Calithera Biosciences Announces FDA Acceptance of Investigational New Drug Application for CB-1158, a Novel Arginase Inhibitor Targeting an Immune Metabolic Checkpoint

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SOUTH SAN FRANCISCO, Calif., July 25, 2016 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), 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, today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Investigational New Drug (IND) application for CB-1158 for the treatment of solid tumors. CB-1158 is a first-in-class, orally available small molecule inhibitor of the enzyme arginase.

"We are pleased to be advancing the first arginase inhibitor into clinical trials. Arginase is a novel target in metabolic immuno-oncology, and these studies will allow us to assess the safety, pharmacokinetics and pharmacodynamics of this exciting new agent," said Susan M. Molineaux, Ph.D., founder, Chief Executive Officer and President of Calithera Biosciences. "CB-1158 has demonstrated significant anti-tumor activity in preclinical models, and 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 prevents activation and proliferation of the immune system's cytotoxic T-cells and natural killer (NK) cells. Inhibition of arginase activity reverses this immunosuppressive block and restores T-cell function. 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 antibody.

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.

CONTACT:Jennifer McNealey
ir@Calithera.com
650-870-1071

Primary Logo

Calithera Biosciences, Inc.