Cullinan Therapeutics Announces Preclinical Data for CLN-978, a CD19-directed T Cell Engager, to be Presented at ACR Convergence 2024

November 14, 2024

Cullinan will present new in vitro preclinical data that provide further strong rationale for broad clinical development of CLN-978 in autoimmune diseases

Cullinan will share details of global Phase 1b study in moderate to severe systemic lupus erythematosus

Company to host in-person investor event on Saturday, November 16, 2024, at 8 p.m. ET

CAMBRIDGE, Mass., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, will present new preclinical data for CLN-978, its novel CD19xCD3 T cell engager. These data and the study schema for a planned Phase 1b study in patients with moderate to severe systemic lupus erythematosus (SLE) will be presented at the annual meeting of the American College of Rheumatology (ACR), ACR Convergence 2024, being held in Washington, D.C., November 14-19. These data will be shared in a poster presentation on November 16, 2024, 10:30 a.m.-12:30 p.m. Eastern Time (Poster Session A, Poster Number 0003). Cullinan will also have a Booth (#2304) in the Exhibit Hall.

CLN-978 Preclinical Data

New *in vitro* preclinical data show CLN-978 induced similar T cell activation, target B cell depletion, and cytokine production in human peripheral blood mononuclear cells (PBMC) derived from patients with SLE (n=12) or rheumatoid arthritis (RA) (n=9) as compared to healthy volunteers (n=11).

These studies collectively suggest that the previously observed cytokine window observed in B-NHL model systems, potentially resulting in a broad therapeutic index, is expected to be preserved in SLE and RA patients.

"These new preclinical data further demonstrate that CLN-978 is a highly potent T cell engager. With the ability to be subcutaneously delivered, CLN-978 offers off-the-shelf convenience while achieving significant B cell depletion, supporting its potential as a promising new therapeutic option for autoimmune diseases," said Jeffrey Jones, MD, MBA, Chief Medical Officer of Cullinan Therapeutics. "With regulatory clearances in the U.S. and Australia, we are launching a global Phase 1b clinical trial of CLN-978 in SLE, collaborating closely with investigators and the patient community in our mission to establish new standards of care for patients."

CLN-978 Global Clinical Development Plan

In October, Cullinan Therapeutics announced U.S. Food and Drug Administration clearance of an Investigational New Drug Application for its global Phase 1 clinical trial to evaluate CLN-978 for the treatment of patients with moderate to severe SLE to proceed in the United States. Cullinan previously announced Human Research Ethics Committee approval to initiate the global clinical trial in Australia (NCT06613360).

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 using a modified single-ascending dose design to determine a recommended target dose for further development. Part A is planned to explore target dose levels of 10, 20, 30, and 45 micrograms (mcg) in a stepwise ascending fashion, enrolling at least three patients in each cohort. Dose levels above 10 mcg will incorporate a step-up dose of 10 mcg administered on Day 1 followed by administration of the higher cohort target dose on Day 8. Part B is a dose expansion phase which will explore two or more recommended 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. Initial clinical data are expected in the fourth quarter of 2025.

Live Investor Event

Cullinan will host an in-person event for analysts and institutional investors on Saturday, November 16, 2024, at 8 p.m. ET, during which members of Cullinan's management team will be available for discussion. The event will also feature a clinician and thought leader discussion, followed by a question-and-answer session. Investors and analysts are invited to register to attend in person by emailing Nick Smith, Director of Investor Relations (nsmith@cullinantx.com).

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 SLE 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 preclinical and clinical developments plans and timelines for CLN-978, the clinical and therapeutic potential of CLN-978, our plans regarding future data presentations, 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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