NEWS RELEASE

Cytokinetics Announces FDA Approval of MYQORZO™ (aficamten) 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

FDA Approval Based on Results of SEQUOIA-HCM

MYQORZO is Company's First FDA-Approved Medicine

Company to Host Investor Conference Call Today at 4:30 PM Eastern Time

SOUTH SAN FRANCISCO, Calif., Dec. 19, 2025 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the U.S. Food and Drug Administration (FDA) has approved MYQORZO™ (*aficamten),* 5 mg, 10 mg, 15 mg, 20 mg tablets for the treatment of adults with 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 oHCM, myosin inhibition with MYQORZO reduces cardiac contractility and left ventricular outflow tract (LVOT) obstruction.

“This is a historic moment for our company and for the patients we serve, as we fulfill our promise to translate our science into medicines that may make a meaningful difference in patients’ lives,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “Our first FDA approval stands as a testament to the strength of our science and the bold, trailblazing research that has defined Cytokinetics’ leadership in muscle biology. I’m pleased that the approved label and REMS reflect the distinct characteristics of MYQORZO including a straightforward, flexible dosing regimen, no requirement for drug-drug interaction monitoring and a predictable safety profile. I am profoundly grateful for the many years of passion and persistence shown by patients with obstructive HCM, as well as healthcare professionals, advocates, partners and employees who have contributed so importantly to reaching this key milestone.”

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.

MYQORZO is expected to be available in the U.S. in the second half of January 2026. Cytokinetics will support 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. For more information, call 833-MYQORZO (833-697-6796).

“HCM is a heart muscle disease associated with a significant symptom burden. This approval of a new drug, MYQORZO, represents a meaningful addition to the treatment options available for symptomatic obstructive HCM patients,” said Martin Maron, M.D., Director, Hypertrophic Cardiomyopathy Center, Lahey Hospital and Medical Center, and Principal Investigator of SEQUOIA-HCM. “In SEQUOIA-HCM, MYQORZO improved exercise capacity and reduced symptoms while also being well-tolerated. For these reasons, MYQORZO represents an important step forward in how we care for people living with obstructive HCM.”

“Living with symptomatic obstructive HCM means managing physical limitations and burdensome symptoms every day of your life,” said Lisa Salberg, Founder and CEO of the Hypertrophic Cardiomyopathy Association (HCMA). “For far too long, we’ve had few options to address our needs, and the approval of MYQORZO is a long-awaited and major addition to bring new hope to patients living with oHCM. We are so grateful to the team at Cytokinetics for listening to the patient community and working in true partnership to bring this therapy to so many in need.”

About SEQUOIA-HCM

The approval is based on the positive results from the pivotal Phase 3 clinical trial, SEQUOIA-HCM,

published in the *New England Journal of Medicine*, which demonstrated robust efficacy, safety, and clinically meaningful benefits across symptoms, exercise capacity, hemodynamics, and biomarker endpoints. The results from SEQUOIA-HCM showed that treatment with MYQORZO for 24 weeks significantly improved exercise capacity compared to placebo, increasing peak oxygen uptake (pVO_2) measured by cardiopulmonary exercise testing (CPET) by 1.8 mL/kg/min compared to baseline in patients treated with MYQORZO versus 0.0 mL/kg/min in patients treated with placebo (least square mean (LSM) difference [95% CI] of 1.74 mL/kg/min [1.04 - 2.44]; p=0.000002).[1] The treatment effect of MYQORZO was consistent across all prespecified subgroups, including age, sex, patient baseline characteristics, and in patients receiving or not receiving background beta-blocker therapy.

MYQORZO was well-tolerated, with no instances of worsening heart failure or treatment interruptions due to low LVEF. Treatment emergent serious adverse events occurred in 5.6% of patients on MYQORZO and 9.3% of patients on placebo. Core laboratory echocardiographic LVEF was observed to be <50% in 5 patients (3.5%) on MYQORZO compared to 1 patient (0.7%) on placebo. Hypertension (8% vs 2%) was the only adverse reaction occurring in >5% of patients and more commonly on MYQORZO than on placebo. MYQORZO-associated increases in blood pressure are consistent with relief of LVOT obstruction and improved cardiac output.

Investor Webcast Information

Cytokinetics will host an investor conference call on December 19, 2025, at 4:30 PM Eastern Time to discuss the FDA approval of MYQORZO. Interested parties can register online at https://myqorzo-fda-approval-call.open-exchange.net/. The live webcast will be available on the Investors & Media section of the Cytokinetics website at www.cytokinetics.com. A replay of the webcast will be archived on the Cytokinetics website for six months.

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.

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 (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.[2]

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. However, there are an estimated 400,000-800,000 additional patients who remain undiagnosed.[3,4,5] Approximately half of patients with HCM have obstructive HCM (oHCM) and half have non-obstructive HCM (nHCM).

People with HCM are at high risk of also developing cardiovascular complications including atrial fibrillation, stroke and mitral valve disease.[6] 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.[7] 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 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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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/b9f8fb42-7a54-4595-ac4a-01d585228003

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