



## **Cytokinetics Announces Phase I and Phase IIa Clinical Trial Results for Omecamtiv Mecarbil Published in the Journal Lancet**

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### **Results From These Trials Form the Basis for Ongoing Phase IIb Activities in Collaboration With Amgen**

SOUTH SAN FRANCISCO, CA, Aug 19, 2011 (MARKETWIRE via COMTEX) --

Cytokinetics, Incorporated (NASDAQ: CYTK) announced today the publication of results from two clinical trials of omecamtiv mecarbil, a novel cardiac myosin activator, in the August 20, 2011 issue of the journal Lancet. These two manuscripts present data regarding the safety, tolerability, pharmacokinetics and pharmacodynamic effects of this investigational drug candidate from a Phase I first-time-in-humans clinical trial in healthy volunteers and a Phase IIa clinical trial in stable heart failure patients, each sponsored by Cytokinetics. Together, these publications provide evidence for the translation into humans of this unique mechanistic approach to activating cardiac muscle contractility and support the further development of omecamtiv mecarbil as a potential treatment for heart failure. Amgen Inc. holds an exclusive, worldwide (excluding Japan) license to omecamtiv mecarbil and related compounds, subject to specified development and commercialization participation rights of Cytokinetics.

"We are pleased that these results from earlier clinical trials of omecamtiv mecarbil, which demonstrated that this novel drug candidate increased certain measurements of cardiac function, have been recognized by these side-by-side publications in a prestigious peer-reviewed journal," stated Fady I. Malik, MD, PhD, FACC, Cytokinetics' Vice President of Biology and Therapeutics. "These two clinical trials have proven especially informative to the further advancement of this novel mechanism drug candidate which is now proceeding in a comprehensive development program under our collaboration with Amgen."

"These results form the foundation for the larger, international Phase IIb clinical trial of omecamtiv mecarbil that is currently enrolling heart failure patients," stated Scott M. Wasserman, M.D., F.A.C.C., Executive Medical Director at Amgen. "We are enthusiastic about the potential that omecamtiv mecarbil may represent for patients suffering from this grievous illness and look forward to advancing the development program in collaboration with Cytokinetics."

#### **Clinical Trial Publications of Omecamtiv Mecarbil in Lancet**

The first publication, titled "Dose-dependent Augmentation of Cardiac Systolic Function with the Selective Cardiac Myosin Activator, Omecamtiv Mecarbil: A First-In-Man Study," summarizes the results from a Phase I clinical trial of omecamtiv mecarbil. The primary objective of this trial was to establish the maximum tolerated dose and plasma concentrations of omecamtiv mecarbil in healthy volunteers. The secondary objectives were to evaluate the pharmacodynamic and pharmacokinetic characteristics of omecamtiv mecarbil and its safety and tolerability profile. The authors concluded that these first-in-man data showed highly dose- and concentration-dependent augmentation of left ventricular systolic function in response to omecamtiv mecarbil and support potential clinical use of the drug candidate in patients with heart failure.

The second publication, titled "The Effects of the Cardiac Myosin Activator, Omecamtiv Mecarbil, on Cardiac Function in Systolic Heart Failure: A Double-Blind, Placebo-Controlled, Crossover, Dose-Ranging Phase II Trial," summarizes the results from a Phase IIa clinical trial of omecamtiv mecarbil. The primary objective of this clinical trial was to assess the safety and tolerability of omecamtiv mecarbil in patients with stable heart failure due to systolic dysfunction. The secondary objectives were to evaluate the relationship between the plasma concentration of omecamtiv mecarbil and its echocardiographic effects and to define a range of pharmacodynamically active, well tolerated target plasma concentrations for subsequent clinical trials. The authors concluded that omecamtiv mecarbil improved cardiac function in these patients with heart failure caused by left ventricular systolic dysfunction and could be the first in a new class of therapeutics for the treatment of heart failure.

#### **Development Status of Omecamtiv Mecarbil**

Omecamtiv mecarbil, a novel cardiac muscle myosin activator, is currently the subject of a clinical trials development program designed to evaluate the safety, tolerability, pharmacodynamic and pharmacokinetic profiles of both intravenous and oral formulations of omecamtiv mecarbil for the potential treatment of heart failure across the continuum of care, in both hospital and outpatient settings. In April 2011, a Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil opened to enrollment. This trial is being conducted by Amgen in collaboration with Cytokinetics and is designed to evaluate the safety and efficacy of an intravenous formulation of omecamtiv mecarbil in patients with left ventricular systolic dysfunction hospitalized for acute heart failure. Cytokinetics and its partner Amgen are discussing plans for the initiation of additional studies designed to assess the safety, tolerability and pharmacokinetics of multiple oral formulations of omecamtiv mecarbil, to occur first in healthy volunteers and then in stable heart failure patients.

Prior to the ongoing Phase IIb clinical trial, omecamtiv mecarbil was the subject of a clinical trials program conducted under Cytokinetics' sponsorship. Two Phase IIa clinical trials of omecamtiv mecarbil were completed in patients with systolic heart failure. In addition, five Phase I clinical trials of omecamtiv mecarbil were completed in healthy volunteers: a first-time-in-humans study evaluating an intravenous formulation, an oral bioavailability study evaluating both intravenous and oral formulations, and three studies of oral formulations: a drug-drug interaction study, a dose proportionality study and a study evaluating modified-release formulations. Data from each of these trials have been reported previously.

#### **About Cytokinetics**

Cytokinetics is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. Cytokinetics' lead drug candidate from its cardiac muscle contractility program, omecamtiv mecarbil (formerly CK-1827452), is in clinical development for the potential treatment of heart failure. Amgen Inc. holds an exclusive license worldwide (excluding Japan) to develop and commercialize omecamtiv mecarbil and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing CK-2017357, a skeletal muscle activator, as a potential treatment for diseases and conditions associated with aging, muscle wasting or neuromuscular dysfunction. CK-2017357 is currently the subject of a Phase II clinical trials program and has been granted orphan-drug designation by the U.S. Food and Drug Administration for the potential treatment of amyotrophic lateral sclerosis, a debilitating disease of neuromuscular impairment in which CK-2017357 demonstrated potentially clinically relevant pharmacodynamic effects in a Phase IIa trial. Cytokinetics is also conducting research and non-clinical

development of compounds that inhibit smooth muscle contractility and which may be useful as potential treatments for diseases and conditions associated with excessive smooth muscle contraction, such as bronchoconstriction associated with asthma and chronic obstructive pulmonary disorder (COPD). In addition, prior Cytokinetics' research generated three anti-cancer drug candidates that have progressed into clinical development: ispinesib, SB-743921 and GSK-923295. All of these drug candidates and potential drug candidates have arisen from Cytokinetics' research activities and are directed towards the cytoskeleton. The cytoskeleton is a complex biological infrastructure that plays a fundamental role within every human cell. Additional information about Cytokinetics can be obtained at [www.cytokinetics.com](http://www.cytokinetics.com).

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 plans for and the initiation, conduct, design and scope of omecamtiv mecarbil clinical trials, the significance and utility of clinical trial results for omecamtiv mecarbil; and the properties and potential benefits of omecamtiv mecarbil (including the use of omecamtiv mecarbil as a potential treatment for heart failure) and Cytokinetics' other drug candidates and potential 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 decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products on acceptable terms, if at all; 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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