

## NEWS RELEASE

# Cytokinetics Announces NMPA Approval of MYQORZO® (aficamten) in China for Patients with Obstructive Hypertrophic Cardiomyopathy

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*Approval Triggers Milestone Payment of \$7.5 Million from Sanofi;  
Cytokinetics Eligible to Receive Additional Milestone Payments and Royalties on Net Sales in Greater China*

SOUTH SAN FRANCISCO, Calif., Dec. 17, 2025 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that MYQORZO® (*aficamten*) has been approved by the China National Medical Products Administration (NMPA) for the treatment of adults with New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (oHCM), to improve exercise capacity and symptoms.

Under the terms of its license and collaboration agreement with Cytokinetics, Sanofi has exclusive rights to develop and commercialize MYQORZO for the treatment of patients with obstructive and non-obstructive hypertrophic cardiomyopathy (HCM) in Greater China. The approval of MYQORZO in oHCM in China triggers a \$7.5 million milestone payment from Sanofi to Cytokinetics. Cytokinetics remains eligible to receive up to \$142.5 million in development and commercial milestone payments from Sanofi as well as royalties in the low-to-high teens on future sales of MYQORZO in Greater China.

MYQORZO is only approved for use in China. *Aficamten* is currently under regulatory review in the U.S, where the FDA is reviewing a New Drug Application (NDA) for *aficamten* with a Prescription Drug User Fee Act (PDUFA) target action date of December 26, 2025. On December 12, 2025 the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending marketing authorization in the European Union (EU) for *aficamten*, and a final decision is anticipated from the European Commission in the first quarter of 2026.

## 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.<sup>1</sup> 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 is assessing its potential as a treatment that improves exercise capacity as measured by peak oxygen uptake (pVO<sub>2</sub>) and relieves symptoms in patients with HCM. MYQORZO was evaluated in SEQUOIA-HCM, a positive pivotal Phase 3 clinical trial in patients symptomatic obstructive hypertrophic cardiomyopathy (HCM). MYQORZO received Breakthrough Therapy Designation for the treatment of symptomatic HCM from the U.S. Food & Drug Administration (FDA) and for the treatment of symptomatic obstructive HCM from the National Medical Products Administration (NMPA) in China.

*Aficamten* is also currently under clinical investigation in ACACIA-HCM, a Phase 3 trial in patients with non-obstructive HCM 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 (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. HCM is the most common monogenic inherited cardiovascular disorder, with approximately 280,000 patients diagnosed, however, there are an estimated 400,000-800,000 additional patients who remain undiagnosed in the U.S.<sup>2,3,4</sup> 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.<sup>5</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>6</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 innovation in muscle biology, and advancing a pipeline of potential new medicines for patients suffering from diseases of cardiac muscle dysfunction with intention to create a muscle biology franchise business focused on medicines designed to optimize muscle performance for patients with cardiac and other diseases of muscle dysfunction. MYQORZO® (*aficamten*), the company's cardiac myosin inhibitor, is approved for the treatment of patients with obstructive hypertrophic cardiomyopathy (HCM) in China, and under regulatory review in the U.S. The Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion recommending marketing authorization in the European Union for *aficamten*, and a final decision is anticipated from the European Commission in the first quarter of 2026. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac myosin activator, in patients with heart failure with severely reduced ejection fraction, *ulacamten*, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten*, for the potential treatment of heart failure with preserved ejection fraction 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](http://www.cytokinetics.com) and follow us on [X](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

### About the Sanofi and Cytokinetics Collaboration

In 2024, Sanofi acquired exclusive rights to develop and commercialize MYQORZO® (*aficamten*) from Corxel Pharmaceuticals (CORXEL) for the treatment of patients with obstructive and non-obstructive hypertrophic cardiomyopathy (HCM) in Greater China. Previously, CORXEL acquired the rights to develop and commercialize MYQORZO in Greater China from Cytokinetics in accordance with Cytokinetics' global registration programs.

### Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Cytokinetics claims the protection of the Act's Safe Harbor for forward-looking statements. Examples of such statements include, but not limited to, statements, express or implied, relating to our or our partners' research and development and commercial readiness activities, our receipt of regulatory approval by FDA or any other regulatory authority to enable our commercialization of *aficamten* in the United States or any other jurisdiction by any date, if ever, or our earning or receiving any milestone payments or specific quantum of royalties from commercialization of MYQORZO in Greater China. 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 commercialization activities of Sanofi, the actions of regulatory activities, and the results of our ongoing clinical trials. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission, particularly under the caption "Risk Factors" in Cytokinetics' Quarterly Report on Form 10-Q for the quarter ended September 30, 2025. 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 information, future events or otherwise, after the date of this press release.

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MYQORZO® is a registered trademark of Cytokinetics in China.

### References:

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