



## Cytokinetics Announces First Patient Enrolled in VIGOR-ALS, an Open-Label Extension Clinical Trial of Tirasemtiv

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### Eligible Patients Have Completed Participation in Phase 3 Clinical Trial VITALITY-ALS

SOUTH SAN FRANCISCO, Calif., Oct. 18, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) today announced the first patient has been enrolled in VIGOR-ALS (Ventilatory Investigations in Global Open-Label Research in ALS), an open-label extension clinical trial designed to assess the long-term safety and tolerability of *tirasemtiv*, in patients with ALS who have completed their participation in VITALITY-ALS, the Phase 3 clinical trial designed to assess the effects of *tirasemtiv* versus placebo on slow vital capacity (SVC) and other measures of respiratory and skeletal muscle function.

"People living with ALS desperately need new therapies and VIGOR-ALS reflects our commitment to the patients that participated in VITALITY-ALS and who contributed enormously to the development of a potential new medicine for patients with ALS," said Fady I. Malik, MD, PhD, Cytokinetics' Executive Vice President, Research & Development. "This trial will provide supplemental data on the effects of long-term use of *tirasemtiv*."

#### About VIGOR-ALS

VIGOR-ALS is an open-label extension trial of *tirasemtiv* in patients with ALS who completed participation in VITALITY-ALS. The primary endpoint of the trial is the incidence of adverse events in the patient population. Secondary endpoints include the time to events such as death or the first use of assisted ventilation or respiratory insufficiency (defined as tracheostomy or the use of non-invasive ventilation for  $\geq 22$  hours per day for  $\geq 10$  consecutive days); decline from baseline in percent predicted slow vital capacity (SVC), ALS functional rating scale-revised (ALSFRS-R); and the slope of change from baseline in percent predicted SVC and ALSFRS-R. Following enrollment, patients will begin dosing of *tirasemtiv* 125 mg twice daily (250 mg/day) for a period of 4 weeks and will titrate to their maximum tolerated dose (based on tolerability), to no higher than 250 mg twice daily (500 mg/day). Additional information on the trial can be found at [clinicaltrials.gov](http://clinicaltrials.gov).

#### 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 currently the subject of VITALITY-ALS, a Phase 3 clinical trial, 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 VITALITY-ALS 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; and 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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