



# Pfizer Awards More Than \$4 Million in Grants to Further Clinical Research in Advanced Breast Cancer for 2015

Tuesday, December 08, 2015 - 03:00am

Additional \$4 million in funding to be awarded in 2016

Pfizer Inc. today announced the first-ever recipients of the Advancing Science through Pfizer Investigator Research Exchange (ASPIRE) Breast Cancer Research Awards. Five grants totaling more than \$4 million in funding were awarded to support clinical research projects investigating IBRANCE® (palbociclib), an oral, first-in-class inhibitor of cyclin-dependent kinases (CDKs) 4 and 6, in advanced breast cancer for 2015. Simultaneously, the company announced that it will award up to \$4 million in new grants through the ASPIRE Breast Cancer Research Awards Program in 2016.

“We are excited to support these five investigator-led studies, which we believe will contribute important new information to our body of knowledge about the role IBRANCE plays in the treatment and clinical management of advanced breast cancer,” said Dr. Julia Perkins Smith, senior medical director, U.S. Breast Cancer Lead, Pfizer Oncology. “At the same time, we are looking forward to continuing the program in 2016 and further supporting investigators’ efforts in this disease area, where there is a substantial need for research that may lead to new options and improved care for metastatic breast cancer patients. Supporting the scientific and clinical exploration of our medicines both within and outside our walls is critical to our ability to make a meaningful impact on patients’ lives.”

The ASPIRE Breast Cancer Research Awards Program is an extension of ASPIRE, Pfizer’s competitive grants program. Recipients were selected through a competitive application

process overseen by an independent review panel of breast cancer experts. The following five investigators and studies have been awarded grants through the program to date:

Sara Tolaney, MD, MPH, Dana-Farber Cancer Institute – A Phase Ib/IIa Study of Palbociclib in Combination With Everolimus and Exemestane in Postmenopausal Women With Estrogen Receptor Positive and HER2 Negative Metastatic Breast Cancer Ewa Mrozek, MD, The Ohio State University Comprehensive Cancer Center - Arthur G. James Cancer Hospital and Richard J. Solove Research Institute – A Phase II Trial of Primary Endocrine Therapy With Combination of Fulvestrant and Palbociclib in Elderly Patients With Hormone Responsive Breast Cancer Who Have Inoperable Tumor or Operable Tumor but Cannot Undergo Surgery Due to Frailty Oana Danciu, MD, University of Illinois at Chicago – A Single Arm Phase II Study of Palbociclib in Combination With Tamoxifen as First Line Therapy for Metastatic Hormone Receptor Positive Breast Cancer Cesar Augusto Santa-Maria, MD, Northwestern University – A Single Arm Phase II Study of Palbociclib in Patients With Metastatic HER2-positive or Triple Negative Breast Cancer With Brain Metastasis Filipa Lynce, MD, Lombardi Comprehensive Cancer Center at Georgetown University Medical Center – A Phase II Safety Study of Palbociclib in Combination With Letrozole in African American Women with Hormone Receptor Positive HER2 Negative Advanced Breast Cancer

For the new 2016 grants, investigators are encouraged to submit for consideration proposals for innovative research in several areas. Some areas of research interest include:

Improving the medical knowledge of palbociclib in the treatment of advanced breast cancer through exploring the safety and efficacy of novel combinations Optimizing clinical management during palbociclib treatment that addresses or improves patient compliance and convenience and/or patient reported outcomes Exploring biomarkers relevant to palbociclib in breast cancer

For more information about the 2016 ASPIRE Breast Cancer Research Awards Program and specifics regarding eligible areas of research, please visit [www.aspireresearch.org](http://www.aspireresearch.org). The proposal submission period ends March 31, 2016.

About IBRANCE® (palbociclib)

IBRANCE is an oral, first-in-class inhibitor of cyclin-dependent kinases (CDKs) 4 and 6. CDKs 4 and 6 are key regulators of the cell cycle that trigger cellular progression.<sup>1,2</sup>

IBRANCE is approved by the FDA for use in combination with letrozole as a treatment for 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.<sup>3</sup> The effectiveness of IBRANCE in these patients is based on a study that measured progression-free survival.<sup>3</sup> 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. The full prescribing information for IBRANCE can be found at [www.IBRANCE.com](http://www.IBRANCE.com).

IBRANCE has also received regulatory approval in Albania, Chile and Macau. In the European Union, the Marketing Authorization Application for IBRANCE, which is based on results from the PALOMA-1 and PALOMA-3 trials, is currently under review with the European Marketing Agency.

### 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 ( $\geq 10\%$ ) 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 ( $\geq 10\%$ ) 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](http://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](http://www.pfizer.com).

DISCLOSURE NOTICE: The information contained in this release is as of December 8, 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) and the ASPIRE program, 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; 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 new or supplemental drug applications may be filed in jurisdictions outside the United States 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 U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

1 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.

2 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.

3 IBRANCE® (palbociclib) Prescribing Information. New York, NY: Pfizer Inc; 2015.

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