



Cytokinetics Announces 2025 Corporate Milestones and Vision 2030

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*PDUFA Target Action Date for Aficamten Set for September 26, 2025;
Commercial Launch Preparations Underway for First Potential Approval*

*Five-Year Aspirations Outline Corporate Strategies
to Becoming Leading Muscle Biology Specialty Biopharma Company*

SOUTH SAN FRANCISCO, Calif., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq: CYTK) today provided guidance for corporate milestones expected to occur in 2025 and outlined its aspirational Vision 2030, five-year strategic objectives designed to propel Cytokinetics to becoming the leading muscle-focused specialty biopharmaceutical company intent on meaningfully improving the lives of patients through global access to innovative medicines.

"In 2025 we are poised for a defining year with principal focus to the potential approval and commercial launch of *aficamten* for obstructive HCM in the United States. At the same time, we are executing on a robust clinical trials development program for *aficamten* inclusive of MAPLE-HCM, with results expected in the first half of this year as may potentially support the use of *aficamten* as monotherapy," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In addition, we are advancing our later-stage development programs for *omecamtiv mecarbil* and CK-586 in adjacent specialty cardiology indications with intention to further augment our pipeline over time. Cytokinetics is well positioned to prudently and meaningfully deliver increased shareholder value as we continue to execute well on key milestones and position the company to achieve longer-term aspirations defining of our Vision 2030."

Expected 2025 Milestones

Cardiac Muscle Programs

Aficamten (cardiac myosin inhibitor)

- Advance go-to-market strategies and prepare to commercially launch *aficamten* in the U.S. in 2H 2025, subject to approval by the U.S. Food & Drug Administration (FDA).
- Continue go-to-market plans in Germany and expand commercial readiness activities in Europe in 2025, in preparation for potential approval by the European Medicines Agency (EMA) in 1H 2026.
- Coordinate with Sanofi to support the potential approval of *aficamten* in China in 2H 2025, pending approval by the National Medical Products Administration (NMPA).
- Report topline results from MAPLE-HCM (**M**etoprolol vs **A**ficamten in **P**atients with **L**VOT Obstruction on **E**xercise Capacity in **H**CM), the Phase 3 clinical trial comparing *aficamten* as monotherapy to *metoprolol* as monotherapy in patients with symptomatic obstructive HCM, in 1H 2025.
- Complete patient enrollment of ACACIA-HCM (**A**ssessment **C**omparing **A**ficamten to **P**lacebo on **C**ardiac Endpoints In **A**dults with **N**on-Obstructive **H**CM), the pivotal Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM, in 2H 2025.
- Complete enrollment of the adolescent cohort in CEDAR-HCM (**C**linical **E**valuation of **D**osing with **A**ficamten to **R**educe Obstruction in a **P**ediatric Population in **H**CM), a clinical trial of *aficamten* in a pediatric population with symptomatic obstructive HCM, in 2H 2025.

Omecamtiv mecarbil (cardiac myosin activator)

- Continue patient enrollment in COMET-HF (**C**onfirmation of **O**mecamtiv **M**ecarbil **E**fficacy Trial in **H**eat **F**ailure), a confirmatory Phase 3 clinical of *omecamtiv mecarbil* in patients with symptomatic heart failure with severely reduced ejection fraction (HFrEF) through 2025 to enable completion of enrollment in 2026.

CK-586 (cardiac myosin inhibitor)

- Complete enrollment of the first two patient cohorts in AMBER-HFpEF, (**A**ssessment of CK-586 in a **M**ulti-Center, **B**linded **E**valuation of **S**afety and **T**olerability **R**esults in **H**FpEF), a Phase 2 clinical trial of CK-586 in patients with symptomatic heart failure with preserved ejection fraction (HFpEF) in 2H 2025.

Skeletal Muscle Program

CK-089 (fast skeletal muscle troponin activator)

- Complete the Phase 1 study of CK-089 in healthy human participants in 2025.

Ongoing Research

- Continue ongoing pre-clinical development and research activities directed to additional muscle biology focused programs.

Vision 2030

The Company also outlined its Vision 2030: “Empowering Muscle, Empowering Lives” with the following objectives:

- **Innovation:** Advance two approved products across three indications and ten novel molecular entities (NMEs) in our pipeline.
- **Ignition:** Achieve broad access and rapid use of our medicines in >15 countries throughout North America and Europe.
- **Impact:** Reach >100,000 patients globally with our medicines.
- **Inspiration:** Foster a patient-centric culture with emphasis on equitable access.
- **Ingenuity:** Extend our leadership in muscle biology deploying multiple therapeutic modalities.

“Our Vision 2030 provides the aspirational roadmap, aligned with our corporate five-year strategic plan, that will propel us forward as a fully integrated and leading specialty biopharma company intent on delivering innovative medicines to patients around the world,” said Mr. Blum. “Vision 2030 articulates ambitious company goals to deliver product approvals, achieve broad access to our medicines, promote equitable access and advance our pioneering research to benefit patients, shareholders and employees.”

About Cytokinetics

Cytokinetics is a late-stage, muscle biology specialty biopharmaceutical company focused on discovering, developing and commercializing muscle biology-directed drug candidates as potential treatments for debilitating diseases in which muscle performance is compromised. As a leader in muscle biology and the mechanics of muscle performance, Cytokinetics is intent on meaningfully improving the lives of patients through global access to innovative medicines. Cytokinetics is readying for potential regulatory approvals and commercialization of *aficamten*, a next-in-class cardiac myosin inhibitor following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial in patients with obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in additional clinical trials enrolling patients with obstructive and non-obstructive HCM. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac myosin activator, in patients with heart failure with severely reduced ejection fraction (HFpEF), CK-586, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten*, for the potential treatment of heart failure with preserved ejection fraction (HFpEF) 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 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 relating to the properties or potential benefits of *aficamten* or any of our other drug candidates, our ability to obtain regulatory approval for *aficamten* for the treatment of obstructive hypertrophic cardiomyopathy or any other indication from FDA or any other regulatory body in the United States or abroad on a timely basis, or at all, the labeling or post-marketing conditions that FDA or another regulatory body may require in connection with the approval of *aficamten*, our ability to timely enroll and complete the ACACIA-HCM, AMBER-HFpEF, CEDAR-HCM, COMET-HF or CK-089 clinical trials, our ability to timely report the results of the MAPLE-HCM trial, and our ability to achieve any element of our Vision 2030. 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 risks related to Cytokinetics’ business outlines in Cytokinetics’ filings with the Securities and Exchange Commission. 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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Contact:

Cytokinetics
Diane Weiser
Senior Vice President, Corporate Affairs
(415) 290-7757



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