# Clementia Announces Completion of Enrollment in Phase 3 MOVE Trial for FOP

August 16, 2018

**Enrollment Completed Four Months Ahead of Schedule; Two Interim Data Analyses On Track for 2019**

MONTREAL, Aug. 16, 2018 (GLOBE NEWSWIRE) -- Clementia Pharmaceuticals Inc. (NASDAQ: CMTA), a clinical-stage company innovating treatments for individuals with ultra-rare bone disorders and other diseases, today announced the early completion of patient enrollment in the MOVE Trial, Clementia's registrational Phase 3 clinical study evaluating the safety and efficacy of palovarotene for the treatment of patients with fibrodysplasia ossificans progressiva (FOP). A total of 99 patients were enrolled in the MOVE Trial at 15 sites in 11 countries worldwide.

Based on the early completion of enrollment, Clementia will conduct two interim data analyses in 2019: the first when the first 35 enrolled patients have had their 12-month whole body CT (WBCT) scans, expected in the second quarter of 2019, and the second when all enrolled patients have had their 12-month WBCT scans, expected in the second half of 2019. Final 24-month results from this study are expected in the fourth quarter of 2020.

"The enthusiastic response to the MOVE Trial amongst the FOP medical and patient communities has resulted in the completion of enrollment in the MOVE Trial four months ahead of schedule," said Clarissa Desjardins, Ph.D., president and chief executive officer of Clementia. "I'd like to thank the patient participants and their families, as well as our study investigators and their clinical teams, whose dedication has helped advance palovarotene for the potential future treatment of FOP patients who have no approved treatment options today."

**About the MOVE Trial**

All patients in the MOVE Trial receive a single daily dose of palovarotene, with increased dosing at the time of a flare-up. Data from Clementia's natural history study (NHS) will serve as the control. Patients are treated with palovarotene for 24 months, with three planned interim analyses. The primary efficacy endpoint of the MOVE Trial is the annualized change in new heterotopic ossification (HO) volume as assessed by low-dose whole body CT (WBCT) scan (excluding head) compared to untreated patients from the NHS. This pivotal study is powered to detect an approximate 50 percent treatment effect on the primary efficacy endpoint at 24 months, with potential to achieve early success if a greater treatment effect can be shown at one of the three earlier interim analyses, per the study protocol. Secondary endpoints include the proportion of patients with any new HO, the number of body regions with new HO, the change in the proportion of patients reporting flare-ups and the rate of flare-up occurrence. Exploratory endpoints include functional assessments of joint function and changes in patient-reported physical function. Safety evaluations include adverse events, assessments of growth in children, clinical laboratory tests and vital signs. Full details of the study can be found at www.clinicaltrials.gov, NCT03312634.

**About Palovarotene**

Palovarotene is an RARγ agonist being developed as a treatment for patients with ultra-rare and debilitating bone diseases, including fibrodysplasia ossificans progressiva (FOP) and multiple osteochondromas (MO), as well as other diseases. Data from the palovarotene Phase 2 program suggest that palovarotene has the

ability to significantly reduce the development of new bone growth in abnormal places, or heterotopic ossification (HO) in patients with FOP. Palovarotene was also found to inhibit the formation of osteochondromas (OCs) in preclinical models of multiple exostoses, supporting the initiation of the MO-Ped Trial in the MO indication. Palovarotene has received Orphan Drug status for FOP and MO from the U.S. Food and Drug Administration (FDA), and orphan status for the treatment of FOP in the EU. In addition, palovarotene has been granted Fast Track and Breakthrough Therapy designations for FOP from the FDA.

**About Fibrodysplasia Ossificans Progressiva (FOP)**
FOP is a rare, severely disabling disorder characterized by heterotopic ossification (HO), or bone that forms outside the normal skeleton in muscles, tendons or soft tissue. In FOP, HO progressively restricts movement by locking joints leading to a cumulative loss of function, progressive disability, and increased risk of early death. FOP is caused by a mutation in the ACVR1 gene, resulting in excess signaling in the bone morphogenetic pathway, a key pathway controlling bone growth and development, by way of both ligand-dependent and independent mechanisms. There are currently no approved treatments for FOP.

**About Clementia Pharmaceuticals Inc.**
Clementia is a clinical-stage company innovating new treatments for people with ultra-rare bone disorders and other diseases with high medical need. The company's lead product candidate, palovarotene, a novel RARγ agonist, is currently being evaluated in the Phase 3 MOVE Trial to treat fibrodysplasia ossificans progressiva (FOP) and in the Phase 2 MO-Ped Trial to treat multiple osteochondromas (MO, also known as multiple hereditary exostoses/MHE). Clementia is also investigating palovarotene for the potential treatment of other conditions that may benefit from RARγ therapy. For more information, please visit www.clementiapharma.com and connect with us on Twitter @ClementiaPharma.

**Cautionary Note Regarding Forward-Looking Statements**
This press release may include "forward-looking statements" within the meaning of the applicable securities laws. Each forward-looking statement contained in this press release is subject to known and unknown risks and uncertainties and other unknown factors that could cause actual results to differ materially from historical results and those expressed or implied by such statement. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms "believes," "belief," "expects," "intends," "anticipates," "will," or "plans" to be uncertain and forward-looking. Applicable risks and uncertainties include, among others, the company's ability to generate revenue and become profitable; the risks related to its heavy reliance on palovarotene, its only current product candidate; the risks associated with the development of palovarotene and any future product candidate, including the demonstration of efficacy and safety; its dependence on licensed intellectual property, including the ability to source and maintain licenses from third-party owners; as well as the risks identified under the heading "Risk Factors" in the company's Annual Report on Form 20-F filed with the Securities and Exchange Commission ("SEC"), as well as the other information its file with the SEC or on SEDAR. Clementia cautions investors not to rely on the forward-looking statements contained in this press release when making an investment decision in its securities. Investors are encouraged to read the company's filings with the SEC or on SEDAR, available at www.sec.gov or www.sedar.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this press release, and the company undertakes no obligation to update or revise any of these statements, whether as a result of new information, future events or otherwise, except as required by law.

**Investor/Media Contact:**
Joseph Walewicz
Clementia Pharmaceuticals Inc.
+1-514-940-1080

Alicia Davis
THRUST Strategic Communications

+1-910-620-3302

Primary Logo

Source: Clementia Pharmaceuticals Inc.