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Zipalertinib Plus Chemotherapy Demonstrates 6-Month Median Progression-Free Survival Benefit in REZILIENT3 Phase 3 Trial in First-Line EGFR Exon 20 Insertion Mutation Non-Small Cell Lung Cancer

Results from the Phase 3 REZILIENT3 trial were featured in a Presidential Symposium at WCLC 2026 and demonstrated a statistically significant improvement in progression-free survival in first-line EGFR exon 20 insertion mutation NSCLC at a planned interim analysis

Taiho Pharmaceutical Co., Ltd., Taiho Oncology, Inc., and Cullinan Therapeutics, Inc. (Nasdaq: CGEM) today announced results from the Phase 3 REZILIENT3 trial evaluating zipalertinib plus chemotherapy versus chemotherapy alone in the first-line treatment of patients with epidermal growth factor receptor (EGFR) exon 20 insertion (ex20ins) mutation-positive non-small cell lung cancer (NSCLC). The data were presented at the International Association for the Study of Lung Cancer's (IASLC) 2026 World Conference on Lung Cancer (WCLC) in Seoul, South Korea. 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.

As previously announced, REZILIENT3 met its primary endpoint of progression-free survival (PFS). The results released today show that the addition of zipalertinib to platinum-based chemotherapy provided a statistically significant and clinically meaningful median PFS improvement of 6.0 months (HR=0.50; 95% CI, 0.34-0.73; P=0.00015) as first-line treatment for advanced NSCLC patients with EGFR ex20ins mutations. At the interim overall survival analysis (30% event maturity), the hazard ratio for death for zipalertinib plus chemotherapy versus chemotherapy was 0.72 (95% CI, 0.42-1.23) with follow up ongoing.

“The combination of zipalertinib plus platinum-based chemotherapy in the REZILIENT3 trial demonstrated a statistically significant and clinically meaningful improvement in progression-free survival for patients with advanced non-small cell lung cancer harboring EGFR exon 20 insertion

mutations," said Helena A. Yu, MD, Thoracic Medical Oncologist at Memorial Sloan Kettering Cancer Center and study investigator. "The combination also produced significantly higher response rates compared with chemotherapy alone. These findings support the potential of zipalertinib plus platinum-based chemotherapy as a first-line treatment option for this patient population. We are grateful to the patients and their families, as well as the investigators whose dedication made these results possible."

These late-breaking results from the planned interim analysis of REZILIENT3 were selected for presentation in the Presidential Symposium 2 at IASLC 2026 WCLC. The Presidential Symposium 2 is a premier plenary session featuring notable advances in lung cancer research and treatment with the potential to change clinical practice.

"We believe these results mark a potentially important step forward in the treatment of EGFR exon 20 insertion mutation-positive non-small cell lung cancer," said Fabio Benedetti, MD, Global Chief Medical Officer, Taiho Pharmaceutical. "To address the unmet medical needs of patients and their families, we will continue working closely with Taiho Oncology and Cullinan to make this treatment available to patients who may benefit from it."

"The findings presented add to previously presented single agent zipalertinib data and support the potential of zipalertinib across multiple treatment settings. We are thankful to patients, their families, and caregivers for participation in REZILIENT3," said Harold Keer, MD, PhD, Chief Medical Officer of Taiho Oncology. "We are excited to discuss these results further with health authorities and collaborate to make zipalertinib available to patients in a timely manner."

"The selection of REZILIENT3 for presentation in a Presidential Symposium reflects the importance of these findings for the lung cancer community," said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. "The magnitude of progression-free survival benefit, together with improvements in response rates and duration of response seen in REZILIENT3, reinforce the potential for zipalertinib plus chemotherapy to play an important role in the first-line treatment of patients with EGFR exon 20 insertion mutation NSCLC."

Summary of Results:

After a safety lead-in (n=6), a total of 279 advanced NSCLC patients with EGFR ex20ins and no prior treatment for advanced disease were randomly assigned to receive zipalertinib 100mg BID plus chemotherapy (n=140) or chemotherapy alone (n=139). Baseline characteristics were balanced between the combination and the control arm, including age (66.5 vs. 64 years), sex (65.7% vs. 63.3% female), and brain metastases (31.4% vs. 31.7%), respectively.

At the pre-planned interim efficacy analysis after 122 PFS events, treatment with zipalertinib plus chemotherapy led to significantly longer median PFS than chemotherapy alone (14.5 vs. 8.5 months;

HR: 0.50; 95% CI 0.34-0.73; P=0.00015). This PFS benefit was consistent across subgroups, including patients with brain metastases (HR: 0.38).

Objective response rate was higher with the combination therapy (65.0% vs. 40.3%), P<0.0001, with a longer median duration of response (14.2 vs. 9.9 months). At the interim overall survival (OS) analysis (30% maturity), the hazard ratio for death for zipalertinib plus chemotherapy as compared with chemotherapy was 0.72 (95% CI, 0.42-1.23). Continued follow-up of REZILIENT3 is ongoing to further characterize the OS benefit and exploratory endpoints (ClinicalTrials.gov number NCT05973773).

Summary of Preliminary Safety and Tolerability:

The observed adverse event (AE) profile of zipalertinib plus chemotherapy was generally consistent with the known safety profiles of the individual agents, and no new safety signals were observed. Grade ≥3 AEs occurred more frequently with the combination (87.1% vs. 54.4%), but these were primarily manageable hematologic AEs (58.6% vs. 28.7%). Grade ≥3 EGFR-related toxicities were infrequent, and those observed only in the combination arm included rash (10.7%) and diarrhea (1.4%).

Session information for the data presentation at WCLC 2026 is listed below:

Title: *Zipalertinib plus Chemotherapy for 1st-line NSCLC with EGFR Exon 20 Insertions: Results from the Phase 3 Trial (REZILIENT3)*
Presenting Author: Dr. Daniel Tan Shao Weng, Duke Health, Singapore
Session Name: PL03 Presidential Symposium 2 Including Lectureship Award Presentations
Session Type: Presidential Symposium 2, a premier plenary session featuring notable advances in lung cancer research and treatment
Session Date: Monday, September 14, 2026
Session Time: 8 a.m. KST
Location: Plenary, Hall D2, 3F

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/us/, and follow us on LinkedIn and X.

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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://cullinantherapeutics.com/, and follow Cullinan on LinkedIn and X.

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.