Cytokinetics Announces Initiation of Phase 1 Study of Aficamten in Healthy Japanese Participants

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SOUTH SAN FRANCISCO, Calif., June 17, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the first participants have been dosed in a Phase 1 study evaluating the pharmacokinetics, safety and tolerability of *aficamten* in healthy Japanese and Caucasian participants.

"We are conducting this Phase 1 bridging study to characterize the pharmacokinetics of *aficamten* in healthy Japanese adults and to gather evidence that we believe will be required for potential approval in Japan," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Executive Vice President of Research & Development. "In parallel, we are continuing to execute on our later-stage global clinical development program for *aficamten* alongside preparing regulatory submissions in the U.S. and Europe which we expect to submit this year."

Phase 1 Clinical Trial Design

The primary objective of this Phase 1 double-blind, randomized, placebo-controlled study is to evaluate the pharmacokinetics of *aficamten* following administration of single ascending doses and multiple doses in 70 healthy Japanese and Caucasian participants. The secondary objective is to evaluate the safety and tolerability of *aficamten* in healthy Japanese and Caucasian participants. The study will enroll four cohorts including three single-ascending cohorts and one multiple dose cohort. Cohorts 1, 2 and 3 will enroll 10 Japanese participants and 10 Caucasian participants each, randomized on an 8:2 basis to receive single-ascending doses of *aficamten* (5 mg, 10 mg and 20 mg, respectively) or placebo. Enrollment of Cohort 2 and Cohort 3 will commence upon evaluation of the safety of the preceding Cohort. Following the completion of the single ascending dose cohorts, Cohort 4 will enroll 10 healthy Japanese participants randomized on an 8:2 basis to receive single doses of *aficamten* (5 mg) or placebo, once daily for 14 days.

About *Aficamten*

Aficamten is an investigational selective, small molecule cardiac myosin inhibitor discovered following an extensive chemical optimization program that was conducted with careful attention to therapeutic index and pharmacokinetic properties and as may translate into next-in-class potential in clinical development. *Aficamten* was designed to reduce the number of active actin-myosin cross bridges during each cardiac cycle and consequently suppress the myocardial hypercontractility that is associated with hypertrophic cardiomyopathy (HCM). In preclinical models, *aficamten* reduced myocardial contractility by binding directly to cardiac myosin at a distinct and selective allosteric binding site, thereby preventing myosin from entering a force producing state.

The development program for *aficamten* is assessing its potential as a treatment that improves exercise capacity and relieves symptoms in patients with HCM as well as its potential long-term effects on cardiac structure and function.

Aficamten was evaluated in SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of **A**ficamten in **HCM**), a positive pivotal Phase 3 clinical trial in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* received Breakthrough Therapy Designation for the treatment of symptomatic obstructive HCM from the U.S. Food & Drug Administration (FDA) as well as the National Medical Products Administration (NMPA) in China. Cytokinetics expects to submit a New Drug Application (NDA) to the FDA in Q3 2024 and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in Q4 2024.

Aficamten is also currently being evaluated in MAPLE-HCM, a Phase 3 clinical trial of *aficamten* as monotherapy compared to metoprolol as monotherapy in patients with obstructive HCM, ACACIA-HCM, a Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM, and CEDAR-HCM, a clinical trial of aficamten in a pediatric population with obstructive HCM, and FOREST-HCM, an open-label extension clinical study of *aficamten* in patients with HCM.

About Cytokinetics

Cytokinetics is a late-stage, specialty cardiovascular 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 cardiac 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 myocardial muscle function and contractility. Cytokinetics is preparing regulatory submissions for *aficamten*, its next-in-class cardiac myosin inhibitor, following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial in obstructive hypertrophic cardiomyopathy. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac muscle activator, in patients with heart failure. Additionally, Cytokinetics is developing CK-586, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten,* for the potential treatment of HFpEF, and CK-136, a cardiac troponin activator for the potential treatment HFrEF and other types of heart failure, such as right ventricular failure resulting from impaired cardiac contractility. Cytokinetics continues its longstanding 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 X, 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 the properties or potential benefits of *aficamten* or any of our other drug candidates, our ability to file a new drug application for *aficamten* with FDA in third quarter 2024, our ability to file a

marketing authorization application for *aficamten* with EMA in the fourth quarter 2024, our ability to obtain regulatory approval for *aficamten* for the treatment of obstructive hypertrophic cardiomyopathy or any other indication from FDA or any other regulatory body in the United States or abroad, and the labeling or post-marketing obligations that may be required by FDA or any other regulatory body in the United States or abroad as a condition to regulatory approval. 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.

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