Cullinan Oncology Announces Phase 1/2a Interim Data For Cullinan Pearl's CLN-081 in NSCLC EGFR Exon 20 Patients

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- **CLN-081 Continues to Demonstrate Acceptable Overall Safety and Tolerability, With Encouraging GI Toxicity Profile**
- **As of the Data Cutoff, No Grade 3 TRAE Diarrhea at Doses Below 150mg BID; No Grade 3 Rash TRAEs**
- **Objective Responses Were Observed Across the Dose Range, with a Confirmed Objective Response Rate of 46% in Patients Treated at 100 mg BID**
- **Phase 2a Expansion Initiated at 100 mg BID**

CAMBRIDGE, Mass., June 04, 2021 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Nasdaq: CGEM) ("Cullinan"), an oncology company seeking to drive shareholder returns by focusing on the patient, today announced additional details pertaining to Cullinan Pearl'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. CLN-081 is an orally available, irreversible EGFR inhibitor, utilizing a unique pyrrolopyrimidine scaffold that was designed to selectively target cells expressing mutant EGFR variants, including exon 20, while sparing cells expressing wild type (WT) EGFR.

These data will be featured in an on-demand poster presentation available this morning at 9:00 am EDT at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and during a company sponsored webinar at 10:30 am EDT today, which can be accessed here or in the 'Events' section on Cullinan's investor website.

"We remain encouraged with CLN-081's emerging profile," stated Owen Hughes, Cullinan's Chief Executive Officer. "In heavily pretreated patients, CLN-081 continues to show antitumor activity across the dose range, with a safety profile that appears to be differentiated, most specifically with respect to GI adverse events."

The current analysis of the ongoing trial evaluated a total of 45 NSCLC patients with EGFR exon 20 insertion mutations who received at least one dose of CLN-081 as of the April 1, 2021, data cutoff, and were evaluable for safety. CLN-081 was dosed orally, at dose levels including 30, 45, 65, 100 and 150 mg twice daily (BID). As of the data cutoff, 42 of 45 patients were response evaluable across all dose cohorts tested.

Overall Safety:

Regarding treatment related adverse events (TRAEs) associated with WT EGFR inhibition:

- Rash has been limited to Grade 1 and 2 events (76% of patients experienced an event across all doses as of the data cutoff); events were manageable with conventional supportive care; no patients have experienced Grade ≥3 TRAE rash.
- Similarly, diarrhea has been mostly limited to Grade 1 and 2 events (22% across the dose range) as of the data cutoff, with a single Grade ≥3 TRAE at the highest dose tested to date, 150 mg BID, which resolved with supportive care. No prophylactic regimen has been required to ameliorate the incidence or severity of diarrhea to date.

Overall Efficacy:

Objective partial responses (PR) were observed in 21 of 42 (50%) response evaluable patients treated across all dose levels.

- Of the 21 PRs as of the data cutoff, 13 were confirmed (31% confirmed objective response rate), 5 were pending confirmation (i.e., patient had not reached their second post-baseline disease assessment as of the data cutoff), and 3 will remain unconfirmed.
- 41 of 42 (98%) response evaluable patients have achieved a best response of stable disease (SD) or PR, with 76% of all patients showing some degree of tumor regression at the initial scan post baseline (week 6).

100 mg BID Expansion Cohort:

In February 2021, Cullinan announced a Phase 2a expansion at the 100mg BID cohort, allowing enrollment of up to 36 patients.

- **Safety**: Treatment-related rash has been limited to Grade 1 and 2 events (66%), manageable with conventional supportive care; no patients have experienced Grade ≥3 TRAE rash. In addition, the overall incidence of treatment-related diarrhea was 26%, with no Grade ≥3 events to date.

- **Efficacy**: As of the data cutoff, objective responses were observed in 7 of 13 (54%) response evaluable patients; 6 of which were confirmed (46%) and 1 will remain unconfirmed.

- Of the 13 response evaluable patients, 9 (69%) patients achieved disease control (PR of any duration or SD ≥ 6 months) as of the data cutoff; an additional 3 patients had stable disease and remained on treatment but had started therapy less than 6 months prior to data cutoff.

"We are pleased with the CLN-081 safety and efficacy data to date in our Phase 1/2a trial. CLN-081 has demonstrated antitumor activity in patients post systemic chemotherapy, including among patients who were also treated previously with other EGFR inhibitors and/or cancer immunotherapy, across the range of CLN-081 doses tested to date, 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 working diligently to evaluate CLN-081 in additional patients, and to set the stage for further clinical advancement of CLN-081 in this group of patients with significant unmet need."

About CLN-081

CLN-081 is an orally available, irreversible EGFR inhibitor that was designed to selectively target cells expressing mutant EGFR variants, including Ins20, while sparing cells expressing wild type EGFR. In preclinical studies, CLN-081 demonstrated inhibition against traditional sensitizing mutations (exon 19 deletions and L858R), Ins20 (the third most common EGFR mutation), and other less common mutations (G719X, L861Q, and S768I).

Cullinan is evaluating various doses of CLN-081 in a Phase 1/2a trial in patients with NSCLC harboring Ins20 mutations that have progressed post chemotherapy. Based on pre-specified efficacy and safety criteria, Cullinan recently initiated Phase 2a dose expansion in the 100 mg BID dosing cohort, which will enable enrollment of up to 36 patients at this dose level, inclusive of 13 previously enrolled patients.

About Cullinan Oncology

Cullinan Oncology is a biopharmaceutical company that strives to deliver results for our various stakeholders through disciplined capital allocation, decisive action, prudent risk taking and creative business development. We seek to drive shareholder returns by focusing on the patient. The Company's strategy is to build a diversified pipeline of targeted and immuno-oncology therapeutic candidates that are uncorrelated across multiple dimensions, with a focus on assets that it believes have novel technology, employ differentiated mechanisms, are in a more advanced stage of development than competing candidates, or have a combination of these attributes. 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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