



## Calithera Biosciences Announces Clinical Trial Collaboration to Evaluate IBRANCE® (palbociclib) and talazoparib in Combination with CB-839

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### Phase 1/2 trials expected to initiate 1Q2019

SOUTH SAN FRANCISCO, Calif., Oct. 05, 2018 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, today announced two new clinical trial collaborations to evaluate Pfizer's palbociclib, also known as IBRANCE®, and the investigational dual-mechanism poly (ADP-ribose) polymerase (PARP) inhibitor talazoparib, each in combination with Calithera's glutaminase inhibitor CB-839. As part of the collaboration, Pfizer will provide palbociclib and talazoparib, as well as financial support.

"Tumor metabolism is a unique therapeutic approach that exploits the way in which cancer cells utilize nutrients to grow and survive," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "CB-839, a novel glutaminase inhibitor, has the potential to be developed in combination with palbociclib or talazoparib to improve patient outcomes. We look forward to collaborating with Pfizer on the combination clinical trials planned in the first quarter of 2019."

Preclinical data suggest that CB-839, which is designed to starve tumor cells of the key nutrient glutamine, synergizes with CDK4/6 inhibitors by enhancing cell cycle arrest and blocking cancer cell proliferation. The combination of CB-839 with CDK4/6 inhibitors has demonstrated synergistic activity in a number of preclinical cancer models, including colorectal cancer (CRC), non-small cell lung carcinoma (NSCLC), triple negative breast cancer (TNBC) and ER+ breast cancer. Based on these data, Calithera will initiate a Phase 1/2 clinical trial of the combination of CB-839 plus palbociclib in patients with KRAS mutated CRC and patients with KRAS mutated NSCLC in the first quarter of 2019.

CB-839 also synergizes with PARP inhibitors to impair DNA synthesis, enhance DNA damage, and block cancer cell proliferation. The combination of CB-839 with PARP inhibitors has demonstrated synergistic activity in a number of preclinical cancer models, including renal cell carcinoma (RCC), TNBC, CRC, NSCLC, ovarian cancer and prostate cancer. Based on these data, Calithera will initiate a Phase 1/2 clinical trial of the combination of CB-839 plus talazoparib in patients with RCC, and TNBC in the first quarter of 2019.

#### About Calithera

Calithera Biosciences, Inc. is a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. Calithera's product candidate, CB-839, is a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839 takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. It is currently being evaluated in randomized clinical trials for the treatment of patients with renal cell carcinoma. INCB-001158 is an immuno-oncology metabolic checkpoint inhibitor targeting arginase, a critical immunosuppressive enzyme responsible for T-cell suppression by myeloid-derived suppressor cells. Arginase depletes arginine, a nutrient that is critical for the activation, growth and survival of the body's cancer-fighting immune cells, known as cytotoxic T-cells. INCB-001158 is being developed in collaboration with Incyte Corporation. 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 and success of Calithera's collaboration with Pfizer, the potential for CB-839 to be developed in combination with therapeutics, such as palbociclib or talazoparib, to improve patient outcomes, the safety, tolerability and efficacy of CB-839, the overall advancement of CB-839 in clinical trials, Calithera's plans to continue development of CB-839 in combination with PARP inhibitor talazoparib for the treatment of TNBC, and RCC 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 CB-839 plus palbociclib in CRC and NSCLC patients in the first quarter of 2019. 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](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.

**SOURCE:** Calithera Biosciences, Incorporated

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