Cytokinetics Announces Cohort 4 of REDWOOD-HCM Is Open to Enrollment

March 2, 2022 12:30 PM EST

Cohort 4 to Enroll Patients with Non-Obstructive Hypertrophic Cardiomyopathy

SOUTH SAN FRANCISCO, Calif., March 02, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced the opening of enrollment in Cohort 4 of REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM**), an ongoing Phase 2 clinical trial of *aficamten*, an investigational next-generation cardiac myosin inhibitor in development for the potential treatment of hypertrophic cardiomyopathy (HCM). Cohort 4 will enroll patients with non-obstructive hypertrophic cardiomyopathy.

"Approximately one third of people with HCM have non-obstructive HCM, and while they do not have left ventricular outflow tract obstruction, they still have considerable functional limitations and symptom burden with few treatment options," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Executive Vice President of Research & Development. "By investigating the safety and tolerability of *aficamten* in patients with non-obstructive HCM in a fourth cohort of REDWOOD-HCM we believe we may be able to advance more expeditiously into a potential pivotal clinical trial in non-obstructive HCM thereafter."

REDWOOD-HCM: Cohort 4

REDWOOD-HCM is a Phase 2, multi-center, randomized, placebo-controlled, double-blind, dose finding clinical trial of *aficamten* in patients with HCM. The primary objective of the trial is to determine the safety and tolerability of *aficamten*. Cohorts 1 and 2 enrolled patients with symptomatic obstructive HCM taking background medications exclusive of *disopyramide* while Cohort 3 enrolled patients taking background medications including *disopyramide*.

Cohort 4 will enroll, in an open label fashion, 30-40 patients with symptomatic non-obstructive HCM receiving background medical therapy. At screening, patients must have a left ventricular ejection fraction (LVEF) of ≥60%, an elevated NT-proBNP >300 pg/mL, and must not have resting or post-Valsalva LVOT gradients (<30 mmHg in each case). The primary objective is to determine the safety and tolerability of *aficamten* in patients with non-obstructive HCM. Other objectives include the effect of *aficamten* on LVEF, NYHA Functional Class and cardiac biomarkers. All patients will receive up to three escalating doses of *aficamten,* with doses being adjusted based on echocardiography according to LVEF alone. Cohort 4 will employ doses of 5, 10 and 15 mg once daily. Overall treatment duration will be 10 weeks with a 4-week follow up period after the last dose. All patients will be eligible to participate in the open label extension study of *aficamten,* REDWOOD-HCM OLE, including the embedded cardiac MRI sub-study. Additional information can be found on www.clinicaltrials.gov.

REDWOOD-HCM: Results from Cohorts 1-3

Cohorts 1 and 2 enrolled patients with symptomatic obstructive HCM taking background medications exclusive of *disopyramide*. Results showed that treatment with *aficamten* for 10 weeks resulted in statistically significant reductions from baseline compared to placebo in the average resting left ventricular outflow tract pressure gradient (LVOT-G) and the average post-Valsalva LVOT-G. A large majority of patients treated with *aficamten* achieved the target goal of treatment, defined as resting gradient <30 mmHg and post-Valsalva gradient <50 mmHg at Week 10, compared to placebo. Patients treated with *aficamten* also saw improvements in heart failure symptoms and reductions in NT-proBNP, a biomarker of cardiac wall stress. Treatment with *aficamten* in REDWOOD-HCM was generally well tolerated and the incidence of adverse events on *aficamten* was similar to that of placebo. No serious adverse events were attributed to *aficamten*, and no treatment interruptions occurred on *aficamten*.

Cohort 3 enrolled patients with symptomatic obstructive HCM taking background medications including *disopyramide*. Topline results showed that substantial reductions in the average resting LVOT-G and post-Valsalva LVOT-G were achieved, with only modest decreases in average left ventricular ejection fraction (LVEF), and no patients whose LVEF fell below the prespecified safety threshold of 50%. New York Heart Association (NYHA) Functional Class was improved in the majority of patients. Pharmacokinetic data as well as the safety and tolerability of *aficamten* were consistent with prior experience in REDWOOD-HCM with no treatment interruptions and no serious adverse events attributed to treatment reported by the investigators. The results from Cohort 3 of REDWOOD-HCM will be presented at the American College of Cardiology 71st Annual Scientific Session & Expo in Washington, D.C., on Saturday, April 2, 2022.

About HCM

Hypertrophic cardiomyopathy (HCM) is a disease in which the heart muscle (myocardium) becomes abnormally thick (hypertrophied). The thickening of cardiac muscle leads to the inside of the left ventricle becoming smaller and stiffer, and thus the ventricle becomes less able to relax and fill with blood. This ultimately limits the heart's pumping function, resulting in symptoms including chest pain, dizziness, shortness of breath, or fainting during physical activity. A subset of patients with HCM are at high risk of progressive disease which can lead to atrial fibrillation, stroke and death due to arrhythmias. There are no FDA approved medical treatments that directly address the hypercontractility that underlies HCM.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and next-in-class muscle inhibitors as potential treatments for debilitating diseases in which muscle performance is compromised. As a leader in muscle biology and the mechanics of muscle performance, the company is developing small molecule drug candidates specifically engineered to impact muscle function and contractility. Cytokinetics is readying for the potential commercialization of *omecamtiv mecarbil*, its cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is also developing *aficamten*, a next-generation cardiac myosin inhibitor, currently the subject of SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). Cytokinetics is also developing *reldesemtiv*, an investigational fast skeletal muscle troponin activator, currently the subject of COURAGE-ALS, a Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (ALS). Cytokinetics continues its over 20-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on Twitter, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Cytokinetics disclaims any intent or obligation to update these forward-looking statements and claims the protection of the Act's Safe Harbor for forward-looking statements. Examples of such statements include, but are not limited to, statements, express or implied, relating to our or our partners' research and development and commercial readiness activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of any of our clinical trials, and more specifically, our ability to fully enroll Cohort 4 of REDWOOD-HCM or SEQUOIA-HCM and statements relating to the potential patient population who could benefit from *aficamten* or any of our other drug candidates. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including, but not limited to the risks related to Cytokinetics' business outlines in Cytokinetics' filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and Cytokinetics' actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Contact:
Cytokinetics
Joanna Siegall
Associate Director, Corporate Communications, Investor Relations
(425) 314-1721

Source: Cytokinetics, Incorporated