ImmunoGen Presents Initial Findings From the Phase 1b/2 Study of IMGN632 in Combination With Vidaza® and Venclexta® in Relapsed/Refractory Acute Myeloid Leukemia at ASH

December 12, 2021

Triplet Data Demonstrating Manageable Safety Profile and Promising Anti-Leukemia Activity Highlighted in Oral Presentation

Expansion Cohorts in Relapsed and Frontline AML Planned

Data for IMGN632 in Three Frontline BPDCN Patients Also Presented in Poster Presentation Showing Clinical Complete Responses and Favorable Safety Profile

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 12, 2021-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that updated initial safety and efficacy findings from the Phase 1b/2 study of IMGN632 in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) in patients with relapsed/refractory (R/R) acute myeloid leukemia (AML) were presented in an oral session at the 63rd American Society of Hematology (ASH) Annual Meeting. Data for IMGN632 in frontline patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) were also presented in a poster session at the conference.

"The unmet need in AML remains large, as patients typically have low survival rates despite initial response," said Naval Daver, MD, Associate Professor in the Department of Leukemia at The University of Texas MD Anderson Cancer Center. "Together, the observed anti-leukemia activity and tolerability of IMGN632 in the relapsed/refractory setting are compelling and support the continued evaluation of this triplet in AML patients. I look forward to the next steps for IMGN632 in combination with azacitidine and venetoclax, with preparations for Phase 2 expansion cohorts already underway in both the relapsed and frontline AML settings."

IMGN632 TRIPLET DATA IN AML

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

Updated key findings from the Phase 1b/2 study of IMGN632 in combination with azacitidine and venetoclax include:

Safety

- IMGN632 was administered to 51 patients at 15 mcg/kg or 45 mcg/kg, azacitidine at 50-75 mg/m^2 for 7 days, and venetoclax at 400 mg daily for 8-21 days per 28-day cycle.
- IMGN632 continued to display a manageable safety profile in R/R AML patients.
- The most common treatment emergent adverse events all grades [grade 3+ events] seen in >20% of patients were infusion-related reactions (33% [2%]), febrile neutropenia (31% [26%]), dyspnea (28% [8%]), fatigue (28% [0%]), hypophosphatemia (26% [2%]), diarrhea (22% [0%]), hypokalemia (22% [2%]), nausea (22% [0%]), vomiting (22% [0%]), and pneumonia (20% [16%]).
- 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=46). The objective response rate (ORR) was 48%, with a composite complete remission (CCR) rate of 30% (4 CR, 8 CRh, 1 CRp, 1 CRi).
- Higher intensity cohorts (n=29) were associated with higher response rates including an ORR of 59% and a CCR rate of 38% (4 CR, 6 CRh, 1 CRp).
- Significant activity was also observed in the FLT3 mutant subset (n=9), with ORR and CCR rates of 89% and 78%, respectively.
- Enrollment continues at the putative recommended Phase 2 dose (IMGN632 45 mcg/kg IV on day 7, azacitidine 50 or 75 mg/m^2 on days 1-7, and venetoclax 400 mg on days 1-14).

"These data reinforce the potential of IMGN632 as a new therapy for patients with relapsed/refractory AML. We are very encouraged by the manageable safety profile and 38% composite complete remission rate seen in the higher intensity cohorts," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "We look forward to further exploring the safety and efficacy of this triplet in Phase 2 expansion cohorts planned for next year. We believe IMGN632 also has the potential to become a best-in-class monotherapy treatment option for patients with BPDCN. Based on the results seen in three frontline patients, we continue to enroll patients in our pivotal study, CADENZA, and look forward to sharing top-line data in the second half of 2022."

IMGN632 MONOTHERAPY IN FRONTLINE BPDCN

Poster Presentation, Abstract #1284

IMGN632, administered as a brief outpatient infusion, was evaluated as monotherapy in frontline BPDCN patients. Three patients received IMGN632 prior to commencement of the enrolling pivotal cohort and achieved a clinical complete remission (CRc). IMGN632 in these three frontline BPDCN patients was associated with a favorable safety profile and limited grade 3+ TEAEs. Enrollment continues in the pivotal frontline and R/R cohorts.

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. 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, including with respect to the Phase 2 expansion cohorts planned for the IMGN632 study in combination with azacitidine and venetoclax and the potential for IMGN632 to become a new therapy for patients; the presentation of preclinical and clinical data on the Company's product candidates, including with respect to top-line data from the Company's CADENZA study in the second half of 2022; 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; 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. 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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