



Results from Phase I Study of CB-839 in Combination with Everolimus or Cabozantinib in Patients with Renal Cell Carcinoma to be Presented at the 2018 American Society of Clinical Oncology Genitourinary Cancer Symposium

February 5, 2018

-Overall response rate of 40% and 100% disease control rate in advanced clear cell renal cell carcinoma patients treated with CB-839 plus Cabozantinib

-Randomized placebo controlled CANTATA Phase 2 trial of CB-839 in combination with Cabozantinib to begin 2Q18

SOUTH SAN FRANCISCO, Calif., Feb. 05, 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 first-in-class glutaminase inhibitor, will be presented at the 2018 Genitourinary Cancer Symposium, February 8-10, 2018 in San Francisco, California. This is the first disclosure of clinical experience evaluating CB-839 in combination with cabozantinib, an oral receptor tyrosine kinase inhibitor. Preliminary results show the combination demonstrated a 40% overall response rate in advanced clear cell RCC patients, and 100% disease control, with the safety profile of CB-839 plus cabozantinib generally consistent with that of cabozantinib monotherapy. The data will be presented on Saturday February 10, 2018 in Poster Session C: Renal Cell Cancer from 11:30am-1:00pm PT (Board F18).

"Despite the advances in the treatment of renal cell carcinoma, there remains a significant unmet need in the treatment of patients with advanced disease," said Susan M. Molineaux, Ph.D., founder, Chief Executive Officer, and President of Calithera Biosciences. "Based on these promising clinical results, we plan to initiate a global, randomized Phase 2 trial of CB-839 in combination with cabozantinib in the second quarter of 2018, and focus our efforts on developing a potential new therapeutic option that could benefit patients who have failed their first therapies."

Dr. Nizar Tannir from MD Anderson Cancer Center will present the results in a poster session, "Phase I study of glutaminase inhibitor CB-839, combined with everolimus or cabozantinib in patients with clear cell and papillary renal cell carcinoma." As of December 22, 2017, 12 advanced renal cell carcinoma patients were treated with CB-839 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 four patients who had a partial response and eight patients who had stable disease. In the clear cell patient population, the disease control rate was 100% and the response rate was 40%. 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 CB-839 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. On the basis of this efficacy and safety data which compares favorably to treatment with cabozantinib, Calithera plans to initiate the CANTATA trial, a Phase 2 randomized, placebo-controlled trial in approximately 300 clear cell renal cell carcinoma patients whom have previously received one or two prior lines of therapy. Exelixis has entered into a material supply agreement with Calithera. The CANTATA trial is expected to begin in the second quarter of 2018.

The updated results of CB-839 in combination with everolimus were also presented. As of the data cut off, 24 renal cell carcinoma patients, with a median of 3 prior therapies, were treated and evaluable for response. Ninety-two percent (92%) of patients experienced control of their disease, including one patient with a partial response and 21 patients with stable disease. The median progression free survival was 5.8 months, which compares favorably to historical data in this patient population. On the basis of this efficacy and safety data, Calithera plans to continue development in combination with everolimus for the treatment of advanced clear cell renal cell carcinoma. The randomized Phase 2 ENTRATA trial of CB-839 in combination with everolimus in later stage patients is currently enrolling, and has been modified to enroll approximately 65 patients.

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, Calithera's clinical trial plans for CB-839 in combination with cabozantinib as well as the overall advancement of CB-839 in clinical trials, the sufficiency of Calithera's agreement with Exelixis, the unmet need in the treatment of patients with advanced disease, and Calithera's plans to continue development of CB-839 in combination with everolimus for the treatment of clear cell renal cell carcinoma. 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 Quarterly Report on Form 10-Q 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.

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