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**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**

Taiho Pharmaceutical Co., Ltd., Taiho Oncology, Inc., and Cullinan Therapeutics, Inc. (Nasdaq: CGEM) today announced that the REZILIENT[®]3 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.

There is no change to the Company's consolidated earnings forecast for the fiscal year ending December 2026 at this time. However, the Company regards zipalertinib as one of its key future growth drivers, and believes that this achievement represents an important milestone toward enhancing its medium- to long-term corporate value.

*REZILIENT : Researching Zipalertinib in EGFR Non-Small Cell Lung Cancer Tumors

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 Pharmaceutical, Taiho Oncology, and Cullinan Therapeutics plan to pursue U.S. regulatory approval for this combination regimen in the first-line setting.

"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.”

“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.”

“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 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 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/>.

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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://cullinatherapeutics.com/>.

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](https://www.jto.org/article/S1556-0864(18)30770-6/pdf).