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

November 4, 2024

CAMBRIDGE, Mass., Nov. 04, 2024 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today announced the upcoming presentation of preclinical data for CLN-978, a novel CD19xCD3 bispecific T cell engager, at American College of Rheumatology (ACR) Convergence 2024, taking place in Washington, D.C. from November 14-19, 2024.

“These preclinical data show that CLN-978 is a highly potent T cell engager that leads to deep B cell depletion, supporting the broad development of CLN-978 as a potential new therapeutic option for patients with autoimmune diseases,” said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. “We look forward to continued collaboration with investigators and the patient community as we initiate our global Phase 1 clinical trial of CLN-978 in systemic lupus erythematosus and deliver on our mission to bring new standards of care to patients.”

The details of the presentation include:
Title: CLN-978, a CD19-directed T Cell Engager (TCE), Leads to Rapid and Deep B Cell Depletion and Has Broad Potential for Development in Autoimmune Diseases
Presenting Author: Stephen Wax, MD, PhD, Vice President, Clinical Development, Cullinan Therapeutics
Poster Number: 0003
Session Type: Poster Session A
Session Date and Time: November 16, 2024, 10:30 AM-12:30 PM Eastern Time
Session Title: B Cell Biology & Targets in Autoimmune & Inflammatory Disease Poster

On October 15, 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 SLE to proceed in the U.S. Cullinan previously announced Human Research Ethics Committee (HREC) approval to initiate the global clinical trial in Australia (NCT06613360).

Live Investor Event
Cullinan will host an in-person event for analysts and institutional investors on Saturday, November 16, 2024, at 8:00 PM Eastern Time 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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2. Hocaoglu M et al. *Arthritis Rheumatol*. 2023
3. Tian J et al. *Ann Rheum Dis.* 2022
4. Dall'Era M. In: Imboden J et al*. CURRENT Diagnosis & Treatment: Rheumatology.* 3rd ed. 2013