Cullinan Oncology Announces Clinical and Regulatory Update for CLN-081 in NSCLC EGFR Exon 20 Patients

March 29, 2022

Confirmed overall response rate improves to 41% at 100mg BID dose level

Continued favorable safety and tolerability profile observed in heavily pre-treated patients

Pivotal study initiation expected 2H 2022 following food effect study

CAMBRIDGE, Mass., March 28, 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 clinical and regulatory updates on its lead program, CLN-081. CLN-081 is being evaluated in an ongoing Phase 1/2a clinical trial in non-small cell lung cancer (NSCLC) patients whose tumors harbor epidermal growth factor receptor (EGFR) exon 20 insertion mutations that have progressed on or after prior therapy.

Clinical Update:

In the ongoing Phase 1/2a study, CLN-081 was administered orally at dose levels including 30, 45, 65, 100 and 150 mg twice daily (BID). The most recent data now include 39 patients treated at 100 mg BID following the addition of 3 patients who were reassigned to receive the 100 mg BID dose after enrollment at 150 mg BID was discontinued.

Key highlights at the 100 mg BID dose level:

- Of 39 response evaluable patients, 16 achieved a confirmed partial response for a 41% confirmed response rate.
- No patients have experienced Grade 3 or greater treatment-related diarrhea or rash.
- Promising response durability previously observed in initial phase 1 patient cohort (n=13) with estimated median response duration > 15 months and median progression free survival of 12 months.

Cullinan expects to provide further data updates at medical conferences in 2022.

Regulatory Update

The Food and Drug Administration (FDA) recently granted CLN-081 Breakthrough Therapy Designation. Consistent with the FDA's Project Optimus initiative regarding dose optimization, the FDA has encouraged Cullinan to explore the potential for a food effect on the clinical profile of the 150mg dose. In the ongoing Phase 1/2a trial, CLN-081 was administered under fasting conditions. The FDA has endorsed Cullinan's plan to conduct a small food effect study (n~20) that is designed to evaluate the potential impact of food on exposure and other pharmacokinetic (PK) parameters at 150mg. Cullinan expects to initiate a pivotal study in the second half of 2022 following the completion of this PK food effect study.

"Today's update reflects the substantial progress we have made on the CLN-081 program," said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. "CLN-081 continues to show a differentiated clinical profile relative to EGFR exon 20 agents, including a high response rate, promising response durability, and favorable safety and tolerability, which provides a potential opportunity to improve the standard of care for patients with EGFR exon 20 mutant NSCLC. The Breakthrough Therapy Designation status for CLN-081 underscores its clinical profile and has facilitated productive engagement with the FDA. As a result, we look forward to expeditiously advancing the regulatory path for CLN-081 through rapid completion of the PK food effect study and initiation of a pivotal study in the second half of 2022."

Additional information is available in a presentation accompanying this press release on the Events section of our website.

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 EGFR exon 20 mutations who have received prior therapy. CLN-081 has received Breakthrough Therapy Designation from the FDA.

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 CLN-081, including but not limited to our expectations and beliefs around its safety and efficacy and plans for future CLN-081 studies. 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 therapeutic 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. 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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