Taiho Oncology, Taiho Pharmaceutical and Cullinan Therapeutics Initiate Rolling Submission of New Drug Application to U.S. Food and Drug Administration for Zipalertinib for Treatment of Locally Advanced or Metastatic Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations

November 20, 2025

PRINCETON, New Jersey, TOKYO, Japan, CAMBRIDGE, Mass., Nov. 20, 2025 — Taiho Oncology, Inc., Taiho Pharmaceutical Co., Ltd., and Cullinan Therapeutics, Inc. (Nasdaq: CGEM) today announced the companies have initiated the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking accelerated approval of zipalertinib, an oral epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion (ex20ins) mutations who have previously received platinum-based systemic chemotherapy.

Zipalertinib previously received Breakthrough Therapy Designation in 2021, which with FDA agreement, allows submission of portions of the application as they are completed. The companies anticipate completion of the NDA submission in the first quarter of 2026 with an associated request for priority review.

The NDA submission is based on the primary efficacy data from the REZILIENT1 trial, a Phase 1/2 clinical trial of zipalertinib (development code: CLN-081/TAS6417) monotherapy in patients with NSCLC harboring EGFR ex20ins mutations who have received prior therapy.

Positive results from the REZILIENT1 trial were presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and were simultaneously published in the *Journal of Clinical Oncology*.

About REZILIENT1

REZILIENT1 (Researching Zipalertinib In EGFR Non-Small Cell Lung Cancer Tumors) is a Phase 1/2 clinical trial (NCT04036682) to evaluate efficacy and safety of zipalertinib in adult patients with locally advanced or metastatic NSCLC harboring EGFR ex20ins mutations who have received prior therapy. Patients were treated with oral zipalertinib 100 mg twice daily. The primary endpoints were objective response rate (ORR) and duration of response (DOR) as assessed by blinded independent central review (ICR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Adverse events were characterized and graded according to the NCI-Common Terminology Criteria for Adverse Events (CTCAE v5.0).

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, 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 FDA. 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 exon 20 insertions, which makes them the third most common EGFR mutation subtype.[1] In the United States, approximately 16% of patients with NSCLC harbor EGFR mutations,[2] with insertions at exon 20 accounting for up to 12% of these mutations.[1]

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, high-impact therapies 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 initiation and expected timing for completion of its rolling NDA submission to the FDA, the clinical development of zipalertinib, the safety and efficacy profile of zipalertinib and its potential to address unmet medical need, 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 regulatory submissions; the risk that any NDAs, INDs or other 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 studies will not be predictive of future results in connection with future studies; 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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