



NEWS RELEASE

# Cytokinetics Announces MYQORZO™ (aficamten) Now Available in the U.S. for the Treatment of Adults with Symptomatic Obstructive Hypertrophic Cardiomyopathy to Improve Functional Capacity and Symptoms

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*MYQORZO, a Cardiac Myosin Inhibitor, Directly Addresses Underlying Hypercontractility Associated with Obstructive HCM*

SOUTH SAN FRANCISCO, Calif., Jan. 27, 2026 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that MYQORZO™ (*aficamten*) is now available for prescription in 5 mg, 10 mg, 15 mg and 20 mg tablets in the U.S. MYQORZO was recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

Experience the full interactive Multichannel News Release here: <https://www.multivu.com/cytokinetics/9379451-en-myqorzo-now-available-ohcm/>.

MYQORZO is a once-daily, oral allosteric and reversible inhibitor of cardiac myosin motor activity. In patients with oHCM, myosin inhibition with MYQORZO reduces cardiac contractility and left ventricular outflow tract (LVOT) obstruction.

"With MYQORZO now available in the U.S., we are delivering on our long-standing commitment to patients living with obstructive HCM and turning the page onto a new chapter as a commercial biopharmaceutical company," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "This product launch is the culmination of decades of rigorous science, clinical development, and commercial readiness preparations, reflecting our unwavering commitment to making a meaningful difference in the lives of patients. We are grateful to the healthcare professionals, patients and advocates across the HCM community whose insights and partnerships helped bring MYQORZO to this important milestone. With our REMS program now live, and our supply chain and specialty pharmacy distribution network fully operational, we are proud to make MYQORZO available as a new treatment option for patients with oHCM."

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  $\geq 40\%$ . 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.

Cytokinetics received U.S. FDA approval for MYQORZO on December 19, 2025. The approval was based on the positive results from the pivotal Phase 3 clinical trial, SEQUOIA-HCM, published in the [New England Journal of Medicine](#).<sup>1</sup>

Cytokinetics is committed to supporting patients with MYQORZO & You™, a personalized program for patients prescribed MYQORZO in the U.S. to help navigate the treatment journey, provide disease and product education, and offer support with insurance benefits investigations or financial assistance for those eligible.

## 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  $\geq 40\%$ . 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](http://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.

Please see full [Prescribing Information](#), including Boxed WARNING and [Medication Guide](#).

### About MYQORZO™ (*aficamten*)

MYQORZO™ (*aficamten*) is a cardiac myosin inhibitor approved by the U.S. FDA for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms. MYQORZO is an allosteric and reversible inhibitor of cardiac myosin motor activity. In patients with HCM, myosin inhibition with MYQORZO reduces cardiac contractility and left ventricular outflow tract (LVOT) obstruction. MYQORZO was engineered to achieve a predictable exposure response, rapid onset of action and reversibility.<sup>2</sup>

On December 17, 2025, the China National Medical Products Administration approved MYQORZO® (*aficamten*) for the treatment of oHCM. On December 12, 2025, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion recommending marketing authorization in the European Union for MYQORZO® (*aficamten*) with a decision expected from the European Commission in the first quarter of 2026.

*Aficamten* is also under clinical investigation in ACACIA-HCM, a Phase 3 trial in patients with non-obstructive HCM (nHCM) and CEDAR-HCM, in a pediatric population with oHCM. *Aficamten* has not been deemed safe or effective for use in either of these patient populations. In addition, *aficamten* is being studied in FOREST-HCM, an open-label extension clinical study.

### 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, with well over 300,000 patients diagnosed in the U.S.<sup>3</sup> However, there are an estimated 400,000-800,000 additional patients who remain undiagnosed.<sup>4,5,6</sup> Approximately half of patients with HCM have obstructive HCM (oHCM) and half have non-obstructive HCM (nHCM).<sup>3</sup>

People with HCM are at high risk of also developing cardiovascular complications including atrial fibrillation, stroke and mitral valve disease.<sup>7</sup> 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.<sup>8</sup> 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 for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms by the

U.S. Food and Drug Administration and the China National Medical Products Administration. The Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion recommending marketing authorization in the European Union for MYQORZO® (*aficamten*) with a decision expected from the European Commission in first quarter in 2026. *Aficamten* is also being studied for the potential treatment of non-obstructive HCM. 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](http://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 any of our clinical trials, statements relating to our ability to obtain regulatory approval for *aficamten* in any jurisdiction by any particular date, if ever. 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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MYQORZO™ is a trademark of Cytokinetics in the U.S., and a registered trademark in the European Union.

MYQORZO & You™ is a trademark of Cytokinetics in the U.S.

## References

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