Calithera Biosciences Announces First Patient Enrolled in Phase 2 Clinical Trial of Mivavotinib in Relapsed/Refractory non-GCB (ABC) Diffuse Large B-Cell Lymphoma

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-- Novel biomarker will be used to identify patients in genetically defined subgroup associated with poorer outcomes

-- Study will evaluate SYK inhibitor both in patients with wild-type disease and those with tumors that harbor MYD88 or CD79b mutations

SOUTH SAN FRANCISCO, Calif., June 23, 2022 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision-oncology biopharmaceutical company, announced that the first patient has been enrolled in a multicenter phase 2 clinical trial evaluating its spleen tyrosine kinase (SYK) inhibitor mivavotinib (CB-659) in patients with relapsed/refractory non-germinal center B-cell like (non-GCB) diffuse large B-cell lymphoma (DLBCL), a DLBCL subpopulation that primarily comprises patients with activated B-cell like disease (ABC).

In a retrospective analysis of prior phase 1/2 studies in patients with DLBCL, patients with non-GCB DLBCL who received mivavotinib had a response rate of 53%, as compared to a response rate of 22% in patients with GCB DLBCL. Additionally, recent preclinical studies have shown enhanced SYK activity, and greater sensitivity to SYK inhibition, in DLBCL tumor-cell lines with mutations in MYD88 and CD79b genes. A significant fraction of patients with non-GCB DLBCL have tumors that harbor these mutations, and this subset of patients is known to have poorer outcomes with standard-of-care therapies.

“Mivavotinib has demonstrated potential to be a first-to-market approach for non-GCB DLBCL, including the genetic subset of patients harboring MYD88 and/or CD79 mutations,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “This study will advance understanding of how our novel biomarker-driven approach could help address this high unmet therapeutic need, and we look forward to sharing data by the first quarter of 2023.”

The phase 2 clinical trial (NCT05319028) is an open-label study of mivavotinib monotherapy in patients with relapsed/refractory non-GCB DLBCL. The main study objectives 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).

Centrally assessed ctDNA-based liquid next-generation sequencing (NGS) will be performed after randomization to ascertain MyD88/CD79b mutation status. The primary endpoints of the study are overall response rate as assessed by an independent radiology review committee and safety. Key secondary endpoints include duration of response, progression-free survival, and complete response.

Data from the trial could position Calithera to initiate a study with registrational intent in biomarker-specific DLBCL 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 mivavotinib trial by the first quarter of 2023, Calithera’s ability to potentially initiate a registrational study in biomarker-specific DLBCL populations 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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