Cullinan Therapeutics Announces Strategic Expansion into Autoimmune Diseases

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CLN-978 clinical development to focus exclusively on autoimmune diseases, pursuing systemic lupus erythematosus as a first indication

Clinical observations from CLN-978 B-NHL study show rapid, deep, and sustained B cell depletion and clinical activity

Corporate name change to Cullinan Therapeutics reflects strategic expansion into autoimmune diseases

Cullinan Therapeutics to host a virtual investor event taking place on April 16 at 8:00 am ET

CAMBRIDGE, Mass., April 16, 2024 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc., formerly Cullinan Oncology, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today announced important updates about its plan to expand into autoimmune diseases, the scientific rationale for developing CLN-978 in autoimmune diseases, and initial clinical observations from its B cell non-Hodgkin lymphoma (B-NHL) study. In a separate announcement, the company also announced a $280 million private placement. The proceeds from the private placement, combined with current cash, cash equivalents, short term investments and interest receivable, are expected to fund Cullinan's current operating plan into 2028.

CLN-978 Development Plan

Cullinan Therapeutics intends to pursue development of CLN-978 in autoimmune diseases, with systemic lupus erythematosus (SLE) as a first indication. The company believes that CLN-978 has the potential to be a first-in-class, off-the-shelf, disease-modifying treatment in autoimmune diseases with a differentiated safety profile. The company plans to submit an investigational new drug application to study CLN-978 in patients with SLE in the third quarter of 2024 and is also planning for future development in other autoimmune diseases. The company has discontinued enrollment in its B-NHL study to focus ongoing development on autoimmune indications.

Recent data demonstrated the potential of CD19 directed CAR T therapies in the treatment of 15 patients with autoimmune diseases (systemic lupus erythematosus, idiopathic inflammatory myositis, systemic sclerosis).[1] While the efficacy was notable, challenges could limit broad uptake of CAR T therapy, such as the requirement for lymphodepleting chemotherapy, risk of secondary malignancies, complex manufacturing processes, and limited patient access. CD19-directed therapies afford significant potential for the breadth of B cell depletion and the necessary immune reset, since CD19 expression occurs across all B lineage cells, including the short-lived plasma cells and plasmablasts that produce the pathogenic autoantibodies present in autoimmune conditions. The company believes that CLN-978 could offer a novel solution for patients and providers as a T cell engager designed to deliver potency with off-the-shelf convenience and subcutaneous dosing.

On April 8, 2024, the Journal of Experimental Medicine published a *Found in Translation* article highlighting the potential advantages of CD19-directed T cell engagers to be superior to CD19 CAR-T cell engaging antibodies relative to CD19 CAR-T cells for the treatment of autoimmune diseases.[2]

Clinical Observations from CLN-978 B-NHL Phase 1 Trial

Clinical observations from three patients treated in a Phase 1 dose escalation trial of patients with B-NHL show that CLN-978 was clinically active at the initial starting dose of 30 µg administered subcutaneously once weekly. Two of the three patients experienced objective clinical benefit including one patient who experienced a complete response. Grade 1 cytokine release syndrome occurred in two patients and no patients experienced immune effector cell-associated neurotoxicity syndrome. Other adverse events were low-grade, manageable, or mechanistically based (e.g. transient lymphopenia after the first dose only). Of the two patients with detectable B cells at baseline, both patients experienced rapid, deep, and sustained B cell depletion after administration of CLN-978. These data show that CLN-978 can deplete peripheral B cells and demonstrate clinical activity in a tissue resident disease at a dose with a favorable safety profile.

Corporate Name Change to Cullinan Therapeutics

The corporate name change to Cullinan Therapeutics reflects the company's transformation as it pursues new indications for autoimmune diseases and continues to advance its clinical-stage oncology pipeline. The new corporate name represents both the expanded therapeutic focus area and Cullinan Therapeutics' vision to evolve to a commercial-stage biotech company. The company's common stock will continue to trade under its current ticker symbol "CGEM". Along with the new name, the company will adopt a new logo and will change its corporate website from www.cullinanoncology.com to www.cullinantherapeutics.com.

"Today's announcements represent a major step forward for Cullinan Therapeutics. Our ethos is to pursue the best science for patients by matching the right target with the right modality, and we believe that CLN-978 could offer a convenient modality and potentially disease-modifying treatment for patients with autoimmune diseases where current treatments often only address symptoms, rather than the underlying disease itself," said Nadim Ahmed, Chief Executive Officer of Cullinan Therapeutics. "Our expertise in drug development and our robust financial resources, now with an additional $280 million through our recent financing activity, position us to execute and expand the development of CLN-978. We also plan to deliver multiple data catalysts from our ongoing oncology clinical programs throughout 2024. I look forward to continuing our positive momentum and I am proud of our team working relentlessly to deliver for patients in need."

Virtual Investor Event

The company will host a virtual investor event on April 16 at 8:00 am ET. Investors and the general public are invited to listen to a live webcast of the call. A link to join the call and to find related materials will be available at: https://cullinantherapeutics.com/events-and-presentations/. A replay of the event will be available on the above link for 90 days.

About CLN-978

CLN-978 is a novel, highly potent, half-life extended CD19xCD3 bispecific T cell engager construct. CLN-978 potently 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 expressing very low CD19 levels. An HSA-binding domain increases the serum half-life of CLN-978 and, with subcutaneous delivery, permits more patient-friendly dosing and potentially reduced toxicity. CLN-978 contains two single-chain variable fragments (scFv), one binding with very high affinity to the CD19 target and the other binding to CD3 on T cells, and a single-domain antibody (VHH) binding to human serum albumin (HSA). CLN-978 was developed by an internal Cullinan team supported by co-founder and Scientific Advisory Board member Patrick Baeuerle, a world-renowned expert in the development of T cell engagers and CD19 biology and is a wholly owned asset. CLN-978 has the potential to offer a convenient, off-the-shelf therapeutic option for patients with autoimmune diseases such as systemic lupus erythematosus.

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[3,4]. SLE is more prevalent in women, people of color, and women of childbearing age. The CDC estimates the prevalence of SLE in the US to be approximately 160,000 to 320,000 cases. 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. We have 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 oncology and autoimmune diseases. Our 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 cancer and autoimmune 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 our company at www.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, the clinical and therapeutic potential of our product candidates, the strategy of our product candidates, our research and development activities, our cash runway, and the completion, timing and size of the private placement. The words "believe," "continue," "could," "estimate," "expect," "intends," "may," "plan," "potential," "project," "pursue," "vison," 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, including the IND that we intend to file for CLN-978; the risk that any INDs we may file are not cleared by the United States Food and Drug Administration or are not cleared on our expected timelines, or at all; success of our clinical trials and preclinical studies; risks related to our ability to protect and maintain our intellectual property position; 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 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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