



## Cytokinetics Announces Opening of Third and Final Cohort in ATOMIC-AHF

November 29, 2012 12:30 PM EST

### ***Independent Data Monitoring Committee Recommends Progression in Ongoing Phase IIb Clinical Trial of Intravenous Form of Omecamtiv Mecarbil in Patients with Acute Heart Failure***

**South San Francisco, CA, November 29, 2012** - Cytokinetics, Incorporated (Nasdaq: CYTK) announced today the opening to enrollment of the third and final cohort in ATOMIC-AHF (Acute Treatment with *Omecamtiv Mecarbil* to Increase Contractility in Acute Heart Failure), the ongoing, international, randomized, double-blind, placebo-controlled Phase IIb clinical trial of an intravenous formulation of *omecamtiv mecarbil*. Following a review of the data from the first and second cohorts in this ongoing Phase IIb clinical trial, the independent data monitoring committee concluded that the current data supports progression of this trial.

The ATOMIC-AHF clinical trial, which is being conducted by Amgen in collaboration with Cytokinetics, is designed to evaluate the safety, tolerability, and efficacy of *omecamtiv mecarbil* compared to placebo in patients with left ventricular systolic dysfunction who are hospitalized with acute heart failure. To date, over 400 patients have been enrolled in this trial. Additional information about ATOMIC-AHF can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Amgen holds an exclusive, worldwide license (excluding Japan) to *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights.

### **ATOMIC-AHF Clinical Trial: Phase IIb Clinical Trial of *Omecamtiv Mecarbil***

ATOMIC-AHF is designed to evaluate an intravenous formulation of *omecamtiv mecarbil*, a novel cardiac muscle myosin activator, in approximately 600 patients enrolled in 3 sequential, ascending-dose cohorts. In each cohort, patients will be randomized to receive *omecamtiv mecarbil* or placebo. The primary objective of this trial is to evaluate the effect of 48 hours of intravenous *omecamtiv mecarbil* compared to placebo on dyspnea (shortness of breath) in patients with left ventricular systolic dysfunction hospitalized for acute heart failure. The secondary objectives are to assess the safety and tolerability of 3 dose levels of intravenous *omecamtiv mecarbil* compared with placebo and to evaluate the effects of 48 hours of treatment with IV *omecamtiv mecarbil* on additional measures of dyspnea, patients' global assessments, change in N-terminal pro brain-type natriuretic peptide (a biomarker associated with the severity of heart failure) and short-term clinical outcomes in these patients. In addition, the trial will evaluate the relationship between *omecamtiv mecarbil* plasma concentrations and echocardiographic parameters in patients with acute heart failure.

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

Prior to this Phase IIb clinical trial, *omecamtiv mecarbil* was the subject of a clinical trials program comprised of multiple Phase I and Phase IIa trials conducted by Cytokinetics. This program was 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. Two Phase IIa clinical trials of *omecamtiv mecarbil* were conducted. In addition, five Phase I clinical trials of *omecamtiv mecarbil* were conducted in healthy subjects. Data from each of these trials were reported previously.

In July 2012, Cytokinetics and Amgen reviewed data from another completed randomized, open-label, 4-period cross-over, Phase I clinical trial designed to assess the safety, tolerability and pharmacokinetics of multiple oral formulations of *omecamtiv mecarbil* in healthy volunteers. The companies have selected oral formulations that warrant further evaluation in patients with heart failure. In recent months, Cytokinetics and Amgen have collaborated to plan the manufacturing of drug product and to draft regulatory submissions to enable the potential initiation in early 2013 of a Phase II double-blind, randomized, placebo-controlled, multicenter, dose escalation study designed to evaluate several modified-release oral formulations of *omecamtiv mecarbil* in patients with heart failure and left ventricular systolic dysfunction. This trial is expected to inform the potential selection of one of these oral formulations for advancement into later-phase clinical trials.

### **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*, is in Phase II 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 *tirasemtiv*, a skeletal muscle activator, as a potential treatment for diseases and conditions associated with aging, muscle wasting or neuromuscular dysfunction. *Tirasemtiv* is currently the subject of a Phase II clinical trials program and 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 amyotrophic lateral sclerosis, a debilitating disease of neuromuscular impairment in which treatment with *tirasemtiv* produced potentially clinically relevant pharmacodynamic effects in Phase II trials. All of these drug candidates have arisen from Cytokinetics' muscle biology focused 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 Amgen's research and development activities, including the progress, conduct, design and results of clinical trials, the significance and utility of clinical trial results, and the properties and potential benefits of omecamtiv mecarbil 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.*

Contact:

Jodi L. Goldstein

Manager, Corporate Communications & Marketing

(650) 624-3000

HUG#1661257