NEWS RELEASE

# Cytokinetics Announces Additional Data Related to Aficamten Presented at the Hypertrophic Cardiomyopathy Medical Society (HCMS) Scientific Sessions Held in Collaboration with the American Heart Association Scientific Sessions 2026

2026-11-09

*New Analyses Across Obstructive and Non-obstructive HCM Expand Clinical Evidence for Aficamten*

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2026 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that new data related to *aficamten* were presented at the Hypertrophic Cardiomyopathy Medical Society (HCMS) Scientific Sessions held in collaboration with the American Heart Association Scientific Sessions 2026 in Chicago, IL including two late-breaking oral abstracts with additional data from ACACIA-HCM, and one poster presentation with new data from FOREST-HCM.

“The new data further enrich the growing body of clinical evidence establishing *aficamten* as a potentially paradigm-shifting therapy across the spectrum of hypertrophic cardiomyopathy,” said Stephen Heitner, M.D., Cytokinetics’ Chief Medical Officer. “The advanced imaging data provide crucial insights into favorable cardiac remodeling, showing that *aficamten* may reduce key structural markers of the disease. Concurrently, additional data highlights meaningful improvements in self-reported measures of symptom burden and quality of life. Together, these data deepen our understanding of the biological effects of MYQORZO® and associated potential clinical benefit.”

**ACACIA-HCM: Effect of *Aficamten* on Cardiac Structure and Function in Non-Obstructive Hypertrophic Cardiomyopathy**

New data from the pre-specified cardiac magnetic resonance (CMR) imaging sub-study of ACACIA-HCM characterized the effects of *aficamten* on cardiac structure in patients with non-obstructive hypertrophic cardiomyopathy (nHCM). After 36 weeks of treatment, *aficamten* was associated with favorable cardiac remodeling in patients with symptomatic nHCM. Patients treated with *aficamten* experienced statistically significant ($p<0.001$) reductions in left ventricular mass index (LVMI) and left ventricular wall thickness compared to placebo (Figure 1).

**Figure 1: Changes Associated with Favorable Cardiac Remodeling**

The reduction in LVMI was driven by a decrease in myocardial cellular mass, with no significant changes observed in measures of extracellular matrix or myocardial fibrosis. Furthermore, these structural improvements correlated with significant decreases in N-terminal pro-B-type natriuretic peptide (NT-proBNP) and high-sensitivity troponin I, established biomarkers of cardiac wall stress and myocardial injury, respectively. This analysis is evidence that the beneficial structural remodeling occurring is somewhat independent from relief of obstruction, and as a direct effect of *aficamten* on the myocardium.

**ACACIA-HCM: Effect of *Aficamten* on Patient-Reported Health Status in nHCM**

New analyses from ACACIA-HCM evaluated the long-term impact of *aficamten* on patient-reported health status utilizing the Kansas City Cardiomyopathy Questionnaire Overall Summary Score (KCCQ-OSS), a broader measure of patient experience than the primary endpoint measure of KCCQ Clinical Summary Score (KCCQ-CSS). The data showed that *aficamten* improved patient-reported health status in patients with nHCM, with treatment effects observed across symptoms, physical limitations, quality of life and social function. At Week 36, patients receiving *aficamten* showed a 4.0-point greater improvement in KCCQ-OSS relative to placebo, and using the clinically accepted thresholds, more patients experienced improvements (33.7% vs. 22.5% respectively) and fewer experienced deterioration (7.4% vs. 13.3% respectively). Authors also demonstrated that there appears to be a greater between-group difference with increasing time, through to Week 72 (Figure 2). Importantly, following treatment withdrawal, these effects declined within four weeks, with no differences remaining at the end of the study.

**Figure 2: Change in KCCQ-OSS**

**FOREST-HCM: Left Ventricular Systolic Dysfunction in Long-Term *Aficamten* Therapy for oHCM**

Published in *Journal of Cardiac Failure*, long-term data from FOREST-HCM, the open-label extension study of *aficamten*, further expands the clinical evidence of the sustained safety and tolerability profile of *aficamten* in patients with oHCM.[1]

This analysis showed that among 410 patients with oHCM, 12 (2.9%) developed a left ventricular ejection fraction (LVEF) <50% and none with LVEF <40%, representing 2.1 events per 100 patient-years. There were no heart failure hospitalizations or deaths associated with systolic dysfunction and the episodes were transient, asymptomatic, and rapidly reversible after dose reduction or temporary interruption. Lastly, the investigators demonstrated that borderline LVEF (≥50% to <55%) was clinically benign and did not require dose adjustment or intervention.

**About MYQORZO® (*aficamten*)**

MYQORZO® (*aficamten*) is a cardiac myosin inhibitor approved in the U.S., China, European Union, United Kingdom and Canada 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 studied in ACACIA-HCM, a completed Phase 3 clinical trial of *aficamten* in patients with nHCM. *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 one 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, United Kingdom and Canada 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"), including within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements can be identified by words such as "anticipate," "believe," "could," "expect," "intend," "may," "plan," "potential," "should," "will" and similar expressions, although not all forward-looking statements contain these words. Cytokinetics disclaims any intent or obligation to update these forward-looking statements, except as required by law, 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 of *aficamten* as a therapy across the spectrum of hypertrophic cardiomyopathy and its potential clinical benefits, including its potential effects on cardiac structure, function and remodeling, on biomarkers of cardiac wall stress and myocardial injury, and on patient-reported health status; the significance, interpretation and durability of the data from ACACIA-HCM and FOREST-HCM, including the long-term safety and tolerability profile of MYQORZO; Cytokinetics'

plans to submit a Supplemental New Drug Application for *aficamten* in non-obstructive hypertrophic cardiomyopathy and the timing thereof; our ability to obtain regulatory approval for *aficamten* in non-obstructive hypertrophic cardiomyopathy in any jurisdiction by any particular date, if ever; the conduct, progress and results of CEDAR-HCM, FOREST-HCM and Cytokinetics' other clinical trials; the development of omecamtiv mecarbil and ulacamten; the number of patients comprising the eligible treatment population for *aficamten*; and market acceptance of *aficamten* for the treatment of non-obstructive 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: results from sub-studies, secondary, exploratory or post hoc analyses and open-label extension studies may not be predictive of, or consistent with, results from other analyses or future clinical trials, and the FDA or foreign regulatory agencies may disagree with Cytokinetics' interpretation of such data; Cytokinetics may be unable to submit the Supplemental New Drug Application for *aficamten* in non-obstructive hypertrophic cardiomyopathy when planned, and the FDA may not accept such application for review, may require additional data or may not approve it; 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 and MYQORZO may have adverse side effects or inadequate therapeutic efficacy; the commercial success of MYQORZO depends on its acceptance by patients, physicians and payors, adequate coverage and reimbursement, and compliance with the MYQORZO REMS Program and other post-approval requirements; Cytokinetics relies on third parties to manufacture MYQORZO and its drug candidates and to conduct its clinical trials; 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; Cytokinetics may need additional capital, and its indebtedness and other funding obligations may limit its operating flexibility; 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, including the risks described under the heading "Risk Factors" in Cytokinetics' most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. Forward-looking statements speak only as of the date of this press release, and readers are cautioned not to place undue reliance on them.

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MYQORZO® is a registered trademark of Cytokinetics in the U.S., the European Union, the United Kingdom and Canada.

**References**

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A photo accompanying this announcement is available at
https://www.globenewswire.com/NewsRoom/AttachmentNg/88ccfe17-b9cc-492f-abde-958182e9a64d

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Figure 1 Changes Associated with Favorable Cardiac Remodeling



Changes Associated with Favorable Cardiac Remodeling
Figure 2 Change in KCCQ-OSS



Change in KCCQ-OSS