Cytokinetics Announces Positive Results From Phase 2 Clinical Trial of Omecamtiv Mecarbil in Japanese Patients With Heart Failure

August 2, 2017 11:30 AM EDT

Data Supports Inclusion of Japan in GALACTIC-HF

Company is Eligible to Earn $10 Million Milestone Payment from Amgenupon First Patient Dosing in Japan in Phase 3 Outcomes Trial

SOUTH SAN FRANCISCO, Calif., Aug. 02, 2017 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) today announced that the Phase 2 clinical trial of *omecamtiv mecarbil* in Japanese patients with heart failure has met its pharmacokinetic primary endpoint and demonstrated statistically significant improvements in systolic ejection time (SET), a secondary endpoint. *Omecamtiv mecarbil*, a novel investigational cardiac myosin activator that increases cardiac contractility, is being developed by Amgen in collaboration with Cytokinetics for the potential treatment of heart failure.

“We are pleased that this Phase 2 trial of *omecamtiv mecarbil* met its objectives in this population of Japanese heart failure patients,” said Fady I. Malik, MD, PhD, Cytokinetics' Executive Vice President, Research and Development. “The pharmacokinetics, pharmacodynamics, safety, and tolerability data from this trial were consistent with previously reported results from COSMIC-HF. We are now collaborating with Amgen on start-up activities for Japanese sites to participate in GALACTIC-HF.”

Cytokinetics is eligible to earn a $10 million milestone payment from Amgen upon the first dosing of a patient in Japan in GALACTIC-HF, the ongoing Phase 3 cardiovascular clinical outcomes trial of *omecamtiv mecarbil*.

Design of Phase 2 Clinical Trial in Japan

This Phase 2 clinical trial in Japanese patients with heart failure was designed to assess the pharmacokinetics of *omecamtiv mecarbil* as well as its effect on cardiac function, safety and tolerability in Japanese patients with chronic heart failure. The trial randomized 81 patients 1:1:1:1 to placebo, 25 mg of *omecamtiv mecarbil* twice daily and two separate PK-based titration groups in which the dose of *omecamtiv mecarbil* could be increased from 25 to 37.5 mg or 50 mg twice daily based on the pre-dose concentration of *omecamtiv mecarbil* at week 2. Patients received study drug for 16 weeks after randomization. The primary endpoint was to assess the plasma concentrations of *omecamtiv mecarbil* at weeks 2, 4, 12 and 16, and the area under the curve (AUC) at week 8. The secondary endpoint was to assess the change from baseline in SET measured by echocardiography at week 16.

About GALACTIC-HF

GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure) is a Phase 3, double-blind, randomized, placebo-controlled multicenter clinical trial designed to determine if treatment with *omecamtiv mecarbil* when added to standard of care is superior to standard of care plus placebo in reducing the risk of cardiovascular death or heart failure events in patients with high risk chronic heart failure and reduced ejection fraction. GALACTIC-HF is planned to enroll approximately 8,000 symptomatic chronic heart failure patients in over 800 sites in 34 countries who are either currently hospitalized for a primary reason of heart failure or have had a hospitalization or admission to an emergency room for heart failure within one year prior to screening. GALACTIC-HF is being conducted under a Special Protocol Assessment (SPA) with the U.S. FDA.

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. Amgen has also entered an alliance with Servier for exclusive commercialization rights in Europe as well as the Commonwealth of Independent States, including Russia. Servier contributes funding for development and provides strategic support to the program.

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 (FSTA). *Tirasemtiv* is the subject of VITALITY-ALS, an international Phase 3 clinical trial in patients with ALS. *Tirasemtiv* has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration (FDA) and orphan medicinal product designation by the European Medicines Agency for the potential treatment of ALS. Cytokinetics is preparing for the potential commercialization of *tirasemtiv* in North America and Europe and has granted an option to Astellas Pharma Inc. (“Astellas”) for development and commercialization in other countries. Cytokinetics is collaborating with Astellas to develop CK-2127107, a next-generation FSTA. CK-2127107 has been granted orphan drug designation by the FDA for the potential treatment of SMA. CK-2127107 is the subject of three ongoing Phase 2 clinical trials enrolling patients with spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Astellas is also conducting a Phase 1b clinical trial of CK-2127107 in elderly adults with limited mobility. Cytokinetics is collaborating with Amgen Inc. (“Amgen”) to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of GALACTIC-HF, an international Phase 3 clinical trial in patients with heart failure. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Astellas holds an exclusive worldwide license to develop and commercialize CK-2127107. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization 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, the properties and potential benefits of Cytokinetics’ drug candidates, including *omecamtiv mecarbil*; the design, timing, results and significance of the Phase 2 clinical trial of *omecamtiv mecarbil* in Japanese subjects with chronic heart failure and reduced ejection fraction and GALACTIC-HF; Cytokinetics’ and Amgen’s collaboration on start-up activities for Japanese sites to participate in GALACTIC-HF; Cytokinetics’ eligibility to receive a milestone payment from Amgen; and the potential for eventual regulatory approval, commercialization and launch of Cytokinetics’ product 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 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; 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.

Contact:
CytokineticsDiane Weiser
Vice President, Corporate Communications, Investor Relations
(415) 290-7757

Cytokinetics

Cytokinetics, Inc