Calithera Achieves Positive Topline Results in Randomized Phase 2 ENTRATA Study of Telaglenastat with Everolimus in Renal Cell Carcinoma

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-Doubled median progression-free survival (PFS) in heavily pre-treated patients with advanced renal cell carcinoma

-Provides first clinical proof of concept for glutaminase inhibitor telaglenastat

-Management to host webcast and conference call today at 8:30 a.m. ET / 5:30 a.m. PT

SOUTH SAN FRANCISCO, Calif., June 17, 2019 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical stage biotechnology company focused on discovering and developing novel small molecule drugs for the treatment of cancer and other life-threatening diseases, today announced positive results from its randomized placebo-controlled Phase 2 ENTRATA study of telaglenastat (CB-839) in combination with everolimus in patients with advanced renal cell carcinoma (RCC). The combination doubled the median progression-free survival (PFS) in heavily pre-treated patients with advanced RCC and had a well-tolerated safety profile. Telaglenastat is the first glutaminase inhibitor to demonstrate clinical activity for the treatment of cancer.

“The achievement of positive topline results in our first randomized trial is a significant milestone for Calithera because it provides clinical proof of concept for telaglenastat,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “This study demonstrates a clinically meaningful improvement in progression free survival in patients with advanced renal cell carcinoma who have been treated with many prior lines of therapy, including immunotherapy and multiple tyrosine kinase inhibitors. We look forward to the outcome of the ongoing CANTATA trial of telaglenastat in combination with cabozantinib for patients with advanced clear cell RCC.”

Patients enrolled were heavily pre-treated with a median of three prior lines of therapy for advanced metastatic disease including 70% with two or more prior tyrosine kinase inhibitors (TKI), and 68% with intermediate/poor MSKCC prognostic score. Eighty-eight percent of patients received prior PD-1/PD-L1 therapy. Telaglenastat, when added to everolimus, doubled the median PFS to 3.8 months as compared to 1.9 months for everolimus alone and reduced the risk of disease progression or death by 36% (HR=0.64, p=0.079 one-sided). The primary endpoint of the trial was PFS per investigator assessment with a predetermined threshold of p≤0.2 one-sided. The secondary endpoint of overall survival is not yet mature.

Frequency of all-grade adverse events in the telaglenastat-containing arm were comparable to that of everolimus alone. Grade 3 or higher adverse events occurred in 80.4% of patients in the telaglenastat plus everolimus arm versus 60.9% in the everolimus plus placebo arm. The most frequently reported Grade ≥3 adverse events in the treatment versus control arms, respectively, were anemia (17.4% vs. 17.4%), pneumonia (6.5% vs. 4.3%), abdominal pain (6.5% vs. 0%), thrombocytopenia (6.5% vs. 0%), and fatigue (4.3% vs. 8.7%). Adverse events leading to discontinuation of any study drug were comparable (28.3% vs. 30.4%).

The ENTRATA trial (NCT03163667) is a randomized, double-blind Phase 2 trial designed to evaluate the efficacy and safety of telaglenastat in combination with everolimus versus placebo with everolimus in patients with advanced clear cell RCC who have been treated with at least two prior lines of systemic therapy, including at least one VEGFR-targeted TKI. Patients were stratified by prior TKI treatment and MSKCC prognostic score. The trial enrolled 69 patients at multiple centers in the United States. Calithera intends to present data at an upcoming medical meeting.

Telaglenastat is an investigational, novel glutaminase inhibitor specifically designed to block glutamine consumption in tumor cells. RCC tumors commonly exhibit specific genetic alterations that cause cancer cells to increase metabolism of glutamine. In preclinical studies, telaglenastat produced synergistic antitumor effects when used in combination with standard-of-care RCC therapies, including everolimus and cabozantinib.

Telaglenastat is also being investigated in the CANTATA trial, a global, randomized, double-blind Phase 2 trial designed to evaluate the efficacy and safety of telaglenastat in combination with cabozantinib versus placebo with cabozantinib in patients with advanced clear cell RCC who have been treated with one or two prior lines of systemic therapy. CANTATA will enroll approximately 400 patients and is designed with registrational intent. The primary endpoint is PFS by blinded independent review. Calithera expects data from this trial in the second half of 2020.

Conference Call Information

Calithera will host an update conference call today, Monday, June 17, at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time. The call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 and referring to conference ID 6492963. To access the live audio webcast or the subsequent archived recording, visit the Investors section of the Calithera website at www.calithera.com. The webcast will be recorded and available for replay on Calithera’s website for 30 days.

About Calithera

Calithera Biosciences is a clinical-stage biopharmaceutical company pioneering the discovery and development of targeted therapies that disrupt cellular metabolic pathways to preferentially block tumor cell growth and enhance immune-cell activity. Driven by a commitment to rigorous science and a passion for improving the lives of people impacted by cancer and other life-threatening diseases, Calithera is advancing a pipeline of first-in-clinic, oral therapeutics to meaningfully expand treatment options available to patients. 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 potential for telaglenastat to be developed in combination with therapeutics, such as everolimus or cabozantinib, to improve patient outcomes, safety, tolerability and efficacy of telaglenastat; the overall advancement and timing of telaglenastat in clinical trials; and the unmet need in the treatment of patients with advanced RCC. 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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