Calithera Biosciences Provides Corporate Updates and Announces Key Executive Promotions to Drive Continued Growth of the Company's Pipeline

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SOUTH SAN FRANCISCO, Calif., Jan. 07, 2019 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical stage biotechnology company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer, today announced several executive promotions. The company also provided corporate updates, including selected fourth quarter 2018 financial results, financial guidance and corporate milestones for 2019.

"I am pleased to announce today's promotions which highlight the talent, skill set and extensive achievements of our executive team," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "It is critical that we have the right leadership in place to reach key clinical milestones as we drive CB-839 towards commercialization with two randomized trials of the glutaminase inhibitor CB-839 for the treatment of patients with advanced renal cell carcinoma. We plan to report data from our Phase 2 ENTRATA trial in 2019, and the global CANTATA trial in 2020. In 2019, we look forward to a number of achievements including the initiation of additional clinical trials of CB-839 in collaboration with Pfizer, and the presentation of data on the arginase inhibitor INCB001158 at a medical meeting in the second half of 2019. Our goal is to have four unique therapeutics in the clinic including CB-280, an oral arginase inhibitor for the treatment of patients with cystic fibrosis, and CB-708, an oral small molecule CD73 inhibitor for the treatment of cancer by the end of 2019."

2019 Milestones

Calithera expects to reach the following milestones in 2019:

- **CB-839 data from Phase 2 renal cell carcinoma randomized ENTRATA trial 2H19.** The ENTRATA trial is a randomized, double-blind trial designed to evaluate the safety and efficacy of CB-839 with everolimus versus everolimus alone in approximately 63 patients with metastatic, clear cell renal cell carcinoma patients who have been treated with at least two prior lines of therapy including a VEGFR-targeting tyrosine kinase inhibitor. The primary endpoint is progression free survival; overall survival will be assessed as a secondary endpoint.
- **CB-839 enrollment of the Phase 2 renal cell carcinoma CANTATA trial 2H19.** The CANTATA trial is a randomized, global, double-blind trial comparing patients treated with CB-839 and cabozantinib to patients treated with cabozantinib alone. The trial will enroll approximately 400 patients with clear cell renal cell carcinoma who have previously received one or two prior lines of therapy. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for CB-839 in combination with cabozantinib for the treatment of this patient population.
- **CB-839 combination trial initiations in collaboration with Pfizer 1H19.** Calithera and Pfizer have two clinical trial collaborations to evaluate Pfizer's CDK4/6 inhibitor palbociclib, also known as IBRANCE®, and the dual-mechanism poly (ADP-ribose) polymerase (PARP) inhibitor talazoparib also known as TALZENNA®, each in combination with the glutaminase inhibitor CB-839.
- **INCB001158 arginase inhibitor data presentation at a medical meeting 2H19.** INCB001158 is a small molecule immuno-oncology therapeutic being evaluated in multiple clinical trials as a single-agent and in combination with immunotherapies and chemotherapy for the treatment of patients with cancer. INCB001158 is being developed as part of a collaboration and license agreement with Incyte.
- **CB-280 IND acceptance and Phase 1 trial initiation in healthy volunteers 1H19.** CB-280 is an arginase inhibitor for the treatment of cystic fibrosis. Arginase is believed to be critical in the pathology of cystic fibrosis. It impairs production of nitric oxide and generates metabolites of arginine that may impair lung function. CB-280 is an orally administered small molecule inhibitor of arginase. An investigational new drug (IND) application for CB-280 is planned for the first half of 2019.
- **CB-708 IND acceptance and Phase 1 trial initiation 2H19.** The immuno-oncology target CD73 is an enzyme that plays a critical role in the process of ATP conversion to adenosine. An IND application for CB-708, an orally administered small molecule inhibitor of CD73, is planned for 2019.

Selected Fourth Quarter 2018 Financial Results and Financial Guidance for 2019

Based upon preliminary estimates, cash, cash equivalents and investments totaled $136.2 million at December 31, 2018. Calithera expects to utilize cash and investments between $75 and $85 million in 2019.

Key Executive Promotions

The promotions for its executive leadership team include Curtis C. Hecht, promoted to Chief Business Officer; Keith Orford M.D., Ph.D., promoted to Chief Medical Officer; and Sam Whiting, M.D., Ph.D., promoted to Senior Vice President of Clinical Development.

Mr. Hecht brings over 25 years of broad pharmaceutical experience including business development, strategic planning and commercialization. He has led business and corporate development efforts since joining Calithera in 2014. Key contributions include the Mars in-licensing agreement for arginase inhibitors, clinical collaborations with Bristol-Myers Squibb, Exelixis and Pfizer and the co-development and commercialization agreement with Incyte for INCB001158. He has built strategic portfolio management and lifecycle team functions, and leads commercial planning. Prior to

Calithera, Mr. Hecht was Vice President of Business Development for inVentiv Heath Commercial Solutions. Until 2011, Mr. Hecht was at Roche in commercialization and business development roles of increasing responsibility, including the Global Alliance Director of the Roche-Genentech collaboration. Mr. Hecht has a B.S. in Chemistry from California State University, Sacramento, and an MBA from Carnegie Mellon University.

Dr. Orford has over 11 years of experience in pharmaceutical drug development in oncology and immuno-oncology. Since joining Calithera in 2015, he has overseen clinical development activities, including Clinical Operations and Medical Affairs. He has provided strategic development leadership for the company's oncology and cystic fibrosis portfolio, including CB-839, a glutaminase inhibitor currently in late stage global clinical trials in renal cell carcinoma as well as multiple other clinical studies across a wide range of tumor types. He also serves as strategic development leader for the clinical collaboration between Calithera and Incyte. Prior to joining Calithera, Dr. Orford was the Clinical Development Lead in the Immuno-Oncology and Combinations Development Performance Unit at GlaxoSmithKline, where he oversaw the clinical activities on multiple early stage clinical trials with targeted agents and novel immune-based therapies. Prior to GlaxoSmithKline, Dr. Orford was at Merck, where he worked on early clinical development programs across oncology and other therapeutic areas. Previously, Dr. Orford was a Research Fellow and Instructor at Massachusetts General Hospital and Harvard Medical School, where he completed clinical training in Internal Medicine, as well as postdoctoral work studying the epigenetic regulation of hematopoietic and embryonic stem cell differentiation. Dr. Orford received his undergraduate, M.D., and Ph.D. degrees from Georgetown University.

Dr. Whiting joined Calithera in May 2016. Dr. Whiting’s deep expertise in clinical oncology gained as an academic medical oncologist and in pharmaceutical drug development have helped fuel the growth of the company's pipeline. Prior to joining Calithera, Dr. Whiting served as Vice President of Research and Clinical Development at Gradalis. Dr. Whiting previously worked in development of small molecule targeted and immune-oncology agents at VentiRx Pharmaceuticals and Oncothyreon. Previously, Dr. Whiting served as Assistant Professor of Medical Oncology at the University of Washington, Assistant Member of Clinical Research at the Fred Hutchinson Cancer Research Center, and Clinical Head of Gastrointestinal Oncology at the Seattle Cancer Care Alliance. Dr. Whiting completed fellowship training in medical oncology at the Fred Hutchinson Cancer Research Center. His training in internal medicine was at the ABIM Research Pathway at the University of Washington. Dr. Whiting received his B.S. with Honors in Chemistry from Lewis and Clark College, and his M.D. and Ph.D. as part of the Medical Scientist Training Program at the University of Washington Medical Center.

About Calithera

Calithera is a clinical-stage biopharmaceutical company focused on fighting cancer by discovering, developing, and commercializing novel small molecule drugs that target tumor and immune cell metabolism. 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, its expected cash, cash equivalents and investments as of December 31, 2018 and expected utilization of cash and investments in 2019; Calithera’s ability to fund its clinical programs; Calithera’s plans to report data from its Phase 2 ENTRATA trial in 2019 and the global CANTATA trial in 2020; the trial design and enrollment of patients in the ENTRATA and CANTATA trials; Calithera’s plan to initiate additional clinical trials of CB-839 in collaboration with Pfizer; Calithera’s goal to have four unique therapeutics in the clinic by the end of 2019; and the timing of the filing of an IND application for CB-280 with the FDA in the first half of 2019. 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.

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