Calithera Biosciences to Present Telaglenastat KEAPSAKE Trial in Progress Poster at ASCO20 Virtual Annual Meeting

May 29, 2020

- KEAPSAKE is a planned Phase 2 randomized trial exploring telaglenastat with standard of care in first-line treatment of patients with lung cancer with KEAP1/NRF2 mutations

SOUTH SAN FRANCISCO, Calif., May 29, 2020 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical stage biotechnology company focused on discovering and developing novel small-molecule drugs for the treatment of cancer and other life-threatening diseases, today announced that an abstract describing a Phase 2 study of telaglenastat, the company’s glutaminase inhibitor, will be presented today at the American Society of Clinical Oncology 2020 (ASCO20) Virtual Annual Meeting.

The KEAPSAKE study (NCT04265534) will explore telaglenastat versus placebo in combination with a standard-of-care regimen of immunotherapy and chemotherapy as first-line treatment for patients with non-small cell lung cancers (NSCLC) with KEAP1/NRF2 mutations. These mutations, which occur in an estimated 20 percent of NSCLC patients, are associated with aggressive tumor growth and poor outcomes to standard-of-care therapy. The ASCO20 poster describes the study design of the Phase 2 KEAPSAKE trial, which is expected to begin enrollment in the third quarter of 2020. In addition, the poster summarizes the clinical outcomes from a retrospective review of NSCLC patients who were enrolled in a prior Phase 1/2 clinical trial, including a subset of patients with a KEAP1 mutation. These patients were progressing on a checkpoint inhibitor at study entry and were treated with telaglenastat plus nivolumab (NCT02771626).

“We are very motivated to prioritize and initiate the KEAPSAKE study given the clear mechanistic rationale, strong preclinical data, and high unmet medical need in the NSCLC population,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “The availability of a new front-line therapy that meaningfully improves outcomes would be transformative for patients with NSCLC and a NRF2/KEAP1 mutation.”

Title: A phase II randomized study of telaglenastat, a glutaminase inhibitor, versus placebo, in combination with pembrolizumab and chemotherapy as first-line treatment for KEAP1/NRF2-mutated non-squamous metastatic non-small cell lung cancer.

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A copy of the poster can be found at www.calithera.com in the publications section.

About Telaglenastat

telaglenastat (CB-839) is an investigational first-in-class, novel glutaminase inhibitor specifically designed to block glutamine consumption in tumor cells. Tumors commonly exhibit metabolic alterations that increase their dependence on glutamine. In preclinical studies, telaglenastat produced synergistic antitumor effects when used in combination with standard-of-care therapies. The randomized CANTATA trial of telaglenastat and cabozantinib in advanced renal cell carcinoma completed enrollment in 2019.

About Calithera

Calithera Biosciences is a clinical-stage biopharmaceutical company pioneering the discovery and development of targeted therapies that disrupt cellular metabolic pathways to preferentially block tumor cells and enhance immune-cell activity. 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 pipeline of first-in-class, oral therapeutics to meaningfully expand treatment options available to patients. 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, the clinical and commercial potential of its product candidates; the presentation of interim data from the randomized trial in NSCLC patients with genetic mutation KEAP1/NRF2; and the impact of telaglenastat for patients with NSCLC and a NRF2/KEAP1 mutation. 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. Calithera's clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release and such product candidates may not be beneficial to patients or successfully commercialized. In addition, the COVID-19 pandemic may result in further delays in Calithera’s studies and trials. 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.

**SOURCE:** Calithera Biosciences, Inc.

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