



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

June 7, 2017

SOUTH SAN FRANCISCO, Calif., June 07, 2017 (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 everolimus, for the treatment of patients with metastatic renal cell carcinoma who have received 2 or more prior lines of therapy. CB-839 is a first-in-class, oral, selective, potent inhibitor of glutaminase being evaluated in Phase 1/2 clinical trials for the treatment of solid tumors including renal cell carcinoma, triple negative breast cancer, non-small cell lung cancer, and melanoma.

"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 relapsed renal cell carcinoma," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "We look forward to initiating a global randomized trial of CB-839 in combination with everolimus for the treatment of renal cell carcinoma in the second half of 2017."

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 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 an inhibitor of glutaminase. CB-839 takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. It is currently being evaluated in Phase 1/2 clinical trials in combination with standard of care agents. CB-1158 is an investigational immuno-oncology metabolic checkpoint inhibitor designed to target arginase, a critical immunosuppressive enzyme responsible for T-cell suppression by myeloid-derived suppressor cells (MDSCs). 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. CB-1158 is being developed in collaboration with Incyte Corporation and is currently in a Phase I clinical trial. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit <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 development, timing and success of clinical trials for CB-839 as well as the FDA's review of CB-839. 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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