ImmunoGen Announces Clinical Collaboration with Gilead to Evaluate Pivekimab Sunirine in Combination with Magrolimab in Relapsed/Refractory Acute Myeloid Leukemia

December 9, 2022

Collaboration to Explore Potential of Complementary Mechanisms of Action for Novel Doublet

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 9, 2022-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced a clinical collaboration with Gilead Sciences, Inc. (Nasdaq: GILD) to evaluate the safety and anti-leukemia activity of pivekimab sunirine (pivekimab) in combination with magrolimab, a potential, first-in-class, investigational CD47 inhibitor, in patients with relapsed or refractory (R/R) CD123-positive acute myeloid leukemia (AML).

"AML is the most common form of acute leukemia among adults and accounts for the largest number of deaths from leukemia in both the United States and Europe," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "Given the potentially complementary mechanisms of action, the limited overlap in safety profiles, and the encouraging data seen with each agent in combinations to date, we are excited to explore this novel doublet in patients with relapsed/refractory AML, where few effective treatment options exist."

Expected to initiate in 2023, the collaboration will be a new cohort in ImmunoGen's 802 study and will evaluate pivekimab in combination with magrolimab in up to 42 patients with R/R CD123-positive AML. The primary endpoint for this cohort is complete response (CR) rate. ImmunoGen's 802 study is an open-label, multicenter, Phase 1b/2 trial to determine the safety and tolerability of pivekimab and assess the anti-leukemia activity of the agent when administered in combination with Vidaza® (azacitidine) and/or Venclexta® (venetoclax) in patients with relapsed and frontline CD123-positive AML.

ABOUT PIVEKIMAB SUNIRINE

Pivekimab sunirine is a CD123-targeting ADC in clinical development for hematological malignancies, including blastic plasmacytoid dendritic cell neoplasm (BPDCN), acute myeloid leukemia (AML), and other CD123+ hematologic malignancies. Pivekimab is currently being evaluated as monotherapy for patients with BPDCN and in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) for patients with untreated and relapsed/refractory AML. Pivekimab uses one of ImmunoGen's novel indolinobenzodiazepine (IGN) payloads, which alkylate DNA and cause single strand breaks without crosslinking. IGNs are designed to have high potency against tumor cells, while demonstrating less toxicity to normal marrow progenitors than other DNA-targeting payloads. The European Medicines Agency (EMA) granted orphan drug designation to pivekimab for the treatment of BPDCN in June 2020. Pivekimab also holds this designation in the U.S. In October 2020, the FDA granted pivekimab Breakthrough Therapy designation in relapsed/refractory BPDCN.

ABOUT MAGROLIMAB

Magrolimab is a potential, first-in-class, investigational treatment designed to inhibit the CD47 protein. CD47 binds to receptors on macrophages to transmit a "don't eat me" signal used by cancer cells to escape natural cell death, called phagocytosis. Targeting the CD47 protein, magrolimab is intended to restore phagocytosis. Magrolimab is being studied in several hematologic cancers as well as solid tumor malignancies. Granted Fast Track Designation by the FDA for the treatment of myelodysplastic syndrome (MDS), AML, diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma, magrolimab has also been granted Orphan Drug Designation by the FDA for MDS and AML and by the European Medicines Agency for AML. More information about clinical trials with magrolimab is available at www.clinicaltrials.gov.

Magrolimab is an investigational product and is not approved by any regulatory authority for any use; its safety and efficacy have not been established.

ABOUT ACUTE MYELOID LEUKEMIA (AML)

AML is a cancer of the bone marrow cells that produce white blood cells. It causes the marrow to increasingly generate abnormal, immature white blood cells (blasts) that do not mature into effective infection-fighting cells. The blasts quickly fill the bone marrow, impacting the production of normal platelets and red blood cells. The resulting deficiencies in normal blood cells leave the patient vulnerable to infections, bleeding problems, and anemia. It is estimated that, in the U.S. alone, more than 20,000 people will be diagnosed with AML this year and more than 11,000 will die from the disease.

ABOUT IMMUNOGEN

ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to TARGET A BETTER NOW™.

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

Vidaza® and Venclexta® are registered trademarks of their respective owners.

FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These statements include, but are not limited to, ImmunoGen's expectations related to: the potential benefits and results that may be achieved through ImmunoGen's clinical collaboration with Gilead; and the occurrence, timing, and outcome of potential preclinical, clinical, and regulatory events related to, and the potential benefits of, ImmunoGen's product candidates. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and outcome of ImmunoGen's preclinical and clinical development

processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of preclinical studies, clinical trials, and regulatory processes; ImmunoGen's ability to financially support its product programs; the timing and outcome of ImmunoGen's anticipated interactions with regulatory authorities; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and the resulting impact on ImmunoGen's industry and business; and other factors as set forth in ImmunoGen's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2022, August 1, 2022 and November 4, 2022, and other reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release speak only as of the date of this press release. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by applicable law.

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INVESTOR RELATIONS
ImmunoGen
Anabel Chan
781-895-0600
anabel.chan@immunogen.com

MEDIA
ImmunoGen
Courtney O'Konek
781-895-0600
courtney.okonek@immunogen.com

OR

FTI Consulting
Robert Stanislaro
212-850-5657
robert.stanislaro@fticonsulting.com

Source: ImmunoGen, Inc.