Calithera Biosciences Reports CANTATA Study of Telaglenastat in Renal Cell Carcinoma Did Not Achieve Primary Endpoint

January 4, 2021

-- Company will continue to advance telaglenastat KEAPSAKE trial in non-small cell lung cancer, arginase inhibitor CB-280 trial in cystic fibrosis and emerging pipeline

-- Company to host webcast and conference call today at 8:30 a.m. ET / 5:30 a.m. PT

SOUTH SAN FRANCISCO, Calif., Jan. 04, 2021 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage biotechnology company focused on discovering and developing novel small-molecule drugs for the treatment of cancer and other life-threatening diseases, today announced topline results from the CANTATA clinical study of the company's glutaminase inhibitor telaglenastat in patients with advanced or metastatic renal cell carcinoma (RCC). As compared to treatment with cabozantinib, the combination of telaglenastat and cabozantinib did not meet the primary endpoint of improving progression free survival (PFS) in the study population.

The primary study endpoint is PFS by blinded independent review. The hazard ratio was 0.94 (p=0.65). Median PFS was 9.2 months among patients treated with telaglenastat and cabozantinib as compared to 9.3 months with cabozantinib and placebo. Sixty-two percent of patients were treated with prior PD(L)-1 containing therapy, and the arms were well balanced. The frequency and severity of adverse events in the telaglenastat-treated population were comparable to that of cabozantinib alone.

"We are disappointed that the CANTATA trial did not achieve its primary endpoint, particularly on behalf of the people living with advanced RCC, many of whom could benefit from additional treatment options with novel mechanisms of action to address this difficult-to-treat disease," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "Based on the strong scientific rationale for telaglenastat in KEAP1/NRF2 mutant non-small cell lung cancer patients, and the safety profile observed in CANTATA, we remain dedicated to advancing our randomized KEAPSAKE trial."

Calithera will focus its financial resources on the ongoing KEAPSAKE trial, the ongoing trial of the arginase inhibitor CB-280 in cystic fibrosis patients and pipeline programs. As a result of the outcome of CANTATA, Calithera will reduce its workforce by approximately 35 percent to allow the company to focus on ongoing programs.

Calithera expects cash, cash equivalents and investments to be approximately $115 million at December 31, 2020 based on preliminary estimates, which management believes will be sufficient to meet its current operating plan through 2022, including the release of interim results of the KEAPSAKE trial and completion of the current cystic fibrosis study in 2021. Calithera anticipates the one-time severance-related charge associated with the workforce reduction to be approximately $1.3 million - $1.5 million, with the majority to be completed by the first quarter of 2021. More financial details will be provided by the company in its fourth quarter 2020 financial report in March 2021.

The information relating to cash, cash equivalents and investments is preliminary, has not been audited and is subject to change upon completion of the audit of Calithera's financial statements as of and for the year ended December 31, 2020.

The CANTATA trial (NCT03428217) is a global, randomized, double-blind trial designed to evaluate the efficacy and safety of telaglenastat in combination with cabozantinib versus placebo with cabozantinib in patients with advanced or metastatic RCC who have been treated with one or two prior lines of systemic therapy, including at least one vascular endothelial growth factor (VEGF)-pathway targeted anti-angiogenic therapy or the combination of nivolumab and ipilimumab. The CANTATA trial enrolled 444 patients at multiple centers globally. Exelixis, Inc. provided cabozantinib for the trial through a material supply agreement with Calithera.

Calithera will submit the CANTATA results for presentation at a medical meeting.

Webcast and Conference Call Information

Calithera will hold a webcast today, Monday, January 4, at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time. To access the link to the webcast, which will be broadcast live in listen-only mode, or the subsequent archived recording, visit the Investors section of the Calithera website at www.calithera.com. Alternatively, the call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4787 (international) and referring to conference ID 5824089. The webcast will be recorded and available for replay on Calithera's website for 30 days.

About Telaglenastat

Telaglenastat (CB-839) is an investigational, first-in-class, novel glutaminase inhibitor specifically designed to block glutamine consumption in tumor cells. While normal cells use glucose to meet cellular energy demands, tumor cells have a unique oncometabolism that increases their dependence on glutamine to fuel growth and survival. Calithera is conducting the randomized Phase 2 KEAPSAKE trial to evaluate telaglenastat in patients with advanced non-small cell lung cancer harboring KEAP1/NRF2 mutations.

About Calithera

Calithera Biosciences is a clinical-stage biopharmaceutical company pioneering the discovery and development of targeted therapies that disrupt cellular metabolic pathways to preferentially block tumor cells and enhance immune-cell activity. Driven by a commitment to rigorous science and a passion for improving the lives of people impacted by cancer and other life-threatening diseases, Calithera is advancing a pipeline of first-in-clinic, oral therapeutics to meaningfully expand treatment options available to patients. 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 overall advancement and timing of telaglenastat in clinical trials, including the randomized Phase 2 KEAPSAKE trial in patients with KEAP1/NRF2 mutations; the ongoing trial of the arginase inhibitor CB-280; the timing of regulatory submissions; our expectations regarding our cash position as of December 31, 2020; and our estimated cash expenditures associated with termination benefits and severance-related charges. 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 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.

SOURCE: Calithera Biosciences, Inc.

CONTACTS:

Investor Relations
Jennifer McNealey
Calithera
ir@Calithera.com
650-870-1071

Media
Michele Parisi
Sam Brown, Inc.
micheleparisi@sambrown.com
925-864-5028

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