impairment: IBRANCE has not been studied in patients with moderate to severe hepatic impairment or in patients with severe renal impairment (CrCl <30 mL/min).

About PALOMA-3

PALOMA-3 (also known as Study A5481023) is a randomized (2:1), multi-center, double blind Phase 3 study designed to assess the PFS of IBRANCE (125 mg once daily for three out of four weeks in repeated cycles) in combination with fulvestrant versus fulvestrant (500 mg intramuscularly on days 1 and 15 of cycle 1, and then on day 1 of each subsequent 28 day cycle) plus placebo in women with HR+, HER2- metastatic breast cancer whose disease has progressed during or after endocrine therapy. PFS is defined as time from randomization to time of disease progression or death from any cause. PALOMA-3 is a multi-center trial with more than 150 global sites participating and 521 patients enrolled.

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.

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DISCLOSURE NOTICE: The information contained in this release is as of April 15, 2015. 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 IBRANCE (palbociclib) 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 IBRANCE’s potential benefits and about a potential indication for the treatment of women with HR+/HER2- metastatic breast cancer following disease progression after prior endocrine therapy (the “Potential Indication”). Risks and uncertainties include, among other things, uncertainties regarding the commercial success of IBRANCE; the uncertainties inherent in research and development, including further investigation of the clinical benefit of IBRANCE, 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 the PALOMA-2 Phase 3 trial of IBRANCE for the indication for the first-line treatment of postmenopausal women with ER+/HER2- advanced breast cancer as initial endocrine-based therapy in combination with letrozole for their metastatic disease (the “Approved U.S. Indication”)

will demonstrate a statistically significant improvement in progression-free survival and whether the other trials of IBRANCE 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 jurisdictions other than the U.S. for the Approved U.S. Indication or in any jurisdictions for any other potential indications for IBRANCE, including the Potential Indication; whether and when any such applications may be approved by 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 regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of the Existing U.S. Indication or any other such indications, including the Potential Indication; 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, 2014 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.

i IBRANCE® (palbociclib) Prescribing Information. New York. NY: Pfizer Inc: 2015.

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