Cullinan Therapeutics to Initiate Study of CLN-978, a Bispecific CD19 T Cell Engager Administered Subcutaneously, in Patients with Sjögren's Disease in the United States

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CLN-978 is the first and only development-stage CD19 T cell engager to receive U.S. FDA IND clearance in autoimmune diseases

Sjögren's disease represents the third indication under development for CLN-978, and is a disease with high unmet need and no currently approved therapies

CAMBRIDGE, Mass., April 29, 2025 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today announced that the Company is initiating a study of CLN-978 in patients with Sjögren's disease (SjD) in the U.S. The Company previously received U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) Application clearance to study the CD19 T cell engager in patients with moderate to severe systemic lupus erythematosus (SLE) and European Medicines Agency (EMA) approval to study CLN-978 in active, difficult-to-treat rheumatoid arthritis.

The trial will enroll patients with active, moderate to severe Sjögren's disease who fulfill the 2016 American College of Rheumatology (ACR)/European Alliance of Associations for Rheumatology (EULAR) classification criteria and are positive for anti-SSA/RO antibodies and/or rheumatoid factor. The dose escalation scheme will be similar to the SLE study. The primary objective of the study is to evaluate the safety and tolerability of CLN-978 in patients with SjD. Secondary objectives include pharmacokinetics, pharmacodynamics, immunogenicity, and effect on disease activity. The Company expects to initiate the study this quarter.

"We are pleased to rapidly progress our global clinical development program for CLN-978, now open for patients living with systemic lupus erythematosus, rheumatoid arthritis, and soon Sjögren's disease," said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. "CLN-978, our investigational novel bispecific T cell engager, targets CD19 and offers a highly differentiated approach to deplete B cells deeply with an off-the-shelf product and convenient subcutaneous administration. We are grateful to the investigators in our systemic lupus erythematosus trial who have been enthusiastic partners in our research, and we look forward to opening this new trial to patients with Sjögren's disease in the U.S."

"Systemic lupus erythematosus and Sjögren's disease share a complex and often debilitating overlap, leaving many patients struggling with chronic pain, fatigue, and organ involvement," said Teja Kapoor, MD, Assistant Professor of Medicine at Columbia University College of Physicians and Surgeons in the Division of Rheumatology. "Despite advancements, there remains a significant unmet need for targeted therapies that address the root causes of these autoimmune conditions. I am encouraged by new research approaches such as CLN-978 that aim to modify the disease and offer sustainable relief to patients."

"There are an estimated four million Americans living with Sjögren's disease, yet it is underdiagnosed and frequently misunderstood," said Janet Church, President and Chief Executive Officer of the Sjögren's Foundation. "There are currently no treatments that comprehensively address the complexities of Sjögren's or slow the progression of the disease. We are encouraged to see new research approaches aimed at providing patients with better treatment options to improve their quality of life."

CLN-978 is being studied in people with SLE in the U.S., Australia, and Europe. CLN-978 will also be studied in people with rheumatoid arthritis at multiple sites in Europe, and in people with SjD at multiple sites in the U.S. and globally.

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, rheumatoid arthritis, and Sjögren's disease.

About Sjögren's Disease

Sjögren's disease (SjD) is a chronic autoimmune disease that affects the entire body. [1] While SjD most commonly manifests with extensive dryness, it can also present other serious complications including profound fatigue, chronic pain, major organ involvement, swelling of lymph nodes and glands, arthritis, hematologic abnormalities, neuropathies, and an increased risk of lymphoma.[1-4] SjD can occur alone or alongside other autoimmune diseases such as lupus, rheumatoid arthritis, or scleroderma.[1] Studies suggest the prevalence of SjD in the U.S. is estimated to impact over 250,000 individuals, making it one of the most common rheumatic diseases.[5] Many more people have SjD associated with other autoimmune diseases, and some people with SjD go undiagnosed. While available therapies address dryness and other symptoms, currently no approved treatment has been shown to comprehensively slow disease progression or treat all aspects of SjD.[1,2]

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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