



Cytokinetics Announces Initiation of Phase 1 Clinical Study of CK-3772271

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Company Advances Second Cardiac Myosin Inhibitor

SOUTH SAN FRANCISCO, Calif., Sept. 23, 2020 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the first participants have been dosed in a Phase 1 placebo-controlled, single ascending dose clinical study of CK-3772271 (CK-271). CK-271 is a second cardiac myosin inhibitor, discovered by company scientists, in development for the potential treatment of hypertrophic cardiomyopathy (HCM).

"This Phase 1 study of CK-271 builds on our longstanding approach to advance back-up and follow-on compounds consistent with our portfolio management strategy," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Executive Vice President of Research & Development. "As we expand the development program for CK-274 currently in Phase 2, we plan to characterize this second cardiac myosin inhibitor to determine how it may align with our objective to develop new therapies for the potential treatment of multiple diseases associated with excessive cardiac contractility."

Phase 1 Clinical Study Design

The primary objective of this Phase 1 placebo-controlled, single ascending dose clinical study in healthy adults is to assess the safety and tolerability of CK-271. The secondary objective is to evaluate the pharmacokinetic profile of CK-271 following single oral ascending doses. The study design includes three cohorts, with 8 adults per cohort randomized (6:2) in a blinded fashion to CK-271 or placebo. Dose escalation decisions will be made after review of the available safety, pharmacokinetic, and echocardiography data.

About CK-271

CK-3772271 (CK-271) is an allosteric cardiac myosin inhibitor that produces reversible dose- and plasma concentration-dependent reductions in cardiac contractility without affecting heart rate in preclinical models. CK-271 reduces compensatory cardiac hypertrophy and cardiac fibrosis in preclinical models of hypertrophic cardiomyopathy and heart failure with preserved ejection fraction. CK-271 is the second cardiac myosin inhibitor arising from the company's extensive chemical optimization program conducted with careful attention to therapeutic index and pharmacokinetic properties and may be therapeutically effective by providing rapid relief of excessive hypercontractility in conditions such as HCM.

About Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is the most common inherited cardiovascular disorder, with approximately 1 in 500 individuals harboring a genetic mutation worldwide. In some, 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 these 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 current 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 and/or declining. 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 collaborating with Amgen Inc. (Amgen) to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omeclamtiv mecarbil* is the subject of an international clinical trials program in patients with heart failure including GALACTIC-HF and METEORIC-HF. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Cytokinetics is developing *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA) for the potential treatment of ALS and other neuromuscular indications following conduct of FORTITUDE-ALS and other Phase 2 clinical trials. The company is considering potential advancement of *reldesemtiv* to Phase 3. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to research, develop and commercialize other novel mechanism skeletal sarcomere activators (excluding FSTAs). Licenses held by Amgen and Astellas are subject to specified co-development and co-commercialization rights of Cytokinetics. Cytokinetics is also developing CK-274 and CK-271, novel cardiac myosin inhibitors that company scientists discovered independent of its collaborations, for the potential treatment of hypertrophic cardiomyopathies (HCM). Cytokinetics has granted Ji Xing Pharmaceuticals Limited an exclusive license to develop and commercialize CK-274 in China and Taiwan, in accordance with Cytokinetics' planned global registration programs. Cytokinetics is conducting REDWOOD-HCM, a Phase 2 clinical trial of CK-274 in patients with obstructive HCM. 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 relating to the timing, design and results of Cytokinetics' Phase 1 clinical trial of CK-271; the potential benefits of CK-271; Cytokinetics' and its partners' research and development activities; the timing of enrollment of patients in Cytokinetics' and its partners' clinical trials; the design, timing, results, significance and utility of preclinical and clinical results; and the properties and potential benefits of Cytokinetics' 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, 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; patient enrollment for or conduct of clinical trials may be difficult or delayed; Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Cytokinetics' partners decisions with respect to research and development activities; standards of care may change, rendering Cytokinetics' drug candidates obsolete; competitive products or alternative therapies may be developed by others for the treatment of indications

Cytokinetics' drug candidates and potential drug candidates may target; and risks and uncertainties relating to the timing and receipt of payments from its partners, including milestones and royalties on future potential product sales under Cytokinetics' collaboration agreements with such partners. 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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