Calithera Biosciences Shares Progress in Sapanisertib and Mivavotinib Clinical Programs at Upcoming Lung Cancer and Lymphoma Conferences

July 13, 2022

-- Overview of phase 2 study evaluating SYK inhibitor mivavotinib in patients with relapsed/refractory non-GCB (ABC) diffuse large B-cell lymphoma --

-- First data from phase 1 investigator-sponsored clinical study of TORC 1/2 inhibitor sapanisertib in combination with telaglenastat in patients with non-small cell lung cancer --

SOUTH SAN FRANCISCO, Calif., July 13, 2022 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision-oncology biopharmaceutical company, announced that updates related to the ongoing clinical programs for sapanisertib (CB-228) and mivavotinib (CB-659) will be presented at the upcoming International Association for Lung Cancer (IASLC) 2022 World Conference on Lung Cancer (WCLC) and the 2022 Pan Pacific Lymphoma Conference, respectively.

“Following our recent announcements that we’ve enrolled patients in both the mivavotinib and sapanisertib clinical trials, we are pleased that details of the mivavotinib trial-in-progress will be shared with the esteemed group of lymphoma physicians who attend the Pan Pacific Lymphoma Conference,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “We are also very interested in the data collected by Dr. Jonathan Riess and colleagues in the investigator-led phase 1 trial combining sapanisertib with telaglenastat in patients with non-small cell lung cancer, particularly given that we are evaluating sapanisertib in patients with NRF2-mutated squamous non-small cell lung cancer in our own, ongoing company-sponsored trial.

“We’re proud of the progress we’ve continued to make in both the sapanisertib and mivavotinib clinical programs since we acquired these compounds late last year, and believe they have the potential to be first-in-class treatments addressing areas of high unmet need,” said Molineaux.

During the Pan Pacific Lymphoma Conference taking place July 18-22 in Koloa, Hawaii, Reem Karmali, MD, MS, associate professor of Medicine at Northwestern University, will present a poster detailing the trial design of Calithera’s phase 2 study of mivavotinib, a spleen tyrosine kinase (SYK) inhibitor. The phase 2 trial (NCT05319028), which enrolled its first patient in June, is an open-label study of mivavotinib monotherapy in patients with relapsed/refractory non-GCB (ABC) diffuse large B-cell lymphoma (DLBCL). The main objectives of the study are to confirm previously seen single-agent activity in non-GCB DLBCL patients, evaluate activity according to MYD88/CD79b mutational status, and refine dose/schedule in this patient population. Approximately 50 non-GCB DLBCL patients, with or without MYD88/CD79b mutations, will be randomized 1:1 to one of two oral dose/schedule cohorts: a continuous dosing schedule (100 mg QD) or an induction dosing schedule (120 mg QD x 14 days, then 80 mg QD starting Day 15). Data from this trial could position Calithera to initiate a study with registrational intent in biomarker-specific DLBCL populations.

During an August 9 mini oral session at IASLC/2022 WCLC, Jonathan W. Riess, MD, MS, director of Thoracic Oncology and associate professor at UC Davis Comprehensive Cancer Center, will present dose-escalation findings from a multi-center phase 1/2 investigator-initiated study evaluating sapanisertib, a potent and selective dual mTORC 1/2 inhibitor, in combination with telaglenastat (CB-839), a novel, investigational glutaminase inhibitor, in biomarker-defined cohorts of patients with advanced non-small cell lung cancer (NSCLC). Sapanisertib targets a key survival mechanism in tumors harboring NRF2 mutations, which are found in a considerable sub-population of patients across multiple solid tumor types and are generally associated with a poorer prognosis. In pre-clinical studies, combining sapanisertib and telaglenastat showed synergistic anti-tumor activity.

After evaluating five combination dosing levels in 13 patients, researchers determined that the sapanisertib/telaglenastat combination is safe and tolerable at the recommended expansion dose (2 mg sapanisertib once daily, 800 mg telaglenastat twice daily). Researchers also observed tumor shrinkage among the majority of evaluable patients (5/8), including patients with lung cancers harboring KEAP1 or NRF2 mutations. As a next step, study investigators plan to enroll patients into one of four expansion cohorts evaluating sapanisertib plus telaglenastat in squamous NSCLC with and without NRF2 or KEAP1 mutations, and adenocarcinoma NSCLC with KRAS and KEAP1 or NRF2 mutations.

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 the presentation of data from the mivavotinib trial in progress and from the investigator-led phase 1 trial combining sapanisertib with telaglenastat, Calithera’s ability to potentially initiate registrational studies in biomarker-specific sqNSCLC populations, sapanisertib and mivavotinib’s potential to be first-in-class treatments in areas of high unmet need, 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.

CONTACTS:
Stephanie Wong
ir@Calithera.com
650.870.1063

INVESTORS:
Burns McClellan
Lee Roth
212.213.0006
lroth@burnsmc.com

MEDIA:
Sam Brown, Inc.
Hannah Hurdle
805.338.4752
hannahhurdle@sambrown.com

Source: Calithera Biosciences, Inc.