



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

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SOUTH SAN FRANCISCO, Calif., Feb. 21, 2019 (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 initiated a Phase 1 clinical trial with CB-280, a novel, orally dosed arginase inhibitor being developed for the treatment of cystic fibrosis (CF).

"The initiation of this Phase 1 study with CB-280 marks an important milestone in the advancement of our arginase program," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "We believe arginase inhibitors may offer an exciting new therapeutic approach for the treatment of patients with cystic fibrosis, independent of mutational status. We anticipate completing this study in 2019."

Pre-clinical studies conducted by Calithera and collaborators have validated the potential of arginase inhibition to reduce infection and improve lung function in CF patients. 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. This second molecule – CB-280 – is wholly owned by Calithera.

The first-in-human Phase 1 trial will evaluate the safety, tolerability and pharmacokinetic profile of oral CB-280 in healthy volunteers. The study will be conducted under a United States Food and Drug Administration Investigational New Drug (IND) application.

Arginase is an enzyme secreted by immune cells and is thought to play an important role in CF pathophysiology. By decreasing production of nitric oxide (NO) in the airways of CF patients, arginase impairs anti-microbial immune response and airway function. It has been observed that lower NO levels directly correlate with worsened lung function and increased pathogen colonization in CF patients. Arginase inhibition with CB-280 represents a novel approach to address an important unmet need in CF airway disease.

### About Calithera

Calithera is a clinical-stage biopharmaceutical company focused on fighting cancer and other life-threatening diseases 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 timing of Calithera's clinical trials, the review, registration and approval of CB-280 by the FDA, and the safety and efficacy 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 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](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.

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