Calithera Expands Oncology Pipeline with Acquisition of Two Clinical-Stage Assets from Takeda Pharmaceuticals

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-- TORC 1/2 inhibitor sapanisertib and SYK inhibitor mivavotinib strengthen Company's precision oncology pipeline --

-- Calithera will initiate Phase 2 clinical trials of sapanisertib and mivavotinib in 2022 --

-- Calithera to host webcast and conference call today at 5:30 p.m. ET / 2:30 p.m. PT --

SOUTH SAN FRANCISCO, Calif., Oct. 18, 2021 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision oncology biopharmaceutical company, today announced an agreement with Takeda Pharmaceutical Company Limited ("Takeda") to acquire two clinical-stage compounds, both of which have demonstrated single-agent clinical activity with the greatest potential in biomarker-defined cancer-patient populations. The compounds, sapanisertib (CB-228, formerly TAK-228) and mivavotinib (CB-659, formerly TAK-659), further strengthen Calithera's pipeline of clinical-stage targeted therapies.

"We believe that these clinical-stage compounds are an excellent complement to our internally-developed pipeline programs, and fit well with our current strategic focus on biomarker-driven therapeutic approaches. We are encouraged by the promising single-agent clinical data that suggest these investigational therapies could help transform treatment for multiple cancer patient populations with high unmet need," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "Specifically, sapanisertib has the potential to be the first targeted treatment for patients with NRF2-mutated squamous non-small cell lung cancer. We have learned a great deal about the unmet medical need of patients with KEAP1/NRF2 mutations, as well as how to identify and recruit these patients, during the conduct of our KEAPSAKE trial evaluating telaglenastat. This complementary approach in KEAP1/NRF2-mutant squamous NSCLC demonstrates our commitment to these patients and the pathway.

"Additionally, mivavotinib has the potential to be a best-in-class SYK inhibitor in non-Hodgkin's lymphoma, as well as a first-to-market approach for patients with diffuse large B-cell lymphoma whose tumors harbor MyD88 and/or CD79 mutations.

"We plan to start a clinical trial in squamous NSCLC with sapanisertib and a clinical trial in DLBCL with mivavotinib, both in biomarker specific populations, and generate data in the next 12 to 18 months that will define the clinical development and potential regulatory approval paths for both of these compounds."

The terms of the transaction include a total upfront cash payment to Takeda of $10 million and $35 million issued to Takeda in Calithera Series A preferred stock. Additionally, Takeda will be eligible to receive from Calithera clinical development, regulatory and sales milestone payments across both programs. Calithera will pay tiered royalties of high single-digits to low teens on future net sales should these candidates achieve regulatory approvals and subsequent commercial availability.

"Collaboration is an important aspect of our R&D strategy and at the center of our efforts to deliver new treatment options to patients. We are confident that Calithera, with their highly capable and experienced team, is the ideal partner to resume the development of sapanisertib and mivavotinib, and to maximize their potential to address underserved patient populations," said Christopher Arendt, Ph.D., head of Oncology Cell Therapy and Therapeutic Area Unit of Takeda. "We look forward to seeing how these programs advance under Calithera's leadership."

Sapanisertib is a dual TORC 1/2 inhibitor that targets a key survival mechanism in KEAP1/NRF2-mutated tumor cells. These mutations are found in a considerable sub-population of patients across multiple solid tumor types. Sapanisertib has demonstrated promising single-agent activity in patients with relapsed/refractory NRF2-mutated squamous non-small cell lung cancer (NSCLC) and exhibits differential anti-tumor activity compared to rapalog inhibitors of TORC1 in NRF2-mutant squamous NSCLC *in vivo* models. A Phase 2 study planned to begin in the first quarter of 2022 will further evaluate sapanisertib as a monotherapy in patients with squamous NSCLC harboring a NRF2 mutation.

Mivavotinib is a SYK inhibitor that targets the constitutively active BCR pathway in many non-Hodgkin's lymphoma (NHL) cases as well as the constitutively active inflammatory signaling pathway in MyD88-mutated NHL. In early phase studies, mivavotinib showed promising single-agent responses in relapsed/refractory diffuse large B-cell lymphoma (DLBCL). In addition, recent preclinical studies have shown enhanced SYK activity and sensitivity to SYK inhibition in DLBCL and other NHLs harboring mutations in MyD88 and/or CD79, which comprise a distinct genetic subset of DLBCL known to have poor outcomes with standard-of-care therapy. Accordingly, Calithera plans to initiate a Phase 2 study of mivavotinib in 2022 for the treatment of patients with DLBCL with and without mutations in MyD88 and CD79. Beyond DLBCL, both preclinical and clinical data support expansion across additional NHL subtypes and other hematologic malignancies as part of long-term plans.

More information about sapanisertib and mivavotinib can be found at calithera.com/pipeline.

Webcast and Conference Call Information

Calithera will hold a webcast today, Monday, October 18 at 5:30 p.m. Eastern Time / 2:30 p.m. Pacific Time. To access the link to the webcast, which will be broadcast live in listen-only mode, or the subsequent archived recording, visit the Investors section of the Calithera website at www.calithera.com. Alternatively, the call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international) and referring to conference ID 6946687. The webcast will be recorded and available for replay on Calithera's website for 30 days.

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 Calithera's clinical trials, the timing and enrollment of the KEAPSAKE, sapanisertib Phase 2 and mivavotinib Phase 2 trials, the payment of future royalties, development, regulatory and sales milestone payments to Takeda, the potential impact and commercialization of sapanisertib for patients with NSCLC and a NRF2/KEAP1 mutation, the potential impact and commercialization of mivavotinib in patients with NHL with and without mutations in MyD88 and CD79. 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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