



Calithera Biosciences Reports CB-839 Phase I Triple Negative Breast Cancer Combination Data at the 2016 San Antonio Breast Cancer Symposium

December 6, 2016

Response rate of 38% in patients refractory to taxanes in metastatic setting

SOUTH SAN FRANCISCO, Calif., Dec. 06, 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 at the 2016 San Antonio Breast Cancer Symposium, December 6-10, 2016 in San Antonio, Texas. The data demonstrate the clinical activity, tolerability and unique mechanism of action of CB-839 in patients with advanced/metastatic triple negative breast cancer (TNBC).

"Triple negative breast cancer in the advanced and metastatic population remains a significant unmet need. We are particularly pleased to observe responses with CB-839 plus paclitaxel in taxane-refractory patients," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera.

Dr. Angela DeMichele from the University of Pennsylvania will present in a poster session, "Phase I study of CB-839, a small molecule inhibitor of glutaminase, in combination with paclitaxel in patients with triple negative breast cancer," (Abstract P6-11-05). The abstract was selected for presentation on Saturday, December 10, 2016. Eligible patients must have locally advanced/metastatic TNBC, with prior paclitaxel treatment allowed. As of November 25, 2016, 28 triple negative breast cancer patients had been treated with doses of CB-839 of 400, 600 or 800 mg bid in combination with 80 mg/m² IV paclitaxel, weekly, three weeks out of four; 23 were evaluable for response. The majority of patients had received at least three prior lines of therapy, with 43% of patients treated with five or more prior therapies in the advanced/metastatic setting. Most patients had received prior taxane therapy in either the neo-adjuvant or metastatic setting. Among evaluable patients treated with CB-839 doses of at least 600 mg bid (n=16), there are 5 partial responses (31%) and disease control (response or stable disease) in 11 patients (69%). In addition, the combination overcomes resistance to paclitaxel in heavily pretreated TNBC patients. There is a 38% response rate and 50% disease control rate in patients who received prior taxanes in the metastatic setting. There is a 50% response rate among taxane-refractory African American patients, consistent with higher glutamine utilization observed in tumors from this population.¹

The combination of CB-839 and paclitaxel has been well tolerated to date, with adverse events that have been easily manageable and reversible, including several paclitaxel related toxicities. There was one case of dose-limiting, recurrent grade 3 neutropenia at the 400 mg dose level, which led to a reduction in the dose of paclitaxel for that patient. The most frequent adverse event? Grade 3 is neutropenia (n=6).

¹Terunuma et al., J Clin Invest 2014

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 advanced/metastatic triple negative breast 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 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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