Pfizer to Award More Than $3 Million in Grants to Further Breast Cancer Research

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The ASPIRE awards underscore Pfizer’s commitment to collaborating with investigators to expand scientific knowledge and improve the treatment of breast cancer.

Pfizer Inc. today announced the recipients of the Advancing Science through Pfizer Investigator Research Exchange (ASPIRE) Breast Cancer Research Awards. Four grants totaling more than $3 million (USD) in funding will be awarded to investigators in the United States (U.S.) to support clinical research projects involving Pfizer compounds in breast cancer. Since 2015, Pfizer has provided more than $16 million in total funding for the ASPIRE Oncology Research Awards Program across breast and hematologic cancers.

“The ASPIRE awards underscore Pfizer’s commitment to collaborating with investigators to expand scientific knowledge and improve the treatment of breast cancer,” said Lynn McRoy, M.D., breast cancer lead, U.S. Medical Affairs, Pfizer Oncology. "The recipients of the 2018 awards submitted outstanding clinical research proposals that have the potential to advance care for people living with breast cancer.”

Recipients of the 2018 awards were selected through a competitive application process overseen by an independent review panel of experts. The following investigators and studies have been selected to receive grants:

Dr. Mylin A. Torres, Glenn Family Breast Center, Winship Cancer Institute, Emory University - A Phase 2 Multi-institutional Study of Concurrent Radiotherapy, Palbociclib, and Hormone Therapy for Treatment of Bone Metastasis in Breast Cancer Patients Dr. Aditya Bardia, Massachusetts General Hospital Cancer Center - Evaluation of Talazoparib, a PARP Inhibitor, for Patients With Somatic BRCA Mutant Metastatic Breast Cancer in a Genotyping Based Clinical Trial Dr. Antoinette Tan, Levine Cancer Institute, Atrium Health

- IGNITE-Immunoprofiling of Gedatolisib, a Dual PI3-Kinase and mTOR Inhibitor, in the Neo-Immunoadjuvant Treatment of Early Stage Breast Cancer Dr. Kari Wisinski, University of Wisconsin Carbone Cancer Center - Phase 2 Trial with Safety Run-In of Gedatolisib Plus Talazoparib in Advanced Triple Negative or BRCA1 or 2 Positive, HER2 Negative Breast Cancers

Investigators in the U.S. were encouraged to submit proposals for the 2018 ASPIRE Breast Cancer Research Awards that advance knowledge in the treatment and disease management of breast cancer. Proposals were eligible for IBRANCE® (palbociclib), an oral, first-in-class inhibitor of cyclin-dependent kinases (CDKs) 4 and 6, for metastatic breast cancer, the most advanced stage of breast cancer (stage IV)1,2; talazoparib, an investigational, once-daily, oral poly ADP ribose polymerase (PARP) inhibitor; and gedatolisib (PF-05212384), an investigational, small molecule, dual inhibitor targeting the phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) signaling pathways in the development of solid tumors.

For more information about ASPIRE, please visit www.aspireresearch.org.

About IBRANCE® (palbociclib) 125 mg capsules 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. 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.

For patients with **severe hepatic impairment** (Child-Pugh class C), the recommended dose of IBRANCE is 75 mg. The pharmacokinetics of IBRANCE **have not been studied** in patients **requiring hemodialysis**.

Please see full Prescribing Information for additional safety information.

About Pfizer Oncology At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference on the lives of patients. Today, Pfizer Oncology has an industry-leading portfolio of 11 approved cancer medicines across 19 indications, including breast, prostate, kidney, lung and hematology. We also have one of the deepest oncology biosimilars pipelines, with two medicines approved globally and several assets in mid to late-stage development for the treatment of cancer or as supportive care. Pfizer Oncology is striving to change the trajectory of cancer.

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, 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.

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1 BreastCancer.org. Stages of breast cancer. http://www.breastcancer.org/symptoms/diagnosis/staging. Accessed August 8, 2018. 2 American Cancer Society. Treatment of invasive breast cancer, by stage. http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-treating-by-stage. Accessed August 8, 2018.

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