ImmunoGen Announces First Patient Dosed in Phase 1 Study of IMGN632 for Hematological Malignancies

January 4, 2018

Second ADC Using ImmunoGen's Novel DNA-Alkylating Payloads to Enter the Clinic

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 4, 2018-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the first patient has been treated with IMGN632 in a Phase 1 clinical trial of patients with CD123-positive hematological malignancies, including acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN).

IMGN632 uses ImmunoGen's novel indolino-benzodiazepine payload, DGN549, which alkylates DNA without crosslinking, as well as novel linker technology with a CD123-targeting antibody. In preclinical studies with IMGN632, ImmunoGen has reported potent and selective activity against AML cells with lower cytotoxicity to normal myeloid progenitor cells than an ADC designed to crosslink DNA.[1] Supporting preclinical data for IMGN632 have also shown compelling activity in AML and acute lymphoblastic leukemia (ALL) models with single and multi-dose regimens.[2,3] These data suggest that IMGN632 has the potential to be a highly effective, yet tolerable ADC.

"We continue to rapidly advance our novel IGN portfolio in a number of hematological malignancies and are pleased to be moving our second IGN ADC, IMGN632, into the clinic," said Anna Berkenblit, M.D., VP and Chief Medical Officer of ImmunoGen. "Our IGN payloads were developed to meet the dual challenges of achieving high potency against target cells, while enabling continued patient treatment. We believe IMGN632 has the potential to be a highly effective therapy with favorable tolerability for the treatment of patients with CD123-positive hematologic malignancies, including AML and BPDCN, cancers where new therapies are desperately needed."

The Phase 1 trial in AML and BCPDN will follow a once every three week dosing schedule while in its dose-finding stage. The selected dose will then be used in expansion cohorts assessing IMGN632 in patients with BPDCN, AML, ALL, and other CD123-positive hematologic malignancies.

"We are excited to be leading off the clinical evaluation of IMGN632, a potential new treatment option for patients with CD123-positive hematologic malignancies," said Hagop M. Kantarjian, M.D., professor and chair of the Department of Leukemia at the University of Texas MD Anderson Cancer Center and principal investigator of the trial of IMGN632.

Data presented at the American Society of Hematology Annual Meeting (ASH) 2017 demonstrated promising activity and safety with IMGN632 in preclinical models of B-cell ALL (B-ALL).[4] CD123 expression is prevalent across ALL subtypes, including 90% of B-ALL and nearly half of T-cell acute lymphoblastic leukemia. IMGN632 demonstrated 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.

This is the second clinical trial using IGNs, a new class of cancer-killing agents developed by ImmunoGen for use in ADCs. ImmunoGen recently reported findings from the Company's ongoing Phase 1 study of IMGN779 in patients with relapsed or refractory adult AML whose tumors express CD33.[5] The data demonstrate that IMGN779 is well-tolerated with no dose-limiting toxicities, pharmacokinetic exposures and pharmacodynamic CD33 saturation increasing with dose, and anti-leukemia activity observed in patients with poor prognostic features.

About IMGN632
IMGN632 is a humanized anti-CD123 ADC that is a potential treatment for AML, BPDCN, myelodysplastic syndrome, B-cell ALL and other CD123-positive malignancies. IMGN632 uses a novel IGN payload, linker and antibody technology, and has demonstrated potent and selective activity, with minimal cytotoxic effects, in preclinical models of AML and ALL.[6,7]

About IGNs
Indolino-benzodiazepine agents, or IGNs, are a new class of cancer-killing agent developed by ImmunoGen for use in ADCs. IGN payloads were designed to meet the dual challenges of achieving high potency against target cells, while having a tolerability profile that can enable continued patient treatment. These ultra-potent, DNA-acting IGNs alkylate DNA without crosslinking, which preclinically has resulted in potent anti-leukemia activity with relative sparing of healthy cells.[8,9]

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.[10]

About Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

BPDCN is a disease of the bone marrow and blood that affects multiple organs, including the lymph nodes and the skin. It often presents as leukemia or lymphoma. There are little data about BPDCN and there is no established treatment. The average age at diagnosis is 60 to 70 years. There are more men than women who are diagnosed with BPDCN.[11,12]

About ImmunoGen, Inc.
ImmunoGen is a late-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, Abstract 768, Presented at the American Society of Hematology, December 3-6, 2016.
[2] S. Adams et al, Abstract 2832, Presented at the American Society of Hematology, December 3-6, 2016.
[3] E. Angelova et al, Abstract 2718, Presented at the American Society of Hematology, December 9-12, 2017.
[4] Angelova, 2017.
[5] J. Cortes et al, Abstract 1312, Presented at the American Society of Hematology, December 9-12, 2017.
[6] Kovtun, 2016.
[7] Angelova, 2017.
[8] Kovtun, 2016.
[9] M. Miller et al. (2016) *Mol Cancer Ther* 15:1870-78.
[10] American Cancer Society (2016), *About Acute Myeloid Leukemia.*
[11] Clinical Advances in Hematology & Oncology Volume 14, Issue 4 April 2016
[12] Leukemia & Lymphoma Society (2018), *Blastic Plasmacytoid Dendritic Cell Neoplasm.*

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 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20180104005181/en/

Source: ImmunoGen, Inc.

For Investors
ImmunoGen, Inc.
Sarah Kiely, 781-895-0600
sarah.kiely@immunogen.com
or
For Media
ImmunoGen, Inc.
Courtney O'Konek, 781-895-0600
courtney.okonek@immunogen.com
or
FTI Consulting, Inc.
Robert Stanislaro, 212-850-5657
robert.stanislaro@fticonsulting.com