Cullinan Therapeutics Receives FDA Orphan Drug Designation for CLN-049, a Novel FLT3xCD3 T Cell Engager, in Relapsed/Refractory Acute Myeloid Leukemia

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Orphan Drug Designation underscores the potential of CLN-049, a novel FLT3xCD3 T cell engager, to address significant unmet need in AML

CAMBRIDGE, Mass., May 19, 2026 (GLOBE NEWSWIRE) -- **Cullinan Therapeutics, Inc.** (Nasdaq: CGEM), a clinical-stage biopharmaceutical company accelerating potential first- or best-in-class, high-impact therapies in autoimmune diseases and cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to CLN-049, a novel, investigational FLT3xCD3 T cell engager, for the treatment of relapsed/refractory (R/R) acute myeloid leukemia (AML).

"FDA Orphan Drug Designation for CLN-049 emphasizes both the urgent need for new therapies for people living with relapsed or refractory acute myeloid leukemia – including patients with *TP53*-mutated AML who currently face a particularly poor prognosis – and the potential of this FLT3-directed T cell engager to expand treatment options across the broadest population of AML patients," said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. "Coupled with promising results from our ongoing Phase 1 program, this designation by the FDA reinforces a shared goal to rapidly advance novel therapies for patients living with AML."

About Orphan Drug Designation

The U.S. FDA's Orphan Drug Designation provides orphan status to drugs and biologics intended to prevent, diagnose, or treat rare diseases or conditions that affect fewer than 200,000 people in the United States. Orphan Drug Designation qualifies sponsors for certain development incentives, including tax credits for qualified clinical trials, exemption from certain FDA user fees, and the potential for seven years of market exclusivity in the United States following marketing approval.

About CLN-049

CLN-049 is a novel, investigational FLT3xCD3 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, enabling 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 (PD), 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 Fast Track designation from the U.S. Food and Drug Administration 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.[1,2] It is characterized by the rapid growth of abnormal white blood cells that crowd out healthy cells, leading to infections, fatigue, and bleeding.[3] Each year in the U.S., approximately 22,000 people are diagnosed with AML, and about half as many lives are lost to the disease.[4] Globally, AML affects an estimated 144,000 people annually, with approximately 130,000 deaths.[5]

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.[4,6] Patients with high-risk genetic features, such as complex karyotype or *TP53* mutations, face especially limited options.[7,8] Intensive treatments like chemotherapy and stem cell transplantation may be inaccessible for many older patients due to severe side effects.[8] 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; "Cullinan") is a biopharmaceutical company developing potential first- or best-in-class, high-impact therapies 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 developments plans and timelines for CLN-049, the clinical and therapeutic potential of CLN-049, 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 NDAs, INDs or other global regulatory submissions we may file with the United States Food and Drug Administration or other global regulatory agencies are not approved or cleared 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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