Calithera Biosciences Reports CB-839 Phase I Renal Cell Carcinoma Combination Data at the 28th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics

November 29, 2016

SOUTH SAN FRANCISCO, Calif., Nov. 29, 2016 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, announced that clinical data from its lead product candidate CB-839, a first-in-class glutaminase inhibitor, will be presented in a plenary session at the 28th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Munich, Germany. The data demonstrate the clinical activity, tolerability and unique mechanism of action of CB-839 in patients with renal cell carcinoma.

"CB-839 is the first tumor metabolism drug to target a pathway that starves cancer cells by directly depriving them of a key nutrient. We are pleased to present combination data of CB-839 with everolimus that demonstrates high rates of disease control with a well-tolerated combination therapy," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera.

Dr. Funda Meric-Bernstam from MD Anderson Cancer Center will present in a plenary session, "Phase I study of CB-839, a small molecule inhibitor of glutaminase, in combination with everolimus in patients with clear cell and papillary renal cell carcinoma." As of October 25, 2016, 15 renal cell carcinoma patients were treated and evaluable for response, including 12 clear cell patients, and three papillary patients. Ninety-three percent (93%) have disease control; one patient has a partial response, one patient has progressive disease, and 13 patients have stable disease. The median progression free survival is 8.5 months and for the majority of patients, their time on therapy is longer than their time on treatment in their prior therapy. In the clear cell patient population the disease control rate is 100% and eight patients remain on study. For comparison, in a separate trial of everolimus vs. cabozantinib, the progression free survival of patients in the everolimus group from the Meteor Phase 3 study in second and third line patients was 3.9 months.[1]

Patients enrolled in the trial had advanced or metastatic disease and had received a median of two prior treatments, which included tyrosine kinase inhibitors, mTOR inhibitors, and checkpoint inhibitors. Patients were administered CB-839 in oral doses that ranged from 400-800 mg twice a day in combination with a fixed oral dose of everolimus at 10 mg once a day. The addition of CB-839 to full dose everolimus has been well tolerated, with a similar safety profile to the known profile of everolimus alone. Grade 3 events include two events of hyperglycemia and one event each of diarrhea, anemia and fatigue. On the basis of this efficacy and safety data, the company plans to continue development in combination therapy for clear cell renal cell carcinoma. Clear cell is the most common form of kidney cancer comprising 75%-85% of cases.

In addition, the following poster presentations will be presented at the meeting:

- **CB-839, a selective glutaminase inhibitor, has anti-tumor activity in renal cell carcinoma and synergizes with everolimus and receptor tyrosine kinase inhibitors**

  Session: Molecular targeted agents II, December 1, 2016

- **Arginase inhibitor CB-1158 elicits immune-mediated anti-tumor responses as a single agent and enhances the efficacy of other immunotherapies**

  Session: Immunotherapy, November 30, 2016

[1] Choueiri, T, Escudier, B. Cabozantinib versus everolimus in advanced renal cell carcinoma (METEOR): final results from a randomised, open-label, phase 3 trial. The Lancet 2016 July; 17: 917-927.

About Calithera Biosciences

Calithera Biosciences, Inc. is a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. Calithera's lead product candidate, CB-839, is a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839 takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. It is currently being evaluated in Phase 1/2 clinical trials in combination with standard of care agents. CB-1158 is a first-in-class immuno-oncology metabolic checkpoint inhibitor targeting arginase, a critical immunosuppressive enzyme responsible for T-cell suppression by myeloid-derived suppressor cells. Arginase depletes arginine, a nutrient that is critical for the activation, growth and survival of the body's cancer-fighting immune cells, known as cytotoxic T-cells. CB-1158 is currently in a Phase I clinical trial. 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 company's plans to continue development of CB-839 in combination therapy for 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 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 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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