FDA Grants Breakthrough Therapy Designation for Cullinan Oncology's CLN-081 in Patients with Locally Advanced or Metastatic EGFR-Mutated Non-Small Cell Lung Cancer

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Breakthrough Therapy Designation further supports the differentiated clinical profile of CLN-081

CAMBRIDGE, Mass., Jan. 04, 2022 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Nasdaq: CGEM) ("Cullinan"), a biopharmaceutical company focused on developing a diversified pipeline of targeted therapies for cancer patients, today announced that the U.S. Food and Drug Administration ("FDA") has granted Breakthrough Therapy Designation for CLN-081 for the treatment of patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") harboring epidermal growth factor ("EGFR") exon 20 insertion mutations who have previously received platinum-based systemic chemotherapy.

"We are extremely pleased that Cullinan has received breakthrough therapy designation from the FDA for CLN-081, a distinction that underscores the urgent need to bring improved targeted treatments to this patient population and further supports the differentiated clinical profile of CLN-081," said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. "The updated data from our ongoing Phase 1/2a study in a larger number of patients have demonstrated a high response rate with durable responses and encouraging progression free survival in heavily pre-treated patients. We are also encouraged by the favorable safety profile observed thus far, and we look forward to ongoing, productive regulatory discussions with the FDA, which are further enabled with this designation."

Breakthrough Therapy Designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

About CLN-081

CLN-081 is an orally available, irreversible EGFR inhibitor that selectively targets cells expressing EGFR exon 20 insertion mutations while sparing cells expressing wild type EGFR. Cullinan is evaluating various doses of CLN-081 in a Phase 1/2a trial in patients with NSCLC harboring exon 20 mutations whose disease has progressed on or after prior therapy.

About Cullinan Oncology

Cullinan Oncology is a biopharmaceutical company that is developing a diversified pipeline of targeted therapeutic candidates across multiple modalities in order to bring important medicines to cancer patients. The Company's strategy is to source innovation through both internal discovery efforts and external collaborations, focusing on advanced stage assets with novel technology platforms and differentiated mechanisms. Learn more about Cullinan at www.cullinanoncology.com.

Forward-Looking Statements

This press release contains forward-looking statements of Cullinan Oncology, Inc. ("Cullinan," "we" or "our") 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, 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 activity of CLN-081. 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, or SEC, 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. 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. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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