

# Cytokinetics Announces First Patient Dosed in Cohort 2 of REDWOOD-HCM

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# Company Earns \$2.5 Million Milestone Payment from Ji Xing Pharmaceuticals

SOUTH SAN FRANCISCO, Calif., Jan. 13, 2021 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq: CYTK) today announced that the first patient has been dosed in Cohort 2 of REDWOOD-HCM (Randomized Evaluation of Dosing With CK-274 in Obstructive Outflow Disease in HCM), an ongoing Phase 2 clinical trial of CK-3773274 (CK-274), a next-generation cardiac myosin inhibitor in development for the potential treatment of hypertrophic cardiomyopathy (HCM). This event triggers a \$2.5 million milestone payment payable from Ji Xing Pharmaceuticals Limited to Cytokinetics under the License and Collaboration Agreement between the companies.

### **REDWOOD-HCM: Clinical Trial Design**

REDWOOD-HCM is a multi-center, randomized, placebo-controlled, double-blind, dose finding clinical trial of CK-274 in patients with symptomatic obstructive HCM (oHCM). The primary objective of the trial is to determine the safety and tolerability of CK-274. The secondary objectives are to describe the concentration-response relationship of CK-274 on the resting and post-Valsalva left ventricular outflow tract gradient as measured by echocardiography during 10 weeks of treatment, to describe the dose response relationship of CK-274, and to evaluate the plasma concentrations of CK-274 in patients with oHCM.

The trial will enroll two sequential cohorts, with an option for a third cohort. Within each cohort, approximately 18 patients will be randomized 2:1 to active or placebo treatment and receive up to three escalating doses of CK-274 or placebo based on echocardiographic guidance. Patients receive an echocardiogram after two weeks of treatment at each dose to determine whether they will be up-titrated. Overall, the treatment duration will be 10 weeks with an echocardiogram to confirm reversibility of effect 2-weeks after the last dose. REDWOOD-HCM is expected to enroll patients in approximately 20 investigative sites in North America and Europe.

Interim analysis of data from Cohort 1 of REDWOOD-HCM showed patients experienced substantial reductions in the average resting left ventricular outflow tract gradient (LVOT-G) as well as the post-Valsalva LVOT-G (defined as resting gradient <30 mmHg and post-Valsalva gradient <50 mmHg). These clinically relevant decreases in pressure gradients were achieved with only modest decreases in average left ventricular ejection fraction (LVEF); there were no dose interruptions due to LVEF falling below 50%, the prespecified safety threshold. Pharmacokinetic data were similar to those observed in Phase 1 in healthy subjects. In addition, the safety and tolerability data were supportive of continued dose escalation with no serious adverse events attributed to study treatment reported by the investigators.

The second cohort of REDWOOD-HCM is open for enrollment in centers in North America and Europe. Enrollment in Cohort 2 of REDWOOD-HCM is expected to complete in Q1 2021 and full results from REDWOOD-HCM, across both Cohort 1 and Cohort 2, are expected in mid-2021.

Additional information about REDWOOD-HCM can be found on www.clinicaltrials.gov.

### **About Hypertrophic Cardiomyopathy**

Hypertrophic cardiomyopathy (HCM) is a disease in which the heart muscle (myocardium) becomes abnormally thick (hypertrophied). The thickening of cardiac muscle leads to the inside of the left ventricle becoming smaller and stiffer, and thus the ventricle becomes less able to relax and fill with blood. This ultimately limits the heart's pumping function, resulting in symptoms including chest pain, dizziness, shortness of breath, or fainting during physical activity. A subset of patients with HCM are at high risk of progressive disease which can lead to atrial fibrillation, stroke and death due to arrhythmias. There are no FDA approved medical treatments that directly address the hypercontractility that underlies HCM.

## **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 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 impact muscle function and contractility. Cytokinetics is preparing for regulatory interactions for *omecamtiv mecarbil*, its novel cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is conducting METEORIC-HF, a second Phase 3 clinical trial of *omecamtiv mecarbil*. Cytokinetics is also developing CK-274, a next-generation cardiac myosin inhibitor, for the potential treatment of hypertrophic cardiomyopathies (HCM). Cytokinetics is conducting REDWOOD-HCM, a Phase 2 clinical trial of CK-274 in patients with obstructive HCM. Cytokinetics is also developing *reldesemtiv*, a fast skeletal muscle troponin activator for the potential treatment of ALS and other neuromuscular indications following conduct of FORTITUDE-ALS and other Phase 2 clinical trials. The company is preparing for the potential advancement of *reldesemtiv* to a Phase 3 clinical trial. 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, Eacebook and YouTube.

## **About Ji Xing Pharmaceuticals**

Backed by RTW Investments, Ji Xing is a privately held, leading Shanghai-based biotechnology company committed to bringing innovative science and medicines to underserved Chinese patients with serious and life-threatening diseases.

### **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 the timing, design and results of Cytokinetics' Phase 2 clinical trial of CK-274; the potential benefits of CK-274; the ability to complete enrollment of Cohort 2 of REDWOOD-HCM in [the first quarter of] 2021 and the impact of the COVID-19 pandemic on such enrollment (for further information regarding the historical and potential prospective impact of the COVID-19 pandemic on our business operations and clinical trials, please refer to Cytokinetics' Form 10-Q for the quarterly period ended September 30, 2020); Cytokinetics' and its partners' research and development activities; the timing of enrollment of patients in Cytokinetics' and its partners'

clinical trials; the design, timing, results, significance and utility of preclinical and clinical results; 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; Cytokinetics' partners decisions with respect to research and development activities; 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

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