Cytokinetics Completes Enrollment in VITALITY-ALS, Phase 3 Clinical Trial of Tirasemtiv in Patients With ALS

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Results Expected 2H 2017; Open-Label Extension Trial to Begin in Q4 2016

SOUTH SAN FRANCISCO, Calif., Aug. 17, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) today announced the completion of patient enrollment in VITALITY-ALS (**V**entilatory **I**nvestigation of ***T****irasemtiv* and **A**ssessment of **L**ongitudinal **I**ndices after **T**reatment for a **Y**ear in ALS), an international Phase 3 clinical trial of *tirasemtiv* in patients with ALS. VITALITY-ALS is designed to assess the effects of *tirasemtiv* versus placebo on slow vital capacity (SVC) and other measures of skeletal muscle strength in patients with ALS. VITALITY-ALS enrolled more than 700 patients in 81 centers in 11 countries. Results from VITALITY-ALS are expected in the second half of 2017. The company also announced that enrollment in the open-label extension to VITALITY-ALS is expected to begin in the fourth quarter of this year.

“Completion of enrollment in VITALITY-ALS marks a significant milestone for Cytokinetics as well as the ALS community as we take another step toward advancing what could be the first potential new medicine for people with ALS in more than 20 years,” said Fady I. Malik, MD, PhD, Cytokinetics’ Executive Vice President, Research & Development. “We would like to express our thanks to the dedicated investigators and clinical site coordinators who are conducting the trial and also patients with ALS and their caregivers who are participating. We look forward to reporting results in the second half of 2017.”

About VITALITY-ALS

VITALITY-ALS is a multi-national, randomized, double-blind, placebo-controlled trial in patients with possible, probable or definite ALS, diagnosed within 24 months, and with percent predicted SVC at baseline ≥ 70 percent. The primary endpoint of the trial will assess change from baseline in SVC, to be assessed after 24 weeks of double-blind, placebo-controlled treatment. Secondary endpoints, to be assessed at 48 weeks, include time to decline from baseline in percent predicted SVC by ≥ 20 percentage points or the onset of respiratory insufficiency or death; time to decline from baseline in percent predicted SVC to ≤ 50 percent predicted or the onset of respiratory insufficiency or death; time to first occurrence of any use of assisted ventilation or death; time to decline in any of the three respiratory domains of the ALSFRS-R or death; and change in the Mega-Score of muscle strength. Patients enrolled in VITALITY-ALS receive two-weeks of open-label treatment with *tirasemtiv* administered at 250 mg/day. Patients are then randomized into a double-blind treatment phase to placebo or one of three target *tirasemtiv* dose levels (250 mg/day, 375 mg/day, 500 mg/day) in a 3:2:2:2 ratio. After 48 weeks of randomized, double-blind, placebo-controlled treatment, patients who received *tirasemtiv* during those 48 weeks of double-blind treatment will be randomized to continue the *tirasemtiv* dose at which they completed the 48 weeks of double-blind treatment or to placebo for a four-week double-blind, *tirasemtiv* withdrawal phase. Patients who received placebo during the 48 weeks of double-blind treatment will continue to receive placebo during the double-blind, *tirasemtiv* withdrawal phase. Following their participation in VITALITY-ALS, patients are eligible to participate in an open-label extension study of *tirasemtiv*.

About ALS

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that afflicts approximately 30,000 people in the United States and a comparable number of patients in Europe. Approximately 6,000 new cases of ALS are diagnosed each year in the United States. The average life expectancy of an ALS patient is approximately three to five years after diagnosis and only 10 percent 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. Few treatment options exist for these patients, resulting in a high unmet need for new therapies to address functional deficits and disease progression.

About *Tirasemtiv*

Tirasemtiv, a novel skeletal muscle activator, selectively activates the fast skeletal muscle troponin complex by increasing its sensitivity to calcium and, in preclinical studies and early clinical trials, demonstrated increases in skeletal muscle force in response to neuronal input and delays in the onset and reductions in the degree of muscle fatigue. *Tirasemtiv* has been studied in clinical trials that have enrolled over 1000 people internationally. *Tirasemtiv* is the subject of a Phase 3 clinical trial program designed to confirm and extend findings on measures of respiratory function and muscle strength from prior studies.

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 conduct, design, enrollment. Progress and timing of results of the Phase 3 clinical trial of *tirasemtiv* in patients with ALS; the significance and utility of preclinical study and clinical trial results; and the properties and potential efficacy and safety profile of *tirasemtiv*

and 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, further clinical development of *tirasemtiv* in ALS patients will require significant additional funding, and Cytokinetics may be unable to obtain such additional funding on acceptable terms, if at all; the FDA and/or other regulatory authorities may not accept effects on slow vital capacity as a clinical endpoint to support registration of *tirasemtiv* for the treatment of ALS; 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 trial 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 FDA 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.

Contact:
Cytokinetics
Diane Weiser
Vice President, Corporate Communications, Investor Relations
(415) 290-7757

Cytokinetics, Inc