ImmunoGen Presents Findings from Expansion Cohorts in Phase 1b/2 Study of Pivekimab Sunirine with Vidaza® and Venclexta® in Acute Myeloid Leukemia at ASH

December 10, 2022

Broad Anti-Leukemia Activity in Relapsed/Refractory and Frontline AML Presented in Oral Session

Recommended Phase 2 Dose Well-Tolerated; Determination of Optimal Venclexta Duration Ongoing in Separate Cohorts

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 10, 2022-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced initial safety and efficacy findings from dose-escalation and expansion cohorts of the Phase 1b/2 study of pivekimab sunirine (pivekimab) in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) in patients with relapsed/refractory (R/R) and frontline acute myeloid leukemia (AML). These findings were presented in an oral session at the 64th American Society of Hematology (ASH) Annual Meeting in New Orleans, Louisiana.

"While azacitidine and venetoclax have improved outcomes for patients with frontline AML, overall survival unfortunately remains poor in both this population and those with relapsed/refractory AML," said Naval Daver, MD, Associate Professor in the Department of Leukemia at The University of Texas MD Anderson Cancer Center. "I am very encouraged by the broad anti-leukemia activity of this triplet, particularly the compelling CR/CRh rates in subgroups of relapsed/refractory AML including first relapse and those with IDH2 or FLT3 mutations as well the preliminary data showing encouraging tolerability and complete responses in the frontline setting."

BROAD ACTIVITY FOR THE PIVEKIMAB SUNIRINE, AZACITIDINE, AND VENETOCLAX TRIPLET IN HIGH-RISK PATIENTS WITH RELAPSED/REFRACTORY ACUTE MYELOID LEUKEMIA (Abstract #62)
Lead Author: Naval Daver, MD
Oral Session: 616
Session Date: December 10, 2022
Session Time: 10:30 AM – 12:00 PM ET

Key findings from the open-label, multicenter, Phase 1b/2 study of pivekimab in combination with azacitidine and venetoclax in patients with R/R and frontline CD123-positive AML include:

Safety:

- 91 patients with CD123-positive R/R AML received pivekimab at 15 mcg/kg or 45 mcg/kg on day 7, azacitidine at 50 mg/m^2 or 75 mg/m^2 on days 1-7, and venetoclax at 400 mg daily for 8, 14 or 21 days per 28-day cycle.
- The triplet displayed a manageable safety profile in R/R AML patients.
- The most common treatment emergent adverse events (all grades [grade 3+ events]) were febrile neutropenia (33%, [29%]), thrombocytopenia (23%, [20%]), dyspnea (22% [6%]), infusion-related reactions (22%, [2%]), hypokalemia (21% [2%]) and fatigue (20% [2%]).
    - Rates of cytopenias were similar to those observed with a hypomethylating agent and venetoclax.
    - No tumor lysis syndrome, veno-occlusive disease, capillary leak syndrome, or cytokine release syndrome were reported.
    - Discontinuations due to pivekimab-related adverse events were 5%.
    - 30-day mortality was 6%, with no treatment-related deaths.

Anti-leukemia activity:

- In the R/R cohort, objective response rate (ORR [CR, CRh, CRp, CRi, MLFS) was 45% with a composite complete remission (CCR [CR, CRh, CRp, CRi]) rate of 25%.
    - Venetoclax-naïve patients had an ORR of 53% and CCR of 38%; in patients who had prior venetoclax exposure, the ORR was 36% and CCR was 11%.
    - Responses were observed in 9 of 11 patients with FLT3-ITD AML with an ORR of 82% and a CCR of 64%.
    - Enrollment in the R/R cohort is complete.
- In the 10 frontline patients enrolled, pivekimab was administered at 45 mcg/kg on day 7, azacitidine at 75 mg/m^2 on days 1-7, and venetoclax at 400 mg for at least 14 days per 28-day cycle.
    - 5/10 (50%) patients achieved a CR and 3/4 (75%) patients tested had a minimal residual disease (MRD)-negative CR.
    - At the time of data cut-off, 5 patients remain on treatment.
    - Enrollment in the frontline cohort continues in the US and EU.

"These data presented at ASH demonstrate this triplet's encouraging anti-leukemia activity and tolerability, and reinforce our belief in pivekimab's potential as a novel addition to the azacitidine and venetoclax regimen for AML," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "Based upon the strong results from the first 10 frontline patients we have enrolled, we have moved forward with gathering

more data for the triplet using 14 days of venetoclax and have opened a second cohort of up to 50 frontline patients with a goal of evaluating up to 28 days of venetoclax per cycle to optimize the duration of therapy. Tolerability and efficacy outcomes from these cohorts will guide pivotal development of the triplet in frontline AML."

Additional information can be found at https://www.hematology.org, including abstracts.

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 being evaluated as monotherapy for patients with BPDCN, as a doublet with magrolimab in patients with relapsed/refractory AML, and as a triplet with Vidaza® (azacitidine) and Venclexta® (venetoclax) in patients with frontline 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 and have been observed in preclinical studies and clinical trials to have 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 US. In October 2020, the FDA granted pivekimab Breakthrough Therapy designation in relapsed/refractory BPDCN.

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 US alone, more than 20,000 people will be diagnosed with AML and more than 11,000 will die from the disease this year.

ABOUT CD123
CD123, the interleukin-3 alpha chain, is expressed on multiple myeloid and lymphoid cancers including AML, BPDCN, ALL, chronic myeloid leukemia, and myeloproliferative neoplasms. With limited expression on normal hematopoietic cells, rapid internalization, and expression on AML leukemia stem cells, CD123 is a clinically validated therapeutic target.

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 of pivekimab as an addition to the azacitidine and venetoclax regimen in AML; the timing and presentation of clinical data for the pivekimab program; and the Company's business and product development strategies. 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 the Company'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; the Company's ability to financially support its product programs; the timing and outcome of the Company'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 the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, the Company's 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 CONTACT
ImmunoGen
Anabel Chan
781-895-0600
anabel.chan@immunogen.com

MEDIA CONTACTS
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.