Calithera Reports Phase I Data for CB-839 in Patients with Solid Tumors at the 2015 American Society of Clinical Oncology

May 30, 2015

- ***Data Support Initiation of Multiple Solid Tumor Expansion Cohorts***
- ***Calithera to Host Investor Webcast on May 30, 2015 at 6:30 p.m. CT***

SOUTH SAN FRANCISCO, Calif., May 30, 2015 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, today announced that data from its lead, first-in-class program CB-839 was presented today at the 2015 American Society of Clinical Oncology (ASCO) in Chicago, Illinois. The data demonstrate the clinical activity, tolerability and unique mechanism of action of CB-839 in patients with solid tumors.

The new data presented by James J. Harding, MD, from the Memorial Sloan Kettering Cancer Center (Abstract # 2512), demonstrated stable disease in a variety of solid tumor types. Two triple negative breast cancer (TNBC) patients and one renal cell carcinoma patient had prolonged stable disease 323, 218, and 240 days respectively, and remain on study. One of the TNBC patients demonstrated a 23% reduction in target lesions. In the cohort dosed twice daily (BID) with food, 7 out of 17 (41%) of response-evaluable patients had stable disease as their best overall radiographic response, and in the dose escalation cohort on the three times daily (TID) schedule 6 out of 31 (19%) response-evaluable patients had stable disease as their best overall radiographic response. It was observed that BID dosing with meals provides the optimal pharmacokinetic and safety profile for CB-839.

"The data presented at ASCO in solid tumors demonstrates biologic response and safety consistent with the exciting data we recently announced in hematologic malignancies," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "We plan to initiate multiple expansion cohorts in solid tumor types of interest including triple negative breast cancer, non-small cell lung cancer, and renal cell carcinoma."

The Phase I multi-center open label dose escalation study was designed to evaluate the safety and tolerability of CB-839 for locally advanced, metastatic and/or refractory solid tumors. Oral CB-839 was administered in doses of 100 mg to 800 mg, in 21 day cycles, using one of two regimens: TID or BID with food. As of May 15, 2015, 76 patients were enrolled in the solid tumor study; 59 of these patients were enrolled as of the safety data collection cutoff of April 15, 2015, and 48 were evaluable for efficacy. All future patients enrolled to the study will be dosed on the BID with food regimen.

Safety Data

Among 59 patients evaluable for safety, a maximum tolerated dose has not yet been established. CB-839 was generally well tolerated with the majority of treatment-emergent adverse events being mild to moderate, Grade 1/2. Treatment related Grade 3/4 adverse events were reported in 8 of 59 (13.6%) patients. Grade 3 alanine aminotransferase (ALT) elevations have occurred in 6 patients. The elevations have been rapidly reversible and the frequency of ALT elevations was reduced when CB-839 was dosed BID with food. A dose limiting toxicity of Grade 3 creatinine elevation occurred in one patient at the 250 mg TID dose level. The patient had type 2 diabetes with retinopathy and nephropathy with Grade 3 proteinuria at baseline.

Clinical Outcome Data

Robust inhibition of glutaminase was observed in platelets and tumor biopsies, with the magnitude of inhibition correlated with CB-839 exposure. Six of 31 (19%) on the TID schedule, and 7 of 17 (41%) on the BID fed schedule had stable disease lasting at least 3 cycles (63 days). Glutaminase expression by immunohistochemistry was moderate to strong in most samples tested from archival tissue or on-study biopsies.

CB-839 Development Plans

The biologic activity and favorable safety profile of CB-839 observed to date, as well as recent preclinical data showing synergistic activity of CB-839 with multiple signal transduction inhibitors support Calithera's strategy to initiate both single agent and combination expansion cohorts in the second half of 2015. The company plans to initiate four single agent solid tumor expansion cohorts in patients with triple negative breast cancer, renal cell carcinoma, KRAS-mutated non-small cell lung cancer, and tumors harboring TCA cycle mutations. In addition, combination expansion cohorts in solid tumors will include CB-839 with paclitaxel in triple negative breast cancer, CB-839 with everolimus in renal cell carcinoma, and CB-839 with docetaxel in KRAS-mutated non-small cell lung cancer.

Investor Event and Webcast

Calithera will host a conference call and webcast on Saturday May 30, 2015, at 6:30 p.m. CT to review the clinical data presented at ASCO from the ongoing Phase I study of CB-839. The live audio webcast can be accessed via the Investor section of the Company's website at www.calithera.com. The conference call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international) and refer to conference ID 43917070. Please log in approximately 5-10 minutes before the event to ensure a timely connection. The archived webcast will remain available for 30 days following the call.

About Calithera Biosciences

Calithera Biosciences is a clinical-stage company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and immuno-oncology. Calithera's lead clinical candidate, CB-839, is a first-in-class inhibitor of glutaminase, a critical enzyme in tumor metabolism, and is currently being tested in patients with solid and hematological cancers. Calithera's lead preclinical program is developing inhibitors of arginase, an enzyme involved in suppression of T-cell activation in tumors. Calithera Biosciences is headquartered in South San Francisco. For more information about Calithera Biosciences, 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 clinical activity, tolerability and unique mechanism of action of CB-839, the safety of CB-839 and the initiate of multiple expansion cohorts in solid tumor types. 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 filed with the Securities and Exchange Commission on May 11, 2015, 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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