

# Cytokinetics to Announce Baseline Characteristics from GALACTIC-HF During ACC.20/WCC

# March 20, 2020 8:00 PM EDT

SOUTH SAN FRANCISCO, Calif., March 20, 2020 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) today announced that patient baseline characteristics and demographics from GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure), the Phase 3 event driven cardiovascular outcomes clinical trial of *omecamtiv mecarbil*, will be published on March 28, 2020 during the American College of Cardiology 69<sup>th</sup> Annual Scientific Session together with the World Congress of Cardiology (ACC.20/WCC Virtual). The poster will be available online at <a href="https://accscientificsession.acc.org/">https://accscientificsession.acc.org/</a> on March 28, 2020 at 8:00 AM Central Time.

Poster Title: Baseline Characteristics from the Cardiovascular Outcomes Trial of *Omecamtiv Mecarbil*, GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure)

Poster Presenter: John Teerlink, M.D., Professor of Medicine, University of California San Francisco, Director of Heart Failure, San Francisco Veterans Affairs Medical Center and Executive Committee Chair, COSMIC-HF and GALACTIC-HF Date: March 28, 2020 Session Title: Heart Failure and Cardiomyopathies: Therapy 2 Session Number: 1157 Time: 8:00 AM Central Time

Poster Number: 074

#### About Omecamtiv Mecarbil and the Phase 3 Clinical Trials Program

*Omecamtiv mecarbil* is a novel investigational selective cardiac myosin activator that binds to the catalytic domain of myosin. Preclinical research has shown that cardiac myosin activators increase cardiac contractility without affecting intracellular myocyte calcium concentrations or myocardial oxygen consumption.<sup>1-3</sup> Cardiac myosin is the cytoskeletal motor protein in the cardiac muscle cell that is directly responsible for converting chemical energy into the mechanical force resulting in cardiac contraction.

*Omecamtiv mecarbil* is being developed for the potential treatment of heart failure with reduced ejection fraction (HFrEF) under a collaboration between Amgen and Cytokinetics, with funding and strategic support from Servier. *Omecamtiv mecarbil* is the subject of a comprehensive Phase 3 clinical trials program comprised of GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure), a large, Phase 3 global, event-driven, cardiovascular outcomes study, and METEORIC-HF (Multicenter Exercise Tolerance Evaluation of *Omecamtiv Mecarbil* Related to Increased Contractility in Heart Failure), a Phase 3 clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity.

## About Cytokinetics and Amgen Collaboration

In 2006, Cytokinetics and Amgen entered into a strategic alliance to discover, develop and commercialize novel small molecule therapeutics designed to activate the cardiac sarcomere for the potential treatment of heart failure. *Omecamtiv mecarbil* is being developed by Amgen in collaboration with Cytokinetics, with funding and strategic support from Servier. Amgen holds an exclusive, worldwide license to *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization rights. Cytokinetics is eligible for pre-commercialization and commercialization milestone payments and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. Cytokinetics has co-invested with Amgen in the Phase 3 development program of *omecamtiv mecarbil* in exchange for increased royalties from Amgen on worldwide sales of *omecamtiv mecarbil* outside Japan and co-promotion rights in institutional care settings in North America. Amgen has also entered an alliance with Servier for exclusive commercialization rights for *omecamtiv mecarbil* in Europe as well as the Commonwealth of Independent States, including Russia.

## 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 and/or declining. 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 collaborating with Amgen Inc. (Amgen) to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of an international clinical trials program in patients with heart failure including GALACTIC-HF and METEORIC-HF. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to develop *reldesemtiv*, a fast skeletal muscle torponin activator (FSTA). Astellas currently holds an exclusive worldwide license to development and co-commercialization rights of Cytokinetics. Cytokinetics is also developing CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations, for the potential treatment of hypertrophic cardiomyopathies (HCM). Cytokinetics is conducting REDWOOD-HCM, a Phase 2 trial of CK-274 in patients with obstructive HCM. 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 <u>www.cytokinetics.com</u> and follow us on <u>Twitter</u>, <u>LinkedIn</u>, <u>Facebook</u> and <u>YouTube</u>.

## **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 relating to the GALACTIC-HF clinical trial, including the planned timing of a second interim analysis for superiority; the potential benefits of *omecamtiv mecarbil*, including its ability to represent a novel therapeutic strategy to increase cardiac muscle function and restore cardiac performance; Cytokinetics' and its partners' research and development activities; the design, timing, results, significance and utility of preclinical and clinical results; and the properties and potential benefits of Cytokinetics' drug uncertainties, including, but not limited to, potential difficulties or delays in the development, testing, regulatory approvals for trial commencement,

progression or product sale or manufacturing, or production of Cytokinetics' drug candidates that could slow or prevent clinical development or product approval; Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; standards of care may change, rendering Cytokinetics' drug candidates obsolete; competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target; and risks and uncertainties relating to the timing and receipt of payments from its partners, including milestones and royalties on future potential product sales under Cytokinetics' collaboration agreements with such partners. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.

#### Contact:

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#### References

<sup>1</sup> Planelles-Herrero VJ, Hartman JJ, Robert-Paganin J. et al. Mechanistic and structural basis for activation of cardiac myosin force production by omecamtiv mecarbil. *Nat Commun.* 2017;8:190.

<sup>2</sup> Shen YT, Malik FI, Zhao X, et al. Improvement of cardiac function by a cardiac myosin activator in conscious dogs with systolic heart failure. *Circ Heart Fail.* 2010; 3: 522-27.

<sup>3</sup> Malik FI, Hartman JJ, Elias KA, Morgan BP, Rodriguez H, Brejc K, Anderson RL, Sueoka SH, Lee KH, Finer JT, Sakowicz R. Cardiac myosin activation: a potential therapeutic approach for systolic heart failure. *Science*. 2011 Mar 18;331(6023):1439-43.



Source: Cytokinetics, Incorporated