Calithera Reports Initial Phase I Data for CB-839 in Patients with Acute Leukemias

May 21, 2015

SOUTH SAN FRANCISCO, Calif., May 21, 2015 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, today announced that data from its lead, first-in-class program CB-839 will be presented at the 20th Congress of the European Hematology Association (EHA) June 11-15, 2015, in Vienna, Austria. These preliminary data demonstrate the clinical activity, tolerability and unique mechanism of action of CB-839 in patients with acute leukemia.

"We are very encouraged by these early clinical data," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "While the primary objectives of this study are to determine the safety and tolerability of CB-839, we were also able to demonstrate promising clinical activity including a complete response in the bone marrow, with incomplete recovery of peripheral counts (CRi) in one patient."

As of March 1, 2015, fifteen patients with acute myeloid leukemia (AML) had been treated in Calithera's Phase I clinical trial of CB-839 in patients with relapsed or refractory acute leukemias. Oral CB-839 was administered continuously in 21-day treatment cycles from 100 to 1000 mg three times daily. There were no dose limiting toxicities identified. Treatment-related adverse events of any grade that occurred in >10% of patients were limited to increases in transaminases (4 patients) and bilirubin (2 patients). There were no Grade ?3 adverse events that were considered treatment-related in >10% of patients. Stable disease for 4-10 cycles was observed in 5 (33%) of 15 efficacy-evaluable AML patients across all dose levels, with patients remaining on study for an average of 134 days (>6 cycles). One of these patients achieved a complete response in the bone marrow with incomplete recovery of peripheral counts (CRi) after 6 cycles of dosing. All of the patients with stable disease or better were over 65 years of age, and not eligible for high dose therapy.

Updated data will be presented at the meeting in a poster titled, "Phase I Study: Safety and Tolerability of Increasing Doses of CB-839, an Orally Administered Small Molecule Inhibitor of Glutaminase, in Acute Leukemia," by lead author Marina Y. Konopleva from the MD Anderson Cancer Center from 9:30 a.m. CEST Friday, June 12, 2015, to 6:45 p.m. CEST Saturday, June 13, 2015 (Abstract #E947). The abstract can be found at the EHA website www.ehaweb.org.

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

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 clinical activity, tolerability and unique mechanism of action of CB-839. 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 filed with the Securities and Exchange Commission on May 11, 2015, 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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