



Updated Results from Phase I Study of CB-839 in Combination with Paclitaxel in Patients with Triple Negative Breast Cancer to be Presented at the 2017 San Antonio Breast Cancer Symposium

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SOUTH SAN FRANCISCO, Calif., Dec. 05, 2017 (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, announced today that updated clinical data from its lead product candidate CB-839, a first-in-class glutaminase inhibitor, will be presented at the 2017 San Antonio Breast Cancer Symposium, December 5-9, 2017 in San Antonio, Texas. The data demonstrate the clinical activity and tolerability of CB-839 in combination with paclitaxel, and highlight the unique mechanism of action of CB-839 in patients with advanced/metastatic triple negative breast cancer (TNBC). Based on these data, Calithera has opened a Phase 2 trial exploring the treatment combination in both first line and late line metastatic TNBC patients.

"Effective treatment for triple negative breast cancer in the advanced and metastatic population remains a significant unmet need. In our Phase 1 study, we were pleased to have observed responses in patients who were heavily pretreated and the Phase 2 study will help us further understand the role of CB-839 in inhibiting glutaminase to help control the progression of cancer in advanced metastatic TNBC patients," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera.

In a poster presentation representing an update from data presented at SABCS 2016, Dr. Kevin Kalinsky from Columbia University Medical Center will present, "Phase I study of CB-839, a first-in-class inhibitor of glutaminase, in combination with paclitaxel in patients with advanced triple negative breast cancer," (Abstract PD3-13). Eligible patients must have locally advanced/metastatic TNBC, with no restrictions on prior exposure to taxanes, or the number of prior therapies. As of October 23, 2017, 49 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; 44 were evaluable for response. Patients were heavily pretreated, having received a median of 3 prior therapies for advanced metastatic disease. A majority of patients had received prior taxane therapy in either the neo-adjuvant (37%) or metastatic setting (51%). Among all evaluable patients treated with CB-839 doses of at least 600 mg bid (n=37), there were 8 partial responses (22%) and disease control (response or stable disease) in 22 patients (59%). Among African Americans, there was a 36% response rate in patients who had received previous taxanes in the metastatic setting; all responders were refractory to prior taxanes. Exploratory biomarker analysis shows a trend for the strongest clinical benefit occurring in patients with LAR and/or desmoplastic stromal gene expression signatures¹.

The combination of CB-839 and paclitaxel has been well tolerated to date, with adverse events that have been primarily low grade and reversible. Consistent with the previous report, 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 \geq Grade 3 was neutropenia (27%). A low rate of \geq Grade 3 peripheral neuropathy (4.2%) was observed despite 88% of the patients having prior taxane exposure.

¹Lehmann et al., J Clin Invest 2011; Chen et al, Cancer Inform 2012; Jovanovic et al BMC Cancer 2017; Saleh et al, Cancer Research 2017

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 ability to understand the role of CB-839 in inhibiting glutaminase to help control the progression of cancer in TNBC patients, and the advancement of CB-839 in clinical 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 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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