Pfizer Announces Palbociclib More Than Doubled Progression-Free Survival in Phase 3 Trial for Patients With HR+, HER2- Metastatic Breast Cancer Whose Disease Has Progressed Following Endocrine Therapy

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PALOMA-3 Data to Be Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO) and Published in The New England Journal of Medicine

Pfizer Inc. (NYSE:PFE) today announced study results demonstrating palbociclib in combination with fulvestrant was superior to treatment with a standard of care, fulvestrant, by significantly extending progression-free survival (PFS) in women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer whose disease has progressed during or after endocrine therapy (HR 0.42, median PFS, 9.2 vs. 3.8 months, in their respective arms, $p<0.000001$). Results from the Phase 3 PALOMA-3 study will be featured today in a press briefing during the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO) and will be presented as a late-breaker on Monday, June 1 at 8:00 a.m. CDT (Abstract #LBA502). The results will also be simultaneously published online by The New England Journal of Medicine. The Principal Investigator for the study, Nicholas C. Turner, MD, PhD, consultant medical oncologist at The Royal Marsden and Institute of Cancer Research in London, United Kingdom, will present these data.

“The current treatment options available for patients with this type of metastatic breast cancer present challenges for physicians and patients, as demonstrated by the limited clinical benefit of additional lines of endocrine therapy, and by the difficult side effects of chemotherapy,” said Dr. Turner. “The PALOMA-3 results demonstrate that palbociclib in combination with fulvestrant more than doubled the time before disease progression compared to fulvestrant alone, and suggest that palbociclib could be a promising treatment option for women with HR+, HER2- metastatic breast cancer after progression on endocrine therapy.”

“The results of PALOMA-3 are compelling and provide evidence that could potentially expand the role of palbociclib as an innovative first-in-class therapy for patients with metastatic breast cancer,” said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology.

PALOMA-3 (also known as Study A5481023) is a multi-center trial with more than 140 global sites participating and 521 patients enrolled. The study is a randomized (2:1), double-blind Phase 3 study designed to assess the PFS of palbociclib (125 mg once daily orally for three out of four weeks in each cycle) in combination with fulvestrant (500 mg intramuscularly on days 1 and 15 of cycle 1, and then on day 1 of each subsequent 28 day cycle) versus fulvestrant plus placebo in pre/perimenopausal and postmenopausal women with HR+, HER2- metastatic breast cancer whose disease has progressed during or after endocrine therapy. Pre/perimenopausal women also received ovarian suppression (goserelin). PFS is defined as time from randomization to time of disease progression or death from any cause.

As previously disclosed, the PALOMA-3 study met its primary endpoint of PFS at the interim analysis and was stopped early in April 2015 due to efficacy based on an assessment by an independent Data Monitoring Committee (DMC). Benefit from palbociclib was also demonstrated across all pre-specified subgroups, including both pre/perimenopausal and postmenopausal patients. At the time of the PFS analysis, overall survival (OS) data was immature.

The adverse events observed with palbociclib in combination with fulvestrant in PALOMA-3 were consistent with their respective labeled adverse event profiles. The most common adverse events reported for the palbociclib-fulvestrant group were neutropenia, leukopenia, fatigue and nausea. The rate of febrile neutropenia (0.6%) was the same in both arms in the study. Serious adverse events were balanced across arms in the study. The discontinuation rate due to adverse events was 2.6% on the palbociclib plus fulvestrant arm and 1.7% on the fulvestrant plus placebo arm.

Based on the results of PALOMA-3, Pfizer is in discussions with global regulatory authorities to determine next steps to potentially make palbociclib available for women with HR+, HER2- metastatic breast cancer whose disease has progressed following endocrine therapy. As previously disclosed, Pfizer intends to file a Marketing Authorisation Application for palbociclib to the European Medicines Agency (EMA) in the second half of 2015. In addition, Pfizer will work closely with the FDA to review these data and determine next steps for potential inclusion in the U.S. label.

Palbociclib, under the brand name IBRANCE®, was approved in combination with letrozole by the U.S. Food and Drug Administration (FDA) in February 2015 for the treatment of postmenopausal women with estrogen receptor-positive (ER+)/HER2- advanced breast cancer as initial endocrine-based therapy for their metastatic disease.1 This indication is approved under accelerated approval based on PFS. 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.

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

About IBRANCE®

IBRANCE (palbociclib) is an oral inhibitor of cyclin-dependent kinases (CDKs) 4 and 6.1 CDKs 4 and 6 are key regulators of the cell cycle that trigger cellular progression.2,3 IBRANCE is indicated in the U.S. for use in combination with letrozole for the treatment of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced breast cancer as initial endocrine-based therapy for their metastatic disease.1

The effectiveness of IBRANCE in these patients is based on a study that measured progression-free survival.1Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT IBRANCE (palbociclib) SAFETY 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 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 May 30, 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, about a planned filing of a Marketing Authorisation Application for palbociclib in Europe and about a potential indication for the treatment of women with HR+/HER2- metastatic breast cancer in combination with endocrine therapy. 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 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 or supplemental drug applications may be filed with the European Medicines

Agency, U.S. Food and Drug Administration, or in any other jurisdictions for potential HR+/HER2- metastatic breast cancer indications for IBRANCE; 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 IBRANCE; 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 and Factors 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.govand www.pfizer.com.

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

2 Weinberg RA. pRb and Control of the Cell Cycle Clock. In: Weinberg RA, ed. The Biology of Cancer. 2nd ed. New York, NY: Garland Science; 2014:275-329.

3 Sotillo E, Grana X. Escape from Cellular Quiescence. In: Enders GH, ed. Cell Cycle Deregulation in Cancer. New York, NY: Humana Press; 2010:3-22.

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