



Calithera Biosciences Initiates Phase 1b Trial of Arginase Inhibitor CB-280 for the Treatment of Cystic Fibrosis

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SOUTH SAN FRANCISCO, July 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, today announced that it has dosed the first patients in its Phase 1b clinical trial of the arginase inhibitor CB-280 in adult patients with cystic fibrosis (CF) and chronic airway infection. The study will evaluate the safety and optimal dose range of CB-280 when added onto existing therapies for CF patients, including CFTR modulators.

"We remain committed to advancing our arginase inhibitor clinical development program to fully explore the potential of this new class of therapeutics in a variety of conditions," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "Based on preclinical data and the unique pathology of this disease, we believe that CB-280's mechanism of action represents an opportunity to further improve upon the current standard-of-care for CF patients, for whom there remains great unmet need despite recent therapeutic advancements."

Research in CF patients has demonstrated that increased arginase activity correlates directly with worsened lung function, and reduced expiratory nitric oxide (NO) levels. Pre-clinical studies conducted by Calithera and collaborators have shown that arginase inhibition increases systemic arginine levels, decreases airway bacterial colonies, and improves lung function in CF mouse models of infection. Inhibiting arginase may reduce infection and improve lung function in people with CF. Chronic poly-microbial infection remains a major area of unmet need in CF.

The Phase 1b randomized, double blind, placebo-controlled, dose escalation trial will evaluate multiple ascending doses of CB-280 compared to placebo in 32 adult CF patients to determine a safe dose range for CB-280, dosed orally twice daily for 14 days. The study follows the completion of a Phase 1 trial that evaluated the safety, tolerability and pharmacokinetic profile of CB-280 in healthy volunteers, which was conducted under a United States Food and Drug Administration Investigational New Drug (IND) application.

In October 2017, Calithera entered into a global collaboration agreement with Incyte, focused on research, development and commercialization of a first-in-class arginase inhibitor in hematology and oncology. As part of this agreement, Calithera retained the rights to develop additional arginase inhibitors in specific non-oncology indications, including CF. The molecule being evaluated in these clinical trials, CB-280, is wholly owned by Calithera.

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 safety, tolerability and efficacy of the arginase inhibitor CB-280 in adult patients with cystic fibrosis, the overall advancement of CB-280 in the Phase 1b clinical trial, the unmet need in the treatment of patients despite recent therapeutic advancements, Calithera's global collaboration with Incyte, and Calithera's plans to continue development of CB-280. 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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