Calithera Biosciences Initiates Phase 1/2 Trial of Telaglenastat in Combination with the PARP Inhibitor Talazoparib

March 26, 2019

Study is part of clinical trial collaboration with Pfizer

SOUTH SAN FRANCISCO, Calif., March 26, 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 the first patient has been treated in the Phase 1/2 open-label clinical trial of the glutaminase inhibitor telaglenastat (CB-839) in combination with Pfizer's poly adenosine diphosphate ribose polymerase (PARP) inhibitor talazoparib, also known as Talzenna ®, in patients with advanced or metastatic solid tumors.

"The initiation of this clinical trial of telaglenastat in combination with talazoparib marks the first of two clinical trials that will evaluate telaglenastat with approved Pfizer therapeutics as part of this collaboration," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "We believe these new combination trials have the potential to broaden the opportunities for telaglenastat to improve patient outcomes."

Preclinical studies have shown that telaglenastat synergizes with PARP inhibitors to impair DNA synthesis, enhance DNA damage and block cancer cell proliferation. The combination of telaglenastat with PARP inhibitors has demonstrated synergistic activity in a number of preclinical cancer models, including renal cell carcinoma (RCC), triple negative breast cancer (TNBC), colorectal cancer (CRC), non-small cell lung cancer (NSCLC), ovarian cancer and prostate cancer. In October 2018, Calithera entered into a clinical trial collaboration agreement with Pfizer to evaluate telaglenastat in two clinical trials. The first trial is a combination of telaglenastat with talazoparib and the second trial is a combination of telaglenastat with palbociclib, also known as Ibrance®. As part of this agreement, Pfizer will provide palbociclib and talazoparib, as well as financial support.

The Phase 1/2 trial (NCT03875313) will evaluate the safety and efficacy of the combination of telaglenastat plus talazoparib in patients with locally advanced/metastatic RCC, TNBC and CRC that are refractory or intolerant to standard therapies. The trial will evaluate the potential of telaglenastat to sensitize tumors to talazoparib in patients regardless of mutations in the BRCA gene.

Telaglenastat is an investigational, novel glutaminase inhibitor specifically designed to block glutamine consumption in tumor cells. Tumors commonly exhibit metabolic alterations that increase their dependence on glutamine. In preclinical studies, telaglenastat produced synergistic antitumor effects when used in combination with standard-of-care therapies.

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.

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 success of Calithera's collaboration with Pfizer, the potential for telaglenastat to be developed in combination with therapeutics, such as palbociclib or talazoparib, to improve patient outcomes, safety, tolerability and efficacy of telaglenastat, the overall advancement of telaglenastat in clinical trials, the unmet need in the treatment of patients with advanced disease, Calithera's plans to continue development of telaglenastat in combination with PARP inhibitor talazoparib for the treatment of TNBC, RCC and TNBC as well as the related timing for clinical trials, and Calithera's plans to initiate a Phase 1/2 clinical trial of the combination of telaglenastat plus palbociclib in CRC and NSCLC patients. 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 Annual Report on Form 10-K 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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