Calithera Biosciences Highlights Breadth of Innovative Pipeline at R&D Day

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-Updated response rate of 50% in advanced renal carcinoma treated with CB-839 + cabozantinib
-CB-839 clinical trial collaboration with Pfizer
-Presentation of INCB001158 data expected in 1H2019
-R&D day hosted today in New York from 8:00 a.m. -10:15 a.m. ET, live webcast available

SOUTH SAN FRANCISCO, Calif., Oct. 05, 2018 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage pharmaceutical company focused on discovering and developing small molecule drugs that target novel and critical metabolic pathways in tumor and cancer-fighting immune cells, will provide an update on the company's growing research pipeline of novel therapies in oncology and cystic fibrosis during an R&D day hosted today in New York City.

Calithera management, including Susan Molineaux, PhD, President and Chief Executive Officer and Keith Orford, MD, PhD, Senior Vice President of Clinical Development will discuss progress on Calithera's clinical and emerging programs. Nizar Tannir, MD, Deputy Department Chair, Department of Genitourinary Medical Oncology, Division of Cancer Medicine, University of Texas MD Anderson Cancer Center will discuss the advanced renal cell carcinoma treatment landscape.

"R&D Day is an opportunity to provide additional insight into our clinical development programs, delineate key milestones, and highlight our innovative pipeline," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "In 2019, we plan to report data from our Phase 2 ENTRATA study in renal cell carcinoma. In addition, we and our partner Incyte expect data on INCB001158 to be presented at a medical meeting in the first half of 2019."

Pipeline Highlights

During R&D Day, Calithera will discuss its clinical development pipeline of innovative therapies including:

- **Two Randomized Phase 2 Combination Trials of CB-839 for the Treatment of Patients with Renal Cell Carcinoma.** The ENTRATA trial, a randomized double-blind placebo-controlled study of late line patients, will enroll approximately 66 patients to receive either everolimus and CB-839 or everolimus alone. Topline results are expected in 2019. CANTATA is a randomized, global, double-blind, placebo-controlled trial comparing patients treated with cabozantinib and CB-839 to patients treated with cabozantinib alone. This trial will enroll approximately 300 clear cell renal cell carcinoma patients who have previously received one or two prior lines of therapy. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for CB-839 in combination with cabozantinib for the treatment of this patient population.
- **CB-839 Phase 1b Cabozantinib Combination Data in Patients with Advanced Renal Cell Carcinoma**. Updated results of CB-839 in combination with cabozantinib will be presented. In the Phase 1b trial, 12 advanced renal cell carcinoma patients, including 10 clear cell and two papillary patients, were treated with CB-839 plus cabozantinib and were evaluable for response. Patients enrolled in the trial have advanced or metastatic disease and had received a median of three prior treatments, which included tyrosine kinase inhibitors, mTOR inhibitors, and checkpoint inhibitors. One hundred percent of evaluable patients experienced tumor shrinkage and disease control, including five patients who had a partial response and seven patients who had stable disease. In the clear cell patient population, the disease control rate was 100% and the response rate was 50%.
- **Pfizer collaboration to develop CB-839 in combination with PARP inhibitors and CDK4/6 inhibitors.** As part of a clinical collaboration with Pfizer announced today, Calithera will initiate Phase 1/2 clinical studies in the first quarter of 2019. Preclinical data suggest that CB-839 synergizes with CDK4/6 inhibitors by enhancing cell cycle arrest and blocking cancer cell proliferation. CB-839 also synergizes with PARP inhibitors to impair DNA synthesis, enhance DNA damage, and block cancer cell proliferation.
- **INCB001158 Arginase Inhibitor Immuno-oncology Program.** INCB001158 is being evaluated in multiple clinical trials for the treatment of patients with solid tumors both as a monotherapy, and in combination with immunotherapies and chemotherapy. INCB001158 is being developed as part of a collaboration and license agreement with Incyte. Data from INCB001158 is expected to be presented at a medical meeting in the first half of 2019.
- **CB-280 Arginase Inhibitor for the Treatment of Cystic Fibrosis.** Arginase is believed to be critical in the pathology of cystic fibrosis. It impairs production of nitric oxide and generates metabolites of arginine that may impair lung function. CB-280 is an orally administered small molecule inhibitor of arginase. An investigational new drug (IND) application for CB-280 with the U.S. FDA is planned for the first half of 2019.
- **CB-708 Oral Small Molecule CD73 Inhibitor.** The immuno-oncology target CD73 is an enzyme that plays a critical role in the process of ATP conversion to adenosine. An IND application for CB-708, an orally administered small molecule inhibitor of CD73, is planned for 2019.

Webcast Information

Calithera will host R&D Day today from 8:00 a.m. - 10:15 a.m. ET in New York, NY. For those not able to attend, a live webcast that will include audio and slides of the presentation can be accessed through the Investors section of the Company's website at www.calithera.com. Following the live presentations, a replay of the webcast will be available on the company's website for at least 90 days.

About Calithera

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 product candidate, CB-839, is a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839 takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. It is currently being evaluated in randomized clinical trials for the treatment of patients with renal cell carcinoma. INCB-001158 is an 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. INCB-001158 is being developed in collaboration with Incyte Corporation. 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 advancement of Calithera's programs toward key milestones; Calithera's product pipeline; timing and enrollment of Calithera's clinical trials, including the ENTRATA trial; and Calithera's and Incyte's receipt and presentation of clinical data from their clinical trials; the expansion of development of CB-839 in combination with PARP inhibitors and CDK4/6 inhibitors and the results of those combinations; the filing of an IND application for CB-280 with the U.S. FDA; clinical and commercial potential of its product candidates; and Calithera's ability to fund its clinical programs. 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 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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