Cytokinetics Regains Rights to Develop and Commercialize Omecamtiv Mecarbil and AMG 594 From Amgen

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Company Committed to Advancing Omecamtiv Mecarbil with Initial Focus on Preparations for Regulatory Interactions Following Positive Results of GALACTIC-HF

Company to Host Conference Call and Webcast Today at 8:30 AM Eastern Time

SOUTH SAN FRANCISCO, Calif., Nov. 23, 2020 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that Amgen has elected to terminate the Collaboration and Option Agreement, dated December 20, 2006 between the companies (the "Agreement") and thereby end its collaboration with Cytokinetics, effective May 20, 2021, and intends to transition development and commercialization rights for *omecamtiv mecarbil* and AMG 594 to Cytokinetics. *Omecamtiv mecarbil* is an investigational cardiac myosin activator, developed for the potential treatment of heart failure with reduced ejection fraction (HFrEF), and was recently studied in GALACTIC-HF, a positive Phase 3 cardiovascular outcomes clinical trial. AMG 594, a novel mechanism cardiac troponin activator, is in Phase 1 development for HFrEF and other types of heart failure.

"We believe this is an important pivot point and opportunity for our company, as we reclaim *omecamtiv mecarbil* following positive Phase 3 clinical trial results," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In one of the largest heart failure clinical trials ever conducted, our novel mechanism drug candidate demonstrated positive efficacy in a diverse patient population with high unmet need and without an imbalance in the overall incidence of adverse events. We look forward to rapidly advancing next steps for *omecamtiv mecarbil,* which we expect will include discussions with regulatory authorities. We believe we are well prepared to press forward given our strong balance sheet and pioneering leadership in the development of muscle-directed therapies."

Terms of Termination

Pursuant to the terms of the Agreement, upon the effective date of Amgen's termination, research, development and commercialization rights for compounds, including *omecamtiv mecarbil* and AMG 594, will transition to Cytokinetics. In addition, Amgen will have certain obligations set forth in the Agreement, including: cooperating with Cytokinetics and its designee(s) to facilitate a reasonably smooth, orderly and prompt transition of the programs, including transfer and assignment to Cytokinetics of specified regulatory filings, data and other information; if requested by Cytokinetics, transferring inventory of compounds to Cytokinetics at Cytokinetics' expense; to the extent possible and requested by Cytokinetics, assigning relevant third-party manufacturing agreements to Cytokinetics; and granting to Cytokinetics exclusive and non-exclusive licenses to certain intellectual property rights. Cytokinetics will have no trailing royalty payment obligations to Amgen for either *omecamtiv mecarbil* or AMG 594. With Cytokinetics' consent, Amgen granted a sublicense to Les Laboratoires Servier and Institut de Recherches Internationales Servier ("Servier") to commercialize *omecamtiv mecarbil* in Europe and the Commonwealth of Independent States, including Russia. Cytokinetics is party to a letter agreement with Amgen and Servier entered into in 2016, which provides that if Amgen's rights to *omecamtiv mecarbil* are terminated, (i) the sublicensed rights previously granted by Amgen to Servier with respect to *omecamtiv mecarbil*, will remain in effect post termination of the Agreement and become a direct license or sublicense of such rights by Cytokinetics to Servier, on substantially the same terms as those in the Option, License and Collaboration Agreement between Amgen and Servier, and (ii) Amgen will, at Cytokinetics' election, transfer to Cytokinetics or its designee (including Servier) certain ongoing development activities.

GALACTIC-HF: Results and Next Steps

Primary 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 event-driven cardiovascular outcomes clinical trial of *omecamtiv mecarbil*, were recently presented at the American Heart Association (AHA) Scientific Sessions 2020, and were simultaneously published in the *New England Journal of Medicine*.[1]

GALACTIC-HF, one of the largest Phase 3 global cardiovascular outcomes trials in heart failure ever conducted, enrolled 8,256 patients who were at risk of hospitalization and death, despite being well treated on standard of care therapy. After a median duration of follow-up of 21.8 months, the trial 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 and no other secondary endpoints were met in accordance with the prespecified statistical analysis. The effect of *omecamtiv mecarbil* was generally consistent across prespecified subgroups and with a potentially greater treatment effect suggested in patients with a lower left ventricular ejection fraction.

Cytokinetics has received positive feedback from key heart failure opinion leaders on the primary results, with particular interest in the potential role of *omecamtiv mecarbil* in the treatment of advanced heart failure patients who remain at risk for hospitalization despite being treated with standard of care regimens. The company will be conducting market research to gain additional feedback from physicians and payors to inform the potential path forward. Cytokinetics expects to seek regulatory feedback regarding a potential registration path for *omecamtiv mecarbil*, subject to cooperation and transitions from Amgen. In parallel, Cytokinetics plans to conduct commercial readiness assessments and to evaluate potential partnering opportunities, including co-promotion options in North America as well as licensing in other territories.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will host a conference call and webcast today, November 23, 2020, at 8:30 AM Eastern Time. The webcast can be accessed through the Investors & Media section of the Cytokinetics website at www.cytokinetics.com. The live audio of the conference call can also be accessed by telephone by dialing either (866) 999-CYTK (2985) (United States and Canada) or (706) 679-3078 (international) and typing in the passcode 2184075.

An archived replay of the webcast will be available via Cytokinetics' website until December 7, 2020. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (international) and typing in the passcode 2184075 from November 23, 2020 at 11:30 AM Eastern Time until December 7, 2020.

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 preparing for regulatory interactions for *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 CK-274, a next- generation cardiac myosin inhibitor, for the potential treatment of hypertrophic cardiomyopathies (HCM). Cytokinetics is conducting REDWOOD-HCM, a Phase 2 clinical trial of CK-274 in patients with obstructive HCM. Cytokinetics is also developing *reldesemtiv*, a fast skeletal muscle troponin activator for the potential treatment of ALS and other neuromuscular indications following conduct of FORTITUDE-ALS and other Phase 2 clinical trials. The company is considering potential advancement of *reldesemtiv* to Phase 3 pending ongoing regulatory interactions. 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.

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; statements relating to the METEORIC-HF clinical trial; Cytokinetics' activities to advance the development of *omecamtiv mecarbil*; the potential benefits of *omecamtiv mecarbil*, including its ability to represent a novel therapeutic strategy to increase cardiac muscle function and restore cardiac performance; the potential approval of *omecamtiv mecarbil* by the FDA or any other regulatory authority; Amgen's fulfillment of its undertakings regarding transition of the *omecamtiv mecarbil* and AMG 594 programs to Cytokinetics; any decision on the part of Servier to maintain or terminate its sublicense in respect of *omecamtiv mecarbil* prior to the effectiveness of the termination of the Amgen-Cytokinetics collaboration; 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' other drug candidates. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and 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; the nature of Amgen's decisions and activities with respect to the transfer of rights to develop and commercialize *omecamtiv mecarbil* and AMG 594 to Cytokinetics; 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.

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References

1. Teerlink J et al. NEJM. 2020

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Source: Cytokinetics, Incorporated