Taiho Pharmaceutical, Taiho Oncology, and Cullinan Therapeutics Announce Primary Endpoint Met in Phase 2b Trial of Zipalertinib in Patients with Non-Small Cell Lung Cancer Harboring EGFR Exon 20 Insertion Mutations Who Have Received Prior Therapy

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TOKYO, Japan, PRINCETON, New Jersey, CAMBRIDGE, Massachusetts, January 28, 2025 — Taiho Pharmaceutical Co., Ltd., Taiho Oncology, Inc., and Cullinan Therapeutics, Inc., announced today the REZILIENT1 trial, a Phase 1/2 clinical trial of zipalertinib (development code: CLN-081/TAS6417) monotherapy in patients with non-small cell lung cancer (NSCLC) harboring the epidermal growth factor receptor (EGFR) exon 20 insertion mutations who have received prior therapy, met its primary endpoint of overall response rate. The safety profile was generally consistent with previous data presentations. These results are based on the Phase 2b part of this study.

Full results from REZILIENT1 will be submitted for presentation at an upcoming international medical conference. Pending discussions with the U.S. Food and Drug Administration (FDA), the companies plan to submit for U.S. regulatory approval in the second half of 2025.

About the REZILIENT1 Trial

REZILIENT1 is a Phase 1/2 clinical trial (NCT04036682) to evaluate efficacy and safety of zipalertinib in patients with NSCLC harboring EGFR exon 20 insertion mutations who have received prior therapy. The topline results obtained at this time are based on the Phase 2b part of this study. Preliminary results of REZILIENT1 have been published in the *Journal of Clinical Oncology*®.[1]

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

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 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 the EGFR exon 20 insertion mutations

NSCLC is a common form of lung cancer and up to 4% of all cases have EGFR exon 20 insertions, which makes them the third most common EGFR mutation subtype.[2] In the United States, approximately 16% of patients with NSCLC harbor EGFR mutations, 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 Zug, Switzerland and Oakville, Ontario, Canada.

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

About Cullinan Therapeutics

Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients. Cullinan has strategically built a diversified portfolio of clinical-stage assets that inhibit key drivers of disease or harness the immune system to eliminate diseased cells in both autoimmune diseases and cancer. Cullinan’s portfolio encompasses a wide range of modalities, each with the potential to be best and/or first in class. Anchored in a deep understanding of oncology, immunology, and translational medicine, we create differentiated ideas, identify the most appropriate targets, and select the optimal modality to develop transformative therapeutics across a wide variety of autoimmune and cancer indications. We push conventional boundaries from candidate selection to differentiated therapeutic, applying rigorous go/no go criteria at each stage of development to fast-track only the most promising molecules to the clinic and, ultimately, commercialization. With deep scientific expertise, our teams exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients. Learn more about Cullinan at https://cullinantherapeutics.com/, and follow us 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 our plans regarding future data presentations, the clinical development plan and timeline of zipalertinib 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 INDs or other global regulatory submissions we may file with the United States Food and Drug Administration or other global regulatory agencies are not 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; 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.

1 Piotrowska Z, Tan DS, Smit EF, et al. Safety, tolerability, and antitumor activity of zipalertinib among patients with non-small-cell lung cancer harboring epidermal growth factor receptor exon 20 insertions. *Journal of Clinical Oncology*. Available at: https://ascopubs.org/doi/full/10.1200/JCO.23.00152. Last accessed: January 2025.

2 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. Last accessed: January 2025.

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