NEWS RELEASE

# Cytokinetics Announces European Commission Approval of MYQORZO® (aficamten) for the Treatment of Adults with Symptomatic Obstructive Hypertrophic Cardiomyopathy

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*European Commission Approval Based on Results of SEQUOIA-HCM*

*First European Launch Expected in Germany in Q2 2026*

SOUTH SAN FRANCISCO, Calif., Feb. 17, 2026 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the European Commission (EC) has approved MYQORZO® (*aficamten),* 5 mg, 10 mg, 15 mg and 20 mg tablets for the treatment of symptomatic (New York Heart Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients. MYQORZO is an allosteric and reversible inhibitor of cardiac myosin motor activity. In patients with oHCM, myosin inhibition with MYQORZO reduces cardiac contractility and consequently, left ventricular outflow tract (LVOT) obstruction.

“The approval of MYQORZO in the European Union is an important milestone towards bringing this medicine to more patients living with obstructive HCM around the world,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “We are pleased that the European label allows providers flexibility to determine whether a patient starts treatment at either 5 mg or 10 mg, based on the severity of their baseline LVOT obstruction. We look forward to making MYQORZO available in Europe, beginning with our first launch in Germany in the second quarter of this year.”

“Myosin inhibition is establishing itself as an important therapy that may improve the lives of patients with hypertrophic obstructive cardiomyopathy. The approval of *aficamten* by the European Commission brings another treatment option into our clinical practice, allowing for more treatment flexibility to reach more patients,” said Prof. Benjamin Meder, FESC, Chair of Precision Digital Health, Head of the Institute for Cardiomyopathies Heidelberg and Deputy Medical Director, Department of Cardiology, Angiology and Pneumology, University Hospital Heidelberg.

“Obstructive HCM can dramatically impact patients’ lives and often requires them to make difficult life choices based on their symptoms and how they feel,” said Emil Tsenov, Founding and Managing

Director, HCM Patient Foundation. “The approval of MYQORZO in the European Union brings hope for patients and reflects meaningful progress for the HCM community.”

The EC approval follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorization in the European Union (EU) for MYQORZO for the treatment of symptomatic (NYHA class II-III) oHCM in adult patients.

MYQORZO was approved by the U.S. Food and Drug Administration (FDA) for the treatment of adults with symptomatic oHCM to improve functional capacity and symptoms, and by the China National Medical Products Administration (NMPA) for the treatment of adults with NYHA class II-III oHCM, to improve exercise capacity and symptoms.

The Summary of Product Characteristics for MYQORZO is available on the EMA website at www.ema.europa.eu.

**About SEQUOIA-HCM**

The EC 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 1.76 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.

During the 24-week treatment period, 3.5% of patients in the treatment group experienced a reversible dose related reduction in left ventricular ejection fraction (LVEF) to < 50% (median 47%; range 34% to 49%). One patient in the treatment group experienced an asymptomatic LVEF < 40%. Reductions in LVEF to < 50% did not require treatment interruption and were not associated with clinical heart failure.

The most commonly reported adverse reactions observed with MYQORZO are dizziness (4.2%), systolic dysfunction defined as LVEF < 50% (3.5%), palpitations (7%) and hypertension (7.7%).

**About MYQORZO® (*aficamten*)**

MYQORZO® (*aficamten*) is a cardiac myosin inhibitor approved in the U.S., China and European Union for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM). In patients with HCM, 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* 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, affecting approximately 1 out of 500 Europeans, according to the European Society of Cardiology guidelines.[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., Europe and China for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM). *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 our ability to commence commercialization of MYQORZO 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.



**References**

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