



Cullinan Oncology Announces U.S. FDA Clearance of Investigational New Drug Application for CLN-978, a Novel T-Cell Engager for the Treatment of Relapsed/Refractory B-cell Non-Hodgkin Lymphoma

January 24, 2023

CAMBRIDGE, Mass., Jan. 24, 2023 (GLOBE NEWSWIRE) -- [Cullinan Oncology, Inc.](#) (Nasdaq: CGEM), a biopharmaceutical company focused on modality-agnostic targeted oncology therapies, today announced the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for CLN-978, a CD19/CD3 T-cell engaging antibody construct with a human serum albumin (HSA) binding domain to increase serum half-life. Cullinan Oncology will initially evaluate CLN-978 in a Phase 1 trial for the treatment of relapsed/refractory B-cell non-Hodgkin lymphoma (B-NHL).

"Despite advances for the treatment of B-cell malignancies, substantial unmet need remains for effective treatments. Preclinical evidence has demonstrated a differentiated profile for CLN-978 as it binds with very high affinity to CD19-expressing cells even at barely detectable levels of CD19," said Jeffrey Jones, MD, MPH, MBA, Chief Medical Officer, Cullinan Oncology. "Consistent with our mission to create new standards of care for patients with cancer, CLN-978 has the potential to become a best-in-class treatment option for patients with B-cell malignancies by offering a highly potent off-the-shelf treatment that is delivered subcutaneously, resulting in more patient-friendly administration and potentially reduced toxicity. We are proud to advance this program, which came through our internal discovery pipeline and is Cullinan Oncology's fourth clinical-stage asset, and we will be working diligently with investigators to enroll patients in our study."

The study is a Phase 1, open-label, dose-escalation and dose-expansion study designed to evaluate the safety and efficacy of CLN-978 in patients with relapsed/refractory B-NHL.

IND submission remains on track for CLN-617 (IL-2, IL-12 fusion protein) in 1H 2023.

ABOUT CLN-978

CLN-978 is a novel, highly potent, half-life extended CD19/CD3 bispecific T-cell engaging antibody construct. CLN-978 contains two single-chain variable fragments (scFv), one recognizing with high affinity CD19 on malignant cells and the other targeting CD3 on T-cells. While CLN-978 resembles the 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 cancer cells via T-cell mediated cytotoxicity.

CLN-978 potentially offers a convenient, off-the-shelf therapeutic option that may provide an alternative to CD19 CAR T-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, but with 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, 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; risks related to the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; 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.

Investors Chad Messer +1 203.464.8900 cmesser@cullinanoncology.com Media Rose Weldon +1 215.801.7644 rweldon@cullinanoncology.com