Calithera to Present New Phase 1 Solid Tumor Dose Expansion Data of CB-839 at the 2015 AACR-NCI-EORTC International Conference

November 8, 2015

- ***Single Agent Solid Tumor Clinical Benefit Seen With Tumor Metabolism Inhibitor CB-839***

- ***Continued Signs of Activity, Tolerability, and Durability***

SOUTH SAN FRANCISCO, Calif., Nov. 08, 2015 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, today will announce new clinical data from the solid tumor expansion cohorts of its lead anti-cancer therapeutic candidate, CB-839, at the 2015 AACR-NCI-EORTC International Conference on Molecular Targets in Boston, Massachusetts. CB-839 is a potent, selective, orally bioavailable glutaminase inhibitor in phase I clinical trials. The data support earlier findings of the clinical activity, tolerability and unique mechanism of action of CB-839 in patients with solid tumors, as well as show one partial response according to RECIST criteria.

The new data to be presented by Funda Meric-Bernstam, MD, from MD Anderson Cancer Center (Abstract #C49), demonstrate stable disease across a variety of tumor types, as well as a single agent partial response (PR, on study >5 months) in a renal cell carcinoma (RCC) patient. This patient showed a 32% reduction in target lesions by RECIST with generalized shrinkage of lymph node metastases. Among the fifteen evaluable patients with RCC, nine (60%) had stable disease lasting at least three cycles (63 days) or a partial response, with four patients remaining on study. Among efficacy-evaluable patients across a range of tumor types treated on the current dosing schedule of twice-daily with food, 22 of 50 patients (44%) experienced stable disease or better. Five stable disease patients currently on study have been treated with CB-839 for over 8 months without progression (2 triple negative breast cancer, 1 RCC, 1 mesothelioma and 1 IDH1 mutant chondrosarcoma).

“We are very encouraged by these findings in that they reinforce the published safety and efficacy profile of CB-839. We believe that this first partial response in solid tumors points to the potential of our novel agent’s efficacy in renal cell carcinoma, and we look forward to sharing data as our single agent and combination studies mature,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “We are currently expanding enrollment of CB-839 as a monotherapy in renal cell carcinoma patients, as well as dosing CB-839 in combination with everolimus.”

The Phase 1 multi-center open label dose escalation study was designed to evaluate the safety and tolerability of CB-839 in locally advanced, metastatic and/or refractory solid tumors. Oral CB-839 was administered in doses of 100 mg to 1000 mg, in 21 day cycles using one of two regimens: TID or BID with food. As of October 1, 2015, 98 patients were enrolled in the solid tumor study (32 TID, 66 BID with food) and evaluable for safety; 77 were evaluable for efficacy. All future patients enrolled to the study will be dosed on the BID with food regimen.

Safety Data

Among 98 patients evaluable for safety, a maximum tolerated dose has not been established. CB-839 was generally well tolerated with the majority of treatment-emergent adverse events being mild to moderate, Grade 1/2 and reversible. Among patients in the BID with food regimen, 4.5% (3/66) experienced a Grade 3/4 adverse event suspected to be related to CB-839 and 3% discontinued due to drug-related adverse events (2/66). The rate of Grade 3 alanine aminotransferase (ALT) elevations of 1.5% (1/66) in the BID with food cohort was substantially reduced relative to that observed in the TID cohort 16% (5/32).

In addition, a preclinical poster was presented by Calithera’s collaborators. Details for the presentation are as follows:

Targeting glutamine metabolism in colorectal cancers with PIK3CA mutations

Abstract #C115
Zhenghe John Wang, Ph.D., Case Western Reserve University
Poster Session C

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 currently being evaluated in three Phase 1 clinical trials in solid and hematological cancers. 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. 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 clinical activity, tolerability and unique mechanism of action of CB-839, the safety of CB-839 and the initiation 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 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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