Calithera Presents Novel Pharmacodynamic Assay Data Confirming Glutaminase Inhibition in Tumor Biopsy Samples From Patients Treated With CB-839

December 10, 2014

SOUTH SAN FRANCISCO, Calif., Dec. 10, 2014 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer agents, today announced results of studies with primary human breast tumors that support glutaminase as a potential target in triple negative breast cancer (TNBC). Using a novel pharmacodynamic assay designed to measure the extent of glutaminase inhibition in a single post-dose tumor biopsy sample, significant glutaminase inhibition was observed following oral administration of CB-839. These data were presented during the San Antonio Breast Cancer Symposium in San Antonio, Texas. Calithera is developing CB-839, a potent, selective and orally bioavailable glutaminase inhibitor that is currently in Phase I clinical trials in solid and hematological malignancies.

"Our development of a novel pharmacological assay allows us to directly assess glutaminase inhibition in patients receiving CB-839 from just a single post-dose tumor biopsy, allowing us to get confirmation that CB-839 is reaching the tumor and inhibiting the target," said Susan Molineaux, Ph.D., President and Chief Executive Officer of Calithera.

The data were presented in a poster titled, "A Novel Pharmacodynamic Assay to Measure Glutaminase Inhibition Following Oral Administration of CB-839 in Triple Negative Breast Cancer Biopsies," on December 10, 2014 (Abstract #P1-08-07). Potent glutaminase inhibition by CB-839 was demonstrated in primary TNBC tumor lysates as well as in tumors from a TNBC xenograft model. In addition, glutaminase inhibition of 75-84% was observed in tumor biopsy samples from three solid tumor patients enrolled in early dose cohorts of the ongoing phase I clinical trial.

Additional data showed that glutaminase mRNA expression, protein expression, and enzyme activity are all elevated in human TNBC tumors when compared to ER+ breast cancer tumors, or normal breast tissue. In breast cancer cell lines, expression of glutaminase is a biomarker that predicts sensitivity to CB-839.

Two posters will be presented by Calithera's collaborators. Details for the presentations are as follows:

Signaling consequences and rational therapeutic combinations with glutaminase inhibitor, CB-839, in basal breast cancer

Abstract # P1-08-01

Jennifer Dennison, Ph,D., MD Anderson

Poster Session 1

Wednesday December 10, 2014, 5:00-7:00 PM

Halls A-B, Henry B. Gonzalez Convention Center

Glutamine metabolism promotes survival through the unfolded protein response in endocrine resistant breast cancer

Abstract # P3-05-11

Ayesha Shajahan-Haq, Ph.D., Georgetown University

Poster Session 3

Thursday, December 11, 2014 at 5:00-7:00 PM

Halls A-B, Henry B. Gonzalez Convention Center

About Calithera Biosciences

Calithera Biosciences is a clinical-stage company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology. Calithera's lead clinical candidate, CB-839, is a first-in-class inhibitor of glutaminase, a critical enzyme in tumor metabolism, and is currently being tested in patients with solid and hematological cancers. Calithera Biosciences is headquartered in South San Francisco. For more information about Calithera Biosciences, please visit www.calithera.com.

Forward-Looking Statements

This news release contains forward-looking statements by Calithera that involve risks and uncertainties. Actual results may differ from Calithera's expectations and important factors that could cause actual results to differ materially. Calithera's product candidates may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, future clinical trials may not show significant glutaminase inhibition following oral administration of CB-839. Furthermore, Calithera's 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 Quarterly Report on Form 10-Q for the period ended September 30, 2014 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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Calithera Biosciences

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