



Cytokinetics and Amgen to Advance Omecamtiv Mecarbil to Phase 3 Clinical Development

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Company Expects the Initiation of Phase 3 Cardiovascular Outcomes Clinical Trial in Q4 2016

SOUTH SAN FRANCISCO, Calif., Sept. 01, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) today announced the advancement of *omecamtiv mecarbil* to Phase 3 clinical development with a cardiovascular outcomes clinical trial expected to initiate in the fourth quarter of 2016. *Omecamtiv mecarbil*, a novel investigational cardiac myosin activator, enhances cardiac function by increasing cardiac contractility and is being developed for the potential treatment of patients with chronic heart failure.

The decision to proceed to Phase 3 development follows the review of results from prior clinical trials, including COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure), a Phase 2 clinical trial evaluating *omecamtiv mecarbil* in patients with chronic heart failure. Data from COSMIC-HF were first presented in a Late-Breaking Clinical Trial session at the American Heart Association Scientific Sessions 2015. COSMIC-HF met its primary pharmacokinetic objective and demonstrated statistically significant improvements in all pre-specified secondary measures of cardiac function in the treatment group employing pharmacokinetic-based dose titration. In addition, Amgen and Cytokinetics have convened meetings with regulatory authorities to inform plans for *omecamtiv mecarbil* in a Phase 3 clinical trials program.

"Progression of *omecamtiv mecarbil* to Phase 3 is a major milestone for our company as well as our collaboration with Amgen and reflects our collective commitment to the heart failure community," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We are pleased that the comprehensive clinical trials program that we have jointly conducted for *omecamtiv mecarbil* has contributed data that provide a compelling rationale to advance the development of our cardiac myosin activator to an international outcomes trial for the potential treatment of patients with chronic heart failure."

The Phase 3 outcomes trial will be conducted by Amgen in collaboration with Cytokinetics. As part of the Phase 3 clinical trials program, Cytokinetics and Amgen are also planning a potential exercise performance/cardiac function clinical trial to be conducted by Cytokinetics. Cytokinetics is eligible to receive pre-commercialization and commercialization milestone payments on *omecamtiv mecarbil* and royalties that escalate based on increasing levels of annual net sales. Cytokinetics has the opportunity to earn increased royalties by sharing certain Phase 3 development costs. In that case, Cytokinetics could co-promote *omecamtiv mecarbil* in North America and would have an agreed role in commercialization activities.

About Heart Failure

Heart failure is a grievous condition that affects more than 23 million people worldwide, about half of whom have reduced left ventricular function. It is the leading cause of hospitalization and readmission in people age 65 and older. Despite broad use of standard treatments and advances in care, the prognosis for patients with heart failure is poor. An estimated one in five people over the age of 40 are at risk of developing heart failure, and approximately 50 percent of people diagnosed with heart failure will die within five years of initial hospitalization.

About Omecamtiv Mecarbil

Omecamtiv mecarbil is a novel cardiac myosin activator. Cardiac myosin is the cytoskeletal motor protein in the cardiac muscle cell that is directly responsible for converting chemical energy into the mechanical force resulting in cardiac contraction. Cardiac myosin activators are thought to accelerate the rate-limiting step of the myosin enzymatic cycle and shift the enzymatic cycle in favor of the force-producing state. Preclinical research has shown that cardiac myosin activators increase contractility in the absence of changes in intracellular calcium in cardiac myocytes.

Omecamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, worldwide license to *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization rights.

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 declining. As a leader in muscle biology and the 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 troponin 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 retains the right to develop and commercialize *tirasemtiv*, subject to an option held by Astellas Pharma Inc. Cytokinetics is also collaborating with Astellas to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. 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 significance and utility of COSMIC-HF clinical trial results and the likelihood and timing for the progression of *omecamtiv mecarbil* to Phase 3 development; and the properties and potential benefits of Cytokinetics' 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 Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; 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 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; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; standards of care may change, rendering Cytokinetics' drug candidates obsolete; and competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and Cytokinetics' actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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