Cytokinetics Announces Results From COSMIC-HF to be Presented in Late Breaking Clinical Trial Session at American Heart Association Scientific Sessions

November 6, 2015 12:30 PM EST

Company to Host Investor Meeting & Webcast Monday, November 9 at 7 a.m. ET

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2015 (GLOBE NEWSWIRE) -- Cytokinetics Incorporated (NASDAQ:CYTK) today announced that results from the expansion phase of COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure), a Phase 2 trial evaluating *omecamtiv mecarbil* in patients with chronic heart failure, will be presented in the Late Breaking Clinical Trial Session at the American Heart Association Scientific Sessions 2015 on November 8 in Orlando, FL.

Clinical Presentation:

Date: Sunday, November 8, 2015

Session Time: 3:45-5:00 p.m. ET (Hall D)

Presentation Time: 4:31-4:40 p.m. ET

Session: LBCT.01 Failure is Not an Option: New Drugs and Systems of Care

Presentation Title: Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure (COSMIC-HF): Final Results from a Double-blind, Randomized, Placebo-controlled, Multicenter Study

Investor Event:

The Company will host an investor meeting and Webcast the following day, Monday, November 9, 2015 from 7:00 AM – 8:00 AM ET in Salon 10 of the Rosen Center.

Presenters include:

- Robert Blum, President & CEO, Cytokinetics
- Fady Malik, M.D., Ph.D., F.A.C.C., SVP of Research & Development, Cytokinetics
- John Teerlink, M.D., F.A.C.C., F.A.H.A, F.E.S.C., F.R.C.P. (London), Professor of Clinical Medicine at the University of California San Francisco and Director of Heart Failure at the San Francisco Veterans Affairs Medical Center

Panelists will include:

- John McMurray, M.D., F.R.C.P, F.A.C.C., F.E.S.C., F.R.S.E., Professor of Medical Cardiology and Honorary Consultant Cardiologist, University of Glasgow
- Scott Solomon, M.D., Professor, Harvard Medical School, Director, Noninvasive Cardiology, Brigham and Women's Hospital
- Michael Felker, M.D., M.H.S., F.A.C.C., F.A.H.A., Professor of Medicine, Chief, Heart Failure Section, Division of Cardiology, Duke University School of Medicine

Webcast and Conference Call Information:

Presentations and accompanying slides will be simultaneously webcast and can be accessed through the Investors & Media section of the Cytokinetics' website at www.cytokinetics.com. The live audio of the meeting will also be accessible via telephone by dialing either (866) 999-CYTK (2985) (United States and Canada) or (706) 679-3075 (international) and typing in the passcode 76975790.

An archived replay of the webcast will be available via Cytokinetics' website until November 16, 2015. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (International) and typing in the passcode 76975790 from November 9, 2015 at 1:00 PM ET until November 16, 2015.

COSMIC-HF Trial Design
COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure) is a double-blind, randomized, placebo-controlled, multicenter, Phase 2 trial designed to evaluate an oral formulation of *omecamtiv mecarbil* in chronic heart failure patients with reduced ejection fraction. The trial consisted of two parts, a dose escalation phase and a larger and longer expansion phase. The dose escalation phase, which completed in 2013, assessed the pharmacokinetics and tolerability of three oral modified-release formulations of *omecamtiv mecarbil* and was used to select one formulation for further evaluation in the expansion phase. In the dose escalation phase, 96 patients were randomized 1:1:1:1 to placebo or one of three *omecamtiv mecarbil* oral modified-release formulations in two cohorts (25 mg twice daily or 50 mg twice daily). Each patient cohort was followed for 35 days.

The expansion phase evaluated 448 chronic heart failure patients with reduced ejection fraction who were dosed with the selected oral formulation of

omecamtiv mecarbil for 20 weeks and followed for a total of 24 weeks. Patients were randomized 1:1:1 to receive either placebo or treatment with *omecamtiv mecarbil* 25 mg twice daily or 25 mg with dose escalation to 50 mg twice daily depending on plasma concentrations of *omecamtiv mecarbil* after two weeks of treatment. The primary endpoints for the expansion phase were to assess the maximum and pre-dose plasma concentration of *omecamtiv mecarbil*. The secondary endpoints were to assess changes from baseline in systolic ejection time, stroke volume, left ventricular end-systolic diameter, left ventricular end-diastolic diameter, heart rate and N-terminal pro-brain natriuretic peptide (a biomarker associated with the severity of heart failure) at week 20, as well as the safety and tolerability of *omecamtiv mecarbil* including incidence of adverse events from baseline to week 24.

COSMIC-HF was not designed to assess the impact of *omecamtiv mecarbil* on cardiovascular outcomes in heart failure patients.

COSMIC-HF was conducted by Amgen in collaboration with Cytokinetics.

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.[i, ii, iii]

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. Additionally, Les Laboratoires Servier obtained an exclusive option to commercialize *omecamtiv mecarbil* in Europe.

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 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*. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy. 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 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 potential 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 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; 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; 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. 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.

[i] Malik FI, Hartman JJ, Elias KA, et al. Cardiac myosin activation: a potential therapeutic approach for systolic heart failure. *Science*. 2011;331(6023):1439-1443.

[ii] Shen YT, Malik FI, Zhao X, et al. Improvement of Cardiac Function by a Cardiac Myosin Activator in Conscious Dogs With Systolic Heart Failure. *Circ Heart Fail*. 2010;3(4):522-527.

[iii] Malik FI, Morgan BP. Cardiac myosin activation part 1: From concept to clinic. *J Mol Cell Cardiol*. 2011;51:454-461.

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Cytokinetics

Cytokinetics, Inc