



Cytokinetics Announces Start of Phase 2 Clinical Trial of CK-2127107 in Patients With Chronic Obstructive Pulmonary Disease

June 30, 2016 11:30 AM EDT

Trial Designed to Assess Effect of Skeletal Muscle Activation to Increase Physical Function and Exercise Tolerance Under Collaboration with Astellas

SOUTH SAN FRANCISCO, Calif., June 30, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) today announced the start of a randomized, double-blind, placebo-controlled, two period crossover clinical trial designed to assess the effect of CK-2127107 (CK-107) on physical function in patients with chronic obstructive pulmonary disease (COPD). CK-107 is a novel fast skeletal muscle troponin activator which is being developed as a potential treatment for people living with SMA, COPD and certain other debilitating diseases and conditions associated with muscular weakness and/or fatigue. Astellas is conducting this Phase 2 clinical trial in collaboration with Cytokinetics.

"Patients with COPD suffer from significant exercise intolerance due to metabolic abnormalities that produce weakness in limb muscles, as well as an associated switch from slow to fast muscle fiber predominance," said Fady I. Malik, Cytokinetics' Executive Vice President and Head of Research & Development. "Given CK-107's selectivity for fast skeletal muscle fibers, we are enthusiastic about exploring this novel therapeutic strategy in this patient population."

Phase 2 Clinical Trial Design

The trial is expected to enroll approximately 40 patients with COPD in the United States and is designed to assess the effect of CK-107 compared to placebo on exercise tolerance. Additionally, the trial will assess cardiopulmonary and neuromuscular effects of CK-107 relative to placebo and the effect of CK-107 on resting spirometry relative to placebo. In addition, the safety, tolerability and pharmacokinetics of CK-107 will be assessed. Additional information on the trial can be found at clinicaltrials.gov.

About COPD

COPD is a progressive obstructive lung disease that typically includes emphysema and chronic bronchitis. The disease is increasingly common and is the third leading cause of death in the U.S. behind cancer and heart disease. While it is estimated that more than 14 million U.S. adults have been diagnosed with COPD, it is widely underdiagnosed and up to 24 million Americans have evidence of impaired lung function. Current estimates suggest that COPD costs the nation almost \$50 billion annually in both direct and indirect health expenditures. Therapeutic strategies for the treatment of COPD have primarily focused to improving lung function and addressing airflow limitations caused by bronchial obstructions. A substantial unmet need exists for disease management strategies related to improved exercise tolerance.

About CK-2127107

In preclinical studies, CK-107 has been shown to slow the rate of calcium release from the regulatory troponin complex of fast skeletal muscle fibers, thus increasing the sensitivity of the skeletal muscle to calcium, which results in an increase in skeletal muscle force production in response to neuronal input and which also delays the onset and reduces the magnitude of fatigue during repetitive muscle stimulation. Thus, CK-107 may improve muscle function and physical performance in people with COPD. In collaboration with Astellas, Cytokinetics is conducting a Phase 2 clinical trial of CK-107 which is designed to assess the effect of CK-107 on measures of muscle function in both ambulatory and non-ambulatory patients with SMA, a severe, genetic neuromuscular disease that leads to debilitating muscle function and progressive, often fatal, muscle weakness.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators 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 increase muscle function and contractility. Cytokinetics' lead drug candidate is *tirasemtiv*, a fast skeletal muscle troponin activator, for the potential treatment of ALS. *Tirasemtiv* has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration and orphan medicinal product designation by the European Medicines Agency for the potential treatment of ALS. Cytokinetics retains the right to develop and commercialize *tirasemtiv*. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy and chronic obstructive pulmonary disease. Amgen holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and Astellas holds an exclusive license worldwide to develop and commercialize CK-2127107. Both licenses are subject to Cytokinetics' specified development and commercialization participation rights. For additional information about Cytokinetics, visit <http://www.cytokinetics.com/>.

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 Cytokinetics' and its partners' research and development activities, including the conduct, design, enrollment and progress of the Phase 2 clinical trial of CK-2127107 in patients with SMA; the significance and utility of preclinical study and clinical trial results; and the properties and potential efficacy and safety profile of CK-2127107 and Cytokinetics' 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, further clinical development of *tirasemtiv* in ALS patients will require significant additional funding, and Cytokinetics may be unable to obtain such additional funding on acceptable terms, if at all; the FDA and/or other regulatory authorities may not accept effects on slow vital capacity as a clinical endpoint to support registration of *tirasemtiv* for the treatment of ALS; 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, including risks that current and past results of clinical trials or preclinical studies may not be indicative of future clinical trial results, 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 U.S. Food and Drug Administration or

foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, and Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil* and CK-107, respectively; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; Cytokinetics may be unable to enter into future collaboration agreements for its drug candidates and programs on acceptable terms, if at all; 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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Cytokinetics

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