Updated Data from Phase 3 Trial of IBRANCE® (palbociclib) Plus Letrozole in ER+, HER2- Metastatic Breast Cancer Confirm Improvement in Progression-Free Survival

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Median follow-up of more than three years is longest for any Phase 3 trial of a CDK 4/6 inhibitor New real-world data for IBRANCE, including in young women, also reported

Pfizer Inc. (NYSE:PFE) today announced updated progression-free survival (PFS) results from the Phase 3 PALOMA-2 trial reinforcing the clinical benefit of IBRANCE® (palbociclib) combined with letrozole. The data, which will be presented at the 2017 San Antonio Breast Cancer Symposium (SABCS) on December 8 [abstract #P5-21-03], demonstrate that the combination of IBRANCE plus letrozole reduced the risk of disease progression by 44 percent and improved median PFS by more than one year compared to letrozole plus placebo (27.6 months [95% CI: 22.4, 30.3] vs 14.5 months [95% CI: 12.3, 17.1]) when used as the initial treatment for postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+, HER2-) metastatic breast cancer (HR=0.56 [95% CI: 0.46, 0.69]). This updated, post-hoc analysis included a median follow-up of more than three years, which is the longest to date of any Phase 3 study of a CDK 4/6 inhibitor.

The updated data are consistent with results from the primary analysis for PALOMA-2, which showed a median PFS for women treated with IBRANCE plus letrozole of 24.8 months (95% CI: 22.1, NE) compared with 14.5 months (95% CI: 12.9, 17.1) for women treated with letrozole plus placebo (HR=0.58 [95% CI: 0.46,0.72], p<0.0001). Consistent

with findings from the primary analysis, the updated data demonstrate that clinical benefit was observed across all patient subgroups receiving the combination of IBRANCE and letrozole. Overall survival data were not yet mature at the time of this updated PFS analysis.

“There currently is no cure for metastatic breast cancer, so prolonging progression-free survival and delaying the need for additional anticancer therapies are critical factors in treating these patients,” said Hope Rugo, MD, lead author and professor of medicine and director of Breast Oncology and Clinical Trials Education at the University of California San Francisco Helen Diller Family Comprehensive Cancer Center. “The updated findings from PALOMA-2 provide additional evidence to support the use of palbociclib with an aromatase inhibitor as a standard of care in the first-line setting for postmenopausal patients with hormone receptor-positive (HR+), HER2- metastatic breast cancer across all patient subgroups.”

At SABCS, 10 additional Pfizer-sponsored abstracts will be presented evaluating IBRANCE, several of which explore further analysis of PALOMA-2 along with three real-world studies of patients treated with IBRANCE in clinical practice. These real-world data include patients who have received IBRANCE in combination with endocrine therapy in various settings and across age groups, including young women (aged 50 years and under, which functioned as a surrogate for premenopausal status in the analysis).

“The real-world data to be presented at SABCS underscore the transformational impact IBRANCE has made on the treatment of HR+, HER2- metastatic breast cancer, and provide important insights into the way in which IBRANCE is being used in clinical practice,” said Mace Rothenberg, MD, chief development officer, Oncology, Pfizer Global Product Development. “The rapid adoption of IBRANCE in young women is particularly notable because premenopausal women with metastatic breast cancer historically have had fewer approved treatment options available to them than postmenopausal women. The PALOMA-3 trial of IBRANCE was the first Phase 3 trial of a CDK 4/6 inhibitor to include premenopausal women and establish its efficacy in this patient population.”

The safety profile of IBRANCE in the PALOMA-2 updated analysis is consistent with previous reports and will be presented at SABCS. In the primary analysis, the most common adverse reactions (≥20%) of any grade reported in the PALOMA-2 study of IBRANCE plus letrozole vs placebo plus letrozole included neutropenia (80% vs 6%), infections (60% vs 42%), leukopenia (39% vs 2%), fatigue (37% vs 28%), nausea (35% vs 26%), alopecia (33% vs 16%), stomatitis (30% vs 14%), diarrhea (26% vs 19%) and anemia (24% vs 9%).1

IBRANCE was the first CDK 4/6 inhibitor approved by any regulatory authority, and now is approved in more than 75 countries. These global approvals are based on data from the PALOMA program, including PALOMA-2 as well as the Phase 3 PALOMA-3 trial, which evaluated IBRANCE in combination with fulvestrant in pre-, peri- and postmenopausal women with HR+, HER2- metastatic breast cancer whose disease progressed on or after prior endocrine therapy. Pre- and peri-menopausal women enrolled in PALOMA-3 received the LHRH agonist goserelin.

To date, IBRANCE has been prescribed to more than 90,000 patients worldwide.

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

About PALOMA-2

PALOMA-2 is a randomized (2:1), multicenter, multinational, double-blind Phase 3 study designed to assess the PFS of IBRANCE (125 mg orally once daily for three out of four weeks in repeated cycles) in combination with letrozole (2.5 mg once daily continuously) versus letrozole plus placebo as a first-line treatment for postmenopausal women with ER+, HER2- metastatic breast cancer. PALOMA-2 evaluated a total of 666 women from 186 global sites in 17 countries.

Results from PALOMA-2 after a median 23-month follow-up were previously published in The New England Journal of Medicine in November 2016.

About IBRANCE® (palbociclib) 125 mg capsules

IBRANCE is an oral inhibitor of CDKs 4 and 6,1 which are key regulators of the cell cycle that trigger cellular progression.2,3 In the U.S., IBRANCE is indicated for the treatment of HR+, HER2- advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or fulvestrant in women with disease progression following endocrine therapy.

IMPORTANT IBRANCE® (palbociclib) SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION

Neutropenia was the most frequently reported adverse reaction in PALOMA-2 (80%) and PALOMA-3 (83%). In PALOMA-2, Grade 3 (56%) or 4 (10%) decreased neutrophil counts were reported in patients receiving IBRANCE plus letrozole. In PALOMA-3, Grade 3 (55%) or Grade 4 (11%) decreased neutrophil counts were reported in patients receiving IBRANCE plus fulvestrant. Febrile neutropenia has been reported in 1.8% of patients exposed to IBRANCE across PALOMA-2 and PALOMA-3. One death due to neutropenic

sepsis was observed in PALOMA-3. Inform patients to promptly report any fever.

Monitor complete blood count prior to starting IBRANCE, at the beginning of each cycle, on Day 15 of first 2 cycles and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Based on the mechanism of action, IBRANCE can cause fetal harm. Advise females of reproductive potential to use effective contraception during IBRANCE treatment and for at least 3 weeks after the last dose. IBRANCE may impair fertility in males and has the potential to cause genotoxicity. Advise male patients with female partners of reproductive potential to use effective contraception during IBRANCE treatment and for 3 months after the last dose. Advise females to inform their healthcare provider of a known or suspected pregnancy. Advise women not to breastfeed during IBRANCE treatment and for 3 weeks after the last dose because of the potential for serious adverse reactions in nursing infants.

The most common adverse reactions (≥10%) of any grade reported in PALOMA-2 for IBRANCE plus letrozole vs placebo plus letrozole were neutropenia (80% vs 6%), infections (60% vs 42%), leukopenia (39% vs 2%), fatigue (37% vs 28%), nausea (35% vs 26%), alopecia (33% vs 16%), stomatitis (30% vs 14%), diarrhea (26% vs 19%), anemia (24% vs 9%), rash (18% vs 12%), asthenia (17% vs 12%), thrombocytopenia (16% vs 1%), vomiting (16% vs 17%), decreased appetite (15% vs 9%), dry skin (12% vs 6%), pyrexia (12% vs 9%), and dysgeusia (10% vs 5%).

The most frequently reported Grade ≥3 adverse reactions (≥5%) in PALOMA-2 for IBRANCE plus letrozole vs placebo plus letrozole were neutropenia (66% vs 2%), leukopenia (25% vs 0%), infections (7% vs 3%), and anemia (5% vs 2%).

Lab abnormalities of any grade occurring in PALOMA-2 for IBRANCE plus letrozole vs placebo plus letrozole were decreased WBC (97% vs 25%), decreased neutrophils (95% vs 20%), anemia (78% vs 42%), decreased platelets (63% vs 14%), increased aspartate aminotransferase (52% vs 34%), and increased alanine aminotransferase (43% vs 30%).

The most common adverse reactions (≥10%) of any grade reported in PALOMA-3 for IBRANCE plus fulvestrant vs placebo plus fulvestrant were neutropenia (83% vs 4%), leukopenia (53% vs 5%), infections (47% vs 31%), fatigue (41% vs 29%), nausea (34% vs 28%), anemia (30% vs 13%), stomatitis (28% vs 13%), diarrhea (24% vs 19%), thrombocytopenia (23% vs 0%), vomiting (19% vs 15%), alopecia (18% vs 6%), rash (17% vs 6%), decreased appetite (16% vs 8%), and pyrexia (13% vs 5%).

The most frequently reported Grade ≥3 adverse reactions (≥5%) in PALOMA-3 for IBRANCE plus fulvestrant vs placebo plus fulvestrant were neutropenia (66% vs 1%) and leukopenia (31% vs 2%).

Lab abnormalities of any grade occurring in PALOMA-3 for IBRANCE plus fulvestrant vs placebo plus fulvestrant were decreased WBC (99% vs 26%), decreased neutrophils (96% vs 14%), anemia (78% vs 40%), decreased platelets (62% vs 10%), increased aspartate aminotransferase (43% vs 48%), and increased alanine aminotransferase (36% vs 34%).

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 CYP3A inducers. The dose of sensitive CYP3A substrates with a narrow therapeutic index may need to be reduced as IBRANCE may increase their exposure.

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 pursuing innovative treatments that have a meaningful impact on people living with cancer. Our growing pipeline of biologics, small molecules, and immunotherapies is focused on identifying and translating the best scientific breakthroughs into clinical application for patients across a diverse array of solid tumors and hematologic cancers. Today, we have 10 approved oncology medicines and 17 assets currently in clinical development. By maximizing our internal scientific resources and collaborating with other companies, government and academic institutions, as well as non-profit and professional organizations, we are bringing together the brightest and most enterprising minds to take on the toughest cancers. Together we can accelerate breakthrough treatments to patients around the world and work to redefine life with cancer.

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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube, and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of December 6, 2017. 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) and Pfizer’s oncology portfolio, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of IBRANCE and Pfizer’s oncology portfolio; 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 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 additional jurisdictions for IBRANCE for potential HR+/HER2- metastatic breast cancer indications or in any jurisdictions for any other potential indications for IBRANCE or any other oncology products; whether and when any such other 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 or other oncology products; 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, 2016 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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

1 IBRANCE® (palbociclib) Prescribing Information. New York. NY: Pfizer Inc: 2017. 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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