Calithera Biosciences Reports Phase I Data for CB-839 in Patients With Hematological Malignancies at the 57th American Society of Hematology Annual Meeting

December 6, 2015

First results of CB-839 dosed in combination therapy

Promising clinical activity with early signs of biologic activity, tolerability, and durability

SOUTH SAN FRANCISCO, Calif., Dec. 06, 2015 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, announced that clinical and preclinical data from its lead product candidate CB-839, a first-in-class glutaminase inhibitor was presented today at the 57th American Society of Hematology Annual Meeting (ASH), in Orlando, Florida. The data demonstrated the clinical activity, tolerability and unique mechanism of action of CB-839 in patients with acute myeloid leukemia (AML) and multiple myeloma.

“We are encouraged by the promising clinical activity of CB-839 as a single agent in AML, and early tolerability and preliminary signals of efficacy in combination therapy in multiple myeloma,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “We are actively enrolling six combination expansion cohorts of CB-839 in solid and hematological malignancies and look forward to presenting additional combination data in 2016.”

CB-839 in Multiple Myeloma

Dr. Dan Vogl from the University of Pennsylvania presented a poster titled, “Phase I study of CB-839, a first in class glutaminase inhibitor in patients with multiple myeloma and lymphoma,” (Abstract #3059). As of November 9, 2015, 23 multiple myeloma patients had been treated, including 14 treated with CB-839 as a monotherapy, and nine patients treated in combination with either dexamethasone (n=5) or pomalidomide and dexamethasone (n=4). The majority of patients had received at least four prior lines of therapy. In the monotherapy cohort, the best response was stable disease, which was reported in seven patients, including one patient who has remained on study for over seven months. The first patient to receive the CB-839 plus pomalidomide and dexamethasone combination has had a clinically significant reduction in myeloma markers, including urine M-protein and serum free light chain. Three of 14 (21%) monotherapy patients experienced Grade 3 events suspected to be related to CB-839, and one dose limiting toxicity (DLT) of Grade 4 neutropenia deemed possibly related to CB-839 occurred in the pomalidomide and dexamethasone combination group. No patients discontinued due to adverse events.

CB-839 in Acute Myeloid Leukemia

Dr. Eunice Wang from Roswell Park Cancer Institute presented a poster titled, “Phase I study of CB-839, a first in class, orally administered small molecule inhibitor of glutaminase in patients with relapsed/refractory leukemia,” (Abstract #2566). As of November 9, 2015, 26 acute leukemia patients had been treated including 24 with AML. This represents an update from the data presented June 11, 2015 at the European Hematology Association. All patients were relapsed and/or refractory, with 61% of patients treated with two or more prior therapies, and 23% of patients treated with prior allogeneic transplant. The mean age of patients 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=10). The 24 AML patients included two IDH1 and three IDH2 mutant AML patients. One patient achieved a complete response in the bone marrow with incomplete recovery of peripheral counts (CRi) and remains on therapy over 16 months. Five of 26 efficacy-evaluable patients across dose levels remained on therapy for at least 4 cycles (12 weeks), and up to 23+ cycles (>16 months). There were no DLTs identified and no patients discontinued due to adverse events.

In addition, Calithera and their collaborators presented two preclinical posters that provide the rationale for use of biomarkers of CB-839 in multiple myeloma, and elucidate the role of glutamine in AML. Details for the presentations are as follows:

Metabolomic, Proteomic and Genomic Profiling Identifies Biomarkers of Sensitivity to Glutaminase

Abstract: #1802

Andrew L. MacKinnon, Ph.D., Calithera Biosciences

Role of Glutamine in Metabolic and Epigenetic Reprogramming in AML

Abstract: #2559

Juliana Velez Lujan, Ph.D., University of Texas MD Anderson Cancer Center

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

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 tolerability and efficacy of CB-839, enrollment of the combination expansion cohorts of CB-839 and the presentation of additional combination data in 2016. 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 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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