



Cullinan Oncology Announces U.S. FDA Clearance of Investigational New Drug Application for CLN-617, a Novel Fusion Protein Harnessing IL-2 and IL-12 Cytokines

March 27, 2023

CAMBRIDGE, Mass., March 27, 2023 (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-617, a fusion protein comprised of two potent and synergistic antitumor cytokines, IL-2 and IL-12, with a collagen binding domain designed for retention in the tumor microenvironment (TME) following intratumoral injection. Cullinan Oncology will initially evaluate CLN-617 in a Phase 1 trial in patients with advanced solid tumors.

"Both IL-2 and IL-12 play a powerful role in stimulating an immune response to cancer, but previous attempts to harness these potent cytokines have been limited by significant systemic toxicities and a narrow therapeutic index" said Jeffrey Jones, MD, MPH, MBA, Chief Medical Officer, Cullinan Oncology. "Preclinical research shows that while CLN-617 is retained in the injected tumor, it mediates a broad anti-tumor immune response that clears both injected tumors and distant non-injected tumors and generates immunological memory to prevent recurrence. We look forward to working closely with investigators to initiate the Phase 1 trial and are proud to advance this program, which will be our sixth clinical-stage asset, to further our mission to create new standards of care for patients with cancer."

The first-in-human clinical study is a Phase 1, open-label, dose-escalation and dose-expansion study designed to evaluate the safety and efficacy of CLN-617 alone and in combination with pembrolizumab in patients with advanced solid tumors.

About CLN-617

CLN-617 is a potential first-in-class cytokine therapy comprised of two potent and synergistic antitumor cytokines, IL-2 and IL-12, in a single molecule. The molecule is intended for intratumoral injection and employs collagen-binding and size-enhancing domains designed to retain the CLN-617 molecule inside the tumor and thereby enhance efficacy and reduce toxicity. While CLN-617 is injected and retained locally in the tumor, it directs a broad immune response that may help eradicate not only the injected tumor, but also attack distant tumor sites, as observed in preclinical studies. Preclinical studies have also demonstrated the potential for enhanced efficacy when CLN-617 is combined with checkpoint inhibitor therapy. Cullinan plans to evaluate CLN-617 in a Phase 1 clinical trial in patients with advanced solid tumors.

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-617. 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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