



Cullinan Oncology and Taiho Pharmaceutical Announce Strategic Collaboration to Jointly Develop and Commercialize CLN-081/TAS6417 and Taiho's Acquisition of Cullinan Pearl

May 12, 2022

Taiho obtains exclusive global rights to CLN-081/TAS6417 outside the U.S.; in the U.S., Taiho and Cullinan Oncology to jointly develop and co-commercialize CLN-081/TAS6417

Cullinan Oncology will receive an upfront cash payment of \$275 million, with potential to receive up to an additional \$130 million in regulatory-based milestone payments

Cullinan Oncology and Taiho will equally share future profits in the U.S.

CAMBRIDGE, Mass., May 12, 2022 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Cullinan Oncology) (Nasdaq: CGEM) and Taiho Pharmaceutical Co., Ltd. (Taiho) today announced an agreement through which Taiho will acquire Cullinan Pearl Corp. (Cullinan Pearl) and co-develop and co-commercialize Cullinan Oncology's lead program, CLN-081/TAS6417 (development code in Cullinan Oncology: CLN-081, development code in Taiho: TAS6417), an orally available, differentiated, irreversible EGFR inhibitor that selectively targets cells expressing EGFR exon 20 insertion mutations while sparing cells expressing wild-type EGFR. Subject to customary closing conditions, including expiration or termination of the waiting period under U.S. antitrust laws, the acquisition is expected to close in the second quarter of 2022.

Under the agreement, Taiho will acquire Cullinan Oncology's subsidiary, Cullinan Pearl, which has worldwide rights outside of Japan* to CLN-081/TAS6417, for an upfront payment to Cullinan Oncology of \$275 million and up to an additional \$130 million tied to EGFR exon20 non-small cell lung cancer (NSCLC) regulatory milestones.

Cullinan Oncology will co-develop CLN-081/TAS6417 and will retain the option to co-commercialize CLN-081/TAS6417 in the United States together with Taiho Pharmaceutical through its U.S. subsidiary, Taiho Oncology, Inc. Taiho will commercialize CLN-081/TAS6417 in territories outside U.S. and China. Taiho and Cullinan Oncology will equally contribute to the future clinical development of CLN-081/TAS6417 in the U.S., with each receiving 50% of the profits from potential U.S. sales. As a result of the upfront cash payment and reduction in development and pre-commercialization costs, Cullinan Oncology anticipates its cash runway to extend through 2026 based on current operating plans. This guidance does not include the potential regulatory milestone cash payments or future U.S. profit share post-launch.

It is estimated that approximately 85%¹ of all newly diagnosed patients with lung cancer, or approximately 1.9 million people worldwide have NSCLC. Among those patients with NSCLC, approximately 2%²⁻³ or 38,000 patients have exon 20 insertions. In the U.S., approximately 16% of NSCLC cases harbor EGFR mutations, with insertions at exon 20 accounting for 12%⁽⁴⁾ of those mutations. Patients with EGFR exon 20 insertions are known to have poorer outcomes than those with more common EGFR mutations, such as exon 19 deletion. CLN-081/TAS6417 is currently in Phase I/IIa development for treatment of patients with NSCLC having an exon 20 insertion mutation.

"We are pleased to bring CLN-081/TAS6417 back into our pipeline and move it towards commercialization with Cullinan Oncology," said Masayuki Kobayashi, President and Representative Director of Taiho Pharmaceutical Co., Ltd. "Cullinan Oncology has carried CLN-081/TAS6417 from pre-IND to planned pivotal study in approximately three years. Meanwhile the Food and Drug Administration (FDA) has granted Breakthrough Designation status for this novel molecule. Utilizing Cullinan Oncology's unique business model through this strategic collaboration, we aim to hasten and maximize the development of CLN-081/TAS6417. Together with Cullinan Oncology, the Taiho group will work to expeditiously deliver this agent to patients as soon as possible."

"We are excited to embark on this collaboration with Taiho. Taiho is an ideal partner with whom to advance CLN-081/TAS6417 into later stage development and commercialization, given their deep understanding of the molecule and strategic focus on targeted therapies, existing stake in Cullinan Pearl, and strong oncology-focused commercial capabilities in the U.S.," said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. "Importantly, the structure of the agreement provides the opportunity to efficiently establish our own commercial infrastructure, which will also be leveraged for our future programs. The transaction payments, reduced development expense, and potential ongoing revenue stream upon future commercialization will help us to devote greater resources to advance our robust pipeline of assets across a wide range of modalities, each with the potential to be the first or best in their class, to deliver on our promise to bring new therapeutic solutions to patients with cancer."

Cullinan Oncology Conference Call Information

Cullinan Oncology will host a conference call today, May 12, at 8 a.m. EDT during which company executives will provide an overview of the collaboration. Investors and the general public are invited to listen to a live webcast of the call. A link to join the call and to find related materials will be available at: <https://investors.cullinanoncology.com/news-events/events>

About CLN-081/TAS6417

CLN-081/TAS6417 is an orally available tyrosine kinase inhibitor 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. CLN-081/TAS6417 is a clinical candidate for NSCLC driven by EGFR exon 20 insertion mutations and is expected to be a novel therapeutic option for patients with highly unmet medical needs. In 2019, Taiho granted Cullinan Pearl, a company that Taiho and its subsidiaries and Cullinan Oncology had established together, an exclusive global license, excluding Japan, for the development and commercialization of CLN-081/TAS6417. Following this agreement, Cullinan Pearl rapidly advanced CLN-081/TAS6417, opening an Investigational New Drug application and initiating a global Phase I/IIa study in NSCLC patients harboring EGFR exon 20 mutations, which is currently ongoing. Cullinan Oncology announced that the FDA granted Breakthrough Therapy Designation for CLN-081/TAS6417 in early 2022. Cullinan Oncology and Taiho expect to initiate a pivotal study in the second half of 2022.

About Cullinan Oncology

[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](#).

About Taiho

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, urology and consumer healthcare products. Our corporate philosophy is simple: "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/>

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 the milestone payments we may receive from Taiho; the anticipated development and commercialization of CLN-081/TAS6417; the development of our commercial infrastructure; potential investments in our pipeline and the potential for such product candidates; and our cash runway. 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; risks related to the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; 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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¹ American Cancer Society. What Is Non-Small Cell Cancer?. <https://www.cancer.org/cancer/lung-cancer/about/what-is.html>

² Konduri et al. (Cancer Discov 2016 6 601)

³ Riess et al. (WCLC2016)

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6764748/>

*Cullinan Pearl previously licensed the rights to CLN-081/TAS6417 in Greater China to Zai Lab in 2020.