



## Cytokinetics Announces Topline Results From METEORIC-HF

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*No Effect of Omecamtiv Mecarbil On Exercise Capacity in Patients with Heart Failure with Reduced Ejection Fraction*

*Results Will Be Presented in Late Breaking Clinical Trial Session  
at the American College of Cardiology 71<sup>st</sup> Annual Scientific Session & Expo*

*NDA for Omecamtiv Mecarbil Recently Accepted  
for Review by FDA Based on Results of GALACTIC-HF*

SOUTH SAN FRANCISCO, Calif., Feb. 15, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced topline results from METEORIC-HF (Multicenter Exercise Tolerance Evaluation of *Omecamtiv Mecarbil* Related to Increased Contractility in Heart Failure), a Phase 3 clinical trial of *omecamtiv mecarbil* in patients with heart failure with reduced ejection fraction (HFrEF). *Omecamtiv mecarbil* is an investigational, selective, small molecule cardiac myosin activator for the treatment of heart failure with reduced ejection fraction.

METEORIC-HF evaluated the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity as determined by cardiopulmonary exercise testing (CPET) following 20 weeks of treatment in patients with HFrEF receiving standard of care therapy. The trial completed enrollment of 276 patients in June 2021. There was no effect on the primary endpoint, which was the change in peak oxygen uptake (pVO<sub>2</sub>) on CPET from baseline to Week 20 in patients treated with *omecamtiv mecarbil* compared to placebo. Adverse events, including major cardiac events, were similar between the treatment arms and the safety profile of *omecamtiv mecarbil* in METEORIC-HF was consistent with prior clinical trials including GALACTIC-HF. Results from METEORIC-HF will be presented at the American College of Cardiology (ACC) 71<sup>st</sup> Annual Scientific Session & Expo, in a Late Breaking Clinical Trial session on Sunday, April 3, 2022 from 9:45-9:55 a.m. ET.

"While medical therapies have demonstrated significant reductions in the risk of adverse clinical outcomes in heart failure patients with reduced ejection fraction, as was also observed with *omecamtiv mecarbil* in GALACTIC-HF, demonstrating an improvement in exercise capacity with these same medical therapies has been elusive," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Executive Vice President of Research & Development. "These neutral results from METEORIC-HF may provide new insights into the role of cardiac function in determining exercise capacity relative to other potential contributors such as skeletal muscle dysfunction. We are grateful to the trial investigators, site personnel, patients and caregivers who participated in the METEORIC-HF, especially given challenges posed by the pandemic."

Cytokinetics recently announced that the U.S. Food & Drug Administration (FDA) has accepted and filed the company's New Drug Application (NDA) for *omecamtiv mecarbil*. The NDA is supported by the results from GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure), 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<sup>1</sup> 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.<sup>2-4</sup>

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. The FDA has accepted for filing the NDA for *omecamtiv mecarbil* based on the results from GALACTIC-HF and has assigned a Prescription Drug User Fee Act (PDUFA) date of November 30, 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 cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. 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](http://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 and 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. 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