Cullinan Oncology Receives Investigational New Drug (IND) Clearance from the FDA for CLN-049, a FLT3 x CD3 Bispecific Antibody for the Treatment of Relapsed/Refractory AML

June 7, 2021

CAMBRIDGE, Mass., June 07, 2021 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Nasdaq: CGEM) ("Cullinan"), an oncology company seeking to drive shareholder returns by focusing on the patient, today announced that the U.S. Food and Drug Administration (FDA) has cleared Cullinan Florentine's IND application for CLN-049, a FLT3 x CD3 bispecific antibody for the treatment of relapsed/refractory acute myeloid leukemia (AML).

"IND clearance by the FDA paves the way to test a differentiated treatment approach by targeting extracellular FLT3, an oncogenic driver in AML," stated Patrick Baeuerle, Cullinan's Chief Scientific Officer, Biologics. "We are excited to initiate human dosing of CLN-049, a T cell-engaging, IgG-like antibody in patients with relapsed/refractory AML."

About CLN-049

CLN-049 is a humanized bispecific antibody being developed for relapsed/refractory AML. CLN-049 is designed to simultaneously bind to FLT3 on target leukemic cells and to CD3 on T cells, triggering the T cells to kill the targeted cancer cells via their intrinsic cytolytic mechanisms. Studies have shown that FLT3 is expressed by FACS staining on AML blasts in at least 75% of AML patients, regardless of an oncogenic driver mutation. The expression of FLT3 on the surface of leukemic blasts in most AML patients and its role as a known oncogenic driver make it an attractive therapeutic target for a T cell engager approach.

In preclinical studies, CLN-049 led to potent FLT3-dependent killing of leukemic cells in vitro at a wide range of FLT3 expression levels on AML cells. Treatment with CLN-049, even at low doses, led to survival benefit in an AML xenograft model and complete elimination of leukemic blasts in various mouse models implanted with primary patient leukemic cells or AML cell lines.

About Cullinan Oncology

Cullinan Oncology is a biopharmaceutical company that strives to deliver results for our various stakeholders through disciplined capital allocation, decisive action, prudent risk taking and creative business development. We seek to drive shareholder returns by focusing on the patient. The Company's strategy is to build a diversified pipeline of targeted and immuno-oncology therapeutic candidates that are uncorrelated across multiple dimensions, with a focus on assets that it believes have novel technology, employ differentiated mechanisms, are in a more advanced stage of development than competing candidates, or have a combination of these attributes. Learn more about Cullinan at www.cullinanoncology.com.

About Cullinan Florentine

Cullinan Florentine is a partially owned subsidiary of Cullinan Oncology that has exclusive worldwide rights to CLN-049 pursuant to a License with the Deutsches Krebsforschungszentrum, or DKFZ, Eberhard Karls University of Tübingen, Faculty of Medicine, or University of Tübingen, and Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen, or UFE.

Forward-Looking Statements

This press release contains forward-looking statements of Cullinan Oncology, Inc. ("Cullinan," "we" or "our") within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Cullinan's beliefs and expectations regarding our preclinical and clinical development plans, clinical trial designs, clinical and therapeutic potential, and strategy of our product candidates, including but not limited to our expectations and beliefs around the safety and efficacy of CLN-049. Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the timing and results of regulatory submissions; success of our clinical trials and preclinical studies; risks related to our ability to protect and maintain our intellectual property position; risks related to manufacturing, supply, and distribution of our therapeutic candidates; risks related to the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; the risk that any one or more of our product candidates, including those that are co-developed, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and success of any collaboration, partnership, license or similar agreements. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release. Moreover, except as required by law, neither Cullinan nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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