Cullinan Therapeutics Announces Positive Initial Data from Pivotal Phase 2b REZILIENT1 Study of Zipalertinib

June 1, 2024

Objective response rate of 39% with manageable safety profile in patients with non-small cell lung cancer (NSCLC) harboring EGFR Exon 20 insertion mutations treated with zipalertinib who had progressed after prior amivantamab treatment

CAMBRIDGE, Mass., June 01, 2024 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today announced positive initial data in patients receiving zipalertinib after prior treatment with amivantamab enrolled in its pivotal Phase 2b REZILIENT1 clinical trial.

As of a January 12, 2024 data cut-off, 31 patients had been enrolled. Patients had received a median of three prior systemic anti-cancer regimens, including prior platinum-based chemotherapy, prior anti-PD1/L1 therapy, and prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy.

At data cut-off, 18 patients were evaluable for response and showed similar anti-tumor activity compared with those post prior chemotherapy in the previously reported Phase 1/2a part of the study.

	Module C (post chemo and Ami+/- other exon20ins treatment) (N=18)	**Phase 1/2a results (post chemo)[1] (N=39)**
ORR (confirmed)	39%	41%
DCR[2]	94%	97%
DOR (months)	NE	NE
PFS (months)	NE	12

NE: Not yet estimable
ORR: Objective response rate; DCR: Disease control rate; DOR: Duration of response; PFS: Progression-free survival
[1] Piotrowska Z, et al. JCO 2023
[2] DCR= (PR+SD) / response-evaluable patients
PR: Partial response; SD: Stable disease

Zipalertinib demonstrated a manageable safety profile, similar to what has been previously reported. There were no grade 4 or grade 5 treatment-related adverse events.

“In an evolving treatment landscape, this is the first ever clinical data to systematically characterize the potential of an irreversible and selective EGFR exon20 insertion mutation TKI such as zipalertinib in patients who were heavily pre-treated and had received amivantamab. Given the recent approval of amivantamab as a first line treatment in combination with chemotherapy, we are encouraged by the initial results of the Phase 2b portion of the REZILIENT1 clinical trial, which show that in a post-amivantamab setting, zipalertinib demonstrated promising efficacy, similar to that in patients who progressed after platinum-based chemotherapy alone, and had a manageable safety profile,” said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. “With a comprehensive development plan for zipalertinib, this data further strengthens our confidence in its potential to address a significant unmet need for patients with NSCLC harboring EGFR exon20 insertion mutations. We remain on track to complete enrollment in the pivotal Phase 1/2b REZILIENT1 trial by the end of this year.”

Zipalertinib has a unique chemical structure that is distinct from other exon20 insertion directed agents, which makes it highly selective for mutant exon 20 versus wild-type EGFR. Cullinan entered into a partnership with Taiho in 2022, with an upfront cash payment of $275M and additional payments totaling $130M to be made for US regulatory approvals in 1L and 2L+ NSCLC. Cullinan also retains a 50/50 profit share in the U.S.

Cullinan and Taiho have a broad development program for zipalertinib through a suite of REZILIENT studies, including two ongoing pivotal studies in 1L and 2L+ exon20 insertion NSCLC as well as studies in other patient populations such as patients with active brain metastases and those with uncommon EGFR mutations. Both Module B2 (post chemo only) and Module C (post approved ex20ins treatments) of the pivotal REZILIENT1 trial remain on track to complete enrollment by end of 2024, consistent with prior projections.

Virtual and Live Investor Event
Cullinan Therapeutics will host an Investor Event on Saturday, June 1, 2024, at 6:30 PM Central Time, during which Dr. Jeff Jones, Chief Medical Officer at Cullinan Therapeutics, will present an overview of this zipalertinib data along with CLN-619 data shared at the 2024 American Society of Clinical Oncology Annual Meeting. Alexander Spira, MD, PhD, FACP, FASCO, Director, Virginia Cancer Specialists Research Institute and Director, NEXT Oncology Virginia, will share an overview of the current treatment landscape for EGFR-mutated NSCLC. Investors and analysts are invited to register to attend in person by emailing Chad Messer, VP Investor Relations (cmesser@cullinantx.com). A live webcast will be available via the events page of the Company’s investor relations website at https://cullinantherapeutics.com/events-and-presentations/, and a replay will be available shortly

after the conclusion of the live event.

About Zipalertinib
Zipalertinib (CLN-081/TAS6417) is an orally available small molecule designed to target activating mutations in EGFR. The molecule was engineered to inhibit EGFR variants with exon 20 insertion mutations, while sparing wild-type EGFR. Zipalertinib is designed as a next generation, irreversible EGFR inhibitor for the treatment of a genetically defined subset of patients with non-small cell lung cancer. Zipalertinib has received Breakthrough Therapy Designation from the FDA.

Zipalertinib is being developed by Taiho Oncology, Inc., its parent company, Taiho Pharmaceutical Co., Ltd., and Cullinan Therapeutics, Inc. Cullinan Pearl Corp., which Taiho Pharmaceutical Co., Ltd., acquired from Cullinan Therapeutics, Inc. in 2022, previously licensed the rights to zipalertinib in Greater China to Zai Lab Limited in 2020.

About Cullinan Therapeutics
Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients. We have strategically built a diversified portfolio of clinical-stage assets that inhibit key drivers of disease or harness the immune system to eliminate diseased cells in both oncology and autoimmune diseases. Our portfolio encompasses a wide range of modalities, each with the potential to be best and/or first in class. Anchored in a deep understanding of oncology, immunology, and translational medicine, we create differentiated ideas, identify the most appropriate targets, and select the optimal modality to develop transformative therapeutics across a wide variety of cancer and autoimmune indications. We push conventional boundaries from candidate selection to differentiated therapeutic, applying rigorous go/no go criteria at each stage of development to fast-track only the most promising molecules to the clinic and, ultimately, commercialization. With deep scientific expertise, our teams exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients. Learn more about our Company at https://cullinantherapeutics.com/, and follow us on LinkedIn and X.

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 the potential benefits and therapeutic potential of zipalertinib; our clinical development plans and timelines; our plans regarding future data presentations and other statements that are not historical facts. 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; 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 the company 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.

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