Cytokinetics Announces Initiation of Phase 1 Clinical Study of CK-3828136

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Advancement of Novel Cardiac Troponin Activator Expands Cardiovascular Franchise for Conditions Associated with Impaired Cardiac Contractility

SOUTH SAN FRANCISCO, Calif., Dec. 07, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the first participants have been dosed in a Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose clinical study of CK-3828136 (CK-136), formerly known as AMG 594. CK-136 is a cardiac troponin activator, discovered under a previous joint research program with Amgen Inc. (Amgen), in development for the potential treatment of patients with heart failure with reduced ejection fraction (HFrEF) and other types of heart failure, such as right ventricular failure, resulting from impaired cardiac contractility.

“This Phase 1 study builds on previous first-in-human data for CK-136 by assessing a wider range of doses to determine a dose range associated with improvements in left ventricular systolic function, in addition to safety and tolerability,” said Fady I. Malik, M.D., Ph.D., Cytokinetics’ Executive Vice President of Research & Development. “The advancement of CK-136 extends our cardiovascular franchise, as it may provide differentiated effects for the potential treatment of certain forms of heart failure and conditions associated with reduced cardiac contractility.”

Phase 1 Clinical Trial Design

The primary objective of this Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose trial is to assess the safety, tolerability and pharmacokinetics of CK-136 when administered orally as single or multiple doses to healthy participants. The study design includes three groups of at least eight participants in single ascending dose cohorts and four groups of at least eight participants in multiple-dose ascending cohorts. A final optional cohort will include eight participants in an open-label, 2-period crossover arm to investigate the effect of food on CK-136.

About CK-3828136

CK-3828136 (CK-136) is a novel, selective, oral, small molecule cardiac troponin activator. In preclinical models, CK-136 increased myocardial contractility by binding to cardiac troponin through an allosteric mechanism that sensitizes the cardiac sarcomere to calcium, facilitating more actin-myosin cross bridge formation during each cardiac cycle thereby resulting in increased myocardial contractility. Similar to cardiac myosin activation, preclinical research has shown that cardiac troponin activation does not change the calcium transient of cardiac myocytes. Development of CK-136 may include the evaluation of this novel mechanism of action as a potential treatment of patients with heart failure with reduced ejection fraction (HFrEF) and other types of heart failure, such as right ventricular failure, resulting from impaired cardiac contractility. Under our prior collaboration, Amgen previously conducted a randomized, placebo-controlled, double-blind, single and multiple ascending dose, single-center Phase 1 study to assess the safety and tolerability, pharmacokinetics and pharmacodynamics of CK-136 in healthy subjects.

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-in-class cardiac myosin inhibitor, currently the subject of SEQUOIA-HCM, the Phase 3 clinical trial of aficamten in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). Aficamten is also being evaluated in non-obstructive HCM in Cohort 4 of the Phase 2 clinical trial, REDWOOD-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 the potential benefits of CK-136 for patients with heart failure with reduced ejection fraction (HFrEF) and other types of heart failure, such as right ventricular failure, resulting from impaired cardiac contractility. 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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