Cytokinetics Announces FDA Acceptance of New Drug Application for Omecamtiv Mecarbil for the Treatment of Heart Failure With Reduced Ejection Fraction

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PDUFA Target Action Date Set for November 30, 2022

FDA is Currently Not Planning to Hold an Advisory Committee Meeting to Discuss the Application

SOUTH SAN FRANCISCO, Calif., Feb. 04, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that the U.S. Food & Drug Administration (FDA) has accepted and filed the company's New Drug Application (NDA) for *omecamtiv mecarbil*, an investigational, selective, small molecule cardiac myosin activator, for the treatment of heart failure with reduced ejection fraction (HFrEF).

The FDA assigned the NDA a standard review with a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2022. The FDA also indicated that it is currently not planning to hold an advisory committee meeting to discuss the application.

"This is an exciting milestone and important next step towards the commercial launch of *omecamtiv mecarbil*," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "More than two million people in the U.S. with HFrEF have signs and symptoms of worsening heart failure despite standard of care therapy, pointing to a clear unmet medical need for more treatment options. We look forward to engaging with the FDA to bring this potential new medicine to patients later this year."

The NDA is supported by the results from GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure), the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil* that enrolled over 8,000 patients in 35 countries across 945 sites. GALACTIC-HF demonstrated a statistically significant effect of treatment with *omecamtiv mecarbil* to reduce risk of the primary composite endpoint of cardiovascular (CV) death or heart failure events (heart failure hospitalization and other urgent treatment for heart failure) compared to placebo in patients treated with standard of care. Additional analyses from GALACTIC-HF demonstrated a greater treatment effect of *omecamtiv mecarbil* in patients with lower left ventricular ejection fraction (LVEF), as well as other characteristics that may indicate worsening heart failure.

About *Omecamtiv Mecarbil*

Omecamtiv mecarbil is an investigational, selective, small molecule cardiac myosin activator, the first of a novel class of myotropes[1] designed to directly target the contractile mechanisms of the heart, binding to and recruiting more cardiac myosin heads to interact with actin during systole. *Omecamtiv mecarbil* is designed to increase the number of active actin-myosin cross bridges during each cardiac cycle and consequently augment the impaired contractility that is associated with heart failure with reduced ejection fraction (HFrEF). Preclinical research has shown that *omecamtiv mecarbil* increases cardiac contractility without increasing intracellular myocyte calcium concentrations or myocardial oxygen consumption.[2-4]

The development program for *omecamtiv mecarbil* is assessing its potential for the treatment of HFrEF. Positive results from GALACTIC-HF, the first Phase 3 clinical trial of *omecamtiv mecarbil* demonstrated a statistically significant effect of treatment with *omecamtiv mecarbil* to reduce risk of the primary composite endpoint of cardiovascular (CV) death or heart failure events (heart failure hospitalization and other urgent treatment for heart failure) compared to placebo in patients treated with standard of care. No reduction in the secondary endpoint of time to CV death was observed. Adverse events and treatment discontinuation of study drug were balanced between treatment arms. METEORIC-HF, a second Phase 3 clinical trial of *omecamtiv mecarbil* is designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity. Results from METEORIC-HF are expected in early 2022.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and next-in-class muscle inhibitors as potential treatments for debilitating diseases in which muscle performance is compromised. As a leader in muscle biology and the mechanics of muscle performance, the company is developing small molecule drug candidates specifically engineered to impact muscle function and contractility. Cytokinetics is readying for the potential commercialization of *omecamtiv mecarbil*, its novel cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is conducting METEORIC-HF, a second Phase 3 clinical trial of *omecamtiv mecarbil*. Cytokinetics is also developing *aficamten*, a next-generation cardiac myosin inhibitor, for the potential treatment of hypertrophic cardiomyopathies (HCM). The company has announced positive results from Cohorts 1, 2 and 3 in REDWOOD-HCM, a Phase 2 clinical trial of *aficamten* in patients with symptomatic obstructive HCM. Cytokinetics is conducting start-up activities for SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with obstructive HCM. Cytokinetics is also developing *reldesemtiv*, an investigational fast skeletal muscle troponin activator, currently the subject of COURAGE-ALS, a Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (ALS). Cytokinetics continues its over 20-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on Twitter, LinkedIn, Facebook and YouTube.

Cytokinetics 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 likelihood of FDA's potential approval of the Company's NDA for *omecamtiv mecarbil* by the target action date of November 30, 2022 or at any other time, statements regarding the potential number of patients that may benefit from treatment with *omecamtiv mecarbil* should the Company's NDA be approved by FDA or any other regulatory authority, and statements regarding any potential future request by FDA to hold an advisory committee meeting to discuss the Company's NDA. Such statements are based on management's current expectations. 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' latest Quarterly Report on Form 10-Q.

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Source: Cytokinetics, Incorporated