



Cullinan Therapeutics Receives Approval from European Medicines Agency to Initiate Phase 1 Trial of CLN-978, a Bispecific CD19 T Cell Engager Administered Subcutaneously, in Patients with Rheumatoid Arthritis

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Company-sponsored clinical trial will be initiated at FAU Erlangen-Nuremberg in Germany and Università Cattolica del Sacro Cuore, Rome in Q2 2025

CLN-978 is also being studied in the U.S., Europe, and Australia for systemic lupus erythematosus

CAMBRIDGE, Mass., April 16, 2025 (GLOBE NEWSWIRE) -- [Cullinan Therapeutics, Inc.](#) (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today announced that the European Medicines Agency (EMA) approved the Company's Clinical Trial Application (CTA) for CLN-978.

The Phase 1 clinical trial will assess CLN-978 in patients with active, difficult-to-treat rheumatoid arthritis meeting the 2010 American College of Rheumatology (ACR)/European Alliance of Associations for Rheumatology (EULAR) Classification Criteria. This open-label study will evaluate the safety, pharmacokinetics, pharmacodynamics, and effects of CLN-978 on disease activity.

"We are pleased to announce the achievement of an important regulatory milestone allowing us to initiate a clinical trial of CLN-978 in rheumatoid arthritis in the second quarter of this year, with leading research institutions in Europe, as we simultaneously advance our systemic lupus erythematosus trial at sites around the globe," said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. "CLN-978 is the only CD19-targeting T cell engager advancing a global regulatory development plan that includes a U.S. FDA-cleared IND. Delivering the potency of T cell redirecting therapy with the potential for disease modification, CLN-978 offers off-the-shelf access and convenient subcutaneous dosing for improved accessibility and treatment flexibility for patients with a range of autoimmune diseases."

"Rheumatoid arthritis remains a challenging disease, where effective treatment is critical to altering its course. Although some patients can achieve remission with current therapies, the majority do not achieve this or lose response and become refractory to treatment," said Ricardo Grieshaber-Bouyer, MD, PhD, MHBA, Professor of Clinical Systems Immunology and Head of the Clinical Trials Unit at FAU Erlangen-Nuremberg, and global Principal Investigator for this trial. "This unmet need underscores the importance of advancing novel approaches like CLN-978, which has the potential to offer deeper B cell depletion than existing therapies. We are excited to collaborate on research that could bring new solutions to patients with refractory rheumatoid arthritis, a population in need of better treatment options."

About CLN-978

CLN-978 is a novel, differentiated and highly potent CD19xCD3 bispecific T cell engager. CLN-978 triggers redirected lysis of CD19-expressing target cells *in vitro* and *in vivo*. CLN-978 is engineered to achieve very high affinity binding to CD19 to efficiently target B cells, including those with very low CD19 levels. Small in molecular size (65 kDa), CLN-978 contains two single-chain variable fragments, one binding with very high affinity to the CD19 target and the other binding to CD3 on T cells, and a single-domain antibody binding to human serum albumin to extend serum half-life. CLN-978 was developed by an internal Cullinan team and is a wholly owned asset. CLN-978 has the potential to offer a convenient, off-the-shelf, subcutaneously delivered therapeutic option for patients with autoimmune diseases such as systemic lupus erythematosus and rheumatoid arthritis.

About Rheumatoid Arthritis

Rheumatoid arthritis is a chronic autoimmune disease primarily characterized by inflammation of the joints, which can lead to pain, swelling, stiffness, and permanent joint damage.^{1,2} The disease often affects multiple joints simultaneously, commonly the hands, wrists, and feet, but it can also involve other organ systems.² Roughly 5.3 million adults live with rheumatoid arthritis across the U.S., France, Germany, Italy, Spain, the UK, Japan, and Australia, and the disease is more common in women than men.³⁻¹⁰ While disease-modifying antirheumatic drugs (DMARDs) have improved treatment outcomes, many patients continue to rely on chronic immunosuppression, have inadequate responses, experience disease flares, and face significant impairments in quality of life.¹¹

About Cullinan Therapeutics

[Cullinan Therapeutics, Inc.](#) (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients. Cullinan has strategically built a diversified portfolio of clinical-stage assets that inhibit key drivers of disease or harness the immune system to eliminate diseased cells in both autoimmune diseases and cancer. Cullinan's portfolio encompasses a wide

range of modalities, each with the potential to be best and/or first in class. Anchored in a deep understanding of oncology, immunology, and translational medicine, we create differentiated ideas, identify the most appropriate targets, and select the optimal modality to develop transformative therapeutics across a wide variety of autoimmune and cancer indications. We push conventional boundaries from candidate selection to differentiated therapeutic, applying rigorous go/no go criteria at each stage of development to fast-track only the most promising molecules to the clinic and, ultimately, commercialization. With deep scientific expertise, our teams exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients. Learn more about Cullinan at <https://cullinantherapeutics.com/>, and follow us 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 preclinical and clinical developments plans and timelines for CLN-978, the clinical and therapeutic potential of CLN-978, 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 or other global regulatory submissions we may file with the United States Food and Drug Administration or other global regulatory agencies are not 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; 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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