Calithera Biosciences Reports Fourth Quarter 2019 Financial Results and Recent Highlights

March 11, 2020

--Calithera to Provide Corporate Update via Conference Call and Webcast at 2:00 p.m. PT on March 11, 2020--

SOUTH SAN FRANCISCO, Calif., March 11, 2020 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical stage biotechnology company focused on discovering and developing novel small molecule drugs for the treatment of cancer and other life-threatening diseases, announced today its financial results for the fourth quarter ended December 31, 2019. As of December 31, 2019, cash, cash equivalents and investments totaled $157.4 million.

“As a whole, 2019 was a productive and positive year in which we made significant progress on our clinical programs. In addition to reading out positive topline data from the ENTRATA trial, we completed enrollment in our registrational CANTATA trial, and we presented the first data from the ongoing trial of the arginase inhibitor INCB001158 in combination with pembrolizumab,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “In the fourth quarter, we maintained a strong cash position and continued to advance our key clinical development programs, including working diligently toward the initiation of our first clinical trial evaluating telaglenastat in non-small cell lung cancer patients with NRF2/KEAP1 genetic mutations.”

Fourth Quarter 2019 and Recent Highlights

- **Completed patient enrollment of randomized CANTATA trial of telaglenastat with cabozantinib in advanced renal cell carcinoma (RCC).** The CANTATA trial is a global, randomized, double-blind clinical trial of telaglenastat combined with cabozantinib, in patients with advanced or metastatic RCC who have received one or two prior treatments. The CANTATA trial enrolled 444 patients at multiple centers globally. The primary endpoint is progression-free survival (PFS). Calithera plans to report top-line efficacy and safety data from the trial in late third quarter or fourth quarter 2020.

- **Advancement toward initiation of a randomized trial in non-small cell lung cancer (NSCLC) patients with genetic mutation NRF2/KEAP1.** The NRF2/KEAP1 pathway is known to drive the development of certain cancers, including a significant proportion of NSCLC, through the management of oxidative stress in a manner that makes the cancer cell highly dependent upon glutaminase activity. Recently presented clinical data demonstrate that activation of this pathway, either through the loss of KEAP1 function or activation of NRF2, results in very poor outcomes in NSCLC patients. In addition, preclinical data demonstrated that activation of the KEAP1/NRF2 pathway make NSCLC cancer more aggressive but also much more sensitive to telaglenastat. The clear mechanistic rationale, strong preclinical data, and high unmet medical need in the NSCLC population have led Calithera to design a clinical study that will evaluate telaglenastat in combination with standard of care chemo-immunotherapy in first line NSCLC patients with tumors that harbor mutations in either KEAP1 or NRF2. This trial is expected to begin enrollment in the first half of 2020. We plan to present interim data from this trial in 2021.

- **Presented results of Phase 2 ENTRATA study of telaglenastat (CB-839) with everolimus in RCC at the ESMO 2019 Congress.** The ENTRATA trial (NCT03163667) was a Phase 2 randomized, double-blind trial designed to evaluate the safety and efficacy of telaglenastat in combination with everolimus versus placebo with everolimus in patients with advanced clear cell RCC who have been treated with at least two prior lines of systemic therapy, including at least one prior VEGFR-targeted tyrosine kinase inhibitor. The trial enrolled 69 patients at multiple centers in the United States. The primary endpoint of the trial was PFS per investigator assessment with a predetermined threshold of $p \leq 0.2$ one-sided. Telaglenastat, when added to everolimus, doubled the median PFS in heavily pretreated patients with advanced RCC to 3.8 months as compared to 1.9 months for everolimus alone, and reduced the risk of disease progression or death by 36% (HR=0.64, p=0.079 one-sided). The secondary endpoint of overall survival is not yet mature.

- **Presented new INCB001158 data at the ESMO 2019 Congress.** Calithera and Incyte are collaborating to conduct this Phase 1 study evaluating INCB001158 as monotherapy and in combination with the PD-1 inhibitor pembrolizumab in checkpoint inhibitor refractory and naïve advanced/metastatic solid tumors. Responses were observed in patients with microsatellite stable (MSS) colorectal cancer, a disease not historically sensitive to checkpoint inhibition.

- **Completed a Phase 1 clinical trial of CB-280 in healthy volunteers**. The first-in-human Phase 1 trial evaluated the safety, tolerability and pharmacokinetic profile of oral CB-280 in healthy volunteers. A Phase 1b clinical study in people with cystic fibrosis (CF), which is expected to start enrollment in the first half of 2020, will test multiple doses of CB-280 compared to placebo in approximately 30 adults with CF to determine a safe dose range, and evaluate pharmacodynamic effects of arginase inhibition in this population.

Selected Fourth Quarter and Full Year 2019 Financial Results

Cash, cash equivalents and investments totaled $157.4 million at December 31, 2019.

Research and development expenses for the full year 2019 were $76.3 million, compared to $66.2 million in the prior year. The increase of $10.1 million was due to a $6.7 million increase in the telaglenastat program, including for our CANTATA trial where we completed enrollment in 2019 and expect top-line results in late third quarter or fourth quarter 2020, an increase of $3.1 million in the INCB001158 program, an increase of $0.2 million in the CB-280 program, and an increase of $0.1 million for investment in our early-stage research programs. Research and development expenses for the fourth quarter of 2019 were $17.9 million, compared to $17.0 million for the same period last year.

General and administrative expenses for the full year 2019 were $16.6 million, compared to $13.3 million in the prior year. The increase of $3.3 million in 2019 was primarily related to $2.1 million higher professional services costs mainly for legal and accounting services and $1.0 million higher personnel-related costs, primarily from higher headcount. General and administrative expenses for the fourth quarter of 2019 were $4.6 million, compared to $3.2 million for the same period last year.

Interest and other income, net for the full year 2019 was $3.0 million, compared to $2.6 million in the prior year. Interest and other income, net for the fourth quarter of 2019 and 2018 were $0.7 million.

Net loss for the three months and year ended December 31, 2019 was $21.7 million and $89.9 million, respectively.

Conference Call Information

Calithera will host an update conference call today, Thursday, March 11, at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time. The call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 and referring to conference ID 8862716. To access the live audio webcast or the subsequent archived recording, visit the Investors section of the Calithera website at www.calithera.com. The webcast will be recorded and available for replay on Calithera's website for 30 days.

About Calithera

Calithera Biosciences is a clinical-stage biopharmaceutical company pioneering the discovery and development of targeted therapies that disrupt cellular metabolic pathways to preferentially block tumor cells and enhance immune-cell activity. 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 pipeline of first-in-clinic, oral therapeutics to meaningfully expand treatment options available to patients. 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 clinical and commercial potential of its product candidates; the receipt of top-line efficacy and safety data in the CANTATA trial; the timing of enrollment of the randomized trial in NSCLC patients with genetic mutation NRF2/KEAP1 and the presentation of interim data from this trial; the safety and anti-tumor activity of telaglenastat plus palbociclib; and the timing that CB-280 will enter clinical trials. 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 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.

SOURCE: Calithera Biosciences, Inc.

Calithera Biosciences, Inc.
Selected Consolidated Statements of Operations Financial Data
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Collaboration revenue	$ —	$ —	$ —	$ 22,254
Total revenue	—	—	—	22,254
Operating expenses:				
Research and development	17,902	16,977	76,290	66,195
General and administrative	4,551	3,247	16,605	13,340
Total operating expenses	22,453	20,224	92,895	79,535
Loss from operations	(22,453)	(20,224)	(92,895)	(57,281)
Interest and other income, net	725	725	3,035	2,652
Net loss	$ (21,728)	$ (19,499)	$ (89,860)	$ (54,629)
Net loss per share, basic and diluted	$ (0.39)	$ (0.51)	$ (1.90)	$ (1.49)

Weighted-average common shares used to compute net loss per share, basic and diluted	55,055	38,333	47,312	36,604

Calithera Biosciences, Inc.
Selected Consolidated Balance Sheet Financial Data
(in thousands)
(unaudited)

	December 31, 2019	December 31, 2018
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 157,361	$ 136,153
Working capital	140,172	125,371
Total assets	168,768	142,725
Total liabilities	26,342	16,011
Accumulated deficit	(286,101)	(196,170)
Total stockholders' equity	142,426	126,714

CONTACT:
Jennifer McNealey
ir@Calithera.com
650-870-1071

Source: Calithera Biosciences, Inc.