ImmunoGen to Present Initial Data Combining IMGN632 with Vidaza® and Venclexta® in Relapsed/Refractory Acute Myeloid Leukemia at ASH

November 4, 2021

Triplet Demonstrated Manageable Safety Profile and Encouraging Activity, with 55% Objective Response Rate Across All Doses/Schedules in Escalation

Data for IMGN632 in Frontline BPDCN Patients Will Also be Presented

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 4, 2021-- 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 its Phase 1b/2 study of IMGN632 in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) (triplet) in patients with relapsed/refractory (R/R) acute myeloid leukemia (AML). These data will be presented in an oral session at the 63rd American Society of Hematology (ASH) Annual Meeting December 11-14. Data for IMGN632 in frontline patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) will also be presented in a poster session at ASH.

IMGN632 is a CD123-targeting ADC comprised of a high-affinity antibody coupled to a DNA-alkylating payload of the novel IGN (indolinobenzodiazepine pseudodimer) class. IGNs are designed to have high potency against leukemic blasts while demonstrating less toxicity to normal marrow progenitors than other DNA-targeting payloads.

"These data demonstrate the promising anti-leukemia activity and manageable safety profile of the IMGN632 triplet in AML, and we are encouraged by its potential in patients with relapsed/refractory AML, where well-tolerated, effective options remain quite limited," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "We are focused on optimizing the safety and efficacy of the IMGN632 triplet, and we look forward to advancing this program into expansion cohorts in both the relapsed/refractory and frontline AML settings."

ORAL PRESENTATION DETAILS
Title (Abstract #372): "Safety and Efficacy from a Phase 1b/2 Study of IMGN632 in Combination with Azacitidine and Venetoclax for Patients with CD123-Positive Acute Myeloid Leukemia"
Oral Session: 616
Session Date: Sunday, December 12, 2021
Session Time: 9:30 am - 11:00 am

Key findings include:

Safety

- IMGN632 was administered to 35 patients at dose levels ranging from 15 to 45 mcg/kg, azacitidine at 50-75 mg/m2 for 7 days, and venetoclax at 400 mg daily for 8-21 days.
- IMGN632 continued to display a manageable safety profile in R/R AML patients.
- The most common treatment emergent adverse events (TEAE) all grades [grade 3+ events] seen in >20% of patients were infusion-related reactions (IRR, 37% [3%]), febrile neutropenia (26% [23%]), hypophosphatemia (26% [3%]), dyspnea (26% [6%]), pneumonia (20% [14%]), and fatigue (20% [0%]).
- No tumor lysis syndrome, veno-occlusive disease, capillary leak, or cytokine release were reported.

Efficacy

- Responses were seen across all cohorts/doses and schedules (efficacy evaluable population, n=29). The objective response rate (ORR) was 55%, with a composite complete remission (CCR) rate of 31% (1 CR, 4 CRh, 2 CRp, 2 CRi).
- Higher intensity cohorts (n=20) were associated with higher response rates including an ORR of 75% and a CCR rate of 40%.
- Significant activity was also observed in the FLT3 mutant subset (n=7), with ORR and CCR rates of 100% and 71%, respectively.

In addition, data from three frontline BPDCN patients who received IMGN632 prior to commencement of the enrolling pivotal cohort will be highlighted in a poster presentation at ASH. All three patients achieved a clinical complete remission (CRc).

POSTER PRESENTATION DETAILS
Title (Abstract #1284): "Experience with IMGN632, a Novel CD123-Targeting Antibody-Drug Conjugate, in Frontline Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm"
Poster Session: 616
Date: Saturday, December 11, 2021
Time: 5:30 pm - 7:30 pm

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

ABOUT IMGN632

IMGN632 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. IMGN632 is currently being evaluated in multiple cohorts, including monotherapy for patients with BPDCN and minimal residual disease positive (MRD+) AML and in combinations with Vidaza® (azacitidine) and Venclexta® (venetoclax) for patients with relapsed/refractory AML. IMGN632 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 FDA granted IMGN632 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 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 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 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 validated therapeutic target, with the approval of a CD123-targeting therapy for BPDCN.

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 based on management's current expectations. These statements include, but are not limited to, ImmunoGen's expectations related to: the occurrence, timing, and outcome of potential preclinical and clinical events related to the Company's product candidates, in particular with respect to IMGN632; and the presentation of preclinical and clinical data on the Company's product candidates, including with respect to IMGN632. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. 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; 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, 2021, and other reports filed with the Securities and Exchange Commission.

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