Cytokinetics Provides Clinical Trials and Business Update in Response to COVID-19 Pandemic

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Top-line Results for GALACTIC-HF Expected in Q4 2020; Enrollment in METEORIC-HF Temporarily Suspended

SOUTH SAN FRANCISCO, Calif., April 14, 2020 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today provided an update regarding the company's clinical trials and business operations related to its response to the COVID-19 pandemic alongside its commitment to prioritize the safety, health and wellbeing of patients, their caregivers, healthcare providers, partners and employees. The company believes it is on track to achieve its key strategic objectives for 2020. Cytokinetics continues to assess the potential impact of the pandemic on its pipeline and business operations and expects to provide further updates in connection with the reporting of its first quarter financial results in May.

omecamtiv mecarbil (cardiac myosin activator)

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), a large, Phase 3, global, event-driven, cardiovascular outcomes trial of *omecamtiv mecarbil* completed enrollment in mid-2019 with 8,256 participants in over 1,000 clinical sites. As previously reported, the Data Monitoring Committee (DMC) for GALACTIC-HF recently completed the second and final planned interim analysis of data from the trial, which included consideration of pre-specified criteria for futility and superiority. The DMC recommended that GALACTIC-HF continue without changes to its conduct. The study record for GALACTIC-HF was recently updated on www.clinicaltrials.gov to reflect an Estimated Study Completion Date of August 7, 2020. Cytokinetics expects results from GALACTIC-HF in Q4 2020. GALACTIC-HF is being conducted by Amgen in collaboration with Cytokinetics.

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 second Phase 3 clinical trial of *omecamtiv mecarbil*, is designed to enroll 270 participants. METEORIC-HF has enrolled participants at approximately 30 clinical sites in North America. Screening and enrollment of patients in METEORIC-HF have slowed in response to the COVID-19 pandemic. In consultation with the DMC, Cytokinetics and Amgen have agreed to temporarily suspend enrollment in METEORIC-HF to protect the safety and health of clinical trial participants and healthcare professionals. For enrolled subjects, Cytokinetics is working closely with clinical sites to monitor study visits and is taking certain steps to mitigate potential risk associated with the COVID-19 pandemic by enabling remote study visits and home delivery of investigational product to ensure study continuity and integrity. Cytokinetics continues to enable site start-up activities with an objective to activate over 50 new sites throughout North America and Europe. Cytokinetics has reviewed logistics associated with the conduct of METEORIC-HF and believes enrollment in METEORIC-HF may be completed by the end of Q4 2020 if enrollment can be reactivated by the end of Q2 2020. METEORIC-HF is being conducted by Cytokinetics in collaboration with Amgen.

AMG 594 (cardiac troponin activator)

Amgen and Cytokinetics have agreed to suspend enrollment in the Phase 1 study of AMG 594 to protect the safety and health of clinical study participants and healthcare professionals as well as reduce the burden on the healthcare systems fighting COVID-19. This Phase 1 study is being conducted by Amgen in collaboration with Cytokinetics.

CK-3773274 (CK-274, cardiac myosin inhibitor)

REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM),** the Phase 2 clinical trial of CK-274, opened to enrollment in Q1 2020. Screening and enrollment of patients in REDWOOD-HCM have slowed in response to the COVID-19 pandemic. Cytokinetics has temporarily suspended enrollment in REDWOOD-HCM to protect the safety and health of clinical trial participants and healthcare professionals. Cytokinetics has been engaging sites to enable patient-specific plans for dispensation of investigational product and accommodations for potential remote visits. The company continues to prioritize start-up activities with an objective to activate over 20 new sites throughout North America and Europe. Cytokinetics has reviewed logistics associated with the conduct of REDWOOD-HCM and believes data from the first cohort of patients enrolled in REDWOOD-HCM can be available in 2H 2020 if enrollment in the first cohort can be completed by mid-year.

Skeletal Muscle Program

reldesemtiv (next-generation fast skeletal muscle troponin activator (FSTA))

Cytokinetics continues to conduct regulatory interactions and feasibility and other planning activities in preparation for the potential advancement of *reldesemtiv* to a Phase 3 trial in patients with ALS. The company does not expect that the COVID-19 pandemic will affect 2020 objectives relating to this program.

Corporate: Business Operations

In response to the COVID-19 pandemic, the company has taken steps to ensure the safety and wellbeing of employees and their families and to comply with guidance from federal, state and local authorities. Cytokinetics has instituted a mandatory work-from-home policy for most of its employees and has implemented support programs and made technology resources available to employees with the objective to minimize disruption to business operations. The policy permits designated employees to attend to certain essential business and corporate activities, including key research and other laboratory activities. For these employees, Cytokinetics has established safety guidelines to limit the number of employees onsite and to ensure physical distancing, and the regular conduct of appropriate disinfection cleanings in its facilities.

The company believes that the fundamentals of its business remain intact and it is on track to achieve its key strategic objectives for 2020. The company also believes that it has manufactured adequate supplies of drug substance and investigational product to complete ongoing trials as well as to support planned clinical trials into 2021 and does not expect delays to its clinical trials due to manufacturing or supply-chain issues. Cytokinetics recently announced that it ended 2019 with cash, cash equivalents and investments totaling $267.7 million representing m*ore than two years of cash runway based on 2020 financial guidance.* The company continues to assess the potential impact to its business given the ongoing nature of the COVID-19 pandemic and plans to provide further updates together with its first quarter financial results in May.

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,[1] 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.[2-4] 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 Phase 3 clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on cardiovascular outcomes and METEORIC-HF, a Phase 3 clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity.

About CK-274 and REDWOOD-HCM

CK-274 is a novel, oral, small molecule cardiac myosin inhibitor that company scientists discovered independent of its collaborations. CK-274 arose from an extensive chemical optimization program conducted with careful attention to therapeutic index and pharmacokinetic properties that may translate into next-in-class potential in clinical development. CK-274 was designed to reduce the hypercontractility that is associated with hypertrophic cardiomyopathy (HCM). In preclinical models, CK-274 reduces myocardial contractility by binding directly to cardiac myosin at a distinct and selective allosteric binding site, thereby preventing myosin from entering a force producing state. CK-274 reduces the number of active actin-myosin cross bridges during each cardiac cycle and consequently reduces myocardial contractility.

REDWOOD-HCM is a multi-center, randomized, placebo-controlled, double-blind, dose-finding Phase 2 clinical trial in patients with symptomatic, obstructive HCM. The primary objective of the trial is to determine the safety and tolerability of CK-274. The secondary objectives are to describe the concentration-response and dose-response relationship of CK-274 on the resting and post-Valsalva left ventricular outflow tract gradient as measured by echocardiography during 10 weeks of treatment.

About *Reldesemtiv* and Potential Phase 3 Clinical Trial

Skeletal muscle contractility is driven by the sarcomere, the fundamental unit of skeletal muscle contraction and a highly ordered cytoskeletal structure composed of several key proteins. Skeletal muscle myosin is the motor protein that converts chemical energy into mechanical force through its interaction with actin. A set of regulatory proteins, which includes tropomyosin and several types of troponin, make the actin-myosin interaction dependent on changes in intracellular calcium levels. *Reldesemtiv*, a next-generation FSTA arising from Cytokinetics' skeletal muscle contractility program, slows the rate of calcium release from the regulatory troponin complex of fast skeletal muscle fibers, which sensitizes the sarcomere to calcium, leading to an increase in skeletal muscle contractility. *Reldesemtiv* has demonstrated pharmacological activity that may lead to new therapeutic options for diseases associated with skeletal muscle weakness and fatigue.

FORTITUDE-ALS, the Phase 2 clinical trial of *reldesemtiv* in patients with ALS, did not achieve statistical significance for a pre-specified dose-response relationship in the primary endpoint of change from baseline in slow vital capacity (SVC) after 12 weeks of dosing. However, patients on all dose groups of *reldesemtiv* declined numerically less than patients on placebo for SVC and ALS Functional Rating Scale-Revised (ALSFRS-R), with larger differences emerging over time. These data may support the advancement of *reldesemtiv* in patients with ALS and we are conducting, feasibility and other planning activities in preparation for a potential Phase 3 clinical trial of *reldesemtiv* in patients with ALS. We are also engaging with FDA, EMA and health technology assessment organizations to define our potential path forward including the clinical and reimbursement value of potential endpoints for a pivotal Phase 3 trial that we are considering. We plan to await results of GALACTIC-HF before potentially starting the next trial. FORTITUDE-ALS was previously conducted by Cytokinetics under our collaboration with Astellas.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and next-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 *omecamtiv mecarbil* 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 currently 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 (HCM). Cytokinetics is conducting REDWOOD-HCM, a Phase 2 trial of CK-274 in patients with obstructive HCM. 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 expected timing of the availability of top-line results; statements relating to the METEORIC-HF clinical trial; the potential benefits of *omecamtiv mecarbil*, including its ability to represent a novel therapeutic strategy to increase cardiac muscle function and restore cardiac performance; statements relating to the REDWOOD-HCM clinical trial; statements relating to the potential benefits of CK-274; statements relating to our interactions with regulatory authorities in connection to the potential advancement of a Phase 3 clinical trial of *reldesemtiv* in patients with ALS; the potential benefits of *reldesemtiv*; 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' other 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; the nature of 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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