

NEWS RELEASE

Cytokinetics Announces Health Canada Approval of MYQORZO® (aficamten) for the Treatment of Adults with Symptomatic Obstructive Hypertrophic Cardiomyopathy

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SOUTH SAN FRANCISCO, Calif., Oct. 19, 2026 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that Health Canada has issued a Notice of Compliance authorizing MYQORZO® (*aficamten*) for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) of New York Heart Association (NYHA) class II-III in adult patients. 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.

"This company milestone marks the fifth regulatory approval for MYQORZO in less than a year and lays the foundation for its future availability for patients in Canada," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Executive Vice President of Research & Development. "Cytokinetics is committed to the global HCM community, and we look forward to expanding access to MYQORZO to patients living with oHCM."

The authorization in Canada, follows the approval of MYQORZO 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. Earlier in 2026, the European Commission (EC) approved MYQORZO, and the Medicines and Healthcare products Regulatory Agency (MHRA) authorized its use across the United Kingdom.

"Many patients with obstructive HCM have spent years living with breathlessness, fatigue and functional limitations in their everyday lives, with limited options for non-invasive therapy," said Rafik Tadros, M.D., Ph.D., Director of the Cardiovascular Genetics Centre at the Montreal Heart Institute. "With improvements in exercise capacity and symptoms observed in SEQUOIA-HCM and a well-tolerated profile, this approval is a major step forward, and I look forward to having it as an option for our patients in Canada."

The approval by Health Canada is supported by positive results from the pivotal Phase 3 clinical trial,

SEQUOIA-HCM, published in the [New England Journal of Medicine](#), which demonstrated statistically significant and clinically meaningful benefits across symptoms, exercise capacity, hemodynamics, and biomarker endpoints.¹

The results from SEQUOIA-HCM showed that treatment with *aficamten* for 24 weeks significantly improved exercise capacity compared to placebo, increasing peak oxygen uptake (pVO₂) 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.

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.

The Product Monograph 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 of LVEF and Valsalva left ventricular outflow tract gradient (LVOT-G) 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 ≥40% and <50%. Interrupt the dose of MYQORZO if LVEF <40% or if the patient experiences worsening heart failure due to systolic dysfunction.

For more information about MYQORZO, see the full [Product Monograph](#).

About MYQORZO® (*aficamten*)

MYQORZO® (*aficamten*) is a cardiac myosin inhibitor approved in the U.S., China and European Union, United Kingdom and Canada 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.¹

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.

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 one out of 350 individuals worldwide.²

Approximately half of patients with HCM have obstructive HCM (oHCM) and half have non-obstructive HCM (nHCM).³

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' MYQORZO® (*aficamten*) is a cardiac myosin inhibitor approved in the U.S., China, European Union, United Kingdom and Canada 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 (nHCM), the company plans to submit a Supplemental New Drug Application in Q4 2026. 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 obtain regulatory approval for *aficamten* in nonobstructive hypertrophic cardiomyopathy in any jurisdiction by any particular date, if ever, the number of patients comprising the eligible treatment population for *aficamten*, or market acceptance of *aficamten* for the treatment of nonobstructive hypertrophic cardiomyopathy. 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 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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