NEWS RELEASE

# Cytokinetics Announces Prescribing Information for MYQORZO® (aficamten) Expanded to Include Data from Phase 3 MAPLE-HCM

2026-11-16

*MYQORZO is the Only Cardiac Myosin Inhibitor with Data in Its U.S. Label Comparing Its Effectiveness to the Beta Blocker Metoprolol*

SOUTH SAN FRANCISCO, Calif., Nov. 16, 2026 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) updating the U.S. Prescribing Information for MYQORZO® *(aficamten)* to include data from MAPLE-HCM, the Phase 3 trial comparing MYQORZO and the standard-of-care beta-blocker *metoprolol,* each as monotherapy, in adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM). MYQORZO is indicated for the treatment of adults with symptomatic oHCM to improve functional capacity and symptoms.

“People living with HCM deserve treatment decisions grounded in rigorous evidence. For decades, beta-blockers have been a cornerstone of treatment for oHCM in the absence of rigorously conducted clinical trials demonstrating their utility in this condition,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “In MAPLE-HCM, MYQORZO demonstrated significantly greater improvements in exercise capacity, symptom burden and cardiac biomarkers compared to *metoprolol*. MYQORZO is now the only cardiac myosin inhibitor with evidence comparing its effectiveness to a beta-blocker for the treatment of oHCM in its U.S. label, providing cardiologists and patients important information to inform treatment decisions.”

MYQORZO was approved by the FDA in December 2025 for the treatment of adults with symptomatic oHCM to improve functional capacity and symptoms based on the results from SEQUOIA-HCM, the pivotal, randomized, placebo-controlled, Phase 3 clinical trial of MYQORZO in patients with oHCM on background therapy. It is also approved for the treatment of patients with oHCM in China, European Union, United Kingdom and Canada.

The full U.S. Prescribing Information for MYQORZO includes a **Boxed WARNING** for the 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 LVEF <55% is not

recommended. Decrease the dose of MYQORZO if LVEF <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. Please see additional Important Safety Information including **Boxed WARNING** below.

**About MAPLE-HCM**

MAPLE-HCM was a Phase 3, multi-center, randomized, double-blind, double-dummy, controlled clinical trial that compared MYQORZO to the standard-of-care beta-blocker *metoprolol* on peak oxygen uptake ($pVO_2$). The results showed that MYQORZO met the primary endpoint of change in $pVO_2$ from baseline to Week 24, an effect that was consistent across all prespecified subgroups, including in patients who were newly diagnosed or treatment naïve.[1]

MYQORZO also significantly improved five of six secondary endpoints, including New York Heart Association (NYHA) Functional Class, Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS), NT-proBNP, post-Valsalva left ventricular outflow tract gradient (LVOT-G) and left atrial volume index (LAVI).

Overall, the rate of adverse events (AEs) was similar between groups. The most common AE reported in excess (>5%) of the comparator was hypertension for MYQORZO and dizziness for *metoprolol*.

**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, randomized, placebo-controlled, Phase 3clinical 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.

**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.

## WARNING 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 was the only adverse reaction occurring in >5% of patients and more commonly on MYQORZO than placebo or metoprolol in SEQUOIA-HCM (8% vs 2%) and MAPLE-HCM (15% vs 3%) respectively.

**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.

**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"). 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.

CYTOKINETICS® and the CYTOKINETICS C-shaped logo are registered trademarks of Cytokinetics in the U.S. and certain other countries.

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

**References**

1. Garcia-Pavia, P, et al. *Aficamten* or Metoprolol Monotherapy for Obstructive Hypertrophic Cardiomyopathy. N Engl J Med. 2025
2. Maron, MS, et al. *Aficamten* for Symptomatic Obstructive Hypertrophic Cardiomyopathy. N Engl J Med. doi:10.1056/NEJMoa2401424
3. Tsenov et al. Healthcare access, symptom burden, and psychological impact in hypertrophic cardiomyopathy: a multinational patient-driven survey. Int J Cardiol Cardiovasc Risk Prev2025 Aug 4;27:200485. doi:10.1016/j.ijcrp.2025.200485.
4. Butzner M, et al. Epidemiology of Hypertrophic Cardiomyopathy in the United States From 2016 to 2023. JACC Adv. 2026. 2026;5(2):102552. doi:10.1016/j.jacadv.2025.102552.
5. Gersh, B.J., Maron, B.J., Bonow, R.O., Dearani, J.A., Fifer, M.A., Link, M.S., et al. 2011 ACCF/AHA guidelines for the diagnosis and treatment of hypertrophic cardiomyopathy. A report of the American

College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. Journal of the American College of Cardiology and Circulation, 58, e212-260.
6. Hong Y, Su WW, Li X. Risk factors of sudden cardiac death in hypertrophic cardiomyopathy. Current Opinion in Cardiology. 2022 Jan 1;37(1):15-21

Contact:
Cytokinetics
Diane Weiser
Senior Vice President, Corporate Affairs
(415) 290-7757

Source: Cytokinetics, Incorporated