New Drug Application Submission Completed for Zipalertinib Plus Chemotherapy in First-Line EGFR Exon 20 Insertion Mutation Non-Small Cell Lung Cancer

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Submission is based on Phase 3 REZILIENT3 data in first-line EGFR ex20ins NSCLC

CAMBRIDGE, Mass., Nov. 12, 2026 (GLOBE NEWSWIRE) -- **Cullinan Therapeutics, Inc.** (Nasdaq: CGEM), a clinical-stage biopharmaceutical company accelerating potential first- or best-in-class, disease-modifying T cell engagers in autoimmune diseases and cancer, today announced their partner Taiho Oncology, Inc. completed a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for zipalertinib in combination with platinum-based chemotherapy for the treatment of patients with previously untreated, locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) exon 20 insertion (ex20ins) mutations.

The submission was made under the FDA's Real-Time Oncology Review (RTOR) program, which allows sponsors to submit clinical data in advance of the complete application to facilitate earlier review of efficacy and safety results. The completed application will undergo the standard review period with the FDA, and, if accepted, a Prescription Drug User Fee Act (PDUFA) target action date will be assigned.

The NDA is based on the Phase 3 REZILIENT3 trial, which met its primary endpoint at an interim analysis, demonstrating a statistically significant and clinically meaningful improvement in median progression-free survival (PFS) for zipalertinib plus chemotherapy versus chemotherapy alone. These results were presented in a Presidential Symposium at the International Association for the Study of Lung Cancer's (IASLC) 2026 World Conference on Lung Cancer (WCLC).

Cullinan Therapeutics is eligible to receive $30 million and $100 million in milestone payments upon second-line and first-line U.S. regulatory approvals, respectively.

About Zipalertinib

Zipalertinib (development code: CLN-081/TAS6417) is an orally available small molecule designed to target activating mutations in EGFR. The molecule was selected because of its ability to inhibit EGFR variants with exon 20 insertion mutations. 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 is investigational and has not been approved by any health authority.

Zipalertinib is being developed by Taiho Oncology, Inc., its parent company, Taiho Pharmaceutical Co., Ltd., and in collaboration with Cullinan Therapeutics, Inc. in the U.S.

About EGFR Exon 20 Insertion Mutations

NSCLC is a common form of lung cancer and up to 4% of all cases globally have EGFR ex20ins.[1] In the United States, approximately 16% of patients with NSCLC harbor EGFR mutations,[1] with insertions at exon 20 accounting for up to 12% of these mutations.[2]

About Cullinan Therapeutics

Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company developing potential first- or best-in-class, disease-modifying T cell engagers for autoimmune diseases and cancer. Cullinan pursues promising therapeutic targets while leveraging core expertise in T cell engagers, which are established in oncology and are now advancing into autoimmune diseases. With a clinical-stage pipeline built on a rigorous scientific approach and purposeful innovation, Cullinan is advancing its mission to deliver new standards of care for patients. Learn more about Cullinan at **https://cullinantherapeutics.com/**, and follow Cullinan 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 the company's beliefs and expectations regarding the clinical development of zipalertinib, the safety and efficacy profile of zipalertinib and its potential to

address unmet medical need, the potential of zipalertinib to become a treatment option, the anticipated timing of the FDA's review of the NDA submission under the RTOR program and other statements that are not historical facts. The words "believe," "continue," "could," "estimate," "expect," "intends," "may," "plan," "potential," "project," "pursue," "will," 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 future results, performance or achievements 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 clinical trial data and regulatory submissions; the risk that any NDAs, INDs or other global regulatory submissions we may file with the United States Food and Drug Administration or other global regulatory agencies are not accepted or cleared on our expected timelines, or at all; the success of our clinical trials and preclinical studies; the risks related to our ability to protect and maintain our intellectual property position; the 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 trials will not be predictive of future results in connection with future studies or clinical trials; the effect of changes in global economic conditions, including uncertainties related to international trade policies, tariffs and supply chain dynamics on our business and operations; and the 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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References

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2. Riess JW, Gandara DR, Frampton GM, et al. Diverse EGFR Exon 20 Insertions and Co-Occurring Molecular Alterations Identified by Comprehensive Genomic Profiling of NSCLC. *Journal of Thoracic Oncology*. 2018 Jul 5;13(10):1560–1568. Available at: https://www.jto.org/article/S1556-0864(18)30770-6/pdf.