Cullinan Therapeutics Licenses Rights to Velinotamig, a Clinical-Stage BCMA-Directed Bispecific T Cell Engager, from Genrix Bio for Development in Autoimmune Diseases

June 4, 2025

Advances Cullinan's leadership in T cell engager (TCE) development for autoimmune diseases with both a CD19 TCE and BCMA TCE in its pipeline

Strengthens Cullinan portfolio of autoimmune programs with the opportunity to address a broader range of diseases while maintaining cash runway into 2028

Company to host conference call today at 4:30 pm ET

CAMBRIDGE, Mass., June 04, 2025 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM; "Cullinan"), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today announced that it has entered into an agreement with Genrix Bio for a global (ex-Greater China), all indication, exclusive license to velinotamig, a BCMAxCD3 bispecific T cell engager. Velinotamig has demonstrated potential best-in-class efficacy at the Phase 2 target dose in nearly 50 patients with relapsed/refractory (r/r) multiple myeloma (MM). Cullinan will develop velinotamig in autoimmune diseases.

"We believe T cell engagers represent the next wave of innovation in autoimmune diseases, and we are excited to build upon our core T cell engager expertise and extensive KOL relationships to develop another potential best-in-class, clinical-stage program. Accumulated data supports BCMA as a promising target in autoimmune diseases, offering a precise and potentially disease-modifying approach by eliminating the entirety of the self-reactive plasma cells that result in certain autoimmune diseases, especially those diseases driven by long-lived plasma cells," said Nadim Ahmed, Chief Executive Officer of Cullinan Therapeutics. "Adding a BCMAxCD3 bispecific T cell engager to our pipeline complements our rapid global clinical development of CLN-978, enabling us to address the needs of more patients across a broader range of autoimmune diseases than with either molecule alone."

Genrix plans to initiate a Phase 1 study in China by the end of this year in patients with autoimmune diseases. Cullinan intends to use the data generated to accelerate global clinical development of the program. Following the completion of the Genrix Bio Phase 1 study, Cullinan will conduct all further development of velinotamig in autoimmune diseases.

"With our planned Phase 1 study of velinotamig in autoimmune diseases, we will be able to quickly leverage our experience in autoimmune diseases to complete the study in China expeditiously," said Dr. Liu Zhigang, Chairman, Chief Executive Officer, and Chief Science Officer of Genrix Biopharmaceutical "Cullinan is a proven leader in developing T cell engagers and we are confident in the company's ability to carry the program forward to address the needs of patients with autoimmune diseases."

Under the agreement, Cullinan will pay Genrix Bio an upfront license fee of $20 million for exclusive rights to develop and commercialize velinotamig in all disease areas globally outside of Greater China. In the future, Genrix will also be eligible to receive up to $292 million in development and regulatory milestones plus up to an additional $400M in sales-based milestones, as well as tiered royalties from mid-single digits up to the mid- teens on potential ex-Greater China net sales.

Importantly, with refinement of the clinical oncology pipeline, Cullinan reiterates its existing guidance to have cash resources into 2028 based on its current operating plan.

Cullinan Therapeutics Conference Call Information

Cullinan Therapeutics will host a conference call today, June 4, at 4:30 pm ET. Investors, analysts 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 under the Events and Presentations section of the Company's investor relations website at https://cullinantherapeutics.com/events-and-presentations/.

About Velinotamig

Velinotamig is a bispecific antibody that can simultaneously bind to the BCMA and CD3 antigens, redirecting cytotoxic T cells to target BCMA-expressing cells. Velinotamig has high affinity for BCMA and lower affinity for CD3. Affinity for BCMA is two orders of magnitude higher than for CD3, ensuring that the bispecific antibody recruits and activates T cells while minimizing non-specific T cell activation and reducing the toxicity mediated by the CD3 antibody.

Genrix Bio received approval from the National Medical Products Administration (NMPA) in January 2022 to conduct clinical trials for the indication of multiple myeloma. Velinotamig received Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) for the treatment of relapsed and refractory multiple myeloma.

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.

About Genrix Bio

Genrix Bio (Stock Code: 688443), founded in 2015, is an innovative biopharmaceutical company driven by advanced antibody drug discovery technology to address critical clinical needs. With antibody drug R&D centers in Beijing, Shanghai, and Chongqing, we are committed to the development of monoclonal and bispecific antibodies for autoimmune diseases, infectious diseases, and oncology. Our capabilities span across antibody molecular discovery, process development and quality research, clinical trials, and large-scale commercialization. Upholding the philosophy of "to deliver affordable and reliable new medicines for patients," we strive to address the clinical needs of a wider population. Learn more about Genrix Bio at https://www.genrixbio.com/#/home.

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 Cullinan's beliefs and expectations regarding the potential benefits of, and plans relating to, the license agreement between Cullinan and Genrix Bio, including anticipated milestone payments under the license agreement, as well as royalties on net sales; the therapeutic potential of velinotamig; the timing of planned clinical development of velinotamig; our expectations regarding our cash resources; and other statements that are not historical facts. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "hope," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," 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 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 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; 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 Cullinan 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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