# Cullinan Therapeutics Presents Positive Updated Data from Module C of Zipalertinib Pivotal Phase 2b Study at ESMO 2024

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*Updated data show consistent objective response rate of 40% and manageable safety profile in patients with non-small cell lung cancer harboring epidermal growth factor receptor exon 20 insertion mutations treated with zipalertinib who progressed on or after prior amivantamab treatment*

*Enrollment of pivotal Phase 2b trial complete ahead of schedule*

CAMBRIDGE, Mass., Sept. 14, 2024 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today shared updated data in patients with non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) exon 20 insertion (ex20ins) mutations receiving zipalertinib after prior treatment with amivantamab enrolled in Module C of its pivotal Phase 2b REZILIENT1 clinical trial. Findings from the clinical trial were presented in a Mini Oral session today at the European Society for Medical Oncology Congress 2024 (Presentation Number 1245MO).

As of a March 29, 2024 data cut-off, 45 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/or prior EGFR tyrosine kinase inhibitor (TKI) therapy, in addition to amivantamab.

At data cut-off, 30 patients were evaluable for response, of which 1 patient (3%) had a complete response (CR), 11 patients (37%) had partial response (PR), and 15 patients (50%) had stable disease (SD), showing similar anti-tumor activity compared with patients receiving zipalertinib after prior chemotherapy in the previously reported Phase 1/2a part of the study.

| | **Module C (post chemo and amivantamab+/- other ex20ins treatment) (N=30)** | **Phase 1/2a results (post chemo)[1] (N=39)** |
|---|---|---|
| ORR (confirmed) | 40% | 41% |
| DCR[2] | 90% | 97% |
| DOR (months) | NE | NE |
| PFS (months) | 9.7 | 12 |

NE: Not 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= (CR+PR+SD) / response-evaluable patients

Zipalertinib demonstrated a manageable safety profile, similar to what has been previously reported. The most common treatment-related adverse events in greater than 10% of patients (n=45) were rash (38%), paronychia (36%), anemia (24%), dry skin (20%), dermatitis acneiform (16%), nausea (16%), and stomatitis (11%), the majority of which were grade 1/2. There were no grade 4 or grade 5 treatment-related adverse events.

“We are pleased to share updated data characterizing the potential of zipalertinib for patients with heavily pre-treated EGFR ex20ins mutation NSCLC who progressed on or after amivantamab,” said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. “With more evaluable patients and longer follow-up, these data continue to strengthen our confidence in the potential of zipalertinib. We remain focused on rapid execution and have successfully completed enrollment of the pivotal Phase 2b study ahead of schedule, which was originally planned for the end of this year. We are pleased to observe consistent positive results throughout the study and continue to advance the program along with our partners at Taiho.”

“This is the first presentation to systematically characterize the anti-tumor activity of zipalertinib, an oral selective tyrosine kinase inhibitor with specific activity against EGFR exon 20 insertion mutations, in heavily treated patients with advanced or metastatic NSCLC harboring EGFR exon 20 insertions-mutation, who have received prior amivantamab,” said Antonio Passaro, MD, PhD, Division of Thoracic Oncology, European Institute of Oncology. “In this setting, which is a significant emerging unmet medical need, zipalertinib demonstrated promising efficacy, including a high overall response rate, and a manageable safety profile.”

Zipalertinib has a unique chemical structure that is distinct from other ex20ins-directed agents, which makes it highly selective for

mutant exon 20 versus wild-type EGFR.

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+ ex20ins NSCLC as well as studies in other patient populations such as patients with active brain metastases and those with uncommon EGFR mutations.

Cullinan entered into a partnership with Taiho in 2022, receiving an upfront cash payment of $275M and the potential for additional payments totaling $130M to be made for the achievement of U.S. regulatory milestones. Cullinan also retains a 50/50 profit share in the U.S.

**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 U.S. 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. Cullinan has 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 autoimmune diseases and cancer. Cullinan's 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 autoimmune and cancer 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 Cullinan 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; the milestone payments we may receive from Taiho 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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