



Cullinan Therapeutics Advances Velinotamig into Global Clinical Development for Autoimmune Cytopenias Following IND Clearance by the U.S. FDA

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Global regulatory clearances in the U.S. and Australia support initiation of a Phase 1b/2a study in relapsing and refractory ITP and wAIHA

Study expands immunology portfolio into autoimmune cytopenias, evaluating a short-duration subcutaneous regimen designed to deplete antibody-producing plasma cells

CAMBRIDGE, Mass., Oct. 27, 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 that the U.S. Food and Drug Administration and Australian Therapeutic Goods Administration have granted clearance to initiate its global Phase 1b/2a clinical trial in adults with relapsing and refractory immune thrombocytopenia (ITP) and warm autoimmune hemolytic anemia (wAIHA). The open-label, multicenter study will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity, and preliminary clinical activity of subcutaneously administered velinotamig, a BCMAxCD3 T cell engager.

ITP and wAIHA are serious, potentially life-threatening autoimmune blood disorders in which pathogenic autoantibodies contribute to the destruction of platelets and red blood cells, respectively. Patients with ITP and wAIHA often experience significant disease burden, including debilitating fatigue and reduced quality of life, as well as severe disease manifestations such as bleeding in ITP and anemia in wAIHA. Despite available therapies, many patients experience persistent or relapsing disease, remain dependent on chronic treatment, or develop substantial adverse events from current therapies, underscoring the need for approaches that can deliver sustained disease control.

"Our autoimmune portfolio is built around complementary T cell engagers targeting CD19 and BCMA, a strategic approach designed to address distinct immune cell populations that drive disease across a spectrum of autoimmune conditions," said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. "ITP and wAIHA are compelling settings for which targeting antibody-producing plasma cells with a defined course of velinotamig may deliver durable clinical benefit. Emerging clinical data with BCMA-directed therapies have provided proof of concept for this mechanism in autoimmune cytopenias, including in some patients whose disease persisted despite prior treatment with CAR T therapy."

Clinical data evaluating velinotamig in autoimmune diseases will be presented by Genrix Bio at the [American College of Rheumatology Convergence 2026 meeting](#) on November 8, 2026. Updated results from an ongoing Phase 1b/2a study in refractory systemic lupus erythematosus are expected to further inform the role of BCMA-directed plasma cell depletion across autoimmune diseases.

About the Study

The Phase 1b/2a study of velinotamig is an open-label, multicenter study evaluating velinotamig in adults with relapsing and refractory ITP or wAIHA ([NCT07738822](#)). The study consists of two parts and will evaluate a defined course of four subcutaneous doses. Part A is the Phase 1b multiple-ascending dose portion and Part B is the Phase 2a dose-expansion portion and will further evaluate the selected dose regimen or regimens in separate ITP and wAIHA expansion groups. The study's primary objectives are to evaluate safety, tolerability, and effect on disease activity.

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 non-specific 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 currently evaluating velinotamig in a Phase 1b/2a clinical trial in patients with refractory systemic lupus erythematosus (SLE) in China, with additional autoimmune indications under consideration. Cullinan Therapeutics has initiated a global, basket, open-label, multicenter study of velinotamig in autoimmune cytopenias, including immune thrombocytopenia (ITP) and warm autoimmune hemolytic anemia (wAIHA).

About Immune Thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) is a heterogeneous autoimmune disease characterized by increased platelet destruction and impaired platelet production.¹ Platelets play a critical role in blood clotting, and reduced platelet levels can lead to bruising, bleeding, debilitating fatigue, and impaired health-related quality of life.^{1,2} In severe cases, bleeding may be life-threatening.¹ ITP may present as an acute, self-limited condition or follow a chronic and relapsing course, particularly in adults.¹ In the U.S., the prevalence of chronic primary ITP among adults has been estimated at approximately 62,000 adults.³ Although currently available therapies can help manage platelet counts and reduce bleeding risk, many patients continue to experience relapses and the burden of ongoing disease management.^{1,2}

About Warm Autoimmune Hemolytic Anemia (wAIHA)

Warm autoimmune hemolytic anemia (wAIHA) is a rare autoimmune disease in which warm-reactive autoantibodies cause the premature destruction of red blood cells, resulting in anemia.⁴ People living with wAIHA may experience debilitating fatigue, shortness of breath, jaundice, and other complications of anemia. The disease can be serious and potentially life-threatening.⁴ The prevalence of wAIHA among adults in the U.S. is estimated at approximately 33,300 adults.^{5,6} Achieving sustained disease control can remain challenging, particularly for patients with relapsing or refractory wAIHA, underscoring the need for additional treatment options.⁷

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://cullinatherapeutics.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, the study design of our clinical trial for velinotamig, 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, 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.

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