



Calithera Biosciences Completes Patient Enrollment in Randomized CANTATA Trial of Telaglenastat and Cabozantinib in Advanced Renal Cell Carcinoma

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-Top-line results expected in second half of 2020-

SOUTH SAN FRANCISCO, Calif., Oct. 03, 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 that it has completed patient enrollment in the ongoing CANTATA trial. CANTATA is a global, randomized double-blind clinical trial of the glutaminase inhibitor telaglenastat (CB-839) combined with cabozantinib, a standard of care, in patients with advanced or metastatic renal cell carcinoma (RCC) who have received one or two prior treatments. The study is designed with registrational intent. Exelixis, Inc. is providing cabozantinib for the trial through a material supply agreement with Calithera.

"We are grateful that both clinicians and patients have expressed real interest in the CANTATA trial, enabling us to complete enrollment ahead of schedule," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "This is an important milestone in the clinical progress of telaglenastat, our novel glutaminase inhibitor. Despite the introduction of new therapies, the treatment of patients with advanced renal cell carcinoma who have progressed on initial treatments remains a critical unmet need."

The CANTATA trial (NCT03428217) is a global, randomized, double-blind trial designed to evaluate the efficacy and safety of telaglenastat in combination with cabozantinib versus placebo with cabozantinib in patients with advanced or metastatic RCC who have been treated with one or two prior lines of systemic therapy, including at least one vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor or the combination of nivolumab and ipilimumab. In April 2018, the U.S. Food and Drug Administration granted Fast Track designation to telaglenastat in this indication. The CANTATA trial enrolled 445 patients at multiple centers globally. The primary endpoint is progression-free survival by blinded independent review, and a key secondary endpoint is overall survival. Calithera plans to report top-line efficacy and safety data from the trial in the second half of 2020.

Telaglenastat is an investigational first-in-class glutaminase inhibitor specifically designed to block glutamine consumption in tumor cells. RCC tumors commonly exhibit metabolic alterations that increase their dependence on glutamine. In preclinical studies, telaglenastat produced synergistic antitumor effects when used in combination with standard-of-care RCC therapies. Earlier this year, Calithera announced that a randomized Phase 2 trial of telaglenastat plus everolimus versus everolimus plus placebo (ENTRATA) met its primary endpoint of improving progression free survival, demonstrating proof of concept for telaglenastat in patients with advanced RCC.

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 cells 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 safety, tolerability and efficacy of Calithera's product candidates, including the potential for telaglenastat to be developed in combination with therapeutics, such as everolimus or cabozantinib, the overall advancement and timing of Calithera's product candidates in clinical trials, the unmet need in the treatment of patients with advanced disease, and Calithera's plans to continue development of its product candidates. 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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