



Cullinan Oncology Announces First Patient Dosed in Phase 1 Trial Evaluating CLN-617, a Novel Fusion Protein Uniquely Harnessing Both IL-2 and IL-12 Cytokines

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CAMBRIDGE, Mass., Dec. 14, 2023 (GLOBE NEWSWIRE) -- [Cullinan Oncology, Inc.](#) (Nasdaq: CGEM), a biopharmaceutical company focused on modality-agnostic, targeted oncology therapies, today announced that the first patient has been dosed with CLN-617 in a Phase 1 clinical trial. This is a first-in-human, multi-center, open label study designed to evaluate the safety, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary efficacy of CLN-617 alone and in combination with pembrolizumab, a programmed death receptor-1 (PD-1) targeted checkpoint inhibitor, in patients with advanced solid tumors.

"While checkpoint inhibitors have revolutionized immuno-oncology, only a minority of patients respond, often due to the tumors lacking appreciable numbers of cancer-specific T cells, referred to as "cold" tumors. IL-2 and IL-12 are cytokines that work together to stimulate an immune response to cancer cells, potentially resulting in increased T cell infiltration, activation, and proliferation and thereby turning the tumor 'hot,'" said Jeffrey Jones, MD, MPH, MBA, Chief Medical Officer, Cullinan Oncology. "CLN-617 is a first-in-class cytokine therapy uniquely combining human IL-2, IL-12, a collagen binding domain, and a size-enhancing domain in a single molecule designed for intratumoral injection. These unique characteristics are intended to promote retention of the cytokines in the injected tumor and potentially provide enhanced safety and efficacy. In pre-clinical models, intratumoral administration of CLN-617 stimulated a broad systemic immune response, resulting in the regression of non-injected distal tumors and the generation of a memory T cell response that enhanced long-term survival. We look forward to working with investigators to explore the potential of CLN-617, Cullinan Oncology's sixth program in clinical development."

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; 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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