Pfizer Presents Data from PALOMA-2 Phase 3 Study Demonstrating Clinical Benefit of IBRANCE® (palbociclib) in Asian Women with ER+, HER2- Metastatic Breast Cancer at ESMO Asia Congress

Monday, December 19, 2016 - 04:59am

Sub-analysis of Asian Patients Data Shows First-in-class IBRANCE in Combination with Letrozole Extended Progression Free Survival (PFS) by More Than 11 Months to Result in Median PFS of More than Two Years

SINGAPORE: Pfizer Inc. today announced results from a sub-analysis studying Asian patients from the Phase 3 PALOMA-2 trial of IBRANCE® (palbociclib), in combination with letrozole, as first-line therapy for postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+, HER2-) metastatic breast cancer. Results showed the combination of IBRANCE and letrozole significantly extended progression-free survival (PFS) by more than 11 months compared with letrozole plus placebo, and demonstrated that the median PFS exceeded two years in these patients. Data from this sub-analysis was shared on December 17 as an oral presentation at the 2nd ESMO Asia Congress in Singapore.

“It is exciting to see that the significant efficacy shown in the PALOMA-2 trial extends to Asian patients, further supporting the potential for IBRANCE to be a standard of care treatment in Asia Pacific, a region where more than 600,000 women are affected by breast cancer each year. ” said Dr. Mahmood Alam, Regional Medical Lead, Pfizer

Oncology for the Asia Pacific region.

In this sub-analysis of the PALOMA-2 trial, investigator-assessed median PFS for Asian women treated with IBRANCE plus letrozole was 25.7 months (95% CI, 19.2-not estimable) compared with 13.9 months (95% CI, 7.4-22.0) for women treated with letrozole plus placebo (HR=0.48 [95% CI, 0.27-0.87], 1-sided P=0.007).

“Across the Asia Pacific region, breast cancer has grown into a major health concern, with significant increases in breast cancer incidence in recent years in several Asian countries,” said Dr. Seock-Ah Im of Seoul National University Hospital, “Patients with metastatic breast cancer, in particular those in Asia, eagerly await new and innovative treatment options.”

The Phase 3 PALOMA-2 trial evaluated the use of IBRANCE in combination with letrozole in the first-line setting, which was first studied in the randomized Phase 2 PALOMA-1 trial, and the results reinforce the clinical benefit of IBRANCE in this treatment setting. The findings of this PALOMA-2 sub-analysis evaluating the efficacy and safety in Asian women are consistent with the overall findings of PALOMA-2. The most common adverse events of all grades with IBRANCE plus letrozole versus placebo plus letrozole were neutropenia (95% vs 13%), infections (66% vs 50%) and stomatitis (49% vs 20%). For more information, please see Important Safety Information for IBRANCE below.

Breast cancer is the most common cancer in women worldwide, with an estimated 1.7 million new cases each year and more than 600,000 in the Asia Pacific region.1 While one-third of women with breast cancer globally were estimated to be under 50 when they were diagnosed, 42 percent of women diagnosed with breast cancer throughout Asia-Pacific were under 50.2 Globally, up to 30 percent of women diagnosed with and treated for early breast cancer will go on to develop metastatic breast cancer,3,4 which currently remains incurable.5 Patients diagnosed with metastatic breast cancer today face a median survival of 18 to 24 months,6 and are in great need of more meaningful advances and options in the treatment to address the high unmet need.

IBRANCE®/palbociclib is currently approved by regulatory authorities in in Asia in Macau, Singapore, Malaysia, Hong Kong, South Korea and India in combination with letrozole for the treatment of postmenopausal women with ER+, HER2- advanced breast cancer as initial endocrine-based therapy for their metastatic disease.

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.7

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

About IBRANCE® (palbociclib)
IBRANCE is the first and only U.S. Food and Drug Administration FDA approved oral inhibitor of CDKs 4 and 6,7 which are key regulators of the cell cycle that trigger cellular progression.8,9 In the U.S., IBRANCE is indicated for the treatment of HR+, HER2- advanced or metastatic breast cancer in combination with letrozole as initial endocrine based therapy in postmenopausal women, or fulvestrant in women with disease progression following endocrine therapy.2 The indication in combination with letrozole 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, PALOMA-2.7

Important IBRANCE (palbociclib) Safety Information from the U.S. Prescribing Information
Neutropenia was the most frequently reported adverse reaction in PALOMA-1 (75%) and PALOMA-3 (83%). In PALOMA-1, Grade 3 (57%) or 4 (5%) decreased neutrophil counts were reported in patients receiving IBRANCE plus letrozole. In PALOMA-3, Grade 3 (56%) or Grade 4 (11%) decreased neutrophil counts were reported in patients receiving IBRANCE plus fulvestrant. Febrile neutropenia has been reported in about 1% of patients exposed to IBRANCE. 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 14 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.

Pulmonary embolism (PE) has been reported at a higher rate in patients treated with IBRANCE plus letrozole in PALOMA-1 (5%) and in patients treated with IBRANCE plus

fulvestrant in PALOMA-3 (1%) compared with no cases in patients treated either with letrozole alone or fulvestrant plus placebo. Monitor for signs and symptoms of PE and treat as medically appropriate.

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-1** of IBRANCE plus letrozole vs letrozole alone 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 (≥10%) in **PALOMA-1** reported at a higher incidence in the IBRANCE plus letrozole group vs the letrozole alone group included neutropenia (54% vs 1%) and leukopenia (19% vs 0%). The most frequently reported serious adverse events in patients receiving IBRANCE plus letrozole were pulmonary embolism (4%) and diarrhea (2%).

Lab abnormalities occurring in **PALOMA-1** (all grades, IBRANCE plus letrozole vs letrozole alone) were decreased WBC (95% vs 26%), decreased neutrophils (94% vs 17%), decreased lymphocytes (81% vs 35%), decreased hemoglobin (83% vs 40%), and decreased platelets (61% vs 16%).

The **most common adverse reactions (≥10%)** of any grade reported in **PALOMA-3** of IBRANCE plus fulvestrant vs fulvestrant plus placebo included 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%), headache (26% vs 20%), diarrhea

(24% vs 19%), thrombocytopenia (23% vs 0%), constipation (20% vs 16%), vomiting (19% vs 15%), alopecia (18% vs 6%), rash (17% vs 6%), decreased appetite (16% vs 8%), and pyrexia (13% vs 5%).

Grade 3/4 adverse reactions (≥10%) in **PALOMA-3** reported at a higher incidence in the IBRANCE plus fulvestrant group vs the fulvestrant plus placebo group included neutropenia (66% vs 1%) and leukopenia (31% vs 2%). The most frequently reported serious adverse reactions in patients receiving IBRANCE plus fulvestrant were infections (3%), pyrexia (1%), neutropenia (1%), and pulmonary embolism (1%).

Lab abnormalities occurring in **PALOMA-3** (all grades, IBRANCE plus fulvestrant vs fulvestrant plus placebo) were decreased WBC (99% vs 26%), decreased neutrophils (96% vs 14%), anemia (78% vs 40%), and decreased platelets (62% vs 10%).

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 those living with cancer. As a leader in oncology speeding cures and accessible breakthrough medicines to patients, Pfizer Oncology is helping to redefine life with cancer. Our strong pipeline of biologics, small molecules and immunotherapies, 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 its breakthrough medicines. Because Pfizer Oncology knows that success in oncology is not measured solely by the medicines

you manufacture, but rather by the meaningful partnerships you make to have a more positive impact on people’s lives.

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 healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare 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. For more information, please visit us at www.pfizer.com. In addition, to learn more, 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 19, 2016. 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), including its 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; 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 regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when the accelerated approval for IBRANCE will be converted to regular approval in the U.S.; 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; whether and when any other applications for IBRANCE 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, 2015 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.

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