Updated Results from Phase 1 Study of Telaglenastat (CB-839) to be Presented at 2019 ASCO Genitourinary Cancer Symposium

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-- Clinical study explored Calithera's lead compound in combination with cabozantinib in patients with advanced renal cell carcinoma --

SOUTH SAN FRANCISCO, Calif., Feb. 16, 2019 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical stage biotechnology company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer, today announced that updated data from a Phase 1 study of the glutaminase inhibitor telaglenastat in combination with cabozantinib in patients with advanced renal cell carcinoma (RCC) will be presented at the American Society of Clinical Oncology Genitourinary Cancer (ASCO GU) Symposium, in San Francisco, California.

"Despite the advances in the treatment of renal cell carcinoma, there remains a significant unmet need among patients with advanced disease," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "Based on promising Phase 1 results, we initiated and are currently enrolling the global, randomized CANTATA trial of telaglenastat plus cabozantinib with the hope of identifying a new therapeutic option that could benefit patients following their initial therapies."

Telaglenastat is an investigational, novel glutaminase inhibitor specifically designed to block glutamine consumption in tumor cells. RCC 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 RCC therapies including cabozantinib.

At the ASCO GU Symposium, Dr. Funda Meric-Bernstam from MD Anderson Cancer Center will present results from the Phase 1 study in an oral presentation (Abstract 549. Rapid Abstract Session C; RCC, Saturday February 16, 11:35 a.m. - 12:30 p.m. PST) and poster presentation, “CB-839, a glutaminase inhibitor, in combination with cabozantinib in patients with clear cell and papillary metastatic renal cell cancer: Results of a phase 1 study.” As of December 24, 2018, 12 advanced renal cell carcinoma patients were treated with telaglenastat plus cabozantinib and evaluable for response, including 10 clear cell patients, and two papillary patients. One hundred percent of evaluable patients experienced tumor shrinkage and disease control; this includes five patients who had a partial response and seven patients who had stable disease. In the clear cell patient population, the disease control rate was 100 percent and the response rate was 50 percent. Patients enrolled in the trial had advanced or metastatic disease and had received a median of three prior treatments, which included tyrosine kinase inhibitors, mTOR inhibitors, and checkpoint inhibitors. Patients were administered telaglenastat in oral doses that ranged from 600-800 mg twice a day in combination with a fixed oral dose of cabozantinib at 60 mg once a day.

In addition, Dr. Nizar Tannir from MD Anderson Cancer Center will present a poster describing the CANTATA trial at ASCO GU (Trials in Progress Poster Session C, Board K13). CANTATA is a global, randomized, double-blind trial designed to evaluate the safety and efficacy of telaglenastat in combination with cabozantinib versus placebo with cabozantinib in patients with advanced clear cell RCC who have been treated with one or two prior lines of systemic therapy. The trial will enroll approximately 400 patients and is designed with registrational intent. The primary endpoint is progression free survival by blinded independent review, and a key secondary endpoint is overall survival.

About Calithera

Calithera is a clinical-stage biopharmaceutical company focused on fighting cancer by discovering, developing, and commercializing novel small molecule drugs that target tumor and immune cell metabolism. 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 CB-839 and the overall advancement of CB-839 in clinical trials, Calithera's plans to continue development of CB-839 in combination with cabozantinib and the clinical and commercial potential of its product candidates and Calithera's receipt of clinical data from, and milestones of, its clinical trials, including the Phase 2 ENTRATA trials. 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 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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