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ImmunoGen Presents Data from Phase I Study of IMGN779 in Acute Myeloid Leukemia

Data demonstrate favorable safety profile with repeat dosing and no dose-limiting toxicities

Dose-dependent biological and anti-leukemia activity observed

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq:IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, presented data from the ongoing Phase 1 study evaluating single agent IMGN779 in patients with relapsed or refractory adult acute myeloid leukemia (AML) whose tumors express CD33. The first-in-human data demonstrate the safety and tolerability of IMGN779 across seven dose levels, with no dose limiting toxicities (DLTs), as well as evidence of dose-dependent biological and anti-leukemia activity. These results were presented in a poster presentation on Saturday, June 24, 2017, at the 22nd Congress of the European Hematology Association (EHA) in Madrid, Spain.

IMGN779 combines a high-affinity, humanized anti-CD33 antibody with one of ImmunoGen's novel indolino-benzodiazepine payloads, called IGNs, which alkylate DNA without crosslinking, resulting in potent anti-leukemia activity with relative sparing of normal hematopoietic progenitor cells.

Safety, pharmacokinetic (PK), and pharmacodynamic (PD) data, as well as initial anti-leukemia activity for IMGN779 through dose level seven were presented at EHA. Key findings included:

- No DLTs have been observed through dose level seven, with reported adverse events consistent with the underlying disease.
- No increase in the nature, frequency, or severity of any treatment-emergent adverse event has been reported with escalating doses and no evidence of cumulative toxicity has been observed with repeated dosing.
- Favorable PK/PD reveal prolonged exposure and CD33 saturation at dose levels six and seven.
- Initial anti-leukemia activity was observed at dose levels six and seven in patients who failed intensive frontline therapy.

The 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. Dose escalation continues.

"We have designed our DNA-alkylating IGNs to be ultra-potent while providing the tolerability necessary for ongoing retreatment," said Richard Gregory, Ph.D., executive vice president and chief scientific officer of ImmunoGen. "We believe that by combining IGNs with our ADC technology, we may be able to treat a number of additional cancers that don't respond to existing ADC therapies. These data suggest favorable tolerability and encouraging activity in patients with AML, and we look forward to determining the recommended dose for IMGN779 and moving quickly into later-stage development."

Preclinical data for IMGN779 were also presented at EHA showing the agent is highly active in multiple AML xenograft models and is well-tolerated in preclinical repeat dosing regimens. Findings from the preclinical evaluation provided the foundation for the clinical evaluation of IMGN779 in AML.

Poster Details

Title: *Initial results from a first-in-human study of IMGN779, a CD33-targeting antibody-drug conjugate (ADC) with novel DNA alkylating activity, in patients with relapsed or refractory AML*
Abstract: P526

Title: *Designing the next generation CD33-targeting ADC: IMGN779, selected for potency, novel mechanism and preclinical tolerability, with high activity in disseminated AML models and multi-dose regimens*
Abstract: P562

Additional information - including the full abstracts - can be found at www.ehaweb.org.

About ImmunoGen, Inc.

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

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, 20,000 patients will be diagnosed with AML this year and 10,000 patients will die from the disease.[1] CD33 is expressed in virtually all cases of AML.

About IMGN779

IMGN779 is the first antibody drug conjugate (ADC) to utilize one of ImmunoGen's new family of indolino-benzodiazepine cancer-killing agents known as IGNs. IMGN779 is comprised of a CD33-targeting antibody with a potent DNA-alkylating agent, the IGN DGN462, attached. The antibody serves to target the ADC to the CD33-positive AML cells which DGN462 can then kill. IMGN779 is wholly owned by ImmunoGen.

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-alkylating IGNs are expected to extend the types of cancers able to be effectively treated with ADC therapies beyond those addressable with ImmunoGen's well-established tubulin-acting agents. Such cancers can include ones insensitive to tubulin-acting agents and/or with reduced antigen expression.

[1]American Cancer Society (2016), Leukemia - Acute Myeloid (Myelogenous) Detailed Guide.

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, 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 six-month transition period ended December 31, 2016 and other reports filed with the Securities and Exchange Commission.

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