

NEWS RELEASE

Cytokinetics Announces Additional Data from ACACIA-HCM Presented at the HFSA Annual Scientific Meeting 2026

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Additional Analyses from ACACIA-HCM Further Characterize Exercise Performance, Treatment Effect, Dose Titration and Safety of Aficamten in Non-Obstructive HCM

SOUTH SAN FRANCISCO, Calif., Oct. 12, 2026 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that additional data from ACACIA-HCM (Assessment Comparing *Aficamten* to Placebo on Cardiac Endpoints In Adults with Non-Obstructive HCM) were presented at the Heart Failure Society of America (HFSA) Annual Scientific Meeting 2026 in Phoenix, AZ.

"These additional analyses from ACACIA-HCM add to the body of evidence supporting the overall benefit-risk profile of *aficamten* in patients with nHCM," said Stephen Heitner, M.D., Cytokinetics' Chief Medical Officer. "The current CPET analysis demonstrates significant improvement in a clinically relevant and novel metric of global exercise performance, while additional data provide insights into dose titration and reinforce our confidence in the safety and treatment effect of *aficamten* in nHCM. We plan to submit a supplemental New Drug Application to the FDA this quarter."

ACACIA-HCM: Effect of *Aficamten* on Comprehensive Exercise Performance

Data from a prespecified analysis of comprehensive exercise performance from ACACIA-HCM were presented in a Late Breaking Clinical Trial Presentation. This analysis examined the effect of *aficamten* on multiple exercise parameters using the novel 2026 Boston Exercise Aggregate Physiologic Response Score (BEAP-RS). The score captures outputs from five individual domains, ranging from submaximal exercise through to recovery, and generates a composite of global exercise performance. At 36 weeks, treatment with *aficamten* significantly improved BEAP-RS compared to placebo ($p < 0.001$), with improvements in individual exercise and recovery measures across all five domains. Improvement in BEAP-RS correlated significantly with improvements in health status measured by both Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS) ($p = 0.001$) and New York Heart Association (NYHA) Functional Class ($p = 0.001$), as well as the cardiac biomarker NT-proBNP ($p < 0.001$). This analysis provides a greater understanding of the complete impact of *aficamten* on exercise capacity in patients with non-obstructive HCM (nHCM).

ACACIA-HCM: Global Efficacy Responder Analysis

Data from a responder analysis of ACACIA-HCM evaluating the global efficacy of *aficamten* in patients with symptomatic nHCM were presented in a Late Breaking Clinical Trial Presentation. The results were published in *Circulation* in August 2026.¹ The analysis assessed clinical improvements across five key domains. At 36 weeks, a greater proportion of patients treated with *aficamten* demonstrated a clinically meaningful response compared to placebo in all five domains, with statistically significant improvements in four domains: relief of limiting symptoms, decrease in left atrial volume index (LAVI), increase in septal e' velocity and $\geq 50\%$ reduction in NT-proBNP (all $p < 0.05$). An increase in peak VO_2 of at least 0.5 mL/kg/min was observed in 45% of patients on *aficamten* compared to 37% on placebo ($p = 0.1$). Overall, 53% of patients on *aficamten* demonstrated a clinical response in three or more domains compared to only 13% of patients on placebo ($p < 0.001$). These data place the primary results into clinical context and underscore the opportunity to impact several aspects of disease burden by addressing the underlying pathobiology in patients living with symptomatic nHCM.

ACACIA-HCM: Dose Titration and Safety

Data related to dose titration and the safety profile of *aficamten* in ACACIA-HCM were also presented. At the end of the titration period, 80.7% of patients were on 15 or 20 mg. Dose titration led to predictable, dose-proportional changes in plasma concentration of *aficamten* and reductions in left ventricular ejection fraction (LVEF), which then remained stable from Week 8 through Week 36. LVEF $< 50\%$ occurred in 27 (10.5%) patients taking *aficamten* and in two (0.8%) patients taking placebo. The only patient characteristics associated with LVEF $< 50\%$ were lower baseline LVEF and permanent atrial fibrillation. As previously reported, two participants on *aficamten* experienced a serious adverse event (SAE) of heart failure associated with LVEF $< 50\%$. Ten additional patients on *aficamten* had SAEs of heart failure not associated with LVEF $< 50\%$, for a total of 12 patients (4.7%) compared to three patients (1.2%) on placebo. All heart failure events in patients treated with *aficamten* occurred during dose titration or prior to Week 12, often following a precipitating event such as rapid atrial fibrillation or infection, and responded to typical medical therapy such as diuretics. Overall, these data suggest that, in ACACIA-HCM, titration of *aficamten* to the maximum tolerated dose based on LVEF alone was generally well tolerated in the great majority of patients with nHCM.

About MYQORZO® (*aficamten*)

MYQORZO® (*aficamten*) is a cardiac myosin inhibitor approved in the U.S., China, European Union and United Kingdom for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM). In patients with oHCM, myosin inhibition with MYQORZO reduces cardiac contractility and consequently, left ventricular outflow tract (LVOT) obstruction. MYQORZO was engineered to achieve a predictable exposure response, rapid onset of action and reversibility.²

Aficamten was also evaluated in a pivotal Phase 3 clinical trial, ACACIA-HCM, in patients with non-obstructive HCM (nHCM), which met both dual primary endpoints, demonstrating statistically significant improvements in both dual primary endpoints of Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS) and maximal exercise performance (pVO_2). Statistically significant improvements compared to placebo were also observed in key secondary endpoints. There were no new safety signals identified. Left ventricular ejection fraction (LVEF) $< 50\%$ occurred in 10% of participants taking *aficamten* and in 1% of participants taking placebo. Overall, 12 (4.7 %) patients on *aficamten* had serious adverse events of heart failure compared to three patients (1.2%) on placebo.

Aficamten is also under clinical investigation in CEDAR-HCM in a pediatric population with oHCM. Safety and efficacy of *aficamten* have not been established in a pediatric patient population. In addition, *aficamten* is being studied in FOREST-HCM, an open-label extension clinical study.

INDICATION

MYQORZO is indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF HEART FAILURE

MYQORZO reduces left ventricular ejection fraction (LVEF) and can cause heart failure due to systolic dysfunction.

Echocardiogram assessments are required prior to and during treatment with MYQORZO to monitor for systolic dysfunction. Initiation of MYQORZO in patients with LVEF <55% is not recommended. Decrease the dose of MYQORZO if LVEF is <50% and ≥40%. Interrupt the dose of MYQORZO if LVEF <40% or if the patient experiences heart failure symptoms or worsening clinical status due to systolic dysfunction.

Because of the risk of heart failure due to systolic dysfunction, MYQORZO is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MYQORZO REMS Program.

CONTRAINDICATIONS

MYQORZO is contraindicated with concomitant use of rifampin.

WARNINGS AND PRECAUTIONS

Heart Failure

MYQORZO reduces cardiac contractility, which can reduce LVEF and cause heart failure. Patients who experience a serious intercurrent illness (eg, serious infection) or arrhythmia (eg, new or uncontrolled atrial fibrillation) may be at greater risk of developing systolic dysfunction and heart failure.

Assess patients' clinical status and LVEF prior to and during treatment and adjust the MYQORZO dose accordingly. New or worsening arrhythmia, dyspnea, chest pain, fatigue, leg edema, or elevations in N-terminal pro-B-type natriuretic peptide may be signs and symptoms of heart failure.

Initiation of MYQORZO in patients with LVEF <55% is not recommended.

MYQORZO REMS Program

MYQORZO is available only through a restricted program called the MYQORZO REMS Program, because

of the risk of heart failure due to systolic dysfunction.

Notable requirements of the MYQORZO REMS Program include:

- Prescribers must be certified by enrolling in the MYQORZO REMS Program
- Patients must enroll in the MYQORZO REMS Program and comply with ongoing monitoring requirements
- Pharmacies must be certified by enrolling in the MYQORZO REMS Program and must only dispense to patients who are authorized to receive MYQORZO
- Wholesalers and distributors must only distribute to certified pharmacies

Further information is available at www.MYQORZOREMS.com, or at 1-844-285-7367.

Cytochrome P450 Interactions Leading to Heart Failure or Loss of Effectiveness

MYQORZO is metabolized primarily by CYP2C9, and to a lesser extent by CYP3A, CYP2D6, and CYP2C19 enzymes. Initiation of medications that inhibit multiple P450 pathways of MYQORZO elimination (eg, fluconazole, voriconazole, or fluvoxamine) or strong CYP2C9 inhibitors, and discontinuation of moderate-to-strong CYP3A inducers may lead to increased blood concentrations of *aficamten* and increase the risk of heart failure due to systolic dysfunction. Conversely, initiation of medications that induce P450 pathways of MYQORZO (eg, rifampin, moderate-to-strong CYP3A inducers) may lead to decreased blood concentrations of *aficamten* and potential loss of effectiveness. Assess LVEF 2 to 8 weeks after initiation of such inhibitors or after discontinuation of such inducers and adjust the dose of MYQORZO accordingly.

Advise patients of the potential for drug interactions. Advise patients to inform their healthcare provider of all concomitant medications prior to and during MYQORZO treatment.

ADVERSE REACTIONS

Hypertension (8% vs 2%) was the only adverse reaction occurring in >5% of patients and more commonly on MYQORZO than on placebo in the pivotal trial.

INDICATIONS AND USAGE

MYQORZO is indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

Please see full [Prescribing Information](#) approved in the U.S., including Boxed WARNING.

Please see full [Summary of Product Characteristics](#) approved in the European Union.

About Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a disease in which the heart muscle becomes abnormally thick. HCM can be obstructive, when thickened muscle blocks blood flow, or non-obstructive, when blood flow is not blocked but heart function is still affected. In obstructive HCM, the thickening of cardiac muscle leads to the inside of the left ventricle becoming smaller, stiffer and less able to relax and fill with blood. Ultimately, HCM limits the heart's pumping function, leading to reduced exercise capacity and a variety of symptoms.

HCM is the most common monogenic inherited cardiovascular disorder, affecting approximately 1 out of 350 individuals worldwide.³

Approximately half of patients with HCM have obstructive HCM (oHCM) and half have non-obstructive HCM (nHCM).⁴

People with HCM are at high risk of also developing cardiovascular complications including atrial fibrillation, stroke and mitral valve disease.⁵ People with HCM are at risk for potentially fatal ventricular arrhythmias and it is one of the leading causes of sudden cardiac death in younger people or athletes.⁶ A subset of patients with HCM are at high risk of progressive disease leading to dilated cardiomyopathy and heart failure necessitating cardiac transplantation.

About Cytokinetics

Cytokinetics is a specialty cardiovascular biopharmaceutical company, building on its over 25 years of pioneering scientific innovations in muscle biology, and advancing a pipeline of potential new medicines for patients suffering from diseases of cardiac muscle dysfunction. Cytokinetics' MYQORZO® (*aficamten*) is a cardiac myosin inhibitor approved in the U.S., China, European Union and United Kingdom for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM). Following positive results in ACACIA-HCM, a Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM (nHCM), the company plans to submit a Supplemental New Drug Application in Q4 2026. Cytokinetics is also developing *omecamtiv mecarbil*, an investigational cardiac myosin activator for the potential treatment of patients with heart failure with severely reduced ejection fraction and *ulacamten*, an investigational cardiac myosin inhibitor for the potential treatment of heart failure with preserved ejection fraction, while continuing pre-clinical research and development in muscle biology.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on [X](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

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 our ability to obtain regulatory approval for *aficamten* in nonobstructive hypertrophic cardiomyopathy in any jurisdiction by any particular date, if ever, the number of patients comprising the eligible treatment population for *aficamten*, or market acceptance of *aficamten* for the treatment of nonobstructive hypertrophic cardiomyopathy. 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 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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MYQORZO® is a registered trademark of Cytokinetics in the U.S., the European Union and the United Kingdom.

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