Calithera Receives FDA Fast Track Designation for Sapanisertib for the Treatment of NRF2-mutated Squamous Lung Cancer

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Enrollment ongoing in Phase 2 study evaluating sapanisertib, a dual mTORC1/2 inhibitor, in patients with squamous non-small cell lung cancer harboring a NRF2 mutation

SOUTH SAN FRANCISCO, Calif., Oct. 03, 2022 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision oncology biopharmaceutical company, today announced that the U.S. Food & Drug Administration (FDA) has granted Fast Track designation for the company's investigational mTORC 1/2 inhibitor sapanisertib (CB-228) for the treatment of adult patients with unresectable or metastatic squamous non-small cell lung cancer (sqNSCLC) whose tumors have a mutation in nuclear factor erythroid 2-related factor (NFE2L2, also called NRF2) and who have received prior platinum-based chemotherapy and immune checkpoint inhibitor therapy.

"While there have been significant advances in targeted treatments for lung cancer, little progress has been made specifically for patients with squamous lung cancer. In addition, we know that patients with lung cancers that harbor mutations in the NRF2/KEAP1 pathway typically have poorer outcomes than those whose tumors do not have these mutations," said Susan Molineaux, chief executive officer of Calithera. "This Fast Track designation allows for a variety of benefits, including the possibility of priority review of sapanisertib as we seek to provide a first-in-class treatment option that may help address the major unmet need in this patient population."

NRF2 mutations are found across multiple solid tumor types, with these mutations occurring in approximately 15% of sqNSCLC patients. Sapanisertib targets a key survival mechanism in NRF2-mutated tumor cells. In a recent investigator-initiated Phase 2 trial, the compound was well-tolerated and demonstrated durable single-agent activity with a 27% (or 3/11) confirmed overall response rate (ORR) and median progression free survival (PFS) of 8.9 months (95% CI: 7 months, not reached) in heavily pretreated patients with NRF2-mutated sqNSCLC.[1]

Calithera's ongoing Phase 2 trial (NCT05275673) is a multi-center, 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. The study is evaluating 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. Calithera plans to share data from this study by the first quarter of 2023. Data generated from this open-label study could position the company to initiate a study with registrational intent in biomarker specific sqNSCLC populations.

The FDA grants Fast Track designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need. A therapeutic that receives Fast Track designation can benefit from early and frequent communication with the agency, in addition to a rolling submission of the marketing application, with potential pathways for expedited approval that have the objective of getting important new therapies to patients more quickly.

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, 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 the potential for accelerated FDA review of sapanisertib, 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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[1] Paik P., et al., Phase II study of TAK228 in patients with advanced non-small cell lung cancer (NSCLC) harboring NFE2L2 and KEAP1 mutations. Poster presented at: American Society of Clinical Oncology (ASCO20) Virtual Scientific Program; 2020 May 29-31; Chicago, IL.

Source: Calithera Biosciences, Inc.