Results from Phase 1 Study of CB-839 in Combination with Capecitabine in Advanced Solid Tumors to be Presented at the 2018 American Society of Clinical Oncology (ASCO)

June 4, 2018

Phase 2 to Continue Enrolling Colorectal Cancer Patients with PIK3CA Mutation

SOUTH SAN FRANCISCO, Calif., June 04, 2018 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, announced today that clinical data from its lead product candidate CB-839, a novel glutaminase inhibitor, will be presented at the 54th Annual Meeting of the American Society of Clinical Oncology (ASCO), which is being held from June 1 to June 5, 2018 in Chicago, Illinois. This is the first presentation of the Case Western investigator-sponsored phase 1/2 trial evaluating CB-839 in combination with capecitabine in patients with treatment refractory advanced solid tumors. The combination demonstrated a median progression free survival of 26 weeks in seven patients with treatment-refractory advanced colorectal cancer harboring a PIKC3A mutation who had disease progression on at least one prior fluoropyrimidine-containing regimen. The data will be presented on Monday June 4, 2018 in the Developmental Therapeutics Poster Session from 8:00 a.m.-11:30 a.m. CT (Abstract #2562, Board 388).

"Investigator sponsored studies are an important part of our strategy to develop CB-839 broadly across cancer indications," said Susan M. Molineaux, Ph.D., founder, Chief Executive Officer and President of Calithera Biosciences. "We are grateful to the investigators and Stand Up 2 Cancer for their contributions to this ongoing trial."

Dr. Jennifer Eads from Case Comprehensive Cancer Center will present the results in a poster entitled, “Phase 1 clinical trial of the glutaminase inhibitor CB-839 plus capecitabine in patients with advanced solid tumors.” The phase 1 portion of the trial is designed to determine safety and the recommended dose of the combination of CB-839 and capecitabine in patients with advanced treatment refractory solid tumors, while the phase 2 portion of the trial is designed to evaluate activity of the regimen in patients with late line PIK3CA mutant colorectal cancer. To date, 16 patients have been enrolled, including 12 patients with colorectal cancer. In the dose escalation phase of the trial, there were no dose limiting toxicities and CB-839 plus capecitabine was well tolerated at full dose of CB-839. The recommended phase 2 dose for the combination is CB-839 800 mg BID with capecitabine 1000 mg/m2 BID. In patients with late-line colorectal cancer that had progressed on at least one prior fluoropyrimidine-containing regimen, the median PFS was 26 weeks for patients with PIK3CA mutated cancer (n=7) and 16 weeks for patients with PIK3CA wild-type cancer (n=5, p=0.058). The phase 2 portion of this study in patients with PIK3CA mutant colorectal cancer is ongoing.

About CB-839

Calithera’s lead product candidate, CB-839, is a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839's onco-metabolism activity takes advantage of the unique metabolic requirements of tumor cells and cancer-fighting immune cells such as cytotoxic T-cells. It is currently being evaluated in Phase 2 clinical trials in multiple tumor types in combination with standard of care agents.

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, and Calithera’s plans to continue development of CB-839 in combination with capecitabine in patients with advanced treatment refractory solid tumors and late line PIK3CA mutant colorectal cancer. 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 most recent Annual Report on Form 10-K filed 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.

NOTE:

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