Cytokinetics Announces Start of Phase 1b Clinical Trial of CK-2127107 in Elderly Subjects With Limited Mobility

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Trial Designed to Assess Effects of Skeletal Muscle Activation on Measures of Muscle Strength and Endurance Under Collaboration with Astellas

SOUTH SAN FRANCISCO, Calif., June 29, 2017 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) today announced the start of a Phase 1b, double-blind, randomized, placebo-controlled, multiple dose, two-period crossover study to assess the effect of CK-2127107 on measures of physical function in elderly adults with limited mobility. CK-2127107 is a next-generation fast skeletal muscle troponin activator (FSTA) which is being developed as a potential treatment for people living with spinal muscular atrophy (SMA), chronic obstructive pulmonary disease (COPD) and certain other debilitating diseases and conditions associated with muscular weakness and/or fatigue. Astellas is conducting this Phase 1b clinical trial in collaboration with Cytokinetics.

“Maintaining muscle strength and mobility is essential for older adults to sustain their independence and minimize the risk of disability,” said Fady I. Malik, Cytokinetics’ Executive Vice President, Research & Development. “We look forward to data from this trial which will investigate the potential for CK-2127107 to increase skeletal muscle force and reduce muscle fatigue in frail subjects, representative of the growing population of aging baby boomers.”

Phase 1b Clinical Trial Design

The clinical trial is expected to enroll at least 60 subjects in the United States who are 70 to 89 years of age with limited mobility. Patients will be randomized to one of two treatment sequences in a 1:1 ratio to receive both CK-2127107 and placebo over two 14-day treatment periods, separated by a 14-day washout period. During treatment periods, patients will receive 500 mg of CK-2127107 or placebo twice daily, except on days 1 and 14, when they receive 500 mg of CK-2127107 once daily. The total study duration including the screening period and follow-up visit will be approximately 12 weeks. The trial is designed to assess the effect of CK-2127107 on skeletal muscle fatigue assessed as change from baseline versus 14 days of treatment in sum of peak torque during isokinetic knee extensions. Additionally, the trial will assess the effects of CK-2127107 on physical performance via a short physical performance battery, stair-climb test and 6-minute walk test. In addition, the safety, tolerability and pharmacokinetics of CK-2127107 will be assessed. Additional information on the trial can be found at clinicaltrials.gov.

About CK-2127107

Skeletal muscle contractility is driven by the sarcomere, the fundamental unit of skeletal muscle contraction. It is 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 several types of troponin, make the actin-myosin interaction dependent on changes in intracellular calcium levels. CK-2127107, a next-generation FSTA arising from Cytokinetics' skeletal muscle contractility program, slows 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. CK-2127107 has demonstrated pharmacological activity that may lead to new therapeutic options for diseases associated with muscle weakness and fatigue. CK-2127107 has been granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of SMA. CK-2127107 has been the subject of five completed Phase 1 clinical trials in healthy volunteers, which evaluated the safety, tolerability, bioavailability, pharmacokinetics and pharmacodynamics of the drug candidate. In addition to the Phase 1b clinical trial, CK-2127107 is the subject of Phase 2 clinical trials in patients with SMA and patients with COPD. An additional Phase 2 clinical trial is planned in patients with ALS for later this year.

About Limited Mobility in Elderly Adults

People over the age of 65 represent the fastest growing segment of the U.S. population and up to 25 percent of older adults experience limitations in mobility. Older persons who lose mobility are less likely to socialize in their communities, have higher rates of morbidity, mortality and hospitalizations and may experience compromised quality of life. Mobility limitations are associated with increased healthcare costs. On average, older adults unable to walk a quarter mile incur $4,000 more per year in health care costs compared to their peers without limited mobility.

About the Cytokinetics and Astellas Collaboration

Cytokinetics and Astellas collaborate on the research, development, and commercialization of skeletal muscle activators. The primary objective of the collaboration is to advance novel therapies for diseases and medical conditions associated with muscle impairment and weakness. Cytokinetics has licensed to Astellas exclusive rights to co-develop and commercialize CK-2127107 and other FSTAs in non-neuromuscular indications and certain neuromuscular indications (including SMA and ALS) and other novel mechanism skeletal muscle activators in all indications, subject to certain Cytokinetics’ development and commercialization rights; Cytokinetics may co-promote and conduct certain commercial activities in North America and Europe under agreed scenarios.

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 (FSTA). *Tirasemtiv* is the subject of VITALITY-ALS, an international Phase 3 clinical trial in patients with ALS. *Tirasemtiv* has been granted orphan drug designation and fast track status by the FDA and orphan medicinal product designation by the European Medicines Agency for the potential treatment of ALS. Cytokinetics is preparing for the potential commercialization of *tirasemtiv* in North America and Europe and has granted an option to Astellas for development and commercialization in other countries. Cytokinetics is collaborating with Astellas to develop CK-2127107, a next-generation FSTA. CK-2127107 has been granted orphan drug designation by the FDA for the treatment of spinal muscular atrophy (SMA). CK-2127107 is the subject of two ongoing Phase 2 clinical trials enrolling patients with SMA and patients with COPD. Astellas holds an exclusive worldwide license to develop and commercialize CK-2127107. Cytokinetics is collaborating with Amgen Inc. (“Amgen”) to develop *omecamtiv mecarbil*, a novel cardiac muscle activator.

Omecamtiv mecarbil is the subject of GALACTIC-HF, an international Phase 3 clinical trial in patients with heart failure. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization 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; the design, timing, results and significance of clinical trials, including Cytokinetics' Phase 1b clinical trial of CK-2127107 on measures of physical function in elderly adults with limited mobility; and the properties and potential benefits of Cytokinetics' 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; 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; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for CK-2127107; 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. 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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