



# Pfizer Announces \$3 Million Grants Program to Further Clinical Research in Advanced Breast Cancer

Thursday, May 28, 2015 - 04:30am

Pfizer Inc. today announced the launch of a competitive, peer-reviewed grants program to support clinical research projects investigating IBRANCE® (palbociclib) in advanced breast cancer. The multi-year program, which will award a total of up to \$3 million in grants to investigators in the United States, is an extension of Pfizer's Advancing Science through Pfizer Investigator Research Exchange (ASPIRE) initiative. It is the first ASPIRE program to focus on breast cancer research.

IBRANCE received accelerated approval by the U.S. Food and Drug Administration in February 2015 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.

"We believe the ASPIRE Breast Cancer Research Awards will contribute important information to our body of knowledge about the role IBRANCE plays in the treatment and clinical management of advanced breast cancer, and will complement the robust clinical development program we have ongoing," said Dr. Julia Perkins Smith, senior medical director, U.S. Breast Cancer Lead, Pfizer Oncology. "Through these awards, we also look forward to supporting the mission of the ASPIRE program to further academic research and nurture the career development of emerging investigators in a disease area of high unmet medical need."

“This is an exciting opportunity to gain a better understanding of the efficacy and tolerability of CDK inhibition in ER+ breast cancer,” said Dr. Ruth O’Regan, head of hematology and oncology in the Department of Medicine at the University of Wisconsin School of Medicine and Public Health.

Grantees will be selected through a competitive application process overseen by an independent review panel of breast cancer experts.

The review panel encourages investigators (with a special interest for emerging researchers at Assistant Professor level or equivalent) to submit applications for innovative research in several areas. Highlights of the research of interest include:

Improving the medical knowledge of palbociclib in the treatment of advanced breast cancer  
Optimizing clinical management during palbociclib treatment that addresses or improves patient compliance and convenience and/or patient reported outcomes  
For more information about the ASPIRE Breast Cancer Research Awards and specifics regarding eligible areas of research, please visit [www.aspireresearch.org](http://www.aspireresearch.org). The application submission period ends September 8, 2015, and successful awardees will be notified in October. Pfizer anticipates providing up to six awards to investigators in the United States.

#### About IBRANCE®

IBRANCE is an oral 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>2,3</sup> 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. The effectiveness of IBRANCE in these patients is based on a study that measured progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

The full prescribing information for IBRANCE can be found at [www.IBRANCE.com](http://www.IBRANCE.com). IBRANCE is not approved for any indication in any market outside the U.S.

#### 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 ( $\text{CrCl} < 30$  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 May 28, 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 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 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 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 SEC and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

1IBRANCE® (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.

Media:Sally Beatty, 212-733-6566orInvestor:Ryan Crowe, 212-733-8160