Cytokinetics Announces Presentation of Additional Results From COSMIC-HF at the HFSA Annual Scientific Meeting

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Data Show Treatment with Omecamtiv Mecarbil May Improve Patient Symptoms at 20 Weeks

SOUTH SAN FRANCISCO, Calif., Sept. 19, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) today announced that additional results from 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, were presented in a Rapid Fire Abstract Session at the 20th Annual Heart Failure Society of America Scientific Meeting in Orlando, FL. The results presented show that *omecamtiv mecarbil* may improve symptoms in patients with moderate to severe heart failure symptoms versus placebo after 20 weeks of double-blind treatment, as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) Total Symptom Score (TSS), one of the sub-domains of a self-administered questionnaire that measures quality-of-life in patients with heart failure. *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.

"It's encouraging to see in these data that patients' self-reported heart failure symptoms may have improved in association with improvements in cardiac function in those receiving *omecamtiv mecarbil* versus placebo," said Fady I. Malik, MD, PhD, Cytokinetics' Executive Vice President, Research and Development. "We look forward to further investigating how these potential improvements may translate to clinical outcomes in our planned Phase 3 clinical trial to be conducted in collaboration with Amgen."

COSMIC-HF: Expansion Phase Design and Results

The expansion phase of COSMIC-HF evaluated the pharmacokinetics, pharmacodynamics, safety and tolerability of oral *omecamtiv mecarbil* in 448 patients with chronic heart failure and left ventricular systolic dysfunction. Patients were randomized 1:1:1 to receive either placebo or treatment with *omecamtiv mecarbil* dosed as 25 mg twice daily or 25 mg twice daily with dose escalation to 50 mg twice daily, depending on a plasma concentration of *omecamtiv mecarbil* after two weeks of treatment. The study met its primary pharmacokinetic objective and showed statistically significant improvements in all pre-specified secondary measures of cardiac function in the treatment group receiving pharmacokinetic-based dose titration. The results were initially presented as a Late-Breaking Clinical Trial at the American Heart Association (AHA) Scientific Sessions 2015. Additional results were also presented at Heart Failure 2016, the annual congress of the Heart Failure Association of the European Society of Cardiology, in May 2016, showing that *omecamtiv mecarbil* improved left ventricular (LV) systolic function, LV end-diastolic volume and NT-proBNP over time, suggesting potentially favorable ventricular remodeling and progressive reduction in myocardial wall stress.

The KCCQ TSS data from COSMIC-HF are shown in the table below. At week 20, the KCCQ TSS was increased (with increases in the score reflecting improvement) in a dose-related fashion, with a 4.9 point improvement in the PK-guided dose titration group (p=0.03). This improvement was greater among patients who were moderately to severely symptomatic at baseline, with the largest magnitude in the PK-guided dose titration treatment group (6.5, p=0.09). Patients who were asymptomatic or mildly symptomatic had modest improvements in the TSS.

	Placebo	OM 25 mg po BID	OM PK-Titration
TSS-Overall (n)	149	150	146
Baseline - Mean (SD)	69.7 (21.2)	70.9 (22.0)	67.3 (21.3)
Change from baseline at Week 20 - Mean (SD)	5.0 (1.6)	6.6 (1.6)	9.9 (1.6)
Difference vs. Placebo - Mean (95%CI)	---	1.7 (-2.8, 6.1)	4.9 (0.5, 9.4)**
TSS-Group 1: Asymptomatic to Mildly Sx (n)	81	86	75
Baseline - Mean (SD)	77.3 (16.4)	80.2 (18.3)	78.4 (17.4)
Change from baseline at Week 20 - Mean (SD)	1.6 (1.8)	2.7 (2.0)	4.3 (1.6)
Difference vs. Placebo - Mean (95%CI)	---	1.2 (-4.1, 6.4)	2.7 (-2.2, 7.6)
TSS-Group 2: Moderately to Very Severely Sx (n)	67	64	71
Baseline - Mean (SD)	60.2 (22.6)	58.3 (20.2)	55.5 (18.7)
Change from baseline at Week 20 - Mean (SD)	9.5 (2.7)	11.3 (2.6)	16.0 (2.7)
Difference vs. Placebo - Mean (95%CI)	---	1.8 (-5.7, 9.3)	6.5 (-1.0, 14.0)*
(*p<0.10; **p<0.05)			

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. Amgen has granted a sublicense to Servier to commercialize *omecamtiv mecarbil* in Europe, as well as the Commonwealth of Independent States, including Russia.

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 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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