



Calithera Biosciences Initiates Phase 1/2 Trial of Telaglenastat in Combination with Pfizer's CDK4/6 Inhibitor Palbociclib

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Study is part of clinical trial collaboration with Pfizer

SOUTH SAN FRANCISCO, Calif., July 02, 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 treatment of the first patient in a Phase 1/2 open-label clinical trial of the glutaminase inhibitor telaglenastat (CB-839) in combination with Pfizer's CDK 4/6 inhibitor palbociclib, also known as Ibrance[®]. The study will evaluate the safety and anti-tumor activity of telaglenastat plus palbociclib in patients with KRAS-mutated colorectal cancer (CRC) and KRAS-mutated non-small cell lung cancer (NSCLC).

"Preclinical data suggest that telaglenastat and palbociclib have synergistic activity in KRAS-mutated tumors, and may offer a new approach to the challenges associated with treating KRAS-mutated cancers," said Susan Molineaux, Ph.D., president and chief executive officer of Calithera. "We are excited to launch this second clinical trial with Pfizer and are hopeful that the telaglenastat-palbociclib combination could fill a significant treatment gap for patients and medical professionals."

Telaglenastat is designed to block glutamine consumption in tumor cells. Genetic alterations, such as mutations in KRAS, can cause cancer cells to increase metabolism of glutamine. In preclinical studies with KRAS-mutated cancer models, telaglenastat showed synergistic antitumor effects when used in combination with CDK4/6 inhibitors, such as palbociclib, enhancing cell cycle arrest and blocking cancer cell proliferation. The Phase 1/2 clinical trial (NCT03965845) will evaluate the safety and anti-tumor activity of the telaglenastat plus palbociclib combination in patients with locally advanced/metastatic KRAS-mutated CRC and KRAS-mutated NSCLC that are refractory or intolerant to standard therapies.

This is the second trial initiated by Calithera as part of an ongoing clinical trial agreement with Pfizer. The first trial, which is investigating the combination of telaglenastat with the PARP inhibitor talazoparib in patients with renal cell carcinoma (RCC), triple negative breast cancer (TNBC) and CRC began enrolling patients in March 2019. As part of the agreement, Pfizer is providing palbociclib and talazoparib, as well as financial support.

About Telaglenastat

Telaglenastat is an investigational selective oral inhibitor against human glutaminase, a critical enzyme that enables cancer cells to utilize glutamine for metabolism and survival. Tumors commonly exhibit metabolic alterations that increase their dependence on glutamine. In pre-clinical studies, telaglenastat has demonstrated synergistic antitumor activity when used in combination with standard-of-care therapies. Telaglenastat in combination with everolimus met the primary endpoint of improving PFS compared to everolimus with placebo in ENTRATA, a randomized Phase 2 clinical study. The compound is currently being evaluated in multiple ongoing combination trials, including with cabozantinib in the global, pivotal Phase 2 CANTATA study.

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 cell growth 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 success of Calithera's collaborations 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 CRC as well as the related timing for clinical trials, and Calithera's plans to continue development 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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