Cytokinetics Outlines Go-To-Market Strategy for Omecamtiv Mecarbil and Provides Updates on Cardiovascular Pipeline at Today's Analyst & Investor Day

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Go-To-Market Strategy Focuses on Educating Healthcare Professionals, Ensuring Managed Care Access, and Enacting Programs for Patient Access, Education and Support

Clinical Trial Design Announced for SEQUOIA-HCM, Phase 3 Clinical Trial of Aficamten Expected to Begin in Q4

Company Details Plan for Developing a Cardiovascular Franchise

SOUTH SAN FRANCISCO, Calif., Oct. 07, 2021 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) plans to outline the company's go-to-market strategy for *omecamtiv mecarbil* in the United States, and present updates on the company's advancing cardiovascular pipeline and strategies to build a commercial franchise at "Charting the Commercial Course," an Analyst and Investor Day today at 8:30 AM Eastern Time in New York and live online. The company also plans to present the clinical trial design for SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with obstructive hypertrophic cardiomyopathy (oHCM).

"Cytokinetics is approaching an inflection point after more than two decades of research and development pioneering the field of muscle biology and advancing the pharmacology of myosin modulators. With new key leadership hires and our establishing of strategic commercial capabilities, we are putting in place the architecture for the potential launch of *omecamtiv mecarbil* in 2022, staging investments with de-risking milestone events and with deliberate focus to building a framework for a potential cardiovascular business franchise as could be enabled by the subsequent launch of *aficamten*," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "As *aficamten* advances into Phase 3 with SEQUOIA-HCM, expected to begin this year, our company is well positioned to deliver on the promise of potential medicines for patients with cardiovascular diseases of impaired muscle function and weakness."

Go-To-Market Strategy for *Omecamtiv Mecarbil*

Cytokinetics leadership will outline the go-to-market strategy for *omecamtiv mecarbil* in the U.S., which will be guided by a sequenced build of core capabilities to ensure success based on key de-risking milestones leading up to the potential launch of *omecamtiv mecarbil*. The four pillars of the strategy include first, establishing a deep understanding of patients with worsening heart failure and the healthcare providers and associated institutions who treat this subset of heart failure patients. Second, engaging and educating cardiologists who treat patients with worsening heart failure about the disease state and the importance of appropriate treatment. Third, working with payers to ensure affordable managed care access to *omecamtiv mecarbil*. Finally, supporting patients and caregivers through education, co-pay assistance where applicable, and innovative models for patient support.

SEQUOIA-HCM: Phase 3 Clinical Trial of *Aficamten*

Cytokinetics is also today presenting the design of SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A**ficamten* in **HCM**). SEQUOIA-HCM is a Phase 3 randomized, placebo-controlled, double-blind, multi-center clinical trial designed to evaluate *aficamten* in patients with symptomatic oHCM on background medical therapy for 24 weeks. The primary objective is to assess the effect of *aficamten* on change in peak oxygen uptake (pVO_2) measured by cardiopulmonary exercise testing (CPET) from baseline to week 24. Secondary objectives include change in Kansas City Cardiomyopathy Questionnaire (KCCQ) score from baseline to week 12 and week 24, the proportion of patients with ≥1 class improvement in New York Heart Association (NYHA) functional class from baseline to week 12 and week 24, change in post-Valsalva left ventricular outflow tract gradient (LVOT-G) to week 12 and week 24, the proportion of patients with post-Valsalva LVOT-G <30 mmHg, and change in total workload during CPET to week 24.

SEQUOIA-HCM is planned to enroll 270 patients, randomized on a 1:1 basis to receive *aficamten* or placebo in addition to standard-of-care treatment. Each patient will receive up to four escalating doses of *aficamten* or placebo based on echocardiographic guidance alone. At screening, patients enrolled in SEQUOIA-HCM must have a resting LVOT-G ≥30 mmHg, post-Valsalva peak LVOT-G ≥50 mmHg, and be NYHA Class II or III. Patients receiving *aficamten* will begin with 5 mg dosed once daily. At weeks 2, 4 and 6 patients will receive an echocardiogram to determine if they will be up-titrated to escalating doses of 10, 15 or 20 mg. Dose escalation will occur only if a patient has a post-Valsalva LVOT-G ≥30 mmHg and a biplane left ventricular ejection fraction (LVEF) ≥55%. Patients who do not meet escalation criteria will continue to receive their current dose or may be down-titrated if appropriate. Cytokinetics expects to begin SEQUOIA-HCM in Q4 2021.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/b88d2178-474e-4cfa-a55f-85e43244500f

Panel of Physician Experts

At today's Analyst & Investor Day, a panel of heart failure experts including Tariq Ahmad, MD, MPH, Associate Professor of Medicine; Medical Director of Advanced Heart Failure, Cardiovascular Medicine, Yale School of Medicine, and Alanna Morris, MD, MSc, FHFSA, FACC, FAHA, Associate Professor of Medicine, Division of Cardiology; Director of Heart Failure Research, Emory University Clinical Cardiovascular Research Institute, will discuss challenges of treating patients with heart failure with reduced ejection fraction (HFrEF) and the unmet need in this patient population.

Cardiovascular Franchise Strategy

The company will elaborate on its strategy to build a cardiovascular franchise by leveraging investments in people, relationships and infrastructure made during the potential commercialization of *omecamtiv mecarbil* to support the potential future commercialization of *aficamten.* The franchise strategy would be enabled by multiple cardiovascular medicines that allow for long-term and effective communications with cardiologists, efficiencies in spend, and field force synergies given the significant overlap of cardiologists and hospitals that treat both patients with worsening heart failure as well as HCM.

Conference Call and Webcast Information

Interested parties must register online at https://bit.ly/3EGnmU3. Registered attendees may access the live virtual event on the Investors & Media section of Cytokinetics' website at www.cytokinetics.com. An archived replay of the event will be available via Cytokinetics' website until April 7, 2022.

About *Omecamtiv Mecarbil*

Omecamtiv mecarbil is an investigational, selective, small molecule cardiac myosin activator, the first of a novel class of myotropes[1] designed to directly target the contractile mechanisms of the heart, binding to and recruiting more cardiac myosin heads to interact with actin during systole. *Omecamtiv mecarbil* was designed to increase the number of active actin-myosin cross bridges during each cardiac cycle and consequently augment the impaired contractility that is associated with heart failure with reduced ejection fraction (HFrEF). Preclinical research has shown that *omecamtiv mecarbil* increases cardiac contractility without increasing intracellular myocyte calcium concentrations or myocardial oxygen consumption.[2-4]

The development program for *omecamtiv mecarbil* is assessing its potential for the treatment of HFrEF and includes GALACTIC-HF and METEORIC-HF, a Phase 3 clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity.

About *Aficamten*

Aficamten is an investigational selective, small molecule cardiac myosin inhibitor discovered following an extensive chemical optimization program that was conducted with careful attention to therapeutic index and pharmacokinetic properties that may translate into next-in-class potential in clinical development. *Aficamten* was designed to reduce the number of active actin-myosin cross bridges during each cardiac cycle and consequently suppress myocardial hypercontractility that is associated with hypertrophic cardiomyopathy (HCM). In preclinical models, *aficamten* reduced myocardial contractility by binding directly to cardiac myosin at a distinct and selective allosteric binding site, thereby preventing myosin from entering a force producing state.

The development program for *aficamten* is assessing its potential for the treatment of HCM and to improve exercise capacity and relieve symptoms in patients with hyperdynamic ventricular contraction and includes REDWOOD-HCM, a Phase 2 clinical trial designed to evaluate the effect of treatment with *aficamten* compared to placebo on measures of safety, tolerability as well as pharmacodynamics and biomarkers.

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 preparing a U.S. NDA submission of *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 *aficamten*, a next-generation cardiac myosin inhibitor, for the potential treatment of hypertrophic cardiomyopathies (HCM). The company has announced positive results from Cohorts 1 and 2 in REDWOOD-HCM, a Phase 2 clinical trial of *aficamten* in patients with obstructive HCM. Cytokinetics expects to start SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with obstructive HCM in Q4 2021. Cytokinetics is also developing *reldesemtiv*, a fast skeletal muscle troponin activator, currently the subject of COURAGE-ALS, a Phase 3 clinical trial in patients with 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.

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 potential benefits of *omecamtiv mecarbil* or *aficamten*, statements relating to the potential submission or approval of an NDA for *omecamtiv mecarbil,* statements relating to the timing of a potential commercial launch of *omecamtiv mecarbil*, and statements relating to the timing of the commencement or completion of the SEQUOIA-HCM clinical trial. 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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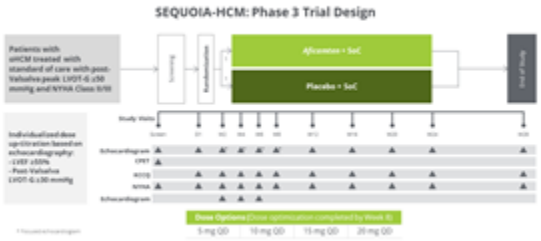
SEQUOIA-HCM: Phase 3 Trial Design



Design of SEQUOIA-HCM, a Phase 3 randomized, placebo-controlled, double-blind, multi-center clinical trial designed to evaluate aficamten in patients with symptomatic oHCM on background medical therapy for 24 weeks.

Source: Cytokinetics, Incorporated