Final Data from Calithera Biosciences' Phase 2 CANTATA Study in Renal Cell Carcinoma Presented at 2021 ASCO Annual Meeting

June 7, 2021

SOUTH SAN FRANCISCO, Calif., June 07, 2021 (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 shared final results from the Phase 2 CANTATA study evaluating the company's glutaminase inhibitor telaglenastat (CB-839). The findings were highlighted in an oral presentation at the virtual American Society of Clinical Oncology (ASCO) 2021 Annual Meeting.

The CANTATA trial evaluated the efficacy and safety of telaglenastat in combination with cabozantinib versus placebo with cabozantinib in patients with advanced or metastatic renal cell carcinoma (RCC) who had been treated with one or two prior lines of systemic therapy, including at least one anti-angiogenic therapy or the combination of ipilimumab and nivolumab.

Results announced previously showed that the addition of telaglenastat to cabozantinib did not improve progression-free survival (PFS) in the study population. Median progression-free survival (mPFS) in patients who received telaglenastat and cabozantinib was 9.2 months versus 9.3 months in patients who received placebo and cabozantinib. The frequency and severity of adverse events in the telaglenastat-treated population were comparable to those of cabozantinib alone and remained consistent with known risks of both agents.

Additional subgroup data was shared today (Abstract 4501), including a pre-specified analysis of CANTATA patients who had received prior immunotherapy that demonstrates patients who received the combination of telaglenastat and cabozantinib had a numerically longer mPFS as compared to patients who received placebo plus cabozantinib (11.1 months versus 9.2 months; HR = 0.77; 95% CI: 0.56, 1.06). Overall survival was not mature at the data cutoff date.

"While we were obviously disappointed by the outcome of the CANTATA study for telaglenastat, we are pleased that the study's findings may contribute to the growing body of knowledge around efficacy outcomes in patients with RCC," said Susan Molineaux, PhD, president and chief executive officer of Calithera, "It also allowed us to learn more about how telaglenastat may interact with immune checkpoint inhibitors. This is important to us because we are continuing the development of telaglenastat in combination with immune checkpoint inhibitors in a biomarker-selected non-small cell lung cancer population, in the KEAPSAKE clinical study".

The data presentation "CANTATA: Primary analysis of a global, randomized, placebo (Pbo)-controlled, double-blind trial of telaglenastat (CB-839) + cabozantinib versus Pbo + cabozantinib in patients (pts) with advanced/metastatic renal cell carcinoma (mRCC) that progressed on immune checkpoint inhibitor (ICI) or anti-angiogenic therapies" was led by Nizar M. Tannir, MD, FACP, Professor, Department of Genitourinary Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Ransom Horne, Jr. Professor for Cancer Research, as part of the virtual "Genitourinary Cancer — Kidney and Bladder" oral session.

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-clinic, 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 the safety, tolerability and efficacy of Calithera's product candidates, the overall advancement of Calithera's product candidates in clinical trials, including the continuing development of telaglenastat in combination with immune checkpoint inhibitors in a biomarker-selected non-small cell lung cancer population, in the KEAPSAKE clinical study, the unmet need in the treatment of patients with advanced disease, and Calithera's plans to continue development of its product candidates. 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 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 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, and other 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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