Cytokinetics Announces Company Participation and Support of ALS Fundraising Activities in Connection With ALS Awareness Month

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SOUTH SAN FRANCISCO, CA, May 09, 2012 (MARKETWIRE via COMTEX) --Cytokinetics, Incorporated (NASDAQ: CYTK) announced today that, in connection with Amyotrophic Lateral Sclerosis (ALS) Awareness Month, the company has committed to several educational and support activities for ALS patients and their families. In addition, Cytokinetics will provide financial support to two upcoming events organized to raise funds and increase awareness in the fight against this grievous illness. On June 23, 2012, Cytokinetics' employees will participate in the Young Faces of ALS (YFALS) National Corntoss Challenge to be held at Fort Mason in San Francisco, California. Cytokinetics is a national sponsor of the National Corntoss Challenge. On September 23, 2012, Cytokinetics' employees will join The ALS Association Golden West Chapter's South Bay Walk to Defeat ALS at Arena Green in San Jose, California.

"At Cytokinetics, our dedicated employees focus our everyday activities towards advancing a potential treatment to assist the courageous patients suffering from this serious disease," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Through our ongoing research and development activities on our skeletal muscle activator, CK-2017357, we engage with patients and caregivers who are battling this disease with persistent optimism and hope. It is a privilege for Cytokinetics to join them to raise awareness and important funding through community events that enable education and continued research into the causes and possible treatments for ALS."

Background on Amyotrophic Lateral Sclerosis

ALS, also known as Lou Gehrig's disease, is a progressive neurodegenerative disease that afflicts 20,000 to 30,000 people in the United States with an incidence rate in both the U.S. and Europe of approximately 1.5 new cases per 100,000 population per year. Approximately 5,600 new cases of ALS are diagnosed each year in the U.S. The average life expectancy of an ALS patient is approximately three to five years and only 10% of patients survive for more than 10 years. Death is usually due to respiratory failure because of diminished strength in the skeletal muscles responsible for breathing. There is only one drug, riluzole, that has been approved for the treatment of ALS, but it neither cures the disease nor addresses the functional deficits associated with ALS. As such, with few treatment options available for these patients, there is a high unmet need for new therapeutic options to address the symptoms and modify the disease progression of this grievous illness.

Background on Young Faces of ALS (YFALS) Campaign

The YFALS Campaign was created by a small group of people living with ALS today who all share a disturbing characteristic -- they all received their diagnosis before their 30th birthday. Most emphasis on ALS is placed on those that develop the disease during midlife, and before YFALS there was no national public recognition of the youth battling ALS. The campaign was created as a community for young patients of ALS as well as young family and friends affected by the disease. YFALS has become a catalyst for accelerating research at the ALS Therapy Development Institute through fundraising events. Additional information about the YFALS Campaign can be obtained at yfals.als.net.

Background on The ALS Association and the Golden West Chapter

Established in 1985, The ALS Association is the only non-profit organization fighting Lou Gehrig's Disease on every front. By leading the way in global research, providing assistance for people with ALS through a nationwide network of chapters, coordinating multidisciplinary care through certified clinical care centers, and fostering government partnerships, The ALS Association builds hope and enhances quality of life while aggressively searching for new treatments and a cure. As the preeminent ALS organization, The ALS Association leads the way in research, patient and community services, public education, and advocacy -- giving help and hope to those facing the disease. The ALS Association's nationwide network of chapters provides comprehensive patient services and support to the ALS community. The mission of The ALS Association is to lead the fight to cure and treat ALS through global cutting-edge research, and to empower people with Lou Gehrig's Disease and their families to live fuller lives by providing them with compassionate care and support. The Golden West Chapter provides service in thirty-one counties throughout California. Additional information about the Golden West Chapter of the ALS Association can be obtained at www.alsagoldenwest.org.

Development Status of CK-2017357 in ALS

Cytokinetics is developing CK-2017357, a skeletal muscle activator, as a potential treatment for diseases and conditions associated with aging, muscle wasting or neuromuscular dysfunction. CK-2017357 is currently the subject of a Phase II clinical development program and has been granted orphan drug designation by the U.S. Food and Drug Administration and orphan medicinal product designation from the European Medicines Agency for the potential treatment of ALS, a debilitating disease of neuromuscular impairment. CK-2017357 also has received Fast Track designation from the U.S. Food and Drug Administration for the potential treatment of ALS.

Cytokinetics recently completed CY 4024, a two-part, Phase II safety, tolerability, pharmacokinetic and pharmacodynamic clinical trial of multiple doses of CK-2017357 in ALS patients. Part A of this trial enrolled 24 patients who were not taking riluzole and Part B of this trial enrolled 25 patients who were concurrently taking riluzole at a reduced dose of 50 mg daily. In both Parts A and B, CK-2017357 appeared to be safe and well-tolerated dosed daily for two weeks at 125 mg, 250 mg, or 375 mg. Adverse events and clinical assessments during treatment with CK-2017357 appeared similar, with or without co-administration of riluzole. While the trial was not designed or powered to evaluate statistically the effects of CK-2017357 on the various outcome measures that were assessed during the study, a combined analysis of patients from both cohorts suggests encouraging trends that appear dose-related and potentially clinically meaningful in magnitude. These clinically relevant trends were observed in the ALS Functional Rating Scale in its revised form (ALSFRS-R) and in Maximum Voluntary Ventilation (MVV). There were no statistically significant differences in outcomes measures between patients in Part A and those in Part B.

Cytokinetics also recently completed CY 4025, a Phase II, randomized, double-blind, placebo-controlled, multiple-dose clinical trial of CK-2017357 in patients with ALS receiving riluzole at a reduced dose of 50 mg daily. The primary objective of CY 4025 was to assess the safety and tolerability of CK-2017357 when administered using this twice-daily dose titration regimen to patients with ALS and to determine if the total daily dose of CK-2017357 could be increased from the 375 mg once-daily dose (that had been evaluated in earlier trials of CK-2017357 in patients with ALS) to a target of 250 mg dosed twice daily in patients enrolled in this trial. The authors concluded that the twice-daily dose titration regimen evaluated in the trial was generally safe and well-tolerated, that the majority of patients could be titrated successfully to a CK-2017357 dose level of 250 mg twice daily, and that encouraging trends toward functional improvements were observed in patients receiving CK-2017357 versus those receiving placebo. CY

4025 was not designed or powered to evaluate statistically the effects of CK-2017357 on the various outcome measures that were assessed during the study; nevertheless, increases in ALSFRS-R and MVV were observed in patients receiving CK-2017357 relative to those receiving placebo that were similar in direction and magnitude to those observed in CY 4024.

Cytokinetics has met with the U.S. Food and Drug Administration's Center for Drug Evaluation and Research's Division of Neurology Products and with the European Medicines Agency to discuss its progress in the development of CK-2017357 as a potential treatment for patients with ALS and the company's plans for its further development, including potential registration strategies. Cytokinetics is assessing options that may enable the initiation of a registration program for CK-2017357 and anticipates having additional interactions with U.S. and European regulatory authorities during 2012 to discuss the further development of CK-2017357 as a potential treatment for patients with ALS, including potential registration strategies.

About Cytokinetics

Cytokinetics is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. Cytokinetics' lead drug candidate from its cardiac muscle contractility program, omecamtiv mecarbil, is in Phase II clinical development for the potential treatment of heart failure. Amgen Inc. holds an exclusive license worldwide (excluding Japan) to develop and commercialize omecamtiv mecarbil and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing CK-2017357, a skeletal muscle activator, as a potential treatment for diseases and conditions associated with aging, muscle wasting or neuromuscular dysfunction. CK-2017357 is currently the subject of a Phase II clinical trials program and 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 amyotrophic lateral sclerosis, a debilitating disease of neuromuscular impairment in which CK-2017357 demonstrated potentially clinically relevant pharmacodynamic effects in Phase II trials. Cytokinetics is also conducting research of compounds that inhibit smooth muscle contractility and which may be useful as potential treatments for diseases and conditions associated with excessive smooth muscle contraction, such as bronchoconstriction associated with asthma and chronic obstructive pulmonary disease (COPD). All of these drug candidates and potential drug candidates have arisen from Cytokinetics' research activities and are directed towards the cytoskeleton. The cytoskeleton is a complex biological infrastructure that plays a fundamental role within every human cell. Additional information about Cytokinetics can be obtained at www.cytokinetics.com.

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' research and development activities, including anticipated interactions with regulatory authorities and the significance and utility of clinical trial results for CK-2017357; the potential size of markets for CK-2017357; and the properties and potential benefits of CK-2017357 and Cytokinetics' other drug candidates and potential drug candidates, including CK-2017357's potential utility in the treatment of patients with ALS. 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, Cytokinetics will require significant additional funding to conduct the registration program for CK-2017357 for the potential treatment of ALS and may be unable to obtain such additional funding on acceptable terms, if at all; 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 (FDA) or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, regulatory authorities may not grant CK-2017357 orphan drug exclusivity in ALS even if it is approved for marketing; Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; funding from the National Institute of Neurological Disorders and Stroke may not be available in future periods; Cytokinetics may incur unanticipated research and development and other costs; Cytokinetics may be unable to enter into future collaboration agreements for its drug candidates and programs on acceptable terms, if at all; 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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