

NEWS RELEASE

Cytokinetics Announces MHRA Marketing Authorisation for MYQORZO®▼ (aficamten) and Positive Guidance from NICE for Symptomatic Obstructive Hypertrophic Cardiomyopathy in England and Wales

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Authorisation from MRHA and Recommendation from NICE

This announcement is intended for business and financial media and investors only

SOUTH SAN FRANCISCO, Calif., July 30, 2026 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) has granted MYQORZO® (*aficamten*) a marketing authorisation across the United Kingdom for the treatment of symptomatic (New York Heart Association, NYHA class II-III) obstructive hypertrophic cardiomyopathy (oHCM) in eligible adult patients. At the same time the National Institute for Health and Care Excellence (NICE) has issued guidance recommending *aficamten* for use in eligible adult patients in England and Wales.

The guidance from NICE states that *aficamten* can be used as an option to treat symptomatic oHCM in eligible adults with a NYHA class of II to III. It can only be used as an add-on to individually optimised standard care including beta-blockers, non-dihydropyridine calcium-channel blockers or disopyramide, or alone if these treatments are contraindicated, and if the company provides it according to the commercial arrangement.

"We are pleased to have secured a marketing authorisation for *aficamten* and to see positive guidance from NICE for eligible adult patients in England and Wales," said Joseph Dagher, Senior Vice President and Head of Europe, Cytokinetics. "We are grateful for the collaborations that made this review possible for concurrent MHRA and NICE decisions and are committed to supporting access for eligible adult patients through the NHS upon availability expected later this year."

The MHRA assessment of *aficamten* drew on data from SEQUOIA-HCM, a phase 3 multicentre double-blind placebo-controlled randomised study in 282 adults (142 *aficamten*, 140 placebo) treated for 24

weeks.¹ The primary endpoint was the change from baseline to Week 24 in peak oxygen uptake (pVO₂) measured by cardiopulmonary exercise testing. *Aficamten* resulted in a statistically significant improvement in peak oxygen uptake compared with placebo (mean change 1.8 mL/kg/min with *aficamten* versus 0.0 mL/kg/min with placebo; least squares mean difference 1.7 mL/kg/min, 95% confidence interval 1.0 to 2.4; $p < 0.001$).¹ Further information, including efficacy and safety data, is provided in the *aficamten* Summary of Product Characteristics.²

The most commonly reported adverse reactions with *aficamten* were hypertension (7.7%), palpitations (7.0%), dizziness (4.2%) and systolic dysfunction (3.5%).²

▼ MYQORZO (*aficamten*) is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at yellowcard.mhra.gov.uk or by searching for MHRA Yellow Card in the Google Play or Apple App Store.

About *Aficamten*

Aficamten is a cardiac myosin inhibitor authorised in the United Kingdom for the treatment of symptomatic (NYHA class II-III) oHCM in eligible adult patients. In patients with oHCM, myosin inhibition with *aficamten* reduces cardiac contractility and, consequently, left ventricular outflow tract (LVOT) obstruction. *Aficamten* has a predictable exposure-response relationship and a reversible mechanism of action.¹

About Obstructive Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a disease in which the heart muscle becomes abnormally thick. In oHCM, thickened heart muscle blocks blood flow, and the inside of the left ventricle becomes smaller, stiffer and less able to relax and fill with blood. This 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 European Society of Cardiology guidelines.³ Approximately half of patients with HCM have oHCM.⁴

People with oHCM are at high risk of also developing cardiovascular complications including atrial fibrillation, stroke and mitral valve disease.⁵ People with oHCM are at risk of potentially fatal ventricular arrhythmias, which is one of the leading causes of sudden cardiac death in younger people or athletes.⁶ A subset of patients with oHCM 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 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 the enrollment, expected results or timing of completion of any of our clinical trials, the clinical meaningfulness, persuasiveness or interpretation of clinical trial results, including for purposes of regulatory approval, labeling, or market acceptance, the results of long-term, secondary or exploratory analyses, including analyses of time to first cardiovascular event, statements relating to our ability to obtain regulatory approval for *aficamten* in nonobstructive hypertrophic cardiomyopathy in 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 including the risk factors included in Cytokinetics' most recent Annual Report on Form 10-K and subsequent reports filed with the SEC.

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MYQORZO® is a registered trademark of Cytokinetics in the U.S., the European Union and the United Kingdom.

References

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