ImmunoGen to Present New Data on IMGN632 at 61st ASH Annual Meeting

November 6, 2019

Updated Phase 1 Data to be Highlighted in Oral Presentation Demonstrate Tolerable Safety Profile and Encouraging Activity in AML and BPDCN

Preclinical Data for IMGN632 in Combination with Azacitidine and Venetoclax Support Clinical Evaluation of Doublets and Triplet in AML

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 6, 2019-- ImmunoGen Inc., (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that abstracts highlighting the Company's investigational ADC therapy, IMGN632, have been accepted for presentation at the upcoming American Society of Hematology (ASH) Annual Meeting to be held December 7-10 in Orlando, FL.

IMGN632 is a CD123-targeting ADC in Phase I testing for hematological malignancies, including acute myeloid leukemia (AML), blastic plasmacytoid dendritic cell neoplasm (BPDCN), and acute lymphocytic leukemia (ALL). IMGN632 uses one of ImmunoGen's novel indolino-benzodiazepine (IGN) payloads, which alkylate DNA without crosslinking. IGNs have been designed to have high potency against AML blasts, while demonstrating less toxicity to normal marrow progenitors than other DNA-targeting payloads.

Updated safety and efficacy findings from the dose escalation and expansion of the first-in-human trial of IMGN632 in patients with relapsed/refractory AML and BPDCN will be reported in an oral presentation. Preclinical data related to IMGN632 in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) and two "trial in progress" posters will also be presented in poster sessions.

"Building on initial data shared at ASH last year, we continue to be encouraged by the anti-leukemia activity and tolerability of IMGN632 in AML and BPCDN," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "These data support the continued development of IMGN632 as a monotherapy for BPDCN and MRD+ AML, and in combinations for AML. Despite recent advances, including the first drug approved for BPDCN and approvals of targeted therapies for molecularly-defined subsets of AML, the need remains for well-tolerated, effective, and convenient therapies in these diseases."

ORAL PRESENTATION DETAILS
Oral Session 613: Monday, December 9, 2019, 3:00pm EST
Title (Abstract #734): "Clinical Profile of IMGN632, a Novel CD123-Targeting Antibody-Drug Conjugate, in Patients with Relapsed/Refractory Acute Myeloid Leukemia or Blastic Plasmacytoid Dendritic Cell Neoplasm"

Initial key findings include:

Safety

- IMGN632 was administered to 74 patients over dose levels ranging from 0.015 to 0.45 mg/kg intravenously on the every 3 week schedule and 0.015-0.06 mg/kg on the fractionated day 1, 4, and 8 schedule every 3 weeks.
- IMGN632 displays a tolerable safety profile and activity at doses up to 0.3 mg/kg.
- The most common treatment-related adverse event was infusion-related reactions (16%; four grade 3); none required treatment discontinuation.
- Single dose-limiting toxicities were seen at the three highest dose levels tested: one prolonged neutropenia and two reversible cases of veno-occlusive disease; no patterns of hepatotoxicity or cytopenias occurred with doses below 0.18 mg/kg.
- Although no maximum tolerated dose was determined on either schedule, based on the efficacy, safety, and pharmacokinetic data generated, the dose and schedule of 0.045 mg/kg given on day 1 every 3 weeks has been selected for Phase 2 development.

AML Efficacy

- In the assessable AML population (n=66), 37 (55%) had a reduction in bone marrow blasts and 13 (20%) achieved an objective response across all dose levels and both schedules achieved an objective response, including three complete remissions (CR) and eight CRs with incomplete recovery (CRi) in heavily pretreated patients. The majority of responders (77%) had failed prior intensive therapies, including three with prior transplant, 62% had an adverse risk classification, and 23% were primary refractory.
- A 32% response rate (6/19 patients; two CR, three CRi, and one morphologic leukemia free state) was seen in primary AML patients treated with dose and schedule selected for Phase 2 development.

BPDCN Efficacy

- Three of seven evaluable BPDCN patients (43%) achieved a response after a single dose of IMGN632, one CR, one CRi, and one partial remission; all three patients had received prior SL-401 (tagraxofusp-erzs; Elzonris®).

POSTER SESSION
Poster Session 616: Saturday, December 7, 2019, 5:30-7:30pm EST

Title (Abstract #1375): “IMGN632, a CD123-Targeting ADC Bearing a DNA-Alkylating IGN Payload, Combines Effectively with Azacitidine and Venetoclax In Vivo, Prolonging Survival in Preclinical Models of Human Acute Myeloid Leukemia (AML)”

TRIALS IN PROGRESS POSTER SESSIONS
Poster Session 613: Saturday, December 7, 2019, 5:30-7:30pm EST
Title (Abstract #1334): “A Phase I Study of IMGN632, a Novel CD123-Targeting Antibody-Drug Conjugate, in Patients with Relapsed/Refractory Acute Myeloid Leukemia, Blastic Plasmacytoid Dendritic Cell Neoplasm, and Other CD123-Positive Hematologic Malignancies”

Poster Session 613: Sunday, December 8, 2019, 6:00-8:00pm EST
Title (Abstract #2601): “A Phase 1b/2 Study of the CD123-Targeting Antibody-Drug Conjugate IMGN632 as Monotherapy or in Combination with Venetoclax and/or Azacitidine for Patients with CD123-Positive Acute Myeloid Leukemia”

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

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, 21,380 patients will be diagnosed with AML this year and 10,590 patients 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 recent approval of a CD123-targeting therapy, the unmet need remains high 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 recent 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. 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. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including risks related to preclinical and clinical studies, their timings and results, and the potential that earlier clinical studies may not be predictive of future results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.

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