



## **Cullinan Oncology Announces First Patient Dosed in Phase 1 Trial Evaluating CLN-978, a Novel CD19xCD3 T cell Engager, in Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma**

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CAMBRIDGE, Mass., Aug. 09, 2023 (GLOBE NEWSWIRE) -- [Cullinan Oncology, Inc.](#) (Nasdaq: CGEM), a biopharmaceutical company focused on modality-agnostic targeted oncology therapies, today announced that the first patient has been dosed in the Phase 1 clinical trial evaluating CLN-978 for the treatment of relapsed/refractory (R/R) B-Cell Non-Hodgkin Lymphoma (B-NHL).

The study is an open-label, dose-escalation, dose-expansion, and first-in-human study designed to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary efficacy of subcutaneously (SC)-administered CLN-978. The study will enroll adult patients with R/R B-NHL for whom there is no available approved standard therapy.

"Despite recent advances in treating B-NHL, there remains significant unmet medical need, particularly among patients with relapsed/refractory disease," said Jeffrey Jones, MD, MPH, MBA, Chief Medical Officer, Cullinan Oncology. "T cell engagers have shown clinical activity in this patient population, and CD19 is a well-validated target for B-cell malignancies. Based on preclinical evidence, we believe CLN-978 has a differentiated profile as it binds with very high affinity to CD19-expressing cells, even those with barely detectable levels of CD19. CLN-978 also offers patient-friendly administration and potentially reduced toxicity with an off-the-shelf treatment that is delivered subcutaneously. Collectively, these features may open up opportunities to investigate CLN-978 in additional CD19 mediated diseases. Advancing CLN-978 into the clinic is an important milestone for Cullinan Oncology, as it is now our fifth program in the clinic."

### **ABOUT CLN-978**

CLN-978 is a novel, highly potent, half-life extended CD19xCD3 T cell engager construct. CLN-978 contains two single-chain variable fragments (scFv), one binding with very high affinity the CD19 target on malignant cells and the other binding CD3 on T cells. While CLN-978 resembles the canonical BiTE format, it also contains a single-domain antibody (VHH) binding to human serum albumin (HSA). CLN-978 redirects and activates T cells to destroy CD19-expressing cancer cells via T cell mediated cytotoxicity.

CLN-978 has the potential to offer a convenient, off-the-shelf therapeutic option that may provide an alternative to CD19 CART cell therapies. High-affinity binding of CLN-978 to CD19 allows for increased potency against tumor cells expressing very low levels of CD19. 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 has the potential to become a highly effective treatment option for patients across a range of B cell malignancies, including those who have relapsed on other CD19-directed therapies due to reduced CD19 target expression. CLN-978 is currently being evaluated as a novel treatment for B-NHL and has potential applicability across the entire spectrum of B cell mediated diseases.

### **About Cullinan Oncology**

Cullinan Oncology, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients with cancer. We innovate without borders to find the most promising clinic-ready cancer therapies, whether from our own discovery efforts or through exceptional engagement with our academic and industry partners. Anchored in a deep understanding of immuno-oncology and translational cancer medicine, we leverage our scientific excellence in small molecules and biologics to create differentiated ideas, identify unique targets, and select the optimal modality to develop transformative therapeutics across cancer indications. Powered by our novel research model, we push conventional boundaries from candidate selection to cancer therapeutic, applying rigorous early experimentation to fast-track only the most promising assets to the clinic and ultimately commercialization. As a result, our diversified pipeline is strategically built with assets that activate the immune system or inhibit key oncogenic drivers across a wide range of modalities, each with the potential to be the best or first in their class.

Our people possess deep scientific expertise, seek innovation openly, and exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients with cancer. Learn more about our Company at [www.cullinanoncology.com](http://www.cullinanoncology.com), and follow us on [LinkedIn](#) and [Twitter](#).

### **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 our preclinical and clinical development plans and timelines, clinical trial designs, clinical and therapeutic potential, and strategy of our product candidates, including but not limited to our expectations and beliefs around the safety and efficacy of CLN-978. 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; 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 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.

**Contacts:**

Investor Relations

Chad Messer

+1 203.464.8900

[cmesser@cullinanoncology.com](mailto:cmesser@cullinanoncology.com)

Media

Rose Weldon

+1 215.801.7644

[rweldon@cullinanoncology.com](mailto:rweldon@cullinanoncology.com)