ImmunoGen Presents New Data Highlighting Potential of Novel ADCs in Oral Presentations at ASH Annual Meeting

December 1, 2018

Initial Data for CD123-Targeting IMGN632 Demonstrate Encouraging Anti-Leukemia Activity and Tolerable Safety Profile in Both AML and BPDCN; Dose Exploration Continues

Maturing Data for CD33-Targeting IMGN779 Reflect Consistent Activity and Tolerability Profile in AML; Dose Exploration Continues

Preclinical Data on IMGN632 from Collaborators Further Support the Potential in AML and BPDCN

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 1, 2018-- ImmunoGen, Inc., (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that new data from the ongoing Phase 1 studies of IMGN632 and IMGN779, next-generation CD123- and CD33-targeting ADCs, respectively, in patients with relapsed or refractory adult acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN) will be presented during an oral session at the 60thAmerican Society of Hematology (ASH) Annual Meeting in San Diego. Preclinical data for IMGN632 as a monotherapy in BPDCN patient-derived xenografts, as well as in combination with a PARP inhibitor in AML models, will also be presented at the conference.

The data presented at ASH demonstrate the potential of ADCs generated from the company's IGN platform to overcome the narrow therapeutic window seen with previous generations of DNA-targeted agents and offer new treatment options for AML and other hematological malignancies.

"We designed our IGN payloads to alkylate one strand of DNA to produce potent anti-leukemia activity, while reducing toxicity to normal cells caused by the double-stranded damage associated with earlier DNA-acting approaches," said Anna Berkenblit, MD, Vice President and Chief Medical Officer of ImmunoGen. "IMGN779 and IMGN632 each incorporate an IGN payload and we are pleased to share Phase I clinical results for both programs today at ASH."

"With IMGN632, we are encouraged by both the tolerability and responses seen thus far, including repeat dosing and complete remissions in AML and BPDCN," said Naval Daver, MD, Associate Professor in the Department of Leukemia at MD Anderson Cancer Center. "We look forward to continuing to enroll patients at several dose levels to establish a recommended Phase 2 dose and schedule for both indications."

"With IMGN779, I am encouraged to see a significant decrease in blasts in many patients with some achieving CRi," said Jorge Cortes, MD, Deputy Chair and Professor of Medicine in the Department of Leukemia at MD Anderson Cancer Center. "The anti-leukemia activity and tolerability seen with both the weekly and the every two week schedule support continued enrollment to identify a dose and schedule to enable further development of IMGN779 as combination therapy in AML."

Phase 1 Data on IMGN632 in AML and BPDCN

Key initial findings from the Phase 1 study of IMGN632 (Abstract #27) include the following:

- IMGN632 was administered to 33 patients over dose levels ranging from 0.015 to 0.45 mg/kg intravenously every three weeks. IMGN632 displays a tolerable safety profile and anti-leukemia activity at doses up to 0.3 mg/kg.
    - Pharmacokinetic (PK) exposures and pharmacodynamic (PD) CD123 saturation increase with dose.
    - Reported adverse events (AEs) were consistent with underlying disease, with no evidence of cumulative toxicity following multiple doses (up to 6 doses).
    - Single dose limiting toxicities (DLTs) were seen at the three highest dose levels tested: one prolonged neutropenia and two reversible cases of veno-occlusive disease.
    - Six of 23 evaluable AML patients (26%) across multiple dose levels achieved an objective response, including two complete remissions (CR) and four CRs with incomplete recovery (CRi) in heavily pretreated patients, including over 60% of patients with primary or relapsed refractory disease.
    - Two of three evaluable BPDCN patients achieved an objective response after a single dose of IMGN632, 1 CRi and 1 partial remission.
    - Enrollment in expansion cohorts continues to identify a recommended Phase 2 dose and schedule for both AML and BPDCN.

Phase 1 Data on IMGN779 in AML

Key findings presented from the Phase 1 study of IMGN779 (Abstract #26) include the following:

- IMGN779 continues to display a tolerable safety profile with repeat dosing across a wide range of doses explored in 57 patients with relapsed AML. Patients across both schedules (weekly and every two weeks) received a median of four doses of IMGN779 (range, 1-40).
    - Plasma IMGN779 concentrations indicate consistent and sustained exposure through seven days at doses ≥0.39 mg/kg; the weekly schedule provides more consistent pharmacodynamic CD33 saturation.
    - Reported AEs were consistent with underlying disease, and with no evidence of cumulative toxicity following

multiple doses (up to 40 doses).
    - One DLT of veno-occlusive disease was observed at the highest dose tested on the weekly schedule, 1.2 mg/kg.
    - Anti-leukemia activity was seen at doses ≥0.39 mg/kg in both schedules:
        - 41% (12 of 29) of evaluable patients showed a >30% reduction in bone marrow blasts with eight patients (28%) having <8% residual blasts, and two having a CR or CRi.
    - Enrollment continues to identify the recommended Phase 2 dose and schedule.

Oral Presentation Details

- **Title:** Maturing Clinical Profile of IMGN779, a Next-Generation CD33-Targeting Antibody-Drug Conjugate, in Patients with Relapsed or Refractory Acute Myeloid Leukemia
- **Presenter:**Jorge Cortes, MD Anderson Cancer Center
- **Day/Time:**Saturday, December 1, 2018, 7:45am PST (Oral session 613)
- **Location:** Manchester Grand Hyatt San Diego, Seaport Ballroom F
- **Abstract:** 26

- **Title**: A Phase I, First-in-Human Study Evaluating the Safety and Preliminary Antileukemia Activity of IMGN632, a Novel CD123-Targeting Antibody-Drug Conjugate, in Patients with Relapsed/Refractory Acute Myeloid Leukemia and Other CD123-Positive Hematologic Malignancies
- **Presenter**: Naval Daver, MD Anderson Cancer Center
- **Senior Author**: Hagop Kantarjian, MD Anderson Cancer Center
- **Day/Time**: Saturday, December 1, 2018, 8:00am PST (Oral session 613)
- **Location**: Manchester Grand Hyatt San Diego, Seaport Ballroom F
- **Abstract**: 27

Preclinical Poster Presentations on IMGN632 in AML and BPDCN

Preclinical data on anti-leukemia activity for IMGN632 in combination with a PARP inhibitor in AML, as well as a monotherapy in BPDCN will also be presented.

Poster Presentation Details

- **Title:** Synergistic anti-leukemia activity of PARP inhibition combined with IMGN632, an anti-CD123 antibody-drug conjugate in acute myeloid leukemia models
- **Day/Time:** Sunday, December 2, 2018, 6:00-8:00pm PST (Poster session 604)
- **Senior author:** Eunice Wang, Roswell Park Cancer Institute
- **Abstract:** 2647

- **Title**: Pre-clinical efficacy of CD123-targeting antibody-drug conjugate IMGN632 in Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) models
- **Day/Time**: Monday, December 3, 2018, 6:00-8:00pm PST (Poster session 605)
- **Senior author:**Marina Konopleva, MD Anderson Cancer Center
- **Abstract:** 3956

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

About IMGN779

IMGN779 is a novel ADC that combines a high-affinity, humanized anti-CD33 antibody, a cleavable disulfide linker, and one of ImmunoGen's novel indolino-benzodiazepine payloads, called IGNs, which alkylate DNA without crosslinking, resulting in potent preclinical anti-leukemia activity with relative sparing of normal hematopoietic progenitor cells.[1,2] IMGN779 is in Phase 1 clinical testing for the treatment of AML.

About IMGN632

IMGN632 is a novel, anti-CD123 antibody-drug conjugate that is a potential treatment for AML, BPDCN, and other CD123-positive malignancies. IMGN632 uses a novel humanized anti-CD123 antibody coupled via a peptide linker to a unique DNA-alkylating IGN payload. In preclinical models, IMGN632 has exhibited potent antitumor activity with a wide therapeutic index in AML, BPDCN, and acute lymphoblastic leukemia (ALL). IMGN632 is in Phase 1 clinical testing for the treatment of AML and BPDCN.

About IGNs

Indolino-benzodiazepine cancer-killing agents, or IGNs, are a new class of cancer-killing agent developed by ImmunoGen for use in ADCs. These ultra-potent, DNA-acting IGNs alkylate DNA without crosslinking, which preclinically has resulted in potent anti-leukemia activity with relative sparing of normal hematopoietic progenitor cells.[3,4] IMGN779, a CD33-targeting ADC in Phase 1 testing for AML, was the first IGN ADC to enter clinical testing. IMGN632, a CD123-targeting ADC entering Phase 1 testing for AML and BPDCN, deploys a novel IGN payload.

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.[5]

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.” Our lead product candidate, mirvetuximab soravtansine, is in Phase 3 study for folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer, and in Phase 1b/2 testing in combination regimens. Our novel IGN candidates for hematologic malignancies, IMGN779 and IMGN632, are in Phase 1 studies.

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

[1] Y. Kovtun et al. (2016) Blood 128:768.

[2] M. Miller et al. (2016) Mol Cancer Ther 15:1870-78.

[3] Y. Kovtun, 2016.

[4] M. Miller, 2016.

[5]American Cancer Society (2016), About Acute Myeloid Leukemia.

This press release includes forward-looking statements. 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. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including IMGN779 and IMGN632, including risks related to preclinical and clinical studies, their timings and results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2017 and other reports filed with the Securities and Exchange Commission.

View source version on businesswire.com: https://www.businesswire.com/news/home/20181201005016/en/

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