



Cytokinetics Provides Regulatory Update Related to New Drug Application for Omecamtiv Mecarbil

May 17, 2022 11:30 AM EDT

FDA Plans to Convene Advisory Committee Meeting

SOUTH SAN FRANCISCO, Calif., May 17, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced the Company recently participated in a mid-cycle communication meeting with the U.S. Food & Drug Administration (FDA) and was informed that the Agency plans to convene an Advisory Committee meeting for the New Drug Application (NDA) for *omecamtiv mecarbil*. Cytokinetics expects the FDA to inform it of the date and topics for the Advisory Committee Meeting in a subsequent communication. A late-cycle communication meeting has been proposed to occur later this year. *Omecamtiv mecarbil* is an investigational, selective, small molecule cardiac myosin activator for the treatment of heart failure with reduced ejection fraction (HFrEF). The FDA has assigned the NDA a standard review with a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2022.

About Omecamtiv Mecarbil

Omecamtiv mecarbil is an investigational, selective, small molecule cardiac myosin activator, the first of a novel class of myotropes¹ 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.

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, currently the subject of SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in non-obstructive HCM in Cohort 4 of the Phase 2 clinical trial, REDWOOD-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 or statements regarding the timing and scope of topics to be addressed or reviewed by any Advisory Committee convened by the FDA. 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