



Cullinan Oncology Receives FDA Clearance of Investigational New Drug (IND) Application for CLN-619, a Novel MICA/B-targeted Antibody for the Treatment of Solid Tumors

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- *CLN-619 will be the first MICA/B-targeted antibody to enter human clinical trials*
- *Cullinan will initiate a FIH trial in 3Q21, including a dose escalation cohort followed by dose expansion cohorts as a monotherapy and in combination with checkpoint inhibitor therapy*

CAMBRIDGE, Mass., June 29, 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 MICA's IND application for CLN-619. CLN-619 is a first-in-class monoclonal antibody designed to promote an antitumor response by engaging both natural killer (NK) and T cells through the MICA/B–NKG2D axis, with therapeutic potential for both solid and liquid tumor indications.

"The MICA/B-targeted antibody CLN-619 represents a novel approach to broadly engage both innate and adaptive immune cells to achieve tumor cell lysis through multiple mechanisms of action," stated Jennifer Michaelson, Cullinan's Chief Development Officer, Biologics. "Given that MICA/B ligands are expressed across a wide range of solid and liquid tumors and the strong biological rationale for combination with other therapies, successful clinical development of CLN-619 may demonstrate the potential to become a novel backbone agent for immuno-oncology therapy. We are excited to now focus our efforts on initiating a clinical trial evaluating the safety, tolerability and single-agent anti-tumor activity of CLN-619 in multiple solid tumor types. The trial design also includes a module to evaluate the safety, tolerability and anti-tumor activity of CLN-619 in combination with checkpoint inhibitor therapy."

About CLN-619

CLN-619 is a humanized IgG1 monoclonal antibody that binds to MICA and MICB expressed on a wide variety of cancer cells. MICA/B are stress-induced ligands that are recognized by both cytotoxic innate and adaptive immune cells via their NKG2D receptor. To evade lysis by these immune cells, tumor cells shed MICA/B from their cell surface. CLN-619 promotes an antitumor response through multiple mechanisms of action, including prevention of the proteolytic release of MICA/B from cancer cells, antibody-dependent cell-mediated cytotoxicity, or ADCC, enhancement of MICA/B binding to NKG2D, and reduction of the inhibitory effect of shed MICA/B.

In preclinical studies, animals treated with CLN-619 as a monotherapy demonstrated significant inhibition of tumor growth and a dramatic reduction of serum levels of soluble MICA. Multiple studies evaluating serum samples from cancer patients have demonstrated that high serum levels of shed MICA correlate with a poor prognosis.

About Cullinan Oncology

Cullinan Oncology is a biopharmaceutical company that strives to deliver results for its 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, unique modes of action, and are either first- or best-in-class. Learn more about Cullinan at www.cullinanoncology.com.

About Cullinan MICA

Cullinan MICA is a Cullinan Oncology company that acquired exclusive worldwide rights to CLN-619, which was discovered by PDI Therapeutics, a portfolio company of Avalon Ventures.

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-619. 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.

Contacts:

Investor Relations

investors@cullinanoncology.com

Jeffrey Trigilio

+1 617.410.4650

jtrigilio@cullinanoncology.com