Cytokinetics Announces Completion of Enrollment in GALACTIC-HF, Phase 3 Clinical Trial of Omecamtiv Mecarbil in Patients With Heart Failure

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Clinical Trial Enrolled Over 8,200 Patients With Reduced Ejection Fraction in 35 Countries

SOUTH SAN FRANCISCO, Calif., July 15, 2019 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced the completion of patient enrollment in 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), the Phase 3 event driven cardiovascular outcomes clinical trial of *omecamtiv mecarbil* which is being conducted by Amgen, in collaboration with Cytokinetics. *Omecamtiv mecarbil*, a novel investigational cardiac muscle activator, is being developed by Amgen in collaboration with Cytokinetics for the potential treatment of heart failure.

GALACTIC-HF enrolled patients in 35 countries: approximately 40% in US and Canada, Western Europe, South Africa, and Australasia; 33% in Eastern Europe and Russia; 19% in Latin America and 8% in Asia. Approximately 25% of patients in GALACTIC-HF were hospitalized at the time of randomization.

"We would like to thank the investigators and clinical site coordinators for their dedication to GALACTIC-HF, which now ranks among the largest heart failure trials ever conducted," said Fady I. Malik, MD, Ph.D., Cytokinetics' Executive Vice President, Research and Development. "Completing enrollment marks an important step forward for the potential treatment of a disease that represents one of the biggest clinical and economic healthcare burdens of our time, for which patients and healthcare systems are in urgent need of novel therapies to decrease mortality, reduce hospitalizations and improve quality of life."

"Despite current treatments for the approximately 26 million people worldwide living with heart failure, these patients continue to suffer from high morbidity and mortality," said John Teerlink, M.D., Professor of Clinical Medicine, University of California San Francisco, Director of Heart Failure, San Francisco Veterans Affairs Medical Center and Chairperson of the GALACTIC-HF Executive Committee. "By directly activating cardiac myosin, treatment with *omecamtiv mecarbil* may represent a novel therapeutic strategy to increase cardiac muscle function in heart failure patients with reduced ejection fraction, potentially leading to improved clinical outcomes."

About *Omecamtiv Mecarbil* and the Phase 3 Clinical Trials Program

Omecamtiv mecarbil is a novel, selective cardiac myosin activator, also known as a cardiac myotrope,[i] that binds to the catalytic domain of myosin. Preclinical research has shown that cardiac myotropes increase cardiac contractility without affecting intracellular myocyte calcium concentrations or myocardial oxygen consumption.[ii,iii] 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. *Omecamtiv mecarbil* is being developed for the potential treatment of heart failure with reduced ejection fraction (HFrEF) under a collaboration between Amgen and Cytokinetics, with funding and strategic support from Servier.

Omecamtiv mecarbil is the subject of a comprehensive Phase 3 clinical trials program comprised of GALACTIC-HF, a large Phase 3 global cardiovascular outcomes study and METEORIC-HF (**M**ulticenter **E**xercise **T**olerance **E**valuation of ***O**mecamtiv Mecarbil***R**elated to **I**ncreased **C**ontractility in **H**eart **F**ailure), a Phase 3 clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity.

About GALACTIC-HF

GALACTIC-HF opened to enrollment in late 2016 and was designed to enroll approximately 8,000 heart failure patients with reduced ejection fraction at over 900 sites in 35 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 a primary reason of heart failure within one year prior to screening. The trial is designed to evaluate whether treatment with *omecamtiv mecarbil*, when added to standard of care, reduces the risk of heart failure events (heart failure hospitalization or other urgent treatment for heart failure) and cardiovascular (CV) death in patients with chronic heart failure with reduced ejection fraction. In March 2019, the Data Monitoring Committee for GALACTIC-HF completed the first planned interim analysis, which included consideration of pre-specified criteria for futility, and recommended that the trial continue without changes to its conduct. A second interim analysis for superiority and futility is planned to be conducted in the first half of 2020.

About Heart Failure

Heart failure is a grievous condition that affects more than 26 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 in the United States. Despite broad use of standard treatments and advances in care, the prognosis for patients with heart failure is poor. In the United States, 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 Cytokinetics and Amgen Collaboration

In 2006, Cytokinetics and Amgen entered into a strategic alliance to discover, develop and commercialize novel small molecule therapeutics designed to activate the cardiac sarcomere for the potential treatment of heart failure. *Omecamtiv mecarbil* is being developed by Amgen in collaboration with Cytokinetics, with funding and strategic support from Servier. Amgen holds an exclusive, worldwide license to *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization rights. Cytokinetics is eligible for pre-commercialization and commercialization milestone payments and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. Cytokinetics has co-invested with Amgen in the Phase 3 development program of *omecamtiv mecarbil* in exchange for increased royalties from Amgen on worldwide sales of *omecamtiv mecarbil* outside Japan and co-promotion rights in institutional care settings in North America. Amgen has also entered an alliance with Servier for exclusive commercialization rights for *omecamtiv mecarbil* 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 and best-in-class muscle inhibitors 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 impact muscle function and contractility. Cytokinetics is collaborating with Amgen Inc. (Amgen) to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of an international clinical trials program in patients with heart failure including GALACTIC-HF and METEORIC-HF. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtivmecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to develop *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA). Astellas holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. Licenses held by Amgen and Astellas are subject to specified co-development and co-commercialization rights of Cytokinetics. Cytokinetics is also developing CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations, for the potential treatment of hypertrophic cardiomyopathies. Cytokinetics continues its over 20-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on Twitter, LinkedIn, Facebook and YouTube.

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 the GALACTIC-HF clinical trial, including the planned timing of a second interim analysis for superiority; the potential benefits of *omecamtiv mecarbil*, including its ability to represent a novel therapeutic strategy to increase cardiac muscle function and restore cardiac performance; Cytokinetics' and its partners' research and development activities; the design, timing, results, significance and utility of preclinical and clinical results; 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, 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; Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy; the FDA 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; Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; 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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[i] Psotka MA, Gottlieb SS, Francis GS et al. Cardiac Calcitropes, Myotropes, and Mitotropes. *JACC*. 2019; 73:2345-53.

[ii] Planelles-Herrero VJ, Hartman JJ, Robert-Paganin J. et al. Mechanistic and structural basis for activation of cardiac myosin force production by *omecamtiv mecarbil*. *Nat Commun*. 2017;8:190.

[iii] 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: 522-27.

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Source: Cytokinetics, Incorporated