



Calithera Biosciences Provides Update on Business Operations

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SOUTH SAN FRANCISCO, April 14, 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, shared an update on business operations, including clinical program adjustments related to COVID-19.

"Our first priority during the COVID-19 pandemic is the health of our employees, as well as patients and medical professionals involved in our clinical programs. We are continuing all clinical operations, with additional COVID-19 related safety measures in place. Given the fluid nature of the current situation, and the impact of the pandemic on clinical sites globally, we are delaying the start of enrollment of patients in our two new clinical trials, while we work towards accelerating the opening of sites," said Susan Molineaux, president and chief executive officer of Calithera. "We believe we are on track to announce top-line CANTATA results this year, and we are narrowing the timeframe to the fourth quarter of 2020."

Clinical programs update:

Randomized CANTATA trial of telaglenastat and cabozantinib in advanced renal cell carcinoma. The CANTATA trial was fully enrolled in October 2019 and Calithera advised at that time that the company planned to report top-line efficacy and safety data from the trial in the second half of 2020, and more recently guided towards late third quarter or fourth quarter of 2020. In light of COVID-19, Calithera now expects top-line data in the fourth quarter of 2020. Calithera has made accommodations to facilitate study conduct during the pandemic, including allowing patients to have scans performed at local clinical centers to facilitate compliance with the study schedule of assessments, and to receive a larger allocation of study drug in order to reduce the number of visits required to the clinical site, if necessary. While affirming that the readout is expected by the end of 2020, the updated guidance allows for additional time for activities that require visits to clinical sites, including data monitoring.

Randomized KEAPSAKE trial in non-small cell lung cancer (NSCLC) patients with genetic mutation NRF2/KEAP1. The randomized Phase 2 trial of telaglenastat for the treatment of lung cancer continues to progress towards multiple site openings. However, given the challenges associated with opening new clinical studies during the current stage of the COVID-19 pandemic, Calithera expects to delay enrollment of the first patient until the third quarter of 2020, pending further developments in the COVID-19 situation. Calithera plans to present interim data from this trial in 2021.

Pfizer clinical collaboration with the CDK4/6 inhibitor IBRANCE®, and the dual-mechanism poly (ADP-ribose) polymerase (PARP) inhibitor TALZENNA®, each in combination with telaglenastat. In March 2019, the company initiated a Phase 1/2 trial of the combination of telaglenastat plus Talzenna in patients with renal cell carcinoma and triple negative breast cancer. In July 2019, the company initiated a Phase 1/2 trial of the combination of telaglenastat plus Ibrance in patients with KRAS mutated colorectal cancer and KRAS mutated non-small cell lung cancer. Dose escalation has been completed for both trials. Dose expansion cohorts have been temporarily paused due to the COVID-19 situation. Calithera expects enrollment to resume in the third quarter of 2020.

INCB001158 program. INCB001158, an internally discovered molecule, is being evaluated in multiple clinical trials for the treatment of patients with solid tumors both as a monotherapy, in combination with anti-PD-1 immunotherapy, and in multiple chemotherapy regimens. INCB001158 is being developed as part of a collaboration and license agreement with Incyte. Calithera has filed a complaint against Incyte in the Superior Court of California, San Francisco County, asserting claims for breach of contract arising out of Incyte's failure to pay two milestone payments the company believes are due under the agreement. Clinical trials being conducted by Calithera and Incyte evaluating INCB001158 are ongoing as planned.

CB-280 arginase inhibitor program. Calithera has completed a first-in-human Phase 1 trial evaluating the safety, tolerability and pharmacokinetic profile of oral CB-280 in healthy volunteers. A Phase 1b clinical study in people with cystic fibrosis is planned and site openings are in progress. However, given the challenges associated with opening new clinical studies during the current stage of the COVID-19 pandemic, Calithera expects to delay enrollment in the first patient until the third quarter of 2020, pending further developments in the COVID-19 situation.

The Company's first quarter 2020 financial results will be released on Thursday, May 7, 2020. Company management will host a conference call on Thursday, May 7, 2020 at 2:00 p.m. Pacific Time/ 5:00 p.m. Eastern Time to discuss the financial results and other recent corporate highlights.

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 clinical trials, the clinical and commercial potential of its product candidates; the timing of the receipt of top-line efficacy and safety data in the CANTATA trial; the timing of enrollment of the randomized trial in NSCLC patients with genetic mutation NRF2/KEAP1 and the presentation of interim data from this trial; the safety and anti-tumor activity of telaglenastat plus palbociclib; and the timing that CB-280 will enter 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 potential product candidates that Calithera develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. Calithera's clinical trials may not confirm any

safety, potency or other product characteristics described or assumed in this press release and such product candidates may not be beneficial to patients or successfully commercialized. In addition, the COVID-19 pandemic may result in further delays in Calithera's studies and trials. The outcome of litigation is inherently uncertain, and Calithera's lawsuit against Incyte, may adversely affect the continued development of INCB001158. 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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