

# Cytokinetics Presents Results From Phase I Studies of CK-2127107

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## **Novel Fast Skeletal Muscle Activator Demonstrated Increases in Skeletal Muscle Force; Data Support Progression to Phase II**

SOUTH SAN FRANCISCO, Calif., June 19, 2015 (GLOBE NEWSWIRE) -- Cytokinetics (Nasdaq:CYTK) announced today that results from three double-blind, randomized, placebo-controlled Phase I studies of CK-2127107 in healthy volunteers were presented in a poster at the 19<sup>th</sup> International SMA (Spinal Muscular Atrophy) Researcher Meeting held during the 2015 Annual SMA Conference at the Westin Crown Center in Kansas City, MO. In a pharmacodynamic study that was designed to assess the translation of the mechanism of CK-2127107 to humans, treatment with the fast skeletal muscle activator increased muscle force produced by the tibialis anterior muscle in response to nerve stimulation. Cytokinetics is developing CK-2127107 in collaboration with Astellas Pharma Inc. ("Astellas," Tokyo: 4503).

"We are encouraged by the findings from our Phase I clinical studies program of CK-2127107 and the potential of CK-2127107 to improve skeletal muscle function," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Senior Vice President, Research and Development. "Based on these results, we look forward to initiating a Phase II trial in patients with SMA later this year in collaboration with our partner, Astellas."

The poster titled, "Pharmacokinetics and Pharmacodynamics of the Selective Fast Skeletal Muscle Troponin Activator, CK-2127107," was presented by Andrew Wolff, MD, FACC, Cytokinetics' Chief Medical Officer, and included data from Phase I studies that evaluated the safety, tolerability, pharmacokinetic (PK) and pharmacodynamic effects of CK-2127107 in healthy volunteers. In these studies, CK-2127107 was well-tolerated at single doses up to 4000 mg and the PK profile of CK-2127107 was linear and dose-proportional across the range of doses studied. Data from the Phase I studies also showed significant dose-, concentration-, and frequency-dependent increases in the force of muscle contraction elicited by nerve stimulation in healthy volunteers. The increases in force were most evident in the mid-range of nerve stimulation frequency, consistent with preclinical studies. By directly increasing skeletal muscle function, CK-2127107 may enhance physical performance in patients with neuromuscular diseases including SMA. These data support further evaluation of CK-2127107 and its potential to effect measures of muscle performance and function.

**About CK-2127107**

Skeletal muscle contractility is driven by the sarcomere, the fundamental unit of skeletal muscle contraction. It is a highly ordered cytoskeletal structure composed of several key proteins. Skeletal muscle myosin is the cytoskeletal motor protein that converts chemical energy into mechanical force through its interaction with actin. A set of regulatory proteins, which includes tropomyosin and several types of troponin, make the actin-myosin interaction dependent on changes in intracellular calcium levels. CK-2127107, a novel skeletal muscle activator arising from Cytokinetics' skeletal muscle contractility program, slows the rate of calcium release from the regulatory troponin complex of fast skeletal muscle fibers, which sensitizes the sarcomere to calcium, leading to an increase in skeletal muscle contractility. CK-2127107 has demonstrated pharmacological activity that may lead to new therapeutic options for diseases associated with muscle weakness and fatigue. CK-2127107 has been the subject of five completed Phase I clinical trials in healthy volunteers, which evaluated safety, tolerability, bioavailability, pharmacokinetics and pharmacodynamics.

## 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 deteriorating. With an unmatched understanding of muscle biology and 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 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 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. 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 planned initiation of a Phase II clinical program for CK-2127107 and the potential significance and utility of the results from clinical trials and preclinical studies; 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, 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 trials 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-2127107, 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.*

Contact:

Diane Weiser

Vice President, Corporate Communications, Investor Relations

(650) 624-3000

Cytokinetics, Inc