Cullinan Therapeutics Receives U.S. FDA Clearance of Investigational New Drug Application for CLN-978 Administered Subcutaneously in Patients with Moderate to Severe Systemic Lupus Erythematosus

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

CAMBRIDGE, Mass., Oct. 16, 2024 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today announced that the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) Application for CLN-978 and its global Phase 1 clinical trial may proceed in the U.S. to assess CLN-978 in patients with moderate to severe systemic lupus erythematosus (SLE).

The trial will enroll patients with a Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) score of eight or greater and who have had an inadequate response to at least two treatments, including one immunosuppressive or biologic standard-of-care agent. Part A is a dose escalation phase that will determine the target dose for further development, with a starting dose of 10 micrograms. Part B is a dose expansion phase which will explore multiple dose schedules informed by data from Part A of the study.

The primary objective of the study is to evaluate the safety of CLN-978 for treatment of active moderate to severe SLE. Secondary objectives include pharmacokinetics, B cell kinetics, immunogenicity, and clinical activity.

"We are pleased to continue progressing our global Phase 1 clinical trial in the U.S. with FDA clearance of our IND Application," said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. "There remains a significant unmet medical need among patients with systemic lupus erythematosus, as current therapies often fail to fully control disease activity and prevent long-term organ damage. CLN-978, our novel bispecific T cell engager, targets CD19, offering a highly differentiated approach to deliver the potency of T cell redirecting therapy with off-the-shelf access and convenient dosing through subcutaneous administration."

The Company previously announced in September that it was cleared to initiate its global clinical trial in Australia (NCT06613360).

About CLN-978
CLN-978 is a novel, 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 Systemic Lupus Erythematosus
Systemic Lupus Erythematosus (SLE) is a chronic, heterogeneous autoimmune disease in which the immune system attacks a patient's own tissues. The most common manifestations of SLE include skin rashes, arthritis, swelling in the feet, and around the eyes, extreme fatigue, and low fevers. Lupus nephritis (LN) is a kidney disease and the most common severe manifestation of SLE. Approximately 40% of patients with SLE develop LN, which has a 10-year 30% mortality rate.[1,2] The prevalence of SLE in the US is estimated at 160,000 to 320,000 cases and SLE affects approximately 3.4 million individuals globally.[3,4] SLE is more prevalent in women and people of color. It occurs most often in people between the ages of 15 and 45 years but can occur in childhood or later in life as well. Currently available treatments do not routinely induce treatment-free remission, and most patients require lifelong immune suppression that treats symptoms without modifying the course of disease.

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 clinical development plan and timeline for CLN-978, the clinical and therapeutic potential of CLN-978, and the study design of our clinical trial for CLN-978. 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 FDA 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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