Calithera Announces First Patient Dosed in a Phase I Study of CB-1158, the First-in-Class Inhibitor of the Immuno-Oncology Target Arginase

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SOUTH SAN FRANCISCO, Calif., Sept. 15, 2016 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, today announced that the first patient has been dosed in a Phase I clinical trial assessing the safety and efficacy of CB-1158, a first-in-class arginase inhibitor for the treatment of advanced solid tumors. Arginase is an enzyme in myeloid-derived suppressor cells (MDSCs), which prevents T-cell and natural killer (NK) cell activation in tumors.

"Arginase, when released by MDSCs, plays an important role in the inhibition of T-cell and NK-cell activation and proliferation, preventing immune-mediated anti-tumor activity. For example, in many solid tumors, including lung, colorectal, esophageal, bladder, head and neck, and kidney cancer, arginase-expressing MDSCs accumulate, establishing an immunosuppressive microenvironment by blocking the ability of T-cells and NK-cells to kill cancer cells. We believe that inhibitors of arginase can promote an anti-tumor immune response and augment the activity of checkpoint inhibitors," said Susan M. Molineaux, Ph.D., founder, Chief Executive Officer and President of Calithera Biosciences. "We look forward to reporting initial clinical results with this compound in 2017."

Arginase exerts its immunosuppressive effect by depleting the amino acid arginine in the tumor microenvironment and preventing activation and proliferation of the immune system's cytotoxic T-cells and NK-cells. We believe that inhibitors of arginase activity promote an anti-tumor immune response by restoring arginine levels in the tumor and reversing this immunosuppressive metabolic checkpoint. The Phase I clinical trial will enroll patients with advanced solid tumors treated with CB-1158 as a monotherapy, as well as in combination with an anti-PD1 therapy.

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 a potent, selective, reversible and orally bioavailable 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 a first-in-class immuno-oncology metabolic checkpoint inhibitor targeting arginase, a critical immunosuppressive enzyme responsible for T-cell suppression by myeloid-derived suppressor cells. 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. 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-1158, enrollment of the combination expansion cohorts of CB-1158 and the presentation of data in 2017. 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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