December 9, 2017

ImmunoGen Presents New Clinical and Preclinical Data at ASH Annual Meeting

CD33-Targeting IMGN779 Demonstrates Favorable Safety Profile and Anti-Leukemia Activity in Ongoing Phase 1 Trial; Dose Escalation Continues with Two Dosing Schedules

Preclinical Data Presentations on IMGN779 in Combination and CD123-Targeting IMGN632 Highlight Breadth of ImmunoGen Hematology Pipeline

WALTHAM, Mass.--(BUSINESS WIRE)-- 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 Company's ongoing Phase 1 study of IMGN779, a next-generation CD33-targeting ADC, in patients with relapsed or refractory adult acute myeloid leukemia (AML) were presented at the 59th American Society of Hematology (ASH) Annual Meeting in Atlanta. Poster presentations on preclinical data for IMGN779 in combination with cytarabine and CD123-targeting IMGN632 in acute lymphoblastic leukemia (ALL) are also being presented at the meeting.

The Phase 1 data presented at ASH demonstrate that IMGN779 was well-tolerated with no dose-limiting toxicities (DLTs) observed in patients with relapsed or refractory AML across nine dose levels administered once every two weeks (Q2W) and one dose level administered once a week (QW). In addition, anti-leukemia activity was seen at doses ≥0.39 mg/kg in both schedules in patients with poor prognostic features. The maximum tolerated dose has not been reached and dose escalation continues. Data across the first seven dose levels on the Q2W schedule were presented in June at the 22nd Congress of the European Hematology Association (EHA).

"The data at ASH build on the initial safety and anti-leukemia data presented earlier this year at EHA, and further support continued dose escalation of IMGN779, a novel, next-generation treatment for AML," said Anna Berkenblit, M.D., vice president and chief medical officer of ImmunoGen. "Given investigator enthusiasm and high unmet need, the dosing cohorts have been rapidly enrolling and we are very encouraged by the initial findings with IMGN779. We are continuing to dose escalate on the every two week schedule and, to evaluate the potential of continuous exposure, we have opened a weekly dosing schedule in parallel. We look forward to establishing the optimal dose and schedule, and quickly moving this compound into later stages of development."

Phase 1 Data on IMGN779 in AML

Key findings presented from the Phase 1 study of IMGN779 at ASH (*Abstract #1312*) include the following:

- IMGN779 displays a tolerable safety profile.
  - No DLTs were observed on either administration schedule at doses examined - up to 0.91 mg/kg Q2W and 0.39 mg/kg QW.
  - No increase in the nature, frequency, or severity of any treatment-emergent adverse event was observed with increasing dose.
  - This profile has enabled repeat dosing, with one patient showing a 93% reduction in bone marrow blasts with extended treatment and who remains on therapy through Cycle 14.
- Pharmacokinetic (PK) exposures and pharmacodynamic (PD) CD33 saturation continue to increase with dose, and support further escalation and exploration of both the QW and Q2W schedules.
- Anti-leukemia activity was seen at doses ≥0.39 mg/kg in both schedules with:
  - 16 of 17 patients showing a decrease in peripheral blasts within 10 days after first dose with a median maximal decrease of 71%; and
  - Seven of 17 patients showing a 48%-96% reduction in bone marrow blasts. These seven patients had poor prognostic features (e.g., prior intense therapy, primary refractory disease, RAS/TP53/FLT3/IDH mutations).

This ongoing Phase 1 trial is designed to establish the maximum tolerated dose and determine the recommended Phase 2 dose for IMGN779 administered as monotherapy. The trial is also intended to evaluate safety and tolerability, and characterize PK, PD, and preliminary anti-leukemia activity in relapsed or refractory AML.

Preclinical Presentations on IMGN779 in Combination with Cytarabine and IMGN632 in ALL

Supporting data evaluating the mechanism, anti-leukemia efficacy, and tolerability of repeated dosing of IMGN779 in combination with cytarabine using *in vitro* and *in vivo* human AML preclinical models were also presented. Key findings from the poster presentation (*Abstract #1357*) include:

- The combination of IMGN779 and cytarabine increased DNA damage response, cell cycle arrest, and apoptosis *in vitro* when compared to single agent treatment.
- The combination of IMGN779 and cytarabine lead to increased survival and greater numbers of complete responses in *in vivo* preclinical AML models.
- Use of cytarabine increased cell surface CD33 levels on AML cells, suggesting a novel mechanism for potentiating IMGN779 uptake.

Preclinical data (*Abstract #2718*) on IMGN632 reporting the prevalence of CD123 expression in acute lymphoblastic leukemia (ALL), and assessing the anti-leukemia activity of IMGN632 on ALL cells will also be presented. Among the findings:

- CD123 expression is prevalent across ALL subtypes including 90% of B-cell ALL (B-ALL) and nearly half of T-cell ALL patient samples.
- IMGN632 demonstrates promising activity against B-ALL cell lines and patient samples *in vitro*, including the elimination of more than 90% of B-ALL blasts in 6 out of 8 patient samples. Normal cells were not affected by IMGN632 at 100-fold higher concentrations.

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

Poster Session Schedule and Details

- Title (*Abstract #1312*): "IMGN779, a Next-Generation CD33-Targeting Antibody-Drug Conjugate (ADC) Demonstrates Initial Antileukemia Activity in Patients with Relapsed or Refractory Acute Myeloid Leukemia"
  - *Poster session #613: Saturday, December 9, 5:30 - 7:30 PM ET.*
- Title (*Abstract #1357*): "IMGN779, a Next Generation CD33-Targeting ADC, Combines Effectively With Cytarabine in Acute Myeloid Leukemia (AML) Preclinical Models, Resulting in Increased DNA Damage Response, Cell Cycle Arrest and Apoptosis *In Vitro*, and Prolonged Survival *In Vivo*"
  - *Poster session #616: Saturday, December 9, 5:30 - 7:30 PM ET.*
- Title (*Abstract #2718*): "CD123 Expression Patterns and Potential of IMGN632, a CD123-Targeted Antibody Drug Conjugate, in Acute Lymphoblastic Leukemia"
  - *Poster session #618: Sunday, December 10, 6:00 - 8:00 PM ET.*

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 humanized anti-CD123 antibody-drug conjugate that is a potential treatment for AML, blastic plasmacytoid dendritic cell neoplasm (BPDCN), myelodysplastic syndrome, B-cell acute lymphocytic leukemia, and other CD123-positive malignancies. IMGN632 uses a novel IGN payload, linker and antibody technology and in AML xenograft models has demonstrated a large therapeutic index.[3] ImmunoGen has filed an investigational new drug (IND) application for IMGN632 and expects to open a Phase I study before year end.

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.[4,5] 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.[6]

About ImmunoGen, Inc.
ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary ADC technology. The Company's lead product candidate, mirvetuximab soravtansine, is in a Phase 3 trial for FRα-positive platinum-resistant ovarian cancer, and is in a Phase 1b/2 trial in combination regimens for earlier-stage disease. ImmunoGen has three additional clinical-stage product candidates, two of which are being developed in collaboration with Jazz Pharmaceuticals. ImmunoGen's ADC technology is also used in Roche's marketed product, Kadcyla®, and in programs in development by Amgen, Bayer, Biotest, CytomX, Debiopharm, Lilly, Novartis, Sanofi and Takeda. More information about the Company can be found at www.immunogen.com.

Kadcyla® is a registered trademark of Genentech, a member of the Roche Group.

[1] Y. Kovtun et al. (2016) *Blood* 128:768.
[2] M. Miller et al. (2016) *Mol Cancer Ther* 15:1870-78.
[3] S. Adams et al, Abstract 2832, Presented at the American Society for Hematology 2016.
[4] Y. Kovtun, 2016.
[5] M. Miller, 2016.
[6] 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 Transition Report on Form 10-KT for the six-month transition period ended December 31, 2016 and other reports filed with the Securities and Exchange Commission.

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