Cytokinetics and the ALS Association Announce Awarding of Grant for Phase 3 Clinical Trial and Biomarker Research Collaboration

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Proceeds From Ice Bucket Challenge Used to Support a Unique Collaboration Between Non-Profit, Academia and Industry

SOUTH SAN FRANCISCO, Calif. and WASHINGTON, DC, July 14, 2015 (GLOBE NEWSWIRE) -- Cytokinetics, Inc., (Nasdaq:CYTK) and The ALS Association today announced that The Association has awarded Cytokinetics a $1.5 million grant to support the collection of clinical data and plasma samples to advance the discovery of biomarkers in ALS (amyotrophic lateral sclerosis) in VITALITY-ALS, a Phase 3 clinical trial of *tirasemtiv* in patients with ALS. For the first time, this unique collaboration between Cytokinetics, The ALS Association, and the Barrow Neurological Institute will enable plasma samples collected from patients enrolled in a Phase 3 clinical trial to be added to The Northeastern ALS Consortium (NEALS) Repository, a resource for the academic research community to identify biomarkers that may help to assess disease progression and underlying disease mechanisms in ALS.

"We are grateful to The ALS Association and everyone who donated to the Ice Bucket Challenge for this grant to assist the funding of VITALITY-ALS and our collaboration with Barrow Neurological Institute for biomarker research," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "This collaboration is an extraordinary opportunity to advance the development of *tirasemtiv* as well as scientific understanding of biomarkers that underlie the progression of ALS at the molecular level."

"Biomarker discovery is a major priority for ALS research, and we have recently witnessed important progress in this field," said Lucie Bruijn, Ph.D., M.B.A., Chief Scientist for The ALS Association. "We are pleased to contribute to this unique collaboration between The Association, industry and academia to progress our shared mission to improve the lives of people living with ALS through the advancement of our knowledge of ALS and through the development of potential novel treatments."

VITALITY-ALS (Ventilatory Investigation of *Tirasemtiv* and Assessment of Longitudinal Indices after Treatment for a Year in ALS), which started today, is a multi-national, randomized, double-blind, placebo-controlled trial that is designed to assess the effects of *tirasemtiv* versus placebo on slow vital capacity and other measures of respiratory function in patients with ALS. As part of the trial, plasma samples and longitudinal clinical data will be obtained from participating patients. The clinical information and collected samples will be integrated into the NEALS Repository to support ongoing activities within the scientific community for research on biomarkers from patients with ALS. VITALITY-ALS is expected to be conducted in more than 75 centers in North America and Europe.

"VITALITY-ALS is the first industry-sponsored clinical trial in which plasma samples from patients with ALS are being collected and shared with the ALS research community," said Jeremy M. Shefner, M.D., Ph.D., Lead Investigator of VITALITY-ALS, Professor and Chair of Neurology at Barrow Neurological Institute, and Professor and Executive Chair of Neurology at the University of Arizona, Phoenix. "It is especially gratifying when all of our respective interests align to serve our patients living with ALS and their caregivers."

About ALS

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. The disease robs people of the ability to walk, talk and even blink an eye. It traps them inside a body they no longer can control and ultimately prevents them from breathing as it takes their life. There is no known cause of the disease, although military veterans are approximately twice as likely to develop ALS as the general population.

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. In a recently completed Phase 2b clinical trial, *tirasemtiv* reduced the decline of slow vital capacity, a key measure of respiratory function in patients with ALS. *Tirasemtiv* is the subject of a Phase 3 clinical trial program designed to confirm and extend findings from prior studies.

About The ALS Association

The ALS Association is the only national 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 Association builds hope and enhances quality of life while aggressively searching for new treatments and a cure. For more information about The ALS Association, visit www.alsa.org.

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. With an unmatched understanding of 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 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 holds the exclusive right to develop and

commercialize *tirasemtiv* throughout the world. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy. 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 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 and progress of VITALITY-ALS and other clinical trials; the significance and utility of preclinical study and clinical trial results; ; the potential further development of tirasemtiv; the potential size of markets for tirasemtiv; and the properties and potential benefits 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 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 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; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil and CK-2127107, respectively; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; 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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