Velinotamig, a BCMAxCD3 T Cell Engager, Achieves Complete Renal Responses and Significantly Reduces Disease Activity in Systemic Lupus Erythematosus in Data Presented at ACR Convergence 2026

November 8, 2026

Clinically meaningful improvement in disease activity among 8 of 9 evaluable patients, including rapid and marked reductions in proteinuria with complete renal responses

Deep and sustained reduction in pathogenic autoantibodies and IgG reduction underscore potential in plasma-cell driven diseases

Favorable safety profile in patients with refractory SLE

CAMBRIDGE, Mass., Nov. 08, 2026 (GLOBE NEWSWIRE) -- **Cullinan Therapeutics, Inc.** (Nasdaq: CGEM), a clinical-stage biopharmaceutical company accelerating potential first- or best-in-class, disease-modifying T cell engagers in autoimmune diseases and cancer, today announced clinical data from the ongoing Genrix Bio Phase 1b/2a study of velinotamig (GR1803) in patients with active, refractory, moderate-to-severe systemic lupus erythematosus (SLE). The results will be presented at the American College of Rheumatology (ACR) Convergence 2026 on November 8 in Poster #0272, “Initial Results of Velinotamig (GR1803, BCMAxCD3 TCE) Therapy in Patients with Refractory Systemic Lupus Erythematosus: a Phase 1b/2a Study.”

As of the September 8, 2026 data cutoff, 12 patients had been treated across three multi-dose cohorts. Velinotamig demonstrated a favorable safety profile, with no dose-limiting toxicities, no immune effector cell-associated neurotoxicity (ICANS), and no Grade 3 or higher cytokine release syndrome (CRS). CRS occurred in two patients and was limited to Grade 1 or 2 events that resolved with standard management. No Grade 2 events were observed after modifications to the step-up dosing regimen.

Among the first nine patients with at least four weeks of follow-up, clinical activity was observed across measures of disease activity, serologic markers, and renal function. Eight of nine evaluable patients achieved a clinically meaningful reduction of at least four points in SLEDAI-2K. Among seven evaluable patients with urine protein excretion greater than 500 mg/24 hours at baseline, five experienced rapid and marked reductions in proteinuria, and four of these patients achieved a complete renal response as demonstrated by proteinuria levels below 500 mg/24 hours, within 24 weeks. Reductions in anti-double-stranded DNA antibodies and blood IgG, improvement in complement C3, and depletion of CD19-positive B cells were also observed.

“These compelling early findings demonstrate consistent and meaningful clinical, serological, and pharmacodynamic evidence in most treated patients, further validating the therapeutic potential of velinotamig as a short-duration BCMA-directed therapy,” said Jeffrey Jones, MD, MBA, Chief Medical Officer of Cullinan Therapeutics. “Combined with the favorable safety profile observed to date, these data reinforce our confidence in the global development plan for velinotamig, including our initial focus on autoimmune cytopenias, where pathogenic autoantibody-producing plasma cells play a central role in disease pathogenesis. Our unique and complementary clinical stage BCMA- and CD19-directed T cell engager portfolio positions us to address the diverse biology of autoimmune diseases, with the goal of bringing differentiated and tailored treatment options to more patients across a broad range of conditions.”

About the Genrix Bio Phase 1b/2a Velinotamig Study

The open-label, multicenter, dose-escalation Phase 1b/2a study (NCT07348055) is evaluating the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of velinotamig in patients with active, refractory, moderate-to-severe SLE despite at least three months of standard-of-care therapy. Patients receive four intravenous doses on Days 1, 4, 8, and 29, with follow-up for up to 48 weeks. Key assessments include adverse events, CRS, ICANS, DLTs, SLEDAI-2K, 24-hour proteinuria, estimated glomerular filtration rate, anti-double-stranded DNA antibodies, complement C3/C4, and B cell depletion.

About Velinotamig (CLN-803, GR1803)

Velinotamig is a BCMAxCD3 T cell engager designed to redirect cytotoxic T cells to target BCMA-expressing cells, including pathogenic, autoantibody-producing plasma cells. Velinotamig is engineered with high-affinity binding to BCMA and lower-affinity binding to CD3, with the goal of enhancing target-cell depletion while minimizing nonspecific T cell activation and associated cytokine-related toxicity. By targeting BCMA-expressing cells, velinotamig has the potential to address autoimmune diseases driven by pathogenic autoantibodies.

Cullinan holds a global (ex-Greater China), all-indication, exclusive license to velinotamig from Genrix Bio. Genrix Bio is evaluating

velinotamig in a Phase 1b/2a clinical trial in patients with refractory SLE in China (NCT07348055). Cullinan Therapeutics is also evaluating subcutaneously administered velinotamig in a global Phase 1b/2a study in patients with relapsing and refractory immune thrombocytopenia and warm autoimmune hemolytic anemia (NCT07738822).

About Systemic Lupus Erythematosus (SLE)

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, 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.[5] 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.[6] Currently available treatments can reduce the signs and symptoms of SLE; however, they do not routinely induce treatment-free remission, and most patients require lifelong immune suppression that treats symptoms without modifying the course of disease.[7-9]

About Cullinan Therapeutics

Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company developing potential first- or best-in-class, disease-modifying T cell engagers for autoimmune diseases and cancer. Cullinan pursues promising therapeutic targets while leveraging core expertise in T cell engagers, which are established in oncology and are now advancing into autoimmune diseases. With a clinical-stage pipeline built on a rigorous scientific approach and purposeful innovation, Cullinan is advancing its mission to deliver new standards of care for patients. Learn more about Cullinan at https://cullinantherapeutics.com/, and follow Cullinan 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 velinotamig, the clinical and therapeutic potential of velinotamig, our plans regarding future data presentations, our beliefs regarding the broader potential of our BCMA- and CD 19-directed T cell engager portfolio in the treatment of autoimmune diseases, and other statements that are not historical facts. The clinical trial referenced in this press release is ongoing, and the data described are interim, subject to change, and based on data available as of a specified date. As patient enrollment continues and additional follow-up data is obtained, the reported safety profile and other clinical outcomes may change materially. There can be no assurance that the interim results will be predictive of final clinical trial results or that additional data will confirm or support these observations. 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, NDAs or other global regulatory submissions we may file with the FDA or other global regulatory agencies are not cleared or approved 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; the effect of changes in global economic conditions, including uncertainties related to international trade policies, tariffs and supply chain dynamics on our business and operations; 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.

Contacts

Investors
Nick Smith
+1 401.241.3516
nsmith@cullinantx.com

Media
Rose Weldon
+1 215.801.7644
rweldon@cullinantx.com

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