



## Calithera Biosciences Completes Patient Enrollment in Randomized Phase 2 ENTRATA Trial of Telaglenastat (CB-839) and Everolimus in Renal Cell Carcinoma

February 4, 2019

### Top line results expected in second half of 2019

SOUTH SAN FRANCISCO, Calif., Feb. 04, 2019 (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, today announced that it has completed patient enrollment in the ongoing Phase 2 ENTRATA trial. ENTRATA is a randomized clinical study of the glutaminase inhibitor CB-839 combined with everolimus versus placebo with everolimus for the treatment of advanced renal cell carcinoma (RCC). CB-839 now has the International Nonproprietary Name (INN) telaglenastat, as recommended by the World Health Organization.

"The ENTRATA trial is the first randomized trial evaluating the glutaminase inhibitor telaglenastat. There is ample evidence demonstrating the potential of glutaminase inhibition to block growth and survival of cancer cells," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "We are pleased that patient enrollment is now complete and look forward to learning more from ENTRATA about how this promising mechanism could help heavily pre-treated patients with advanced renal cancer."

The ENTRATA trial ([NCT03163667](#)) is a Phase 2 randomized, double blind trial designed to evaluate the safety and efficacy 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 a VEGFR-targeted tyrosine kinase inhibitor. The trial enrolled 69 patients at multiple centers in the United States. The primary endpoint of ENTRATA is progression-free survival (PFS). Calithera plans to report efficacy and safety data from the trial in the second half of 2019.

Telaglenastat is an investigational, novel 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.

Telaglenastat is also being investigated in the CANTATA trial, which will enroll approximately 400 patients and is designed with registrational intent. It is a global, randomized, double-blind trial designed to evaluate the safety and efficacy 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. The primary endpoint is PFS by blinded independent review, and a key secondary endpoint is overall survival.

### 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](http://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 timing of Calithera's clinical trials, the clinical and commercial potential of its product candidates, Calithera's expected cash, cash equivalents and investments and expected utilization of cash and cash investments in 2019, ability to fund its clinical programs, and Calithera's receipt of clinical data from, and milestones of, its clinical trials, including the Phase 2 ENTRATA 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 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 periodic filings with the Securities and Exchange Commission at [www.sec.gov](http://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.

**SOURCE:** Calithera Biosciences, Inc.

### CONTACT:

Jennifer McNealey

[ir@Calithera.com](mailto:ir@Calithera.com)

650-870-1071

 [Calithera\\_Logo\\_Primary\\_I](#)

Source: Calithera Biosciences, Inc.