Calithera Biosciences Announces First Patient Enrolled in Phase 2 Clinical Trial of Sapanisertib in Relapsed/Refractory NRF2 (NFE2L2)-Mutated Squamous Non-Small Cell Lung Cancer

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-- Patients with tumors harboring NRF2-mutations have a poorer prognosis and no available targeted therapies --

SOUTH SAN FRANCISCO, Calif., July 06, 2022 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision-oncology biopharmaceutical company, today announced that it has enrolled the first patient in a phase 2 clinical trial of sapanisertib (CB-228) in patients with relapsed/refractory NRF2 (NFE2L2)-mutated squamous non-small cell lung cancer (sqNSCLC).

NRF2 mutations are found in a considerable sub-population of patients across multiple solid tumor types. Sapanisertib is a potent and selective, dual mTORC 1/2 inhibitor that targets a key survival mechanism in tumors harboring these mutations. The compound previously demonstrated single-agent clinical activity in patients with relapsed/refractory NRF2-mutated sqNSCLC. Approximately 50,000 to 60,000 individuals are diagnosed with sqNSCLC in the United States alone each year, and about 15% of all sqNSCLC tumors harbor the NRF2 mutation.

“Our experience enrolling biomarker-driven clinical trials has allowed us to quickly advance sapanisertib since acquiring it from Takeda in the fourth quarter of last year. Enrollment of the first patient in this phase 2 study marks an important milestone for the program,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “Sapanisertib has the potential to be a first-in-class treatment for patients with NRF2-mutated squamous lung cancer, a patient population with poor prognosis and high unmet need. This study is designed to further validate the NRF2 mutation as a selection biomarker, and we plan to share data from the trial by the first quarter of 2023.”

The phase 2 trial (NCT05275673) is a multicenter, open-label study of sapanisertib monotherapy in patients with NRF2-mutated sqNSCLC whose disease has progressed on or after platinum-doublet chemotherapy and immune checkpoint inhibitor therapy (anti-PD-L1) with or without anti-CTLA-4, administered as separate lines of therapy or in combination. The study will evaluate sapanisertib 2 mg twice a day or 3 mg once a day in patients with sqNSCLC harboring either wild-type (WT) or mutated NRF2, as detected by next-generation sequencing.

The study is designed to confirm the selective activity of sapanisertib in NRF2-mutated tumors compared to WT tumors, and to refine dose in this biomarker-defined population. The primary endpoints of the study are investigator-assessed overall response rate (ORR) per RECIST v1.1, and safety. Secondary endpoints include duration of response, progression-free survival and overall survival.

Data from this study could position Calithera to initiate a study with registrational intent in biomarker-specific sqNSCLC populations.

About Calithera

Calithera Biosciences is a clinical-stage, precision oncology biopharmaceutical company developing targeted therapies to redefine treatment for biomarker-specific patient populations. 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 robust pipeline of investigational, small-molecule oncology compounds with a biomarker-driven approach that targets genetic vulnerabilities in cancer cells to deliver new therapies for patients suffering from aggressive hematologic and solid tumor cancers for which there are currently limited treatment options.

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 safety, tolerability and efficacy of Calithera’s product candidates, the overall advancement of Calithera’s product candidates in preclinical development and clinical trials, including Calithera’s plan to share data from its sapanisertib trial by the first quarter of 2023, Calithera’s ability to potentially initiate registrational studies in biomarker-specific sqNSCLC populations, sapanisertib’s potential to be a first-in-class treatment for patients with NRF2-mutated squamous lung cancer, and the unmet need in the treatment of patients with advanced disease. 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 be 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. 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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