Calithera Biosciences Announces FDA Fast Track Designation Granted to CB-839 in Combination with Cabozantinib for Treatment of Patients with Advanced Renal Cell Carcinoma

April 18, 2018

Randomized CANTATA trial open for enrollment

SOUTH SAN FRANCISCO, Calif., April 18, 2018 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CB-839 in combination with cabozantinib for the treatment of patients with metastatic renal cell carcinoma who have received one or two prior lines of therapy, including at least one vascular endothelial growth factor tyrosine kinase inhibitor or the combination of nivolumab and ipilimumab. CB-839 is a first-in-class, oral, selective, potent inhibitor of glutaminase being evaluated in the CANTATA trial. The trial is a randomized double-blind clinical study of cabozantinib in combination with CB-839 or placebo in 298 patients with clear cell renal cell carcinoma. The primary endpoint is progression free survival and the global study is open for enrollment.

“Despite a number of new therapies for the treatment of renal cell carcinoma, there remains a significant unmet need among advanced patients who have received prior treatment,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “We are pleased that CB-839 has been granted Fast Track designation, demonstrating the FDA’s commitment to facilitate the development and expedite the review of our glutaminase inhibitor as an important new therapy for patients with advanced or metastatic renal cell carcinoma who have failed prior systemic therapy.”

The FDA’s Fast Track designation is designed to facilitate the development and expedite the review of drugs and biologics, to treat serious or life threatening conditions, and to fill an unmet medical need. Specifically, Fast Track designation facilitates frequent interactions with the FDA review team, including meetings to discuss all aspects of development to support approval, and also provides the opportunity to submit sections of an NDA on a rolling basis as data become available.

About CB-839

Calithera’s lead product candidate, CB-839, is a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839’s onco-metabolism activity takes advantage of the unique metabolic requirements of tumor cells and cancer-fighting immune cells such as cytotoxic T-cells. It is currently being evaluated in Phase 2 clinical trials in multiple tumor types, in combination with standard of care agents.

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.

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 CB-839, the overall advancement of CB-839 in clinical trials, the unmet need in the treatment of patients with advanced disease, the timing of the FDA’s review of CB-839 and whether the FDA will support further development of CB-839, and Calithera’s plans to continue development of CB-839 in combination with cabozantinib for the treatment of clear cell renal cell carcinoma. 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 Annual Report on Form 10-K 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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