NEWS RELEASE

Cytokinetics Announces Positive CHMP Opinion of MYQORZO® (Aficamten) for the Treatment of Obstructive Hypertrophic Cardiomyopathy

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Final Decision from European Commission Expected in Q1 2026

SOUTH SAN FRANCISCO, Calif., Dec. 12, 2025 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization in the European Union (EU) for MYQORZO® (*aficamten*), a cardiac myosin inhibitor, for the treatment of symptomatic (New York Heart Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients. A final decision is anticipated from the European Commission in the first quarter of 2026.

“We are pleased with CHMP’s positive recommendation based on the robust clinical evidence from SEQUOIA-HCM that demonstrated the safety and efficacy of MYQORZO in patients with oHCM, and we are accelerating commercial readiness activities accordingly,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “Given the urgency to bring new treatment options to the European oHCM patient community, pending the final European Commission decision, we look forward to making MYQORZO available to patients in Europe.”

“This positive opinion from the CHMP is an important milestone toward bringing a new treatment option with distinct attributes to patients with oHCM,” said Iacopo Olivotto, M.D., Head of the Cardiomyopathy Center and Professor of Cardiovascular Medicine at the University of Florence, Italy.

Aficamten is currently under regulatory review in the U.S., where the Food & Drug Administration (FDA) is reviewing a New Drug Application (NDA) with a Prescription Drug User Fee Act (PDUFA) target action date of December 26, 2025. Additionally, the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) is reviewing an NDA for *aficamten* with Priority Review.

About SEQUOIA-HCM

The CHMP recommendation for MYQORZO 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.[1]

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).

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 left ventricular ejection fraction (LVEF). Treatment emergent serious adverse events occurred in 5.6% and 9.3% of patients on MYQORZO and placebo, respectively. Core lab echocardiographic LVEF was observed to be <50% in 5 patients (3.5%) on MYQORZO compared to 1 patient (0.7%) on placebo.

About MYQORZO® (*aficamten*)

MYQORZO® (*aficamten*) is an investigational selective, small molecule cardiac myosin inhibitor discovered following an extensive chemical optimization program that was conducted with careful attention to therapeutic index and pharmacokinetic properties.[2] MYQORZO was designed to reduce the number of active actin-myosin cross bridges during each cardiac cycle and consequently suppress the myocardial hypercontractility that is associated with HCM. In preclinical models, MYQORZO reduced myocardial contractility by binding directly to cardiac myosin at a distinct and selective allosteric binding site, thereby preventing myosin from entering a force producing state.

The development program for MYQORZO assessed its potential as a treatment that improves exercise capacity and relieves symptoms in patients with obstructive HCM. MYQORZO was evaluated in SEQUOIA-HCM, a positive pivotal Phase 3 clinical trial in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). MYQORZO received Breakthrough Therapy Designation for the treatment of symptomatic HCM from the FDA and for the treatment of symptomatic obstructive HCM from the NMPA in China.

Aficamten is also currently being evaluated in ACACIA-HCM, a Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM; CEDAR-HCM, a clinical trial of *aficamten* in a pediatric population with oHCM; and FOREST-HCM, an open-label extension clinical study of *aficamten* in patients with HCM. *Aficamten* was also the subject of MAPLE-HCM, a Phase 3 randomized, double-blind, active-comparator clinical trial in patients with oHCM.

About Hypertrophic Cardiomyopathy

HCM is the most common monogenic inherited cardiovascular disorder, affecting approximately 1 out of 500 Europeans, according to the European Society of Cardiology guidelines.[3] Hypertrophic cardiomyopathy (HCM) is a disease in which the heart muscle (myocardium) becomes abnormally thick (hypertrophied). The thickening of cardiac muscle leads to the inside of the left ventricle becoming smaller and stiffer, and thus the ventricle becomes less able to relax and fill with blood. This ultimately limits the heart's pumping function, resulting in reduced exercise capacity and symptoms including chest pain, dizziness, shortness of breath, or fainting during physical activity.

Two-thirds of patients with HCM have obstructive HCM (oHCM), where the thickening of the cardiac muscle leads to left ventricular outflow tract (LVOT) obstruction, while one-third have non-obstructive HCM (nHCM), where blood flow isn't impacted, but the heart muscle is still thickened.

People with HCM are at high risk of also developing cardiovascular complications including atrial fibrillation, stroke and mitral valve disease.[4] 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.[5] 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 is readying for potential regulatory approvals and commercialization of *aficamten*, a cardiac myosin inhibitor, following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial in patients with obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in additional clinical trials enrolling patients with obstructive and non-obstructive HCM. In addition, Cytokinetics is developing *omecamtiv mecarbil*, a cardiac myosin activator, in patients with heart failure with severely reduced ejection fraction (HFrEF), *ulacamten*, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten*, for the potential treatment of heart failure with preserved ejection fraction (HFpEF) and CK-089, a fast skeletal muscle troponin activator with potential therapeutic application to a specific type of muscular dystrophy and other conditions of impaired skeletal muscle function.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on X, LinkedIn, Facebook and YouTube.

Disclaimer

Aficamten, omecamtiv mecarbil, ulacamten and CK-089 are investigational medicines. They have not been approved nor determined to be safe or efficacious for any disease state or any indication by FDA or any other regulatory agency.

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 the potential approval of MYQORZO® (*aficamten*) by FDA, EMA or any other regulatory agency as a treatment for obstructive hypertrophic cardiomyopathy or any other indication, Cytokinetics' and its partners' research and development activities of Cytokinetics' product candidates. 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 the risks related to Cytokinetics' business outlines in Cytokinetics' filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and Cytokinetics' actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new

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

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