



Calithera Presents Preclinical Study Findings for CB-1158 at the 2015 AACR-NCI-EORTC International Conference

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- Potential to Combine With Anti-CTLA-4, Anti-PD-1 and Other Immuno-Oncology Therapies
- IND Filing Remains on Track for 1H2016

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2015 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, will announce preclinical data today for its lead immuno-oncology therapeutic candidate, CB-1158, at the 2015 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston, Massachusetts. CB-1158 is a first-in-class immuno-oncology metabolic checkpoint inhibitor targeting arginase, a key immunosuppressive enzyme that limits T-cell proliferation in a wide range of tumors.

"We believe that drugs targeting metabolic checkpoints have the potential to be transformational in the treatment of cancer. At Calithera, we are dedicated to researching and developing first-in-class therapies that could significantly advance the field of oncology. We have made significant progress on our CB-1158 program and remain on track to file an Investigational New Drug application (IND) in the first half of 2016," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera.

Preclinical data will be presented in a poster titled, "CB-1158 Inhibits the Immuno-Oncology Target Arginase and Causes an Immune Mediated Anti-Tumor Response," (Abstract #A195). CB-1158, a highly selective, orally bioavailable, small molecule inhibitor of human arginase with nanomolar potency, demonstrated single agent efficacy in animal models. Inhibition of tumor growth was accompanied by a rapid increase in the local concentration of arginine, and the induction of multiple pro-inflammatory changes in the tumor microenvironment. CB-1158, when administered with anti-CTLA-4, increased CD8+ T-cell infiltrates in the tumor. The addition of CB-1158 to anti-CTLA-4 and anti-PD-1, significantly inhibited tumor growth in a mouse model that was resistant to dual checkpoint inhibitor therapy. CB-1158 was well tolerated as a single agent and in combination with checkpoint inhibitors in animal studies.

Arginase is a critical immunosuppressive enzyme responsible for T-cell suppression. 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. Arginase inhibitors can restore arginine levels and reverse this immunosuppressive effect of myeloid-derived suppressor cells (MDSCs). Myeloid cells are present in many human tumors and are correlated with poor prognosis. CB-1158 has the potential for anti-tumor activity in renal cell cancer, breast cancer, non-small cell lung cancer, acute myeloid leukemia, and other tumor types where arginase-secreting MDSCs are known to play an immunosuppressive role.

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 currently being evaluated in three Phase 1 clinical trials in solid and hematological cancers. 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

This news release contains forward-looking statements by Calithera that involve risks and uncertainties. These statements include those related to the potential for CB-1158 to inhibit arginase, induce anti-cancer activity and combine with other immuno-oncology therapies that target T-cell activation, the timing of Calithera's submission of an IND application to the FDA for its oral arginase inhibitor and the potential for drugs targeting metabolism pathways of immune cells to be transformational in the treatment of cancer. Actual results may differ from Calithera's expectations and important factors that could cause actual results to differ materially. Calithera's arginase program or other 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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