Cullinan Oncology Announces U.S. FDA Clearance of Investigational New Drug Application for Novel MICA/B Antibody, CLN-619, for Relapsed/Refractory Multiple Myeloma

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Company will initiate Phase 1 study of CLN-619 for relapsed or refractory multiple myeloma, first MICA/B antibody clinical study in hematologic malignancies

Follows ongoing clinical study of CLN-619 alone and in combination with pembrolizumab in solid tumors, with anticipated updated clinical data in Q2 2024

CAMBRIDGE, Mass., March 01, 2024 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on modality-agnostic targeted oncology therapies, today announced the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for CLN-619 in relapsed/refractory multiple myeloma. CLN-619 is a potential first-in-class humanized IgG1 monoclonal antibody that binds to stress-induced ligands, MICA and MICB, which are expressed on a wide variety of solid tumors and hematologic malignancies. The company will commence a Phase 1 dose-escalation and dose-expansion trial of CLN-619.

“Multiple myeloma remains incurable, and most patients experience sequential relapses. The response to treatment is typically shorter with each relapse, so novel treatments are still needed,” said Jeffrey Jones, MD, MPH, MBA, Chief Medical Officer, Cullinan Oncology. “Multiple myeloma is another example of a malignancy where MICA/B shedding from tumor cells allows for immune evasion. As we shared at SITC 2023, CLN-619 restores MICA/B expression on tumor cells, enabling immune recognition. This Phase 1 trial will assess CLN-619 in patients with multiple myeloma, and, given the safety profile shown to date for CLN-619, we believe there is an opportunity to combine the monoclonal antibody with multiple standard therapies. With clinical studies in both solid tumors and hematologic malignancies, we look forward to assessing the full potential of CLN-619 to address multiple areas of unmet clinical need.”

About CLN-619

CLN-619 is a potential first-in-class humanized IgG1 monoclonal antibody that binds to the stress-induced ligands MICA and MICB, which are expressed on a wide variety of solid tumors and hematologic malignancies. Engagement of MICA/B by the activating receptor NKG2D, present on both cytotoxic innate and adaptive immune cells, results in target cell lysis. However, tumor cells can shed MICA/B via proteases they release into the tumor microenvironment, resulting in evasion of immune-mediated destruction. CLN-619 functions by restoring MICA/B expression on the surface of tumor cells, enhancing the interaction between MICA and NKG2D, and inducing antibody-dependent cellular toxicity (ADCC), together promoting anti-tumor activity via multiple immune-mediated mechanisms. CLN-619 is being studied in an ongoing Phase 1 clinical trial (NCT05117476) both as a monotherapy and in combination with pembrolizumab in patients with solid tumors. The study design allows dose level extensions as well as expansion in tumor-specific cohorts. CLN-619 will also be studied in a Phase 1 clinical trial in patients with relapsed/refractory multiple myeloma.

About Cullinan Oncology

Cullinan Oncology, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients with cancer. We innovate without borders to find the most promising clinic-ready cancer therapies, whether from our own discovery efforts or through exceptional engagement with our academic and industry partners. Anchored in a deep understanding of immuno-oncology and translational cancer medicine, we leverage our scientific excellence in small molecules and biologics to create differentiated ideas, identify unique targets, and select the optimal modality to develop transformative therapeutics across cancer indications. Powered by our novel research model, we push conventional boundaries from candidate selection to cancer therapeutic, applying rigorous early experimentation to fast-track only the most promising assets to the clinic and ultimately commercialization. As a result, our diversified pipeline is strategically built with assets that activate the immune system or inhibit key oncogenic drivers across a wide range of modalities, each with the potential to be the best or first in their class.

Our people possess deep scientific expertise, seek innovation openly, and exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients with cancer. Learn more about our Company at www.cullinanoncology.com, and follow us on LinkedIn and Twitter.

Forward-looking statements

This press release contains forward-looking statements 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 and timelines, 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. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “hope,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “target,” “should,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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 product 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, 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, except to the extent required by law. 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.

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