REZILIENT3 Global First-Line Trial of Zipalertinib Launched in Patients With Non-Small Cell Lung Cancer Harboring EGFR Exon 20 Insertion Mutations

Phase 3 trial will assess progression-free survival of zipalertinib plus chemotherapy versus chemotherapy in adult patients with previously untreated, locally advanced or metastatic non-squamous non-small cell lung cancer with EGFR exon 20 insertion mutations

Princeton, N.J., and Cambridge, Mass., August 3, 2023 – Taiho Oncology, Inc., Taiho Pharmaceutical Co., Ltd., and Cullinan Oncology, Inc., announced today the launch of the REZILIENT3 trial (NCT05973773, Researching Zipalertinib In EGFR Non-Small Cell Lung Cancer Tumors), a global Phase 3 clinical trial evaluating the combination of zipalertinib and chemotherapy as a potential first-line treatment for adult patients with previously untreated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring the epidermal growth factor receptor (EGFR) exon 20 insertion mutation and who meet additional criteria.

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.[1] 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.[1]

“Patients with NSCLC who have EGFR exon 20 insertion mutations are known to have poorer outcomes than those with more common EGFR mutations,[1]” said Volker Wacheck, MD, PhD, Senior Vice President, Clinical Development, Taiho Oncology, Inc. “Advancing care for this subset of patients with NSCLC is essential to advancing care in NSCLC overall.”

The launch of the REZILIENT3 trial follows a Phase 1 / 2a clinical trial (NCT04036682) of zipalertinib in patients with NSCLC harboring EGFR exon 20 insertion mutations. Results demonstrated the therapeutic potential of zipalertinib in heavily pretreated patients and were presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.[2] Updated data from this trial were recently published in the *Journal of Clinical Oncology.*[3]

“The initiation of the Phase 3 trial for zipalertinib in the first-line setting is an important step forward for this clinical research program, as it represents an opportunity for zipalertinib to help more patients with EGFR exon 20 insertion mutation NSCLC,” said Jeffrey Jones, MD, MPH, MBA, Chief Medical Officer, Cullinan Oncology, Inc. “We look forward to working with our partners at Taiho to rapidly assess zipalertinib in the front line, while in parallel continuing to advance our pivotal Phase 2b trial in patients who have received prior systemic treatment for locally advanced or metastatic disease.”

About the REZILIENT3 Trial

This multicenter, randomized, controlled, open-label global trial is currently enrolling 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. Approximately 312 patients will ultimately be enrolled in this trial from around the world.

About Zipalertinib
Zipalertinib (development code: CLN-081/TAS6417) is an orally available small molecule designed to target activating mutations in EGFR. The molecule was engineered 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 Cullinan Oncology, Inc. Cullinan Pearl Corp., which Taiho Pharmaceutical Co., Ltd., acquired from Cullinan Oncology, Inc. in 2022, previously licensed the rights to zipalertinib in Greater China to Zai Lab Limited in 2020.

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 Twitter.

About Taiho Pharmaceutical Co., Ltd.
Taiho Pharmaceutical Co., Ltd., a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma company with a focus on oncology. Taiho Pharmaceutical also has development programs in allergy and immunology, and consumer healthcare products. Our corporate philosophy takes the form of a pledge: "We strive to improve human health and contribute to a society enriched by smiles." For more information about Taiho Pharmaceutical Co., Ltd., please visit: https://www.taiho.co.jp/en/

About Cullinan Oncology, Inc.

Cullinan Oncology, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients with cancer. We innovate without borders to find the most promising clinic-ready cancer therapies, whether from our own discovery efforts or through exceptional engagement with our academic and industry partners. Anchored in a deep understanding of immuno-oncology and translational cancer medicine, we leverage our scientific excellence in small molecules and biologics to create differentiated ideas, identify unique targets, and select the optimal modality to develop transformative therapeutics across cancer indications. Powered by our novel research model, we push conventional boundaries from candidate selection to cancer therapeutic, applying rigorous early experimentation to fast-track only the most promising assets to the clinic and ultimately commercialization. As a result, our diversified pipeline is strategically built with assets that activate the immune system or inhibit key oncogenic drivers across a wide range of modalities, each with the potential to be the best or first in their class.
Our people possess deep scientific expertise, seek innovation openly, and exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients with cancer. Learn more about our Company at www.cullinanoncology.com, and follow us on LinkedIn and Twitter.

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 Cullinan's beliefs and expectations regarding our clinical development plan, clinical trial design and the clinical and therapeutic potential of zipalertinib. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "hope," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," 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 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; success of our clinical trials and preclinical studies; risks related to our ability to protect and maintain our intellectual property position; 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 performance and results 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 (SEC), 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 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 Cullinan 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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