ImmunoGen Announces FDA Breakthrough Therapy Designation for IMGN632 in Relapsed or Refractory Blastic Plasmacytoid Dendritic Cell Neoplasm

October 5, 2020

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 5, 2020-- 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 granted Breakthrough Therapy designation for IMGN632 for the treatment of patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm (BPDCN).

“We are pleased FDA has granted Breakthrough Therapy designation for IMGN632, our novel CD123-targeted ADC, as it underscores the urgent need for effective and well-tolerated treatments for patients with this rare and aggressive cancer,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “We look forward to continuing to work with FDA to further define the development path for IMGN632 in BPDCN, in addition to pursuing our ongoing evaluation of IMGN632 in AML and other hematological malignancies.”

According to FDA guidelines, Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition and have generated preliminary clinical evidence that the drug may demonstrate substantial improvement over available therapy. Breakthrough Therapy designation was granted for IMGN632 based on the findings from the BPDCN cohort of the first-in-human study of IMGN632, for which initial data were presented in an oral session at the American Society of Hematology (ASH) Annual Meeting in 2019. Updated data from the IMGN632 monotherapy BPDCN dose expansion cohort will be presented at ASH this December.

ABOUT IMGN632
IMGN632 is a CD123-targeting ADC in clinical development for hematological malignancies, including blastic plasmacytoid dendritic cell neoplasm (BPDCN), acute myeloid leukemia (AML), and acute lymphocytic leukemia (ALL). IMGN632 is currently being evaluated in multiple cohorts, including monotherapy for patients with BPDCN and minimal residual disease positive (MRD+) AML following frontline induction therapy and in combinations with Vidaza® (azacitidine) and Venclexta® (venetoclax) for patients with relapsed/refractory AML. IMGN632 uses one of ImmunoGen's novel indolino-benzodiazepine (IGN) payloads, which alkylate DNA without crosslinking. IGNs have been designed to have high potency against AML blasts, while demonstrating less toxicity to normal marrow progenitors than other DNA-targeting payloads.

ABOUT BLASTIC PLASMACYTOID DENDRITIC CELL NEOPLASM
BPDCN is a rare form of blood cancer that has features of both leukemia and lymphoma, with characteristic skin lesions, lymph node involvement, and frequent spread to the bone marrow. This aggressive cancer requires intense treatment often followed by stem cell transplant. Despite the recent approval of a CD123-targeting therapy, the unmet need remains high for patients, particularly in the relapsed/refractory setting.

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.”

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

FORWARD-LOOKING STATEMENTS
This press release includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, ImmunoGen’s expectations related to: the occurrence, timing, and outcome of potential pre-clinical, clinical, and regulatory events related to ImmunoGen’s product candidates; and the presentation of pre-clinical and clinical data on ImmunoGen’s product candidates. 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. Various factors could cause ImmunoGen’s actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and outcome of ImmunoGen’s pre-clinical and clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of pre-clinical studies, clinical trials, and regulatory processes; ImmunoGen’s ability to financially support its product programs; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting impact on ImmunoGen’s industry and business; and other factors more fully described in ImmunoGen’s Annual Report on Form 10-K for the year ended December 31, 2019 and other reports filed with the Securities and Exchange Commission.

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