



Calithera Biosciences Provides Overview of 2020 Corporate Milestones and Financial Guidance

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SOUTH SAN FRANCISCO, Calif., Jan. 13, 2020 (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, provided today an overview of select expected fourth quarter 2019 financial results, initial 2020 financial guidance and upcoming corporate milestones.

"We anticipate that 2020 will be an exciting year for Calithera, building on the substantial progress we made in 2019 and the potential for several significant clinical and regulatory milestones," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "We remain in a strong financial position to advance our key clinical programs and robust pipeline this year, and we are pleased with our strong cash balance at the end of 2019."

2020 Milestones

Calithera expects to achieve the following milestones in 2020:

- **Announce topline data from randomized CANTATA trial of telaglenastat with cabozantinib in advanced renal cell carcinoma (RCC).** The CANTATA trial is a global, randomized, double-blind clinical trial of telaglenastat combined with cabozantinib, in patients with advanced or metastatic RCC who have received one or two prior treatments. The CANTATA trial enrolled 445 patients at multiple centers globally. The primary endpoint is progression-free survival. Calithera plans to report top-line efficacy and safety data from the trial in the second half of 2020.
- **Initiate Phase 2 trial of telaglenastat in non-small cell lung cancer (NSCLC) patients with genetic mutation NRF2/KEAP1.** The NRF2/KEAP1 pathway is known to drive the development of certain cancers, including a significant proportion of NSCLC through the regulation of reactive oxygen species in a manner that is dependent upon glutaminase activity. Recently presented clinical data demonstrate that activation of this pathway, either through the loss of KEAP1 function or activation of NRF2, results in very poor outcomes in NSCLC patients. The clear mechanistic rationale, strong preclinical data, and high unmet medical need in the NSCLC population have led Calithera to design a clinical study that will evaluate telaglenastat in combination with chemo-immunotherapy in first line NSCLC patients with tumors that harbor mutations in either KEAP1 or NRF2 that activate this pathway. This trial is expected to begin in the first half of 2020.
- **Enroll telaglenastat (CB-839) combination trials in collaboration with Pfizer.** Calithera and Pfizer have two clinical trial collaborations to evaluate Pfizer's CDK4/6 inhibitor palbociclib, also known as IBRANCE[®], and the dual-mechanism poly (ADP-ribose) polymerase (PARP) inhibitor talazoparib, also known as TALZENNA[®], each in combination with glutaminase inhibitor telaglenastat.
- **Continue enrollment of multiple clinical trials evaluating Calithera's arginase inhibitor INCB001158.** INCB001158 is a small-molecule immuno-oncology therapeutic being evaluated in multiple clinical trials as a single-agent and in combination with immunotherapies and chemotherapy for the treatment of patients with cancer. INCB001158 is being developed as part of a collaboration and license agreement with Incyte.
- **Enroll clinical dose escalation trial evaluating CB-280, an oral arginase inhibitor, in cystic fibrosis (CF).** 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. A Phase 1b clinical study in people with CF, which is expected to start enrollment in the first half of 2020, will test multiple doses of CB-280 compared to placebo in approximately 30 adults with CF to determine a safe dose range, and pharmacodynamics effects of arginase inhibition in this population. Patients with any CF transmembrane conductance regulator mutational status will be eligible for the study.

Select Expected Fourth Quarter 2019 Financial Results and Financial Guidance for 2020

Based upon preliminary estimates, cash, cash equivalents and investments totaled \$157.4 million at December 31, 2019. Calithera expects to utilize cash and investments between \$75 and \$85 million in 2020. 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, 2019.

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 Calithera's expected operating results as of December 31, 2019, including cash, cash equivalents and investments, the announcement of topline data in Calithera's CANTATA trial, the advancement of clinical programs in 2020, the safety, tolerability and efficacy of Calithera's product candidates, the overall advancement of Calithera's product candidates in clinical trials, the unmet need in the treatment of patients with advanced disease, and Calithera's plans to continue development of its product candidates. 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.

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