

# Cytokinetics Launches MYQORZO® (aficamten) in European Union, with First Commercial Availability in Germany

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*European Launch Follows Strong U.S. Start*

SOUTH SAN FRANCISCO, Calif., and ZUG, Switzerland, June 01, 2026 (GLOBE NEWSWIRE) -- [Cytokinetics, Incorporated](#) (Nasdaq: CYTK) today announced the first commercial European launch of MYQORZO® (*aficamten*) in Germany 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 reduces cardiac contractility and consequently, left ventricular outflow tract (LVOT) obstruction.

Marking the first of several planned European launches, the availability of MYQORZO in Germany follows the European Commission approval in February 2026. The approval was based on positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial of *aficamten* in patients with oHCM, demonstrating robust efficacy, safety, and clinically meaningful benefits across symptoms, exercise capacity, hemodynamics, and biomarker endpoints.<sup>1</sup> These clinical results were published in the [New England Journal of Medicine](#).

“Bringing MYQORZO to Europe marks an exciting new chapter for Cytokinetics as we extend our reach to more patients with symptomatic oHCM,” said Joseph Dagher, Senior Vice President and Head of Europe, Cytokinetics. “This milestone further strengthens our leadership in muscle biology and reinforces Cytokinetics’ commitment to the global HCM community.”

MYQORZO was previously approved in December 2025 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 latest advancement in myosin inhibition brings a new treatment option into our clinical practice in Europe and Germany to help patients with symptomatic oHCM,” 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.

The results from SEQUOIA-HCM showed that treatment with *aficamten* for 24 weeks significantly improved exercise capacity compared to placebo, increasing peak oxygen uptake (pVO<sub>2</sub>) 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).<sup>1</sup> 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.

Statistically significant (p<0.0001) and clinically meaningful improvements were also observed in all 10 prespecified secondary endpoints, including Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS) at weeks 12 and 24, the proportion of patients with ≥1 class improvement in New York Heart Association (NYHA) functional class at weeks 12 and 24, change in provoked left ventricular outflow tract gradient (LVOT-G) and proportion <30 mmHg at weeks 12 and 24, as well as exercise workload and guideline-eligibility for septal reduction therapy.

“Obstructive HCM can have life-altering effects on all aspects of patients’ lives and having more treatments options allows for more personalized choices based on their symptoms and lifestyle,” said Emil Tsenov, Founding and Managing Director, HCM Patient Foundation. “The availability of MYQORZO in Germany brings hope for patients around the European Union and reflects meaningful progress for the HCM community.”

### **About MYQORZO<sup>®</sup> (*aficamten*)**

MYQORZO<sup>®</sup> (*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 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.<sup>1</sup>

*Aficamten* was studied in ACACIA-HCM, a completed Phase 3 clinical 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.

Please see full [Summary of Product Characteristics](#) approved in the European Union.

Please see full [Prescribing Information](#) approved in the U.S., including Boxed WARNING and [Medication Guide](#).

### **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 350 individuals worldwide.<sup>2</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>4</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>5</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<sup>®</sup> (*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). Following positive topline results in ACACIA-HCM, a Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM, the company is preparing to present the full results at an upcoming medical meeting and discuss them with the U.S. FDA and other regulatory authorities. 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, express or implied, related to Cytokinetics' research and development activities; clinical trial initiation, design, enrollment, conduct, progress, continuation, completion, timing and results; regulatory submissions, review processes, approval timing and outcomes, including with respect to supplemental applications and approvals in jurisdictions outside the United States; the scope, expansion, modification, durability or continuation of labeling and promotional claims; commercial readiness, launch timing, market access and reimbursement; anticipated patient, prescriber and payer adoption; expectations regarding market opportunity, growth and market share; pipeline development and expansion into additional indications or geographies; access to and use of capital; and Cytokinetics' business strategy, objectives and future plans. Such statements are based on management's current expectations and assumptions; however, actual results may differ materially due to various risks and uncertainties, including, but not limited to, uncertainties inherent in drug development and commercialization; the timing, conduct and outcomes of clinical trials; regulatory review and approval processes in the United States and other jurisdictions; differences in regulatory requirements, labeling, market access or promotional restrictions across jurisdictions; the ability to obtain, expand, maintain or continue desired labeling, promotional claims or

commercial positioning for approved products; potential legal, intellectual property or regulatory constraints affecting commercialization and marketing claims; patient and prescriber acceptance of MYQORZO as compared to alternative therapies; the availability and terms of reimbursement from commercial and government payers; manufacturing, supply and distribution risks; competition; and the availability of sufficient capital to execute Cytokinetics' business plans. These forward-looking statements speak only as of the date they are made, and Cytokinetics undertakes no obligation to subsequently update any such statement, except as required by law. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission (the "SEC").

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MYQORZO<sup>®</sup> is a registered trademark of Cytokinetics in the U.S. and the European Union.

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