Calithera to Receive $12 Million Milestone Payment From Incyte for Achievement of Pharmacokinetic and Pharmacodynamic Goals in Phase 1 Study

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SOUTH SAN FRANCISCO, Calif., March 28, 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, announced today that it has achieved pharmacokinetic and pharmacodynamic goals for CB-1158 which, under its agreement with Incyte Corporation, entitles the Company to receive a $12 million payment from Incyte.

“We are very excited to achieve this early milestone under our collaboration with Incyte as CB-1158 has demonstrated the desired pharmacologic activity in humans, with a corresponding elevation in plasma arginine levels to those achieved with efficacious doses in preclinical models of cancer. Through our collaboration with Incyte, we will continue to evaluate the role of arginase inhibition in the immuno-oncology setting with CB-1158 and we expect to present additional clinical data mid-2017,” said Susan Molineaux, President and Chief Executive Officer of Calithera Biosciences.

In January, 2017, Calithera and Incyte established a global collaboration and license agreement for the research, development and commercialization of Calithera’s first-in-class, small molecule arginase inhibitor CB-1158 in hematologic and oncology. CB-1158 is currently being studied in a monotherapy dose escalation clinical trial and also in combination with anti-PD-1 therapy. Additional studies are expected to evaluate CB-1158 in combination with other immuno-oncology agents.

**About Arginase**

Arginase is an enzyme produced by immunosuppressive myeloid cells, including myeloid-derived suppressor cells (MDSCs) and neutrophils, which prevents T-cell and natural killer (NK) cell activation in tumors. Arginase exerts its immunosuppressive effect by depleting the amino acid arginine in the tumor microenvironment which subsequently prevents activation and proliferation of the immune system’s cytotoxic T-cells and NK-cells. Inhibition of arginase activity reverses this immunosuppressive block and restores T-cell function. In preclinical models, arginase inhibition has been shown to enhance anti-tumor immunity and inhibit tumor growth.

**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 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. CB-1158 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](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 pharmacologic activity and efficacy of CB-1158, the timing of initiation of Calithera’s clinical trials, 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](http://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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