ImmunoGen Presents Updated Findings from CADENZA Trial of Pivekimab Sunirine in Blastic Plasmacytoid Dendritic Cell Neoplasm at EHA 2023 Congress

June 9, 2023

Interim Analysis from Phase 2 Trial Demonstrates Compelling Anti-Tumor Activity in Patients with Frontline and Relapsed/Refractory BPDCN; No New Safety Signals Identified

Enrollment Continues in Frontline CADENZA Cohort; Top-Line Pivotal Data Expected in 2024

WALTHAM, Mass.--(BUSINESS WIRE)--Jun. 9, 2023-- ImmunoGen Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced updated data from an interim analysis of the Phase 2 CADENZA trial of pivekimab sunirine (pivekimab) in patients with frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN). The data will be presented in an oral session on Sunday, June 11 at the European Hematology Association (EHA) 2023 Congress in Frankfurt, Germany.

The CADENZA trial is enrolling frontline BPDCN patients, including those with *de novo* disease and those with a prior or concomitant hematologic malignancy (PCHM). As announced in August 2022, ImmunoGen aligned with the US Food and Drug Administration (FDA) that the efficacy analysis will be conducted in *de novo* BPDCN patients with CR/CRc as the primary endpoint. The secondary endpoint is duration of CR/CRc. With enrollment in the R/R cohort complete, ImmunoGen expects to complete enrollment in the pivotal frontline *de novo* cohort this year and report top-line data in 2024.

"BPDCN is a rare and aggressive blood cancer characterized by extremely low survival rates and limited treatment options that are often associated with significant toxicities," said Naveen Pemmaraju, MD, Associate Professor of Leukemia at The University of Texas MD Anderson Cancer Center and co-investigator of the Phase 2 study. "We are encouraged by these updated data in a larger population of patients, which demonstrated impressive anti-tumor activity and durable responses in both frontline and R/R patients. These efficacy data, coupled with outpatient administration, reinforce the potential of pivekimab as a promising, novel option for this challenging disease. I look forward to its continued evaluation in the trial."

INTERIM ANALYSIS OF A REGISTRATION-ENABLING STUDY OF PIVEKIMAB SUNIRINE, A CD123-TARGETING ANTIBODY-DRUG CONJUGATE, IN PATIENTS WITH BLASTIC PLASMACYTOID DENDRITIC CELL NEOPLASM
Lead Author: Naveen Pemmaraju, MD
Presentation ID: S139
Session Date: Sunday, June 11
Session Time: 11:30am-12:45pm CEST / 5:30am-6:45am EDT

Pivekimab is administered at 0.045 mg/kg on day 1 of a 21-day cycle as an outpatient infusion of approximately 30 minutes. As of the May 19, 2023 data cutoff, data were available for 79 BPDCN patients (30 frontline, 49 R/R). Key interim and updated safety and efficacy findings include:

Efficacy

- In frontline-treated patients including those with *de novo* and PCHM, the objective response rate (ORR [CR, CRc, CRh, CRi, PR]) is 80% (24/30 patients) with a composite complete remission (CCR [CR, CRc, CRh, CRi]) rate of 73% (22/30 patients), and an additional patient achieving a CR post-transplant.
    - Median duration of response (DOR) for all responders in frontline-treated patients was 12.7 months.
- In R/R patients, the ORR was 33% (16/49 patients), with a CCR rate of 20% (10/49 patients), including those who previously failed intensive chemotherapy and/or transplant.
    - Median DOR for all responders in R/R patients was 7.1 months.

Safety

- Pivekimab continues to exhibit manageable safety; no new safety signals were observed.
- The most common treatment-emergent adverse events (TEAEs) (all grades [grade 3+ events]) occurring in 15% or more of patients were peripheral edema (46% [10%]), thrombocytopenia (27% [19%]), fatigue (25% [4%]),infusion-related reactions (25% [4%]), constipation (23% [0%]), nausea (22% [0%]) anemia (20% [8%]), headache (19% [4%]), neutropenia (18% [17%]), diarrhea (17% [0%]), hypokalemia (17% [3%]), dyspnea (15% [1%]), hyperglycemia (15% [6%]) and pyrexia (15% [1%]).
- No capillary leak syndrome or cytokine release syndrome are reported.
- Discontinuations due to pivekimab-related adverse events are 3%.
- 30-day mortality is 0% in frontline-treated patients and 4% (2 deaths due to disease progression) in R/R patients.

"We look forward to completing enrollment in CADENZA this year and are pleased with the interim data in frontline BPDCN, particularly the 73% CCR rate observed in this population, as well as the responses seen in those patients with more advanced R/R disease," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "With promising anti-tumor activity, manageable safety including no observed capillary leak or cytokine release syndrome, and the convenience of potential outpatient administration, we believe pivekimab could serve as a critical option for BPDCN patients."

Additional information can be found at www.ehaweb.org.

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 US. In October 2020, the FDA granted pivekimab Breakthrough Therapy designation in relapsed/refractory BPDCN.

ABOUT BLASTIC PLASMACYTOID DENDRITIC CELL NEOPLASM (BPDCN)

BPDCN is a rare form of blood cancer that has features of both leukemia and lymphoma, with characteristic skin lesions, lymph node involvement, and frequent spread to the bone marrow. This aggressive cancer requires intense treatment often followed by stem cell transplant. Despite the approval of a CD123-targeting therapy, the unmet need remains high for patients, both in the frontline and in the relapsed/refractory setting.

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.

FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These statements include, but are not limited to, the potential clinical benefits of pivekimab in BPDCN and AML and the potential for regulatory approval of pivekimab. 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; top-line data may change as more patient data become available and are subject to audit and verification procedures; 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 timing and outcome of the Company's anticipated interactions with regulatory authorities; the risk that the Company may not be able to obtain adequate price and reimbursement for any approved products, including the potential for delays or additional difficulties for ELAHERE in light of the FDA granting accelerated approval; 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 March 1, 2023, the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commision on April 28, 2023, 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. ImmunoGen undertakes 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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