Pfizer Announces Expansion of ASPIRE Awards Program for 2017 to Include $5.5M in Funding for Breast and Hematologic Cancers

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2016 ASPIRE Breast Cancer Research Award Winners Also Unveiled

Pfizer Inc. (NYSE:PFE) today announced that it will expand the company's Advancing Science through Pfizer Investigator Research Exchange (ASPIRE) program in 2017 to award up to $5.5 million (USD) in new competitive grants to fund research studies involving Pfizer products in both breast and hematologic cancers. This expanded program will be known as the ASPIRE Oncology/Hematology Clinical Research Awards.

"We look forward to enhancing this important grants program in 2017 to further support investigator-initiated efforts in both breast and hematologic cancers where there is a substantial need for research that may lead to improved care," said Graciela Mabel Woloj, PhD, senior director, Medical Affairs, Pfizer Oncology. "Supporting research projects that advance medical and scientific knowledge about our therapies is at the cornerstone of our commitment to meeting the needs of the cancer community."

Investigators in the United States are encouraged to submit proposals for innovative clinical research that evaluates select Pfizer compounds and that is aimed at advancing knowledge in the treatment and disease management of breast cancer as well as hematologic malignancies. Proposals should include 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] Mylotarg (gemtuzumab ozogamicin), an investigational antibody-drug conjugate (ADC) targeting CD33, for acute myeloid leukemia (AML),[2],[3] the most common leukemia in adults;[4] and inotuzumab

ozogamicin, an investigational ADC targeting CD22, for acute lymphoblastic leukemia (ALL), a rapidly progressing blood cancer with the lowest five-year survival rate among all leukemias.[5]

Pfizer also announced the 2016 ASPIRE Breast Cancer Research Award recipients, who were selected through a competitive application process overseen by an independent review panel of breast cancer experts. Four grants totaling more than $3 million in funding were awarded to investigators in the United States in support of clinical research projects investigating IBRANCE. The following investigators and studies have been awarded grants:

Drs. Ingred Mayer and Carlos Arteaga, Vanderbilt University School of Medicine – Phase Ib trial of Fulvestrant, Palbociclib (CDK 4/6 Inhibitor) and Erdafitinib (JNJ-42756493, pan-FGFG tyrosine kinase inhibitor) in ER+/HER2-/FGFR- amplified metastatic breast cancer Dr. Amy Tiersten, Mount Sinai School of Medicine – Multicenter, Phase I/II Trial of Arimidex, Palbociclib, Trastuzumab and Pertuzumab in HR-positive, HER2-positive Metastatic Breast Cancer Drs. Elena Shagisultanova and Virginia Borges, University of Colorado-Denver – Phase Ib/II Open-Label Single Arm Study to Evaluate Safety and Efficacy of ONT-380 in Combination with Palbociclib and Letrozole in Patients with Hormone Receptor-Positive and HER2-Positive Metastatic Breast Cancer

The $5.5 million (USD) allocated for the 2017 ASPIRE Oncology/Hematology Clinical Research Awards will fund six to eight studies. The proposal submission period ends March 31, 2017.

For more information about the 2017 ASPIRE Oncology/Hematology Clinical Research Awards and to submit your proposal, please visit www.aspireresearch.org.

About IBRANCE® (palbociclib)

IBRANCE is the first and only FDA approved oral inhibitor of CDKs 4 and 6,[6] which are key regulators of the cell cycle that trigger cellular progression.[7],[8]

IBRANCE is indicated for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2-negative (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.6 The indication in combination with letrozole is approved under accelerated approval based on

progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

About Mylotarg (Gemtuzumab Ozogamicin)

Mylotarg is an investigational ADC comprised of the cytotoxic agent calicheamicin attached to a monoclonal antibody (mAB) that targets CD33, an antigen expressed on the surface of leukemic blasts in more than 80 percent of AML patients.[9],[10],[11] When Mylotarg binds to the CD33 antigen on leukemia cells it is absorbed into the cell, at which point the cytotoxic agent calicheamicin is released to destroy the cell.[12],[13]

About Inotuzumab Ozogamicin

Inotuzumab ozogamicin is an investigational ADC comprised of a mAb targeting CD22, a cell surface antigen found on cancer cells in almost all B-ALL patients, linked to a cytotoxic agent.[14],[15] When inotuzumab ozogamicin binds to the CD22 antigen on malignant B-cells, it is thought to be internalized into the cell, where the cytotoxic agent calicheamicin is released to destroy the cell.[16]

Inotuzumab ozogamicin originates from a collaboration between Pfizer and Celltech, now UCB. Pfizer has sole responsibility for all manufacturing and clinical development activities for this molecule.

IBRANCE® (palbociclib) IMPORTANT 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. I nform 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).

For more information, please see IBRANCE Patient Information and full Prescribing Information.

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 worldTM

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.

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