Cytokinetics Announces Start of Open-Label Extension Study for Patients Completing COURAGE-ALS

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Managed Access Program for People Who Have Completed Prior Cytokinetics ALS Trials to Begin in 2H 2022

SOUTH SAN FRANCISCO, Calif., June 16, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced the start of COURAGE-ALS OLE (**C**linical **O**utcomes **U**sing ***R**eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS O**pen **L**abel **E**xtension), an open-label extension clinical study designed to assess the long-term safety and tolerability of *reldesemtiv* in people with amyotrophic lateral sclerosis (ALS). Patients will be eligible for COURAGE-ALS OLE after completing their participation in COURAGE-ALS, the Phase 3 clinical trial of *reldesemtiv*, a next-generation fast skeletal muscle troponin activator (FSTA) for the potential treatment of ALS.

"We are pleased to provide continued access to *reldesemtiv* through the open-label extension study of COURAGE-ALS as is aligned with our commitment to people with ALS. This open-label extension will also allow us to gather longer-term data related to the effect of treatment with *reldesemtiv* on disease progression in ALS," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Executive Vice President of Research & Development. "Additionally, we look forward to opening a Managed Access Program for *reldesemtiv* later this year for participants who completed our prior ALS clinical trials. ALS is a devastating, fatal disease with few approved therapies, and we recognize the urgency to provide access to people who have committed to our extensive clinical research while we also advance *reldesemtiv* in our ongoing Phase 3 clinical trial"

COURAGE-ALS OLE: Clinical Study Design

COURAGE-ALS OLE is an open-label extension clinical study of *reldesemtiv* in people with ALS who have completed participation in COURAGE-ALS. Following enrollment in COURAGE-ALS OLE, participants will continue to receive 300 mg of *reldesemtiv* dosed orally twice daily for 48 weeks after which they may transition into the Managed Access Program. The primary endpoint is the incidence of adverse events. Secondary endpoints include the time to the first occurrence of respiratory insufficiency or death, time to the first hospitalization, combined assessment of change in ALSFRS-R total score, time to onset of respiratory insufficiency, and survival time, changes in ALSFRS-R total score, and the slope of changes in ALSFRS-R total score. Additional information on COURAGE-ALS OLE can be found at clinicaltrials.gov.

About *Reldesemtiv*

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 the troponin complex, make the actin-myosin interaction dependent on changes in intracellular calcium levels. *Reldesemtiv* is an investigational, selective, small molecule fast skeletal muscle troponin activator (FSTA) arising from Cytokinetics' skeletal muscle contractility program. *Reldesemtiv* was designed to slow 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.

The development program for *reldesemtiv* is assessing its potential for the treatment of ALS and includes FORTITUDE-ALS and COURAGE-ALS, the ongoing Phase 3 clinical trial designed to evaluate the effect of treatment with *reldesemtiv* compared to placebo on measures of disease progression, functional outcomes and survival.

About ALS

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that afflicts approximately 27,000 people in the United States and a comparable number of patients in Europe. Approximately 6,300 new cases of ALS are diagnosed each year in the United States. The average life expectancy of a person with ALS is approximately three to five years after diagnosis and only approximately 10 percent of people with ALS 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 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. 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 readying for the potential commercialization of *omecamtiv mecarbil*, its cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is also developing *aficamten*, a next-generation cardiac myosin inhibitor, currently the subject of SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in non-obstructive HCM in Cohort 4 of the Phase 2 clinical trial, REDWOOD-HCM. Cytokinetics is also developing *reldesemtiv*, an investigational fast skeletal muscle troponin activator, currently the subject of COURAGE-ALS, a Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (ALS). 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 any of our other clinical trials, statements relating to the potential benefits of *omecamtiv mecarbil*, *aficamten*, or any of our other drug candidates. Cytokinetics' 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' ability to conduct clinical trials; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; 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. 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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