### **Cytokinetics Pharmaceuticals**

All information was copied verbatim from Wikipedia (Link in Description of video)

Cytokinetics, Inc. is a publicly traded biopharmaceutical company based in South San Francisco, California, that develops muscle activators as potential treatments for people with diseases characterized by impaired or declining muscle function.

In collaboration with Astellas, Cytokinetics is also developing CK-2127107, a next-generation fast skeletal muscle troponin activator (FSTA).

CK-2127107 has been granted orphan drug designation by the FDA for the potential treatment of SMA, or Spinal Muscular Atrophy. It is currently being studied in three Phase 2 clinical trials, one in spinal muscular atrophy (SMA), one in chronic obstructive pulmonary disease (COPD), and one in ALS, as well as a Phase 1b clinical trial in elderly adults with limited mobility. Astellas holds an exclusive license for the development and commercialization of CK-2127107 worldwide.

All information was copied verbatim from the Cure SMA website (Link in Description of video)

#### **Cytokinetics Opens Enrollment for Phase 2 Trial**

BY CURE SMA | PUBLISHED ON JANUARY 4, 2016

Cytokinetics has opened enrollment for a Phase 2 study testing CK-2127107 in teens and adults with SMA type II, III or IV. We are excited to see the continued progress of this drug into the next phase of clinical trials, and particularly excited to see this trial focused on teens and adults. This latest trial announcement speaks to two of Cure SMA's primary goals: pursuing a breadth of treatment options, and ensuring we have treatments for all types, all ages, and all stages of SMA.



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The clinical trial is designed to assess the effect of CK-2127107 on multiple measures of muscle function in both ambulatory and non-ambulatory patients with SMA, a severe, genetic neuromuscular disease that leads to debilitating muscle function and progressive, often fatal, muscle weakness. In collaboration with Astellas, Cytokinetics is developing CK-2127107 as a potential treatment for people living with SMA and certain other debilitating neuromuscular and non-neuromuscular diseases and conditions associated with skeletal muscle weakness and/or fatigue.

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The primary objective of this double-blind, randomized, placebo-controlled clinical trial is to determine the potential pharmacodynamic effects of a suspension formulation of CK-2127107 following multiple oral doses in patients with Type II, Type III, or Type IV SMA.

Secondary objectives are to evaluate the safety, tolerability and pharmacokinetics of CK-2127107. The trial will enroll seventy-two patients in two sequential, ascending dose cohorts (two cohorts of 36 patients each, half ambulatory and half non-ambulatory). Each cohort will be stratified by ambulatory versus non-ambulatory status to receive CK-2127107 dosed twice daily for 8 weeks.

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"Initiating this first Phase 2 trial of CK-2127107
represents a major step forward given our interests to
serve the many adolescents and adults who are living
with SMA, a disorder with few treatment options," said
Robert I. Blum, Cytokinetics' President and Chief
Executive Officer. "We look forward to working closely
with the investigators and clinical trial sites to evaluate
the effects of our next-generation skeletal muscle activator, which we believe holds promise for
the potential treatment of patients battling this devastating disease."



All information was copied verbatim from the ClinicalTrials.gov website (Link in Description of video)

A Study of CK-2127107 in Patients With Spinal Muscular Atrophy - The primary objective of this study is to demonstrate a pharmacodynamic effect of CK-2127107 on measures of skeletal muscle function or fatigability in patients with Spinal Muscular Atrophy Types II-IV. This is the first study being conducted in these patients and is designed to assess the effect of 8 weeks of dosing of CK-2127107 on measures of muscle function in both ambulatory and non-ambulatory patients with SMA. The plasma concentration of CK-2127107 will be measured at selected time points during the course of dosing and the plasma concentrations obtained in this study may be used to conduct exposure-response analysis.

The trial identifier is NCT02644668 **Estimated Enrollment: 72 participants** 

Actual Study Start Date: December, 2015

Estimated Primary Completion Date: February, 2018

Estimated Study Completion Date: February, 2018

Ages Eligible for Study: 12 Years and older (Child, Adult, Senior)