



ImmunoGen Presents Updated Findings from Phase 1/2 Study of IMG632 in Blastic Plasmacytoid Dendritic Cell Neoplasm at ASH Annual Meeting

December 5, 2020

Updated Data Demonstrating Favorable Safety Profile and Encouraging Monotherapy Activity in BPDCN Presented During Oral Session

Preclinical Combination Data in Relapsed/Refractory AML Support Further Evaluation of Triplet; Trial in Progress Poster for Phase 1b/2 Study Presented

Conference Call to be Held on Monday, December 7 at 8:00 a.m. ET

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 5, 2020-- [ImmunoGen Inc.](#) (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that new safety and efficacy findings from the expansion phase of the Phase 1/2 study of IMG632 in patients with relapsed/refractory blastic plasmacytoid dendritic cell neoplasm (BPDCN) were presented during an oral session at the 62nd American Society of Hematology (ASH) Annual Meeting.

"Comprising the largest prospective study with a single agent in patients with relapsed/refractory BPDCN, the results presented at ASH build on the previous data reported for IMG632 and reinforce the potential of this CD123-targeting ADC as a best-in-class treatment option for BPDCN," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "Given IMG632's favorable safety profile, demonstrated anti-tumor activity, and ease of administration via short infusion in an outpatient setting, we continue to enroll both frontline and relapsed/refractory BPDCN patients in this trial. In addition, the preclinical data presented by our partners at MD Anderson Cancer Center in relapsed/refractory AML further support the combination of IMG632 with azacitidine and venetoclax, which we are actively enrolling in a Phase 1b/2 clinical trial."

"BPDCN is a rare, aggressive hematologic malignancy that is characterized by historically low overall survival rates," said Naveen Pemmaraju, MD, Associate Professor in the Department of Leukemia at MD Anderson Cancer Center. "Despite currently available therapies, outcomes for relapsed/refractory patients remain poor and there is an urgent need to develop better-tolerated treatment options in the frontline setting. These updated safety and efficacy findings for IMG632 in patients with relapsed/refractory BPDCN are encouraging, and I look forward to advancing IMG632 into pivotal development."

IMG632 MONOTHERAPY DATA IN BPDCN

Title: "Clinical Profile of IMG632, a Novel CD123-Targeting Antibody-Drug Conjugate, in Patients with Relapsed/Refractory Blastic Plasmacytoid Dendritic Cell Neoplasm" (Abstract #167)

Oral Presentation Session: 616
Date: Saturday, December 5, 2020
Time: 12:30pm PT/3:30pm ET
Updated key findings include:

Safety

- IMG632 demonstrated a favorable safety profile in 29 patients who received 0.045 mg/kg once every 3 weeks via a short (under 30 minutes) intravenous infusion, with limited grade ≥ 3 treatment-related adverse events (AEs) and no treatment-related deaths.
- The most common grade ≥ 3 AEs were febrile neutropenia, hyperglycemia, and thrombocytopenia (10% each).
- Grade ≥ 3 liver function test elevations were seen in one patient (3%).
- No capillary leak syndrome was reported.

Efficacy

- In all relapsed/refractory BPDCN patients, the overall response rate (ORR) was 29% (8/28) with a composite complete remission (CCR) rate of 18% (5/28).
- In patients with prior SL-401 exposure (tagraxofusp-erzs), the ORR was 31% (4/13) with a CCR of 15% (2/13).
- Among patients with bone marrow response assessment, 60% (9/15) achieved a bone marrow complete response (blasts $< 5\%$).
- Durable responses were seen in multiple patients, up to 9.2 months without hematopoietic stem cell transplant.
- Two patients have been successfully bridged to hematopoietic stem cell transplant.

TRIAL IN PROGRESS POSTER

Title: "A Phase 1b/2 Study of IMG632, a CD123-Targeting Antibody-Drug Conjugate, As Monotherapy or in Combination with Venetoclax and/or Azacitidine for Patients with CD123-Positive Acute Myeloid Leukemia" (Abstract 1047)

Poster Session: 616
Date: Saturday, December 5, 2020
Time: 7:00am – 3:30pm PT/10:00am – 6:30pm ET

PRECLINICAL POSTER

In addition, our partners at MD Anderson Cancer Center will present preclinical data from their study combining IMG632, venetoclax, and azacitidine in *in vitro* and *in vivo* AML models.

Title: "Combining IMG632, a Novel CD123-Targeting Antibody Drug Conjugate with Azacitidine and Venetoclax Facilitates Apoptosis in Vitro and Prolongs Survival In Vivo in AML Models" (Abstract 2886)

Poster Session: 617

Date: Monday, December 7, 2020

Time: 7:00am – 3:30pm PT/10:00am – 6:30pm ET

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

CONFERENCE CALL INFORMATION

ImmunoGen will hold a conference call on Monday, December 7 at 8:00 a.m. ET to discuss the data presented at ASH, the pathway to FDA approval in BPDCN, and an AML program progress update; Dr. Naveen Pemmaraju, Associate Professor in the Department of Leukemia at MD Anderson Cancer Center, will join the call to review the BPDCN data presented at ASH. To access the live call by phone, dial (877) 621-5803; the conference ID is 1795760. The call, along with associated slides, may also be accessed through the Investors and Media section of immunogen.com. Following the call, a replay will be available at the same location.

ABOUT IMG632

IMG632 is a CD123-targeting ADC in clinical development for hematological malignancies, including blastic plasmacytoid dendritic cell neoplasm (BPDCN), acute myeloid leukemia (AML), and acute lymphocytic leukemia (ALL). IMG632 is currently being evaluated in multiple cohorts, including monotherapy for patients with BPDCN and minimal residual disease positive (MRD+) AML following frontline induction therapy and in combinations with Vidaza® (azacitidine) and Venclexta® (venetoclax) for patients with relapsed/refractory AML. IMG632 uses one of ImmunoGen's novel indolinobenzodiazepine (IGN) payloads, which alkylate DNA without crosslinking. IGNs have been designed to have high potency against tumor cells, while demonstrating less toxicity to normal marrow progenitors than other DNA-targeting payloads. FDA has granted IMG632 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 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 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.

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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 pre-clinical, clinical, and regulatory events related to ImmunoGen's product candidates; and the presentation of pre-clinical and clinical data on ImmunoGen's product candidates. 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 ImmunoGen's pre-clinical and clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of pre-clinical studies, clinical trials, and regulatory processes; ImmunoGen's ability to financially support its product programs; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting impact on ImmunoGen's industry and business; and other factors more fully described in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2019 and other reports filed with the Securities and Exchange Commission.

INVESTOR RELATIONS AND MEDIA

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