October 16, 2017

ImmunoGen Announces Investigational New Drug Application for IMGN632 for Hematological Malignancies is Active

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 the U.S. Food and Drug Administration (FDA) has completed the safety review of its investigational new drug (IND) application for IMGN632 in patients with CD123-positive hematological malignancies, including acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN). Filed in mid-September, the IND is now in effect and ImmunoGen plans to open a Phase 1 study to enrollment before the end of the year.

"IMGN632 is the second ADC from our pipeline to use one of ImmunoGen's indolino-benzodiazepine cancer-killing agents known as IGNs," said Richard Gregory, Ph.D., Executive Vice President and Chief Scientific Officer of ImmunoGen. "Our 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. Based on the encouraging preclinical findings, IMGN632 represents a potentially promising therapeutic approach for a range of hematological malignancies and we are working to transition this compound rapidly into clinical development before the end of the year."

IMGN632 uses ImmunoGen's novel DGN549 IGN payload, linker, and antibody technology and in preclinical models has demonstrated an impressive therapeutic window against CD123-positive malignancies. Preclinical findings reported at the 58th American Society of Hematology (ASH) Annual Meeting show that IMGN632, which alkylates DNA, had potent selective activity against AML cells with lower cytotoxicity to normal myeloid progenitor cells than an ADC designed to crosslink DNA activity. These data suggest IMGN632 has the potential to be a highly effective, yet tolerable ADC for AML patients. Supporting preclinical data for IMGN632 showed compelling activity in AML xenograft models.

About IMGN632
IMGN632 is a humanized anti-CD123 antibody-drug conjugate that is a potential treatment for AML, 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.[1]

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.[2,3] IMGN779, a CD33-targeting ADC in Phase 1 testing for AML, was the first IGN ADC to enter clinical testing.

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.[4]

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] S. Adams et al, Abstract 2832, Presented at the American Society of Hematology, December 3-6, 2016.

[2] S. Adams et al, Abstract P526, Presented at the 22nd Congress of the European Hematology Association, June 22-25, 2017.

[3] Y. Kotvun et al. (2016) *Blood* 128:768.

[4]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 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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