Zipalertinib Plus Chemotherapy Meets Primary Endpoint of Progression-Free Survival in Planned Interim Analysis of Phase 3 REZILIENT3 Trial in First-Line EGFR Exon 20 Insertion Mutation Non-Small Cell Lung Cancer

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PRINCETON, New Jersey, TOKYO, Japan, CAMBRIDGE, Mass., August 12, 2026 — Taiho Oncology, Inc., Taiho Pharmaceutical Co., Ltd., and Cullinan Therapeutics, Inc. (Nasdaq: CGEM) today announced that the REZILIENT3 trial, a global Phase 3 clinical trial evaluating the combination of zipalertinib and platinum-based chemotherapy compared with chemotherapy alone in the first-line treatment of adult 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, met its primary endpoint of progression-free survival (PFS) at a planned interim analysis.

In this analysis, the study demonstrated a statistically significant and clinically meaningful improvement in PFS in the zipalertinib containing arm. Observed safety for the zipalertinib containing arm was manageable. Based on these data, the Independent Data Monitoring Committee recommended unblinding the study. The trial will continue to monitor efficacy and safety.

Full results from REZILIENT3 will be submitted for presentation at an upcoming international medical conference. Based on these results, pending discussions with the U.S. Food and Drug Administration (FDA), Taiho Oncology, Taiho Pharmaceutical and Cullinan Therapeutics plan to pursue U.S. regulatory approval for this combination regimen in the first-line setting.

“The positive topline results from the planned interim analysis of REZILIENT3 further support the potential of zipalertinib to meet the high unmet medical need in patients with NSCLC harboring EGFR exon 20 insertion mutations,” said Harold Keer, MD, PhD, Chief Medical Officer, Taiho Oncology. “We look forward to pursuing regulatory approval of zipalertinib in combination with chemotherapy in the first-line treatment setting with the goal of providing a new treatment option for this group of patients.”

“Zipalertinib is a compound created through Taiho Pharmaceutical's proprietary drug discovery technology," said Fabio Benedetti, MD, Global Chief Medical Officer, Taiho Pharmaceutical. "Achieving positive results in this Phase 3 trial in the first-line setting represents an important milestone for this program. We will continue to work closely with Taiho Oncology and Cullinan Therapeutics to bring zipalertinib in combination with chemotherapy to patients as soon as possible.”

“Meeting the primary endpoint early at a planned interim analysis marks an important milestone for the REZILIENT3 study and supports the potential role of zipalertinib in the first-line treatment setting,” said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. “These topline results give us confidence in the potential for zipalertinib to offer a first-line treatment option for patients with NSCLC with EGFR exon 20 insertion mutations.”

About the REZILIENT3 Trial

This multicenter, randomized, controlled, open-label global trial enrolled 285 adults with previously untreated, locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutations. The primary objective of this trial is to assess progression-free survival in the zipalertinib plus chemotherapy arm versus the chemotherapy arm.

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 Taiho Oncology, Inc.

The mission of Taiho Oncology, Inc. is to improve the lives of patients with cancer, their families and their caregivers. The company specializes in the development and commercialization of orally administered anti-cancer agents for various tumor types. Taiho Oncology has a robust pipeline of small-molecule clinical candidates targeting solid-tumor and hematological malignancies, with additional candidates in pre-clinical development. Taiho Oncology is a subsidiary of Taiho Pharmaceutical Co., Ltd. which is part of Otsuka Holdings Co., Ltd. Taiho Oncology is headquartered in Princeton, New Jersey and oversees its parent company's European and Canadian operations, which are located in Baar, Switzerland and Oakville, Ontario, Canada.

For more information, visit https://www.taihooncology.com/, and follow us on LinkedIn and X.

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About Taiho Pharmaceutical Co., Ltd. (Japan)

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd. (https://www.otsuka.com/en/), is an R&D-driven specialty pharma focusing on the fields of oncology and immune-related diseases. Its corporate philosophy takes the form of a pledge: "We strive to improve human health and contribute to a society enriched by smiles." In the field of oncology, in particular, Taiho Pharmaceutical is known as a leading company in Japan for developing innovative medicines for the treatment of cancer, a reputation that is rapidly expanding through their extensive global R&D efforts. In areas other than oncology, as well, the company creates and markets quality products that effectively treat medical conditions and can help improve people's quality of life. Always putting customers first, Taiho Pharmaceutical also aims to offer consumer healthcare products that support people's efforts to lead fulfilling and rewarding lives. For more information about Taiho Pharmaceutical, please visit https://www.taiho.co.jp/en.

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, anticipated data results and our plans regarding future data presentations 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

1. Burnett H, Emich H, Carroll C, et al. Epidemiological and clinical burden of EGFR exon 20 insertion in advanced non-small cell lung cancer: a systematic literature review. *PLOS ONE*. 2021;16(3): e0247620. Available at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247620.
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.