Calithera Announces First Patient Treated in Phase 1 Cohort of INCB01158 dosed in Combination with Keytruda

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SOUTH SAN FRANCISCO, Calif., Oct. 19, 2017 (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 first patient has been treated in the Phase 1 cohort of INCB01158 (also known as CB-1158) in combination with Keytruda® (pembrolizumab), an anti-PD1 immune checkpoint inhibitor. INCB01158 is a potent, selective, oral inhibitor of arginase being developed pursuant to a global collaboration and license agreement with Incyte Corporation.

"Arginase is involved in the metabolism of a key amino acid that is required for optimal anti-cancer immune function," said Susan M. Molineaux, Ph.D., founder, Chief Executive Officer and President of Calithera Biosciences. "In combination with an anti-PD1 therapy, an inhibitor of arginase may reduce immunosuppression caused by myeloid cells and broaden the reach of immuno-oncology therapies."

The Phase 1 trial (NCT02903914) is designed to evaluate the safety and recommended Phase 2 dose of INCB01158 as a monotherapy, and in combination with immune checkpoint therapy. The trial was initiated in September 2016 and is designed to enroll monotherapy expansion cohorts of patients with advanced non-small cell lung cancer, colorectal cancer and other solid tumors. The recommended Phase 2 monotherapy dose has been selected, and several cohorts of additional tumor types have been added to the trial design. Expansion cohorts of INCB01158 dosed in combination with Keytruda® are expected to enroll patients diagnosed with non-small cell lung cancer, melanoma, urothelial cell carcinoma, colorectal cancer, gastroesophageal cancer, squamous cell head and neck cancer and mesothelioma.

About Calithera
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 2 clinical trials in combination with standard of care agents. INCB01158 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. INCB01158 is being developed in a global collaboration and license agreement with Incyte Corporation and is currently in a Phase 1 clinical trial. 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 timing of Calithera's clinical trials, the clinical and commercial potential of its product candidates, including whether INCB01158 will be effective in the treatment of cancer or successfully advance through clinical studies, Calithera's ability to fund its clinical programs, and Calithera's receipt of clinical data from its clinical 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. 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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