Cullinan Therapeutics Announces Positive End-of-Phase 1 Meeting with FDA for CLN-049 and Advances Program to a Potentially Registrational Phase 2 Study in AML

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CAMBRIDGE, Mass., July 28, 2026 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM; “Cullinan”), a clinical-stage biopharmaceutical company accelerating potential first- or best-in-class, disease-modifying T cell engagers in autoimmune diseases and cancer, today announced positive feedback from the U.S. Food and Drug Administration (FDA) following an End-of-Phase 1 (EOP1) meeting for CLN-049, a FLT3xCD3 T cell engager being evaluated in patients with acute myeloid leukemia (AML).

The EOP1 meeting focused on the planned Phase 2 development strategy for CLN-049. Based on discussions with the FDA, Cullinan will initiate a potentially registrational Phase 2 study of CLN-049 in patients with relapsed/refractory AML in the third quarter of 2026. The study design agreed with the FDA incorporates a short dose-optimization phase with seamless progression to a single-arm cohort at the recommended Phase 2 dose.

"Patients with AML continue to face poor outcomes and have limited treatment options, underscoring the need for new therapeutic approaches," said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. "The FDA's feedback reinforces our confidence in the development strategy for CLN-049 and provides a clear path forward for potential regulatory approval. We look forward to continuing to advance the CLN-049 program and exploring its potential across AML patient populations."

As presented at the 2025 American Society of Hematology (ASH) Annual Meeting, CLN-049 demonstrated promising clinical activity and a favorable safety profile in patients with relapsed/refractory AML. The Company plans to share an update from the dose escalation portion of this study in Q4 2026.

Following the positive feedback from the FDA, the Company plans to initiate a potentially registrational Phase 2 study in patients with relapsed/refractory AML in Q3 2026. The Company will also initiate a Phase 1/2 study evaluating the combination of CLN-049, venetoclax, and azacitidine in patients with previously untreated AML (NCT07722767).

About CLN-049

CLN-049 is a novel, investigational FLT3xCD3 bispecific T cell engager. CLN-049 is designed to target FLT3-expressing leukemia cells, offering a new immunotherapeutic approach for treating acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). CLN-049 binds to both mutated and non-mutated FLT3, allowing targeted action regardless of FLT3 mutational status, making the investigational treatment widely applicable to a broad population.

CLN-049 is being studied in a Phase 1, open-label, multicenter, first-in-human, multiple ascending dose study evaluating safety, tolerability, pharmacokinetics (PK), pharmacodynamics, and preliminary efficacy of intravenously (IV) administered CLN-049 in patients with relapsed/refractory AML or MDS (**NCT05143996**) and in a parallel Phase 1, open-label, dose escalation and dose expansion study for the treatment of patients with AML with measurable residual disease (MRD) (**EUCT 2023-506572-27-00**).

CLN-049 has received Orphan Drug designation and Fast Track designation from the U.S. FDA for the treatment of relapsed/refractory AML.

About Acute Myeloid Leukemia

Acute myeloid leukemia (AML) is a cancer of the blood and bone marrow, and the most common form of acute leukemia in adults.[1] It is characterized by the rapid growth of abnormal white blood cells that crowd out healthy cells, leading to infections, fatigue, and bleeding.[2] Each year in the U.S., approximately 23,000 people are diagnosed with AML, and about half as many lives are lost to the disease.[3] Globally, AML affects an estimated 145,000 people annually, with approximately 130,000 deaths.[4]

Despite recent advances, outcomes for patients with AML remain poor, particularly for those with relapsed or refractory disease, where five-year survival is 10% or less.[5] Patients with high-risk genetic features, such as complex karyotype or TP53 mutations, face especially limited options.[6,7] Intensive treatments like chemotherapy and stem cell transplantation may be inaccessible for many older patients due to severe side effects.[7] Currently, there are no approved immunotherapies for AML, underscoring the urgent need for novel therapeutic approaches that can improve outcomes for patients and their families facing this life-threatening

disease.

About Cullinan Therapeutics

Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company developing potential first- or best-in-class, disease-modifying T cell engagers for autoimmune diseases and cancer. Cullinan pursues promising therapeutic targets while leveraging core expertise in T cell engagers, which are established in oncology and are now advancing into autoimmune diseases. With a clinical-stage pipeline built on a rigorous scientific approach and purposeful innovation, Cullinan is advancing its mission to deliver new standards of care for patients. Learn more about Cullinan at https://cullinantherapeutics.com/, and follow Cullinan on LinkedIn and X.

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 the company's beliefs and expectations regarding: our clinical development plans and timelines for CLN-049, the clinical and therapeutic potential of CLN-049, the strategy of CLN-049, our research and development activities, and other statements that are not historical facts. The words "believe," "continue," "could," "estimate," "expect," "intends," "may," "plan," "potential," "project," "pursue," "will," 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 future results, performance or achievements 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; the risk that any INDs, NDAs or other global regulatory submissions we may file with the United States Food and Drug Administration or other global regulatory agencies are not cleared or approved on our expected timelines, or at all; the success of our clinical trials and preclinical studies; the risks related to our ability to protect and maintain our intellectual property position; the 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; the effect of changes in global economic conditions, including uncertainties related to international trade policies, tariffs and supply chain dynamics on our business and operations; and the 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 the company 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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