



Cytokinetics Announces Opening of Second Cohort in Phase IIb Clinical Trial of Intravenous Omecamtiv Mecarbil in Patients With Acute Heart Failure

May 24, 2012 11:32 AM EDT

Independent Data Monitoring Committee Recommends Progression to Second Cohort

SOUTH SAN FRANCISCO, CA, May 24, 2012 (MARKETWIRE via COMTEX) --Cytokinetics, Incorporated (NASDAQ: CYTK) announced today the opening to enrollment of the second cohort in the ongoing, international, randomized, double-blind, placebo-controlled Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil, known as ATOMIC-AHF (Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure). Following a review of the data from the first cohort in this ongoing Phase IIb clinical trial, the independent data monitoring committee concluded that the current safety data supports progression to the second cohort of this trial. Amgen holds an exclusive, worldwide license (excluding Japan) to omecamtiv mecarbil and related compounds, subject to Cytokinetics' specified development and commercialization participation rights.

The ATOMIC-AHF clinical trial, conducted by Amgen in collaboration with Cytokinetics, is designed to evaluate the safety, tolerability, and efficacy of omecamtiv mecarbil in patients with left ventricular systolic dysfunction who are hospitalized with acute heart failure. Additional information about ATOMIC-AHF can be found at www.clinicaltrials.gov.

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: 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 were reported previously.

In addition, in February 2012, Cytokinetics announced the initiation of a Phase I clinical trial designed to assess the safety, tolerability and pharmacokinetics of multiple oral formulations of omecamtiv mecarbil in healthy volunteers. This clinical trial is being conducted by Amgen in collaboration with Cytokinetics and will be used to guide selection of an oral formulation of omecamtiv mecarbil for later-stage clinical trials. This clinical trial is a randomized, open-label, 4-period cross-over study designed to determine the oral bioavailability of multiple formulations of omecamtiv mecarbil in healthy subjects. Approximately 60 subjects were planned to be enrolled in this trial. Each subject will receive two of the six oral formulations included in the trial, each administered as a single dose under fasted and fed conditions. The primary objective of this trial is to determine the effect of food on the bioavailability of omecamtiv mecarbil when administered in multiple oral formulations. The secondary objectives are to evaluate the bioavailability, safety, tolerability and pharmacokinetic profiles of omecamtiv mecarbil when administered in multiple oral formulations.

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 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 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 CK-2017357 demonstrated potentially clinically relevant pharmacodynamic effects in Phase II trials. Cytokinetics is also conducting research 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 disease (COPD). 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.

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

SOURCE: Cytokinetics, Inc.