



## Cytokinetics Announces Progress Against Vision 2020

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*Multiple Clinical Trials Advance Under Collaborations with Astellas and Amgen*

*Results from Four Clinical Trials of CK-2127107 Expected in 2018*

*Pipeline Expands with Three New Programs Advancing  
from Muscle Biology Research to Development*

SOUTH SAN FRANCISCO, Calif., Jan. 03, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) today announced progress against its Vision 2020 initiatives designed to advance and expand its pipeline of muscle biology directed drug candidates in late-stage development to address urgent needs of people living with conditions characterized by impaired muscle function and weakness.

"We are continuing to execute against our Vision 2020 strategy with expected results from four mid-stage clinical trials of CK-2127107 under our collaboration with Astellas and the continued enrollment of patients with chronic heart failure in GALACTIC-HF under our collaboration with Amgen," said Robert I. Blum, Cytokinetics' President & CEO. "In parallel, our research continues to power innovation in 2018 as we are advancing three potential drug candidates to development."

### **CK-2127107: Results from Four Trials Expected in 2018 Under Collaboration with Astellas**

CK-2127107 is the subject of four mid-stage clinical trials enrolling patients in both neuromuscular and non-neuromuscular diseases or conditions in which impaired muscle function and weakness play a meaningful role. These include Phase 2 clinical trials in patients with spinal muscular atrophy (SMA), chronic obstructive pulmonary disease (COPD) and amyotrophic lateral sclerosis (ALS) and a Phase 1b clinical trial in elderly adults with limited mobility or frailty.

- Cytokinetics is conducting a Phase 2 double-blind, randomized, placebo-controlled clinical trial in patients with SMA which is designed to determine potential pharmacodynamic effects of a suspension formulation of CK-2127107 following 8 weeks of oral dosing in each of two cohorts of 36 patients with Type II, Type III, or Type IV disease. Secondary objectives are to evaluate the safety, tolerability and pharmacokinetics of CK-2127107. There is no single primary endpoint in this hypothesis-generating trial. Multiple assessments of skeletal muscle function and fatigability are being performed, including respiratory assessments, upper limb strength and functionality for non-ambulatory patients, as well as six-minute walk and timed-up-and-go for ambulatory patients. Patients enrolled in the second cohort will also be assessed with the SMA Health Index, a patient reported outcome measure.
- Astellas is conducting a Phase 2 clinical trial which is designed to assess the effect of CK-2127107 compared to placebo on exercise tolerance in approximately 40 patients with COPD. Additionally, the trial will assess cardiopulmonary and neuromuscular effects of CK-2127107 relative to placebo and the effect of CK-2127107 on resting spirometry relative to placebo. In addition, the safety, tolerability and pharmacokinetics of CK-2127107 will be assessed.
- Astellas is conducting a Phase 1b clinical trial which is designed to assess the effect of CK-2127107 on skeletal muscle fatigue in approximately 60 subjects who are 70 to 89 years of age and who have limited mobility. Endpoints to be measured include the 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 as well as assess the safety, tolerability and pharmacokinetics of CK-2127107.
- Cytokinetics is conducting FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of **I**vestigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**) which is expected to enroll 450 patients with ALS and is designed to assess the change from baseline in the percent predicted slow vital capacity (SVC) and other measures of skeletal

muscle function after 12 weeks of treatment with CK-2127107. Secondary endpoints include the slope of the change from baseline in the mega-score of muscle strength measured by hand held dynamometry (HHD) and handgrip dynamometry in patients on CK-2127107; change from baseline in the ALS Functional Rating Scale – Revised (ALSFRRS-R); incidence and severity of treatment-emergent adverse events (TEAEs); and plasma concentrations of CK-2127107 at sampled time points in the trial.

Astellas has exclusive rights to co-develop and commercialize CK-2127107 in non-neuromuscular indications and neuromuscular indications, subject to Cytokinetics' development and commercialization rights. Under the terms of the collaboration, all four trials of CK-2127107 are being funded by Astellas; results are expected in 2018. Cytokinetics is eligible for milestone payments and royalties on sales based on the further development and commercialization of CK-2127107. Additional information regarding these trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### ***Omecamtiv Mecarbil*: Enrollment of Patients in GALACTIC-HF is on Track in 2018**

Amgen is conducting GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure), the Phase 3 cardiovascular outcomes trial of *omecamtiv mecarbil*, in collaboration with Cytokinetics. GALACTIC-HF is on schedule. GALACTIC-HF is planned to enroll approximately 8,000 symptomatic chronic heart failure patients in over 900 sites in 35 countries who are either currently hospitalized for a primary reason of heart failure or have had a hospitalization or admission to an emergency room for heart failure within one year prior to screening. The primary endpoint is a composite of time to cardiovascular death or first heart failure event, which is defined as either a hospitalization for heart failure or other urgent treatment for worsening heart failure. Secondary endpoints include time to cardiovascular death; patient reported outcomes as measured by the Kansas City Cardiomyopathy Questionnaire Total Symptom Score; time to first heart failure hospitalization; and all-cause death. Additional information regarding GALACTIC-HF can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

The companies will also continue collaborating in 2018 to finalize plans for the second Phase 3 trial of *omecamtiv mecarbil* which is intended to evaluate its potential to increase exercise performance and, potentially, its ability to reverse the progressive enlargement of the heart in patients with heart failure.

Amgen holds an exclusive, worldwide license to *omecamtiv mecarbil* subject to Cytokinetics' specified development and commercialization rights. Amgen has granted a sublicense to Servier to commercialize *omecamtiv mecarbil* in Europe, as well as the Commonwealth of Independent States, including Russia. Under the terms of the collaboration, Cytokinetics is eligible to receive milestone payments and royalties on sales of *omecamtiv mecarbil*.

#### **Pipeline Expands with Three Potential Drug Candidates Proceeding to Development in 2018**

Three new muscle biology directed compounds are advancing from research to development in 2018. Under our collaboration with Amgen, a next-generation cardiac muscle activator has recently been nominated as a development candidate by the Joint Research Committee. This milestone triggered a \$1 million payment from Amgen to Cytokinetics. Under our collaboration with Astellas, a next-generation skeletal muscle activator was recently nominated as a development candidate, and the joint research program has been extended through 2019. In addition, Cytokinetics is advancing an unpartnered cardiac sarcomere directed compound from research into IND-enabling studies in 2018.

#### **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 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. Cytokinetics is collaborating with Astellas Pharma Inc. ("Astellas") to develop CK-2127107, a next-generation FSTA. CK-2127107 has been granted orphan drug designation by the FDA for the potential treatment of SMA. CK-2127107 is the subject of three ongoing Phase 2 clinical trials enrolling patients with spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Astellas is also conducting a Phase 1b clinical trial of CK-2127107 in elderly adults with limited mobility. Astellas holds an exclusive worldwide license to develop and commercialize CK-2127107. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization rights. For additional information about Cytokinetics, visit [www.cytokinetics.com](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, significance and utility of preclinical and clinical results, including Cytokinetics' expectations regarding the timing or results from its clinical trials of CK-2127107, enrollment of patients in GALACTIC-HF and pipeline expansion in 2018; and the properties and potential benefits of CK-2127107 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, 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; Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for CK-2127107; Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; 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.

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