



## Initial Results from Phase 2 Study of CB-839 in Combination with Opdivo® (nivolumab) to be Presented at the Society for Immunotherapy of Cancer Meeting

November 7, 2017

*Achieved confirmed responses in melanoma patients progressing on PD-1/PD-L1 therapy*

*Expanding Bristol-Myers Squibb clinical collaboration*

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2017 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), 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 today announced that initial data from the ongoing trial of CB-839 in combination with Opdivo® in patients with melanoma, renal cell carcinoma and non-small cell lung cancer will be presented Saturday, November 11<sup>th</sup>, 2017, at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. Calithera also announced it has expanded its existing clinical collaboration with Bristol-Myers Squibb, evaluating CB-839 in combination with Opdivo®. CB-839 is an orally bioavailable glutaminase inhibitor currently in Phase 2 trials, and Opdivo® is a PD-1 immune checkpoint inhibitor designed to overcome immune suppression.

"This trial is designed to include patients who are currently receiving checkpoint inhibitor therapy and experiencing disease progression at the time of enrollment. There is significant unmet need among these patients, and the responses observed would not be expected with treatment with Opdivo® alone in this population," said Susan M. Molineaux, Ph.D., founder, Chief Executive Officer and President of Calithera Biosciences. "The expanded clinical collaboration with Bristol-Myers Squibb will help us pursue our strategy of developing CB-839 in combination with Opdivo® with the hope of improving treatment options for patients with cancer."

Calithera is conducting a Phase 1/2 trial (NCT02771626) in collaboration with Bristol-Myers Squibb designed to evaluate the safety, tolerability and efficacy of CB-839 in combination with Opdivo® in patients with renal cell carcinoma, melanoma or non-small cell lung cancer. The study will be expanded to enroll additional melanoma patients. As part of the expanded collaboration, melanoma development costs will be shared, and a joint development committee will be established to guide the development and regulatory strategy.

The ongoing study enrolled three cohorts of patients who have received a checkpoint inhibitor (PD-1/PD-L1) in the most recent line of therapy.

- Among 16 evaluable melanoma patients, all of whom were progressing on a checkpoint inhibitor at study entry, one patient achieved a complete response and two patients achieved partial responses. The overall response rate in this cohort was 19%, and the overall disease control rate was 44%.
- Among six evaluable non-small cell lung cancer patients, all of whom were progressing on a checkpoint inhibitor at study entry, 67% experienced stable disease.
- Among eight evaluable renal cell carcinoma patients, 75% were progressing and 25% had stable disease at study entry. Stable disease was achieved in 75%, all of whom were progressing on a checkpoint inhibitor at study entry.

The study enrolled one cohort of renal cell carcinoma patients who have received a checkpoint inhibitor in any prior line of therapy, but never achieved a response to checkpoint therapy.

- Among seven evaluable checkpoint inhibitor experienced renal cell carcinoma patients, with a median of four prior lines of therapy, 57% experienced stable disease.

The study enrolled one cohort of renal cell carcinoma patients who were previously treated with VEGF inhibiting therapy, and were naïve to checkpoint inhibitors.

- Among 19 evaluable checkpoint inhibitor naïve renal cell carcinoma patients, four patients (21%) achieved a partial response and disease control rate was 74%. Fifty percent of the enrolled patients remain on study treatment.

An analysis of all safety evaluable patients demonstrated that CB-839 was well tolerated when combined with Opdivo® in melanoma, renal cell carcinoma and non-small cell lung cancer patients. During dose escalation of the combination therapy, there was one report of dose limiting Grade 3 ALT increase, however no maximum tolerated dose was reported. The majority of adverse events reported have been mild to moderate with the most common being fatigue, nausea and photophobia. With 3.7% immune-related adverse events Grade  $\geq$  3, the data suggest there was no apparent increase in the rate or severity of immune related events compared to historical rates.

Dr. Funda Meric-Bernstam from MD Anderson Cancer Center will present the results on Saturday, November 11, 2017, in an oral and poster session (Abstract #O16), "A phase 1/2 study of CB-839, a first-in-class glutaminase inhibitor, combined with nivolumab in patients with advanced melanoma, renal cell carcinoma or non-small cell lung cancer." The oral presentation slides and the poster will be available on the Company's website in the publication section at <https://www.calithera.com/publications>.

Calithera will webcast a clinical update on CB-839 on Saturday, November 11th at 3:30 p.m. Pacific Time/ 6:30 p.m. Eastern Time. The call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and referring to conference ID 1878409. To access the live audio webcast or the subsequent archived recording, visit the Investors section of the Calithera website at [www.calithera.com](http://www.calithera.com). The webcast will be recorded and available for replay on Calithera's website for 30 days.

**About CB-839**

Calithera's lead product candidate, CB-839, is a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839's onco-metabolism activity takes advantage of the unique metabolic requirements of tumor cells and cancer-fighting immune cells such as cytotoxic T-cells. It is currently being evaluated in Phase 2 clinical trials in multiple tumor types, in combination with standard of care agents.

**About Calithera**

Calithera is a clinical-stage biopharmaceutical company focused on fighting cancer by discovering, developing, and commercializing novel small molecule drugs that target tumor and immune cell metabolism. Calithera is headquartered in South San Francisco, California. For more information about Calithera, 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 safety, tolerability and efficacy of CB-839, Calithera's plans to continue development of CB-839 in combination therapy for clear cell renal cell carcinoma, the potential for combining nivolumab (marketed as Opdivo®) with CB-839 to drive improved and sustained efficacy in clear cell renal cell carcinoma and other cancers, including NSCLC and melanoma, and the advancement of CB-839 in clinical trials. 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission, 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.*

**Contact:**

Jennifer McNealey  
[ir@Calithera.com](mailto:ir@Calithera.com)  
650-870-1071

Source: Calithera Biosciences, Inc.