



## Calithera Biosciences Reports Phase I Data for CB-839 in Patients With Acute Leukemias at the 20th Congress of the European Hematology Association

June 11, 2015

*Promising Clinical Activity With Early Signs of Biologic Activity, Tolerability, and Durability*

*Clinical Response Reported With Single Agent CRi in AML*

SOUTH SAN FRANCISCO, Calif., June 11, 2015 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, announced that data from its lead, first-in-class glutaminase inhibitor CB-839 was presented today at the 20<sup>th</sup> Congress of the European Hematology Association (EHA), in Vienna, Austria. The data demonstrated the clinical activity, tolerability and unique mechanism of action of CB-839 in patients with acute leukemia. The poster presented today contained additional data relative to the abstract published in May, including baseline patient characteristics, pharmacokinetics, pharmacodynamics, and updated safety and efficacy results.

"We remain 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 IDH2 mutant patient who has remained on monotherapy for over 10 months."

As of April 15, 2015, eighteen acute leukemia patients, including sixteen with acute myeloid leukemia (AML), had been treated in Calithera's Phase I clinical trial of CB-839 in patients with acute leukemias. This represents an update from the abstract originally published May 21, 2015 which was based on data as of March 1, 2015. All patients were relapsed and/or refractory, with 67% of patients treated with 2 or more prior therapies, and 22% of patients treated with prior allogeneic transplant. The mean age was 75 years. Oral CB-839 was administered continuously in 21-day treatment cycles from 100 to 1000 mg three times daily (n=16) or twice daily (n=2). The sixteen AML patients included one IDH1 mutant and two IDH2 mutant AML patients.

There were no dose limiting toxicities identified. Grade 3 drug related events occurred in 16.7% (3/18) patients. No patients discontinued due to an adverse event. One patient achieved a complete response in the bone marrow with incomplete recovery of peripheral counts (CRi). In this patient, bone marrow blast counts steadily declined from a baseline count of 16% to less than 5% over the course of 8 cycles; the patient remains on therapy (316 days). Five of 18 efficacy-evaluable patients across dose levels remained on therapy for at least 4 cycles (12 weeks), and up to 14+ cycles (>10 months).

An additional recently enrolled patient achieved a rapid reduction in peripheral blasts from 30% at baseline to 3% on Day 20. As further indication of biological activity, peripheral blasts rose to 13% over two days upon discontinuation of CB-839 due to central nervous system disease progression. This patient was reported in the poster subsequent to the most recent safety data cut off.

In a preclinical study, CB-839 had anti-tumor activity in an AML cell line that was enhanced by addition of azacitidine (Vidaza), a standard of care therapy in the treatment of AML in elderly patients. A cohort of AML patients will be added to the clinical study utilizing this combination.

The data was 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 (Abstract #E947).

### **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](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 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](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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