Calithera Biosciences Awarded up to $2.4M from Cystic Fibrosis Foundation to Support Clinical Development of Arginase Inhibitor, CB-280

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SOUTH SAN FRANCISCO, Calif., Nov. 02, 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, has been awarded up to $2.4M from the Cystic Fibrosis Foundation. The award will support clinical development of CB-280, Calithera's investigational first-in-class arginase inhibitor, which promotes higher tissue levels of nitric oxide (NO) to reduce the risk of infections in people with cystic fibrosis (CF).

"We are grateful to the Cystic Fibrosis Foundation for their support to accelerate the clinical development of CB-280 as a potentially first-in-class new treatment for this often devastating disease," said Susan Molineaux, Ph.D., president and chief executive officer of Calithera. "Based on preclinical data and the unique pathology of cystic fibrosis, we believe that arginase inhibition represents a novel, promising opportunity to improve the standard-of-care for CF patients."

Cystic fibrosis is a progressive, genetic disease that causes persistent lung infections and limits the ability to breathe over time. Research in CF patients has demonstrated that increased arginase activity correlates directly with worsened lung function and decreased airway nitric oxide, promoting pathogen colonization. Preclinical studies conducted by Calithera and collaborators have validated arginase inhibition as a therapeutic approach in CF, and have demonstrated that inhibiting arginase may reduce infection and improve lung function in people with CF.

Calithera's ongoing randomized, double-blind, placebo-controlled, multiple ascending dose-escalation study (NCT04279769) is exploring CB-280 versus placebo in adults with cystic fibrosis and chronic infection with Pseudomonas aeruginosa who are stable on cystic fibrosis medications, including cystic fibrosis transmembrane conductance regulator (CFTR) modulators. The study is evaluating the safety, pharmacokinetics, pharmacodynamics and biological activity of four dose cohorts versus placebo. Calithera expects to share interim data in 2021.

About CB-280

CB-280 is an investigational, first-in-class, selective oral inhibitor of human arginase that Calithera is developing for the treatment of cystic fibrosis. Because arginine is required for nitric oxide NO production, which is critical to the body's ability to fight infections and maintain pulmonary airway function, inhibiting arginase may allow the body to improve its NO production and subsequently better combat CF. 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 Calithera's clinical trials, the clinical and commercial potential of its product candidates; the presentation of interim data from the randomized trial in cystic fibrosis patients; the impact of CB-280 for patients with cystic fibrosis; and the amount of the award from the Cystic Fibrosis Foundation. 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 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.

SOURCE: Calithera Biosciences, Inc.

CONTACTS:

Investor Relations
Jennifer McNealey
Calithera
ir@Calithera.com
650-870-1071

Media
Michele Parisi
Sam Brown, Inc.

micheleparisi@sambrown.com
925-864-5028

Source: Calithera Biosciences, Inc.