Cytokinetics Announces Initiation of Phase 1 Clinical Study of CK-4015089

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Advancement of Fast Skeletal Muscle Troponin Activator Expands Pipeline of Muscle-Directed Drug Candidates

SOUTH SAN FRANCISCO, Calif., Nov. 11, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the first participants have been dosed in a Phase 1 randomized, double-blind, placebo-controlled, multi-part, single and multiple ascending dose clinical study of CK-4015089 (CK-089) in healthy human participants. CK-089 is a fast skeletal muscle troponin activator (FSTA) with potential therapeutic application to a specific type of muscular dystrophy and other conditions of impaired muscle function.

"We are pleased to begin clinical development of CK-089, a promising fast skeletal muscle troponin activator arising from our research in neuromuscular diseases," said Stuart Kupfer, M.D., Senior Vice President, Chief Medical Officer. "In the pre-clinical setting, CK-089 increased muscle force and function in animal models of a neuromuscular disease characterized by muscle weakness, atrophy and fatigue, suggesting it may have therapeutic application to a specific type of muscular dystrophy but also other conditions of impaired muscle function. While our specialty cardiology franchise remains our top priority, CK-089 represents a unique opportunity to leverage our expertise in muscle biology to potentially make a difference for patients living with neuromuscular diseases of impaired muscle function."

Phase 1 Clinical Trial Design

The primary objective of this Phase 1 randomized, double-blind, placebo-controlled, multi-part single and multiple ascending dose clinical study is to evaluate the safety, tolerability and pharmacokinetics of CK-089 when administered orally as single or multiple doses to healthy participants. The study design includes single ascending dose cohorts and multiple-dose ascending cohorts comprised of 10 participants each.

About CK-4015089

CK-4015089 (CK-089) is a novel, selective, oral, small molecule fast skeletal muscle troponin activator (FSTA) with potential therapeutic application to a specific type of muscular dystrophy and other conditions of impaired muscle function. CK-089 is designed to selectively activate the fast skeletal muscle troponin complex by increasing its affinity for calcium. CK-089 has a different chemical structure from previously developed FSTAs and in preclinical research, has been observed to have higher bioavailability, solubility and pharmacodynamic efficacy. In preclinical models, CK-089 improved muscle force and function in a mouse model with a specific type of muscular dystrophy associated with muscle weakness and fatigue.

About Cytokinetics

Cytokinetics is a late-stage, specialty cardiovascular biopharmaceutical company focused on discovering, developing and commercializing muscle biology-directed drug candidates 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. Following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial evaluating *aficamten,* a next-in-class cardiac myosin inhibitor, in obstructive hypertrophic cardiomyopathy (HCM), Cytokinetics submitted an NDA for *aficamten* to the U.S. Food & Drug Administration and is progressing regulatory submissions for *aficamten* for the treatment of obstructive HCM in Europe. *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, 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. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac muscle activator, in patients with heart failure with severely reduced ejection fraction (HFrEF), CK-586, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten* for the potential treatment of heart failure with preserved ejection fraction (HFpEF), and CK-089, a fast skeletal muscle troponin activator (FSTA) with potential therapeutic application to a specific type of muscular dystrophy and other conditions of impaired muscle function.

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 potential benefits of CK-089 in specific types of muscular dystrophy and other conditions of impaired muscle function. 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, potential difficulties or delays in the development, testing, regulatory approvals for trial commencement, progression or product sale or manufacturing, or production of Cytokinetics' drug candidates that could slow or prevent clinical development or product approval; Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' ability to conduct clinical trials; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; standards of care may change, rendering Cytokinetics' drug candidates obsolete; and competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.

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