



Cytokinetics Provides Update Regarding Omecamtiv Mecarbil Clinical Development Program

February 9, 2011 12:32 PM EST

Initiation of a Phase IIb Clinical Trial Expected in the First Half of 2011

SOUTH SAN FRANCISCO, CA, Feb 09, 2011 (MARKETWIRE via COMTEX) -- Cytokinetics, Incorporated (NASDAQ: CYTK) announced today that, in the first half of 2011, the company and its partner, Amgen Inc., plan to initiate a Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil to evaluate its safety and efficacy in patients with left ventricular systolic dysfunction hospitalized for acute heart failure. This trial will be conducted by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, world-wide (excluding Japan) license to omecamtiv mecarbil and related compounds, subject to specified development and commercialization participation rights of Cytokinetics.

"This Phase IIb clinical trial was designed to evaluate specific heart failure symptoms to assess the potential clinical efficacy, safety, and tolerability of omecamtiv mecarbil for the treatment of patients hospitalized for acute heart failure," stated Andrew A. Wolff, MD, FACC, Cytokinetics' Senior Vice President of Clinical Research and Development and Chief Medical Officer. "The objective of this clinical trial is to determine if the increases in left ventricular systolic function observed in patients with stable heart disease treated with omecamtiv mecarbil in an earlier Phase IIa trial may translate into a clinical benefit in patients hospitalized for acute heart failure, a large and growing population that is underserved by currently available treatments."

"This Phase IIb clinical trial represents a significant step forward for this program," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "The progress in the clinical development of omecamtiv mecarbil, combined with the recent successful completion of an Evidence of Effect Phase IIa clinical trial of our fast skeletal muscle troponin activator, CK-2017357, in patients with ALS, demonstrates the promise of our focused research and development activities in the biology of muscle function."

Phase IIb Clinical Trial of Omecamtiv Mecarbil

This Phase IIb clinical trial is planned to be an international, multicenter, randomized, double-blind, placebo-controlled study in approximately 600 patients, enrolled sequentially in 3 ascending-dose cohorts. In each cohort, patients will be randomized to receive omecamtiv mecarbil or placebo. The primary objective of the Phase IIb clinical trial will be to evaluate the effect of 48 hours of intravenous (IV) omecamtiv mecarbil compared to placebo on dyspnea (or 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 IV 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.

Oral Program Development of Omecamtiv Mecarbil

Cytokinetics and its partner Amgen are in active discussions regarding the oral development strategy for omecamtiv mecarbil. The company anticipates that these plans may include studies designed to investigate the safety, tolerability and pharmacokinetics of multiple oral formulations of omecamtiv mecarbil. Additional information will be provided following the finalization of these plans.

Development Status of Omecamtiv Mecarbil

Omecamtiv mecarbil, a novel cardiac muscle myosin activator, has been the subject of a clinical trials program comprised of multiple Phase I and Phase IIa trials previously conducted under the sponsorship of 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 from this program have been completed. 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 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.

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 initiation, conduct, design, scope and results of omecamtiv mecarbil clinical trials and the provision of updated guidance with respect to such clinical trials; 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 omeacamtiv 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; 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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SOURCE: Cytokinetics, Inc.