Calithera Announces Enrollment of First Patient in CB-839 in Combination with Checkpoint Modulator

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SOUTH SAN FRANCISCO, Calif., Aug. 04, 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 enrolled in a Phase 1/2 clinical trial assessing the safety and efficacy of CB-839, a first-in-class glutaminase inhibitor, in combination with nivolumab for the treatment of renal cell carcinoma, malignant melanoma and non-small cell lung cancer.

“In preclinical models, glutaminase inhibition with CB-839 substantially increased the number of tumor regressions in combination with PD-1 and PD-L1 antibodies by overcoming a metabolic checkpoint blocking T-cell activation,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “We have demonstrated that CB-839 can safely be added to standard of care therapeutics to treat solid tumors with the potential to improve clinical outcomes, and we look forward to the results of this trial testing an immuno-oncology therapy in combination with our first-in-class glutaminase inhibitor.”

The Phase 1/2 study will assess the safety, pharmacokinetics and pharmacodynamics of CB-839 and nivolumab. The study will enroll patients with clear cell renal cell carcinoma who are either naïve to checkpoint inhibitors, or were recently treated with nivolumab without tumor response, as well as melanoma and non-small cell lung cancer patients who have received anti-PD-1 monotherapy as their most recent line of therapy without tumor response.

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-839, the ability for CB-839 to safely be added to standard of care therapeutics and improve clinical outcomes and the results of our 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 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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