NEWS RELEASE

Cytokinetics Announces New PDUFA Date for Aficamten in Obstructive Hypertrophic Cardiomyopathy

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SOUTH SAN FRANCISCO, Calif., May 01, 2025 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) action date for the New Drug Application (NDA) for *aficamten* for the treatment of patients with obstructive hypertrophic cardiomyopathy (oHCM) to December 26, 2025. The FDA recently notified Cytokinetics that additional time is required to conduct a full review of the company's proposed Risk Evaluation and Mitigation Strategy (REMS).

Following pre-NDA discussions with FDA in which safety and risk mitigation were discussed, Cytokinetics submitted the NDA for *aficamten* in oHCM without an accompanying REMS, and the FDA accepted the NDA for filing. Recently, during the NDA review, the FDA requested that Cytokinetics submit a REMS, based on the inherent characteristics of *aficamten*, which the company provided. The submission of a REMS has now been determined by FDA to be a Major Amendment to the NDA resulting in a standard three-month extension to the original PDUFA action date. No additional clinical data or studies have been requested of Cytokinetics by FDA.

"We remain confident in the distinct benefit-risk and pharmaceutic profile of *aficamten* and continue to expect a differentiated label and risk mitigation profile upon its potential approval by FDA," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We look forward to continuing our constructive engagement with the FDA regarding the NDA for *aficamten*."

About Cytokinetics

Cytokinetics is a specialty cardiovascular biopharmaceutical company, building on its over 25 years of pioneering scientific innovations in muscle biology to advance a pipeline of potential new medicines for patients suffering from diseases of cardiac muscle dysfunction. Cytokinetics is readying for potential regulatory approvals and commercialization of *aficamten,* a 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 (HFrEF), 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 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 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 the target PDUFA date or any other date, if ever, and statements regarding our expectation that *aficamten* will be approved with a differentiated label and REMS. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including FDA's on-going review of our NDA for *aficamten* in obstructive hypertrophic cardiomyopathy. 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' Annual Report on Form 10-K for the year ended December 31, 2024. 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.

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

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