Pfizer Unveils 2017 ASPIRE Oncology/Hematology Clinical Research Awards Winners; Grants Totaling More than $6M in 2017

Tuesday, December 05, 2017 - 02:00am

Pfizer Inc. (NYSE:PFE) today announced the recipients of the expanded Advancing Science through Pfizer Investigator Research Exchange (ASPIRE) Oncology/Hematology Clinical Research Awards. Nine grants totaling more than $6 million (USD) in funding were awarded to investigators in the United States (U.S.) to support clinical research projects involving Pfizer medicines in both breast and hematologic cancers for 2017. This program started in 2015 in breast cancer and chronic myeloid leukemia.

“The ASPIRE Oncology/Hematology Clinical Research Awards program underscores Pfizer’s commitment to supporting investigators in advancing their academic research,” said Julia Perkins Smith, M.D., Vice President, Oncology Medical North America, Pfizer. "The recipients of the 2017 Awards submitted outstanding and innovative clinical research proposals that are poised to advance knowledge in the treatment and disease management of breast cancer and acute leukemia. We look forward to their research findings.”

Recipients of the 2017 awards were selected through a competitive application process overseen by an independent review panel of experts. The following investigators and studies have been awarded grants: Awards in Hematologic Cancer • Dr. John Reagen, Warren Alpert Medical School of Brown University – Infusional Gemtuzumab Ozogamicin Followed by Nonengraftment Donor Lymphocyte Infusions for Refractory Acute Myeloid

Leukemia

• Dr. Maureen O’Brien, Cincinnati Children’s Hospital – A Phase 2 Study of Inotuzumab Ozogamicin in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL)

• Drs. Anjali Advani and Cecilia Yeung, Cleveland Clinic – A Phase 1 Study of Glasdegib in Combination with Inotuzumab Ozogamicin for Patients with Relapsed / Refractory CD22+ Acute Lymphoblastic Leukemia (ALL)

• Dr. Elizabeth Raetz, University of Utah — A Phase 1 Study of Palbociclib in Combination with Chemotherapy in Children with Relapsed Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma

• Drs. Aaron Goldberg and Martin Tallman, Memorial Sloan Kettering Cancer Center (MSKCC)— A Phase 1b Safety and Preliminary Clinical Activity Study of Combination Palbociclib plus Quizartinib in Patients with Relapsed / Refractory Acute Myeloid Leukemia (AML) with FLT3-ITD Mutations

Awards in Breast Cancer • Dr. Cesar A. Santa-Maria, Johns Hopkins University – Immune MOdulation in Early Stage Estrogen Receptor Positive Breast Cancer treated with NeoADjuvant Avelumab, Palbociclib, and Tamoxifen: the ImmunoADAPT study

• Dr. Hadine Joffe, Brigham and Women’s Hospital – Incidence, Course, and Predictors of Fatigue Developing on Palbociclib in Advanced HR+ HER2- Breast Cancer • Dr. Lauren Nye, University of Kansas Cancer Center – A Phase 1/2 Study of Palbociclib, Letrozole and T-DM1 in Trastuzumab Refractory Estrogen Receptor Positive and HER2 Positive Metastatic Breast Cancer

• Dr. Paula Pohlmann, Georgetown University Hospital – A Phase 1 trial of Palbociclib and Bosutinib with Fulvestrant in Patients with Metastatic Hormone Receptor Positive and HER2 negative (HR+ HER2-) Breast Cancer Refractory to an Aromatase Inhibitor and a CDK4/6 Inhibitor

Investigators in the U.S. were encouraged to submit proposals for the 2017 ASPIRE Oncology/Hematology Research Awards that advance knowledge in the treatment and disease management of breast cancer as well as hematologic malignancies. 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); MYLOTARG™ (gemtuzumab ozogamicin), the only

approved antibody-drug conjugate (ADC) for newly diagnosed and relapsed or refractory CD33-positive acute myeloid leukemia (AML), the most common leukemia in adults; and BESPONSA® (inotuzumab ozogamicin), the first and only CD22-directed ADC indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), a rapidly progressing blood cancer with the lowest five-year survival rate among all leukemias.

For more information about ASPIRE, please visit www.aspireresearch.org. Information about the 2018 ASPIRE Oncology/Hematology Clinical Research Awards will be available soon.

About IBRANCE® (palbociclib) 125 mg capsules IBRANCE is an oral inhibitor of CDKs 4 and 6, which are key regulators of the cell cycle that trigger cellular progression. , In the U.S., 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. Including the U.S., IBRANCE is approved in more than 60 countries.

About MYLOTARG™ (gemtuzumab ozogamicin) MYLOTARG is an antibody-drug conjugate (ADC) comprised of the cytotoxic agent calicheamicin, attached to a monoclonal antibody (mAB) targeting CD33, an antigen expressed on the surface of myeloblasts in up to 90 percent of AML patients. , , When MYLOTARG binds to the CD33 antigen on the cell surface it is absorbed into the cell and calicheamicin is released causing cell death. , ,

MYLOTARG is commercially available in the U.S. for adults with newly diagnosed CD33-positive AML, and adults and children two years and older with relapsed or refractory CD33-positive AML. It is also available in Japan for the treatment of patients with relapsed or refractory CD33-positive AML who are not considered candidates for other cytotoxic chemotherapy.

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

About BESPONSA® (inotuzumab ozogamicin) BESPONSA is an antibody-drug conjugate (ADC) approved in the U.S. for adults with relapsed or refractory B-cell precursor ALL. BESPONSA is composed of a monoclonal antibody (mAb) targeting CD22, a cell surface antigen expressed on cancer cells in almost all B-ALL patients, linked to a

cytotoxic agent. Non-clinical data suggests when BESPONSA binds to the CD22 antigen on B-cells, it is internalized into the cell, where the cytotoxic agent calicheamicin is released causing cell death. BESPONSA is administered as a one-hour intravenous infusion that can be given in the outpatient setting of care for appropriate patients.

BESPONSA originates from a collaboration between Pfizer and Celltech, now UCB. Under the terms of this agreement, Pfizer has sole responsibility for all commercialization, manufacturing and clinical development activities for this molecule. Pfizer also collaborated with SFJ Pharmaceuticals Group on the registrational program (INO-VATE ALL) for BESPONSA.

IBRANCE® (palbociclib) IMPORTANT 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/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). The full prescribing information for IBRANCE can be found here.

IMPORTANT MYLOTARG™ (gemtuzumab ozogamicin) SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION WARNING: Hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), has been reported in association with the use of MYLOTARG as a single agent, and as part of a combination chemotherapy regimen. Monitor frequently for signs and symptoms of VOD after treatment with MYLOTARG. Hepatotoxicity, Including Veno-occlusive Liver Disease (VOD): An increased risk of VOD was observed in patients with moderate/severe hepatic impairment and patients who received MYLOTARG either before or after HSCT. Assess ALT, AST, total bilirubin, and alkaline phosphatase prior to each dose of MYLOTARG. After treatment with MYLOTARG, monitor frequently for signs and symptoms of VOD; these may include elevations in ALT, AST, and total bilirubin, hepatomegaly, rapid weight gain, and ascites. Monitoring only total bilirubin may not identify all patients at risk of VOD. For patients who develop abnormal liver tests, more frequent monitoring of liver tests and clinical signs and symptoms of hepatotoxicity is recommended. For patients who proceed to HSCT, monitor liver tests frequently during the post-HSCT period, as appropriate. Manage signs or symptoms of hepatic toxicity by dose interruption or discontinuation of MYLOTARG. In patients who experience VOD, discontinue MYLOTARG and treat according to standard medical practice.

Infusion-Related Reactions (Including Anaphylaxis): Life-threatening or fatal infusion-related reactions can occur during or within 24 hours following infusion of MYLOTARG. Signs and symptoms of infusion-related reactions may include fever, chills, hypotension, tachycardia, hypoxia, and respiratory failure. Premedicate prior to MYLOTARG infusion. Monitor vital signs frequently during infusion. Interrupt infusion immediately for patients who develop evidence of infusion reaction, especially dyspnea, bronchospasm, or hypotension. Monitor patients during and for at least 1 hour after the end of the infusion or until signs and symptoms completely resolve. Discontinue use of MYLOTARG in patients who develop signs or symptoms of anaphylaxis, including severe respiratory symptoms or clinically significant hypotension.

Hemorrhage: MYLOTARG is myelosuppressive and can cause fatal or life-threatening hemorrhage due to prolonged thrombocytopenia. Assess blood counts prior to each dose of MYLOTARG and monitor blood counts frequently after treatment with MYLOTARG until resolution of cytopenias. Monitor patients for signs and symptoms of bleeding during

treatment with MYLOTARG. Manage severe bleeding, hemorrhage, or persistent thrombocytopenia using dose delay or permanent discontinuation of MYLOTARG, and provide supportive care per standard practice.

QT Interval Prolongation: QT interval prolongation has been observed in patients treated with other drugs containing calicheamicin. When administering MYLOTARG to patients who have a history of or predisposition for QTc prolongation, who are taking medicinal products that are known to prolong QT interval, and in patients with electrolyte disturbances, obtain electrocardiograms and electrolytes prior to the start of treatment and as needed during administration.

Adverse Cytogenetics: In a subgroup analysis in ALFA-0701, the addition of MYLOTARG to standard combination chemotherapy did not improve event-free survival in the subgroup of patients having adverse-risk cytogenetics. For patients being treated with MYLOTARG in combination with daunorubicin and cytarabine for newly diagnosed de novo AML, when cytogenetics testing results become available consider whether the potential benefit of continuing treatment with MYLOTARG outweighs the risks for the individual patient.

Embryo-Fetal Toxicity: MYLOTARG can cause embryo-fetal harm when administered to a pregnant woman. Advise patients of reproductive potential to use effective contraception during and for 3 and 6 months following treatment for males and females, respectively. Apprise pregnant women of the potential risk to the fetus. Advise women to contact their healthcare provider if they become pregnant or if pregnancy is suspected during treatment with MYLOTARG. Adverse Reactions: The most common adverse reactions (greater than 15%) were hemorrhage, infection, fever, nausea, vomiting, constipation, headache, increased AST, increased ALT, rash, and mucositis.

Contraindications: Hypersensitivity to MYLOTARG or any of its components. Reactions have included anaphylaxis. The full prescribing information, including BOXED WARNING, for MYLOTARG can be found here: http://labeling.pfizer.com/ShowLabeling.aspx?id=9548

IMPORTANT BESPONSA® (inotuzumab ozogamicin) SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION WARNING: HEPATOTOXICITY, INCLUDING HEPATIC VENO-OCCLUSIVE DISEASE (VOD) (ALSO KNOWN AS SINUSOIDAL OBSTRUCTION SYNDROME) and INCREASED RISK OF POST–HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) NON-RELAPSE MORTALITY (NRM):

• Hepatotoxicity, including fatal and life-threatening VOD, occurred in patients who received BESPONSA. The risk of VOD was greater in patients who underwent HSCT after

BESPONSA treatment. The use of HSCT conditioning regimens containing 2 alkylating agents and last total bilirubin ≥ upper limit of normal (ULN) before HSCT were significantly associated with an increased risk of VOD • Other risk factors for VOD in patients treated with BESPONSA included ongoing or prior liver disease, prior HSCT, increased age, later salvage lines, and a greater number of BESPONSA treatment cycles • Elevation of liver tests may require dosing interruption, dose reduction, or permanent discontinuation of BESPONSA. Permanently discontinue treatment if VOD occurs. If severe VOD occurs, treat according to standard medical practice • There was a higher post-HSCT non-relapse mortality rate in patients receiving BESPONSA, resulting in a higher Day 100 post-HSCT mortality rate

Hepatotoxicity, Including Hepatic VOD: Hepatotoxicity, including fatal and life-threatening VOD, occurred in 23/164 patients (14%) during or following treatment with BESPONSA or following subsequent HSCT. VOD was reported up to 56 days after the last dose during treatment or follow-up without an intervening HSCT. The median time from HSCT to onset of VOD was 15 days.

Patients with prior VOD or serious ongoing liver disease are at an increased risk of worsening liver disease, including development of VOD, following treatment with BESPONSA. Monitor closely for signs and symptoms of VOD; these may include elevations in total bilirubin, hepatomegaly (which may be painful), rapid weight gain, and ascites. For patients proceeding to HSCT, the recommended duration of treatment with BESPONSA is 2 cycles. A third cycle may be considered for patients who do not achieve a CR or CRi and MRD-negativity after 2 cycles. Monitor liver tests closely during the first month post HSCT, then less frequently thereafter, according to standard medical practice.

Grade 3/4 increases in aspartate aminotransferase, alanine aminotransferase, and total bilirubin occurred in 7/160 (4%), 7/161 (4%), and 8/161 (5%) patients, respectively.

Increased Risk of Post-HSCT Non-Relapse Mortality (NRM): There was a higher post-HSCT NRM rate in patients receiving BESPONSA, resulting in a higher Day 100 post-HSCT mortality rate. The rate of post-HSCT NRM was 31/79 (39%) with BESPONSA and 8/35 (23%) with Investigator’s choice of chemotherapy. In the BESPONSA arm, the most common causes of post-HSCT NRM included VOD and infections. Monitor closely for toxicities post HSCT, including signs and symptoms of infection and VOD.

Myelosuppression: Myelosuppression, and severe, life-threatening, and fatal complications of myelosuppression, including hemorrhagic events and infections, have

occurred with BESPONSA. Thrombocytopenia and neutropenia were reported in 83/164 patients (51%) and 81/164 patients (49%), respectively. Febrile neutropenia was reported in 43/164 patients (26%).

Monitor complete blood counts prior to each dose of BESPONSA and monitor for signs and symptoms of infection, bleeding/hemorrhage, or other effects of myelosuppression during treatment and provide appropriate management. As appropriate, administer prophylactic anti-infectives during and after treatment with BESPONSA. Dose interruption, dose reduction, or permanent discontinuation may be required.

Infusion-Related Reactions: Infusion-related reactions (all Grade 2) were reported in 4/164 patients (2%). Premedicate with a corticosteroid, antipyretic, and antihistamine prior to dosing. Monitor patients closely during and for at least 1 hour after the end of the infusion for the potential onset of infusion-related reactions including symptoms such as fever, chills, rash, or breathing problems. Interrupt the infusion and institute appropriate medical management if an infusion-related reaction occurs. Depending on the severity, consider discontinuation of the infusion or administration of steroids and antihistamines. For severe or life-threatening infusion reactions, permanently discontinue BESPONSA.

QT Interval Prolongation: Increases in QT interval corrected for heart rate using Frederica's formula of ≥60 msec from baseline were measured in 4/162 patients (3%). Administer BESPONSA with caution in patients who have a history of or predisposition to QTc prolongation, who are taking medicinal products that are known to prolong QT interval, and in patients with electrolyte disturbances. Obtain electrocardiograms and electrolytes prior to treatment and after initiation of any drug known to prolong QTc, and periodically monitor as clinically indicated during treatment.

Embryo-Fetal Toxicity: BESPONSA can cause embryo-fetal harm. Apprise pregnant women of the potential risk to the fetus. Advise males and females of reproductive potential to use effective contraception during BESPONSA treatment and for at least 5 and 8 months after the last dose, respectively. Advise women to contact their healthcare provider if they become pregnant or if pregnancy is suspected during treatment with BESPONSA.

Adverse Reactions: The most common (≥20%) adverse reactions observed with BESPONSA were thrombocytopenia, neutropenia, infection, anemia, leukopenia, fatigue, hemorrhage, pyrexia, nausea, headache, febrile neutropenia, transaminases increased, abdominal pain, gamma-glutamyltransferase increased, and hyperbilirubinemia. The most common (≥2%) serious adverse reactions were infection, febrile neutropenia,

hemorrhage, abdominal pain, pyrexia, VOD, and fatigue.

Nursing Mothers: Advise women against breastfeeding while receiving BESPONSA and for 2 months after the last dose.

Please see full Prescribing Information, including BOXED WARNING here: http://labeling.pfizer.com/ShowLabeling.aspx?id=9503

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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