Calithera Biosciences Announces Decision to Discontinue KEAPSAKE Clinical Trial

November 5, 2021

--KEAPSAKE interim analysis demonstrated lack of clinical benefit among patients treated with telaglenastat

--Company will focus on advancing newly acquired targeted oncology compounds sapanisertib and mivavotinib, as well as the ongoing trial of CB-280 for the treatment of cystic fibrosis

SOUTH SAN FRANCISCO, Calif., Nov. 05, 2021 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision oncology biopharmaceutical company, announced today the decision to terminate its phase 2 KEAPSAKE clinical trial based on a lack of clinical benefit observed in patients treated with telaglenastat in an interim analysis.

“We are disappointed in this outcome for the KEAPSAKE trial, but it was a well-run study with an interim analysis that gave us an answer to an important clinical question. We also want to express our sincere gratitude to the patients who participated in the trial and their families, as well as the physicians who served as investigators for the trial and their site staff,” said Susan Molineaux, PhD, chief executive officer of Calithera. “We remain committed to patients with difficult-to-treat cancers and will continue to advance our investigational targeted therapies for biomarker-specific patient populations. Our near-term clinical development plans include leveraging our clinical and biomarker expertise in the KEAP1/NRF2 pathway in the development of our mTORC1/2 inhibitor sapanisertib in squamous non-small cell lung cancer, as well as advancing the development of our SYK inhibitor mivavotinib in specific biomarker-defined populations of diffuse large B-cell lymphoma. In addition, we are continuing the development of our arginase inhibitor CB-280 for the treatment of cystic fibrosis.”

The phase 2 randomized, placebo-controlled, double-blind KEAPSAKE study was designed to evaluate the safety and anti-tumor activity of telaglenastat plus standard-of-care chemoimmunotherapy as front-line therapy among patients with stage IV non-squamous non-small cell lung cancer (NSCLC) whose tumors have a KEAP1 or NRF2 mutation. At the time of unblinding on October 27, 2021, there were 40 patients randomized. The available efficacy data at unblinding, including investigator-assessed progression-free survival (PFS), did not demonstrate clinical benefit, and analysis of the data led to the conclusion that there was a very low probability for the study to achieve a positive result. No difference in safety profile was seen between the two arms. The company has communicated these findings to the U.S. Food & Drug Administration (FDA) and has voluntarily discontinued the phase 2 study with agreement from members of the KEAPSAKE Steering Committee. Calithera has no plans to continue the development of telaglenastat at this time. Calithera estimates the cost savings resulting from the discontinuation of this trial will be $10-15 million.

Webcast and Conference Call Information

Calithera will hold a webcast today, Friday, November 5 at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time. To access the link to the webcast, which will be broadcast live in listen-only mode, or the subsequent archived recording, visit the Investors section of the Calithera website at www.calithera.com. Alternatively, the call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international) and referring to conference ID 9529058. The webcast will be recorded and available for replay on Calithera’s website for 30 days.

About Calithera

Calithera Biosciences is a clinical-stage, precision oncology biopharmaceutical company developing targeted therapies to redefine treatment for biomarker-specific patient populations. Driven by a commitment to rigorous science and a passion for improving the lives of people impacted by cancer and other life-threatening diseases, Calithera is advancing a robust pipeline of investigational, small molecule oncology compounds with a biomarker-driven approach that targets genetic vulnerabilities in cancer cells to deliver new therapies for patients suffering from aggressive hematologic and solid tumor cancers for which there are currently limited treatment options. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," "poised" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those related to Calithera’s clinical trials and our estimated cost savings associated with the discontinuation of the KEAPSAKE trial. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The potential product candidates that Calithera develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release. Such product candidates may not be beneficial to patients or be successfully commercialized. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Calithera's stock price. Additional information concerning these and other risk factors affecting Calithera's business can be found in Calithera's periodic filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Calithera disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

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