Cullinan Oncology Announces Updated Phase 1/2a Data for CLN-081 in NSCLC EGFR Exon 20 Patients

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CLN-081 continues to demonstrate a differentiated clinical profile at the recommended Phase 2 dose of 100mg BID

Continued high response rate with favorable safety and tolerability profile observed in heavily pre-treated patients at 100mg BID

Encouraging durable responses and progression free survival at 100mg BID

CAMBRIDGE, Mass., Dec. 16, 2021 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Nasdaq: CGEM) ("Cullinan"), a biopharmaceutical company focused on developing a diversified pipeline of targeted therapies for cancer patients, today reported updated data from the Company's ongoing Phase 1/2a trial of CLN-081 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.

"The updated data from our ongoing Phase 1/2a study in a larger number of patients further reinforce CLN-081's differentiated clinical profile. CLN-081 has demonstrated both a high response rate and durable responses in heavily pre-treated patients," said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. "For many lung cancer patients currently receiving EGFR inhibitors, treatment related side effects can significantly impact their daily lives. In this regard, we are encouraged by CLN-081's favorable safety profile at the 100mg BID dose."

The current analysis of the ongoing trial included a total of 73 NSCLC patients with EGFR exon 20 insertion mutations who received at least one dose of CLN-081 and were evaluable for safety as of the data cutoff. CLN-081 was administered orally, at dose levels including 30, 45, 65, 100 and 150 mg twice daily (BID). Based on prespecified safety and efficacy criteria, enrollment at the Phase 2a cohort for 100mg BID was expanded up to the planned maximum of 36 patients. Additional patients were also enrolled at the 150mg BID dose level, although enrollment was subsequently discontinued after a total of 11 patients based on overall assessment of the clinical profile at this dose level. Guided by these data,100mg BID was nominated as the Recommended Phase 2 Dose (RP2D) for CLN-081.

Efficacy Highlights:

Efficacy data from patients enrolled in the 100mg BID cohort:

- Of 36 response evaluable patients, 14 achieved a confirmed PR for a 39% confirmed response rate and one additional patient had a PR that was pending confirmation at the time of the data cut-off.
- The median duration of response was >15 months and the median progression free survival was 12 months in the initial cohort of phase 1 patients (N=13).

Safety and Tolerability Highlights:

Treatment related EGFR associated adverse event (AE) data for patients enrolled in the 100mg BID cohort:

- Rash has been limited to Grade 1 and 2 events (54% and 18% of patients, respectively). Events were manageable with conventional supportive care and no patients have experienced Grade 3 or greater treatment-related rash.
- Diarrhea has been limited to Grade 1 and 2 events (26% and 8% of patients, respectively). No prophylactic regimen has been required to ameliorate the incidence or severity of diarrhea to date, and no patients have experienced Grade 3 or greater treatment-related diarrhea.

"We are pleased with CLN-081's safety and efficacy to date. CLN-081 has demonstrated antitumor activity among heavily pre-treated patients, including patients treated previously with other EGFR inhibitors or immunotherapy, and across a spectrum of exon 20 mutational sub-types," said Jon Wigginton, M.D., Chairman of the Cullinan Oncology Scientific Advisory Board and Senior Advisor. "We are similarly encouraged by the emerging durability data shown in this update, which we believe could also reflect the benefit of the drug's favorable safety and tolerability profile. Our goal now is to review these results and potential future clinical development with the FDA and to move CLN-081 as expeditiously as possible into late-stage development."

Additional data are 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 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 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. 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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