Cytokinetics Announces Sanofi Acquired Rights to Develop and Commercialize Aficamten in Greater China

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SOUTH SAN FRANCISCO, Calif., Dec. 20, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that Sanofi will acquire exclusive rights to develop and commercialize *aficamten* from Corxel Pharmaceuticals (CORXEL) for the treatment of patients with obstructive and non-obstructive hypertrophic cardiomyopathy (HCM) in Greater China. *Aficamten* is a next-in-class cardiac myosin inhibitor for the potential treatment of patients with HCM.

In 2020, CORXEL (formerly Ji Xing) acquired the rights to develop and commercialize *aficamten* in Greater China (including the Chinese mainland, Hong Kong SAR and Macau SAR, and Taiwan) from Cytokinetics in accordance with Cytokinetics' global registration programs. *Aficamten* received Breakthrough Therapy Designation for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) from The Center for Drug Evaluation of the China National Medical Products Administration which recently accepted the New Drug Application for *aficamten* tablets for the treatment of oHCM for Priority Review.

Sanofi will now acquire CORXEL's rights relating to *aficamten* in Greater China for an undisclosed amount. Cytokinetics remains eligible to receive up to $150 million in development and commercial milestone payments from Sanofi as well as royalties in the low-to-high teens on future sales of *aficamten* in Greater China. Cytokinetics is now also eligible to receive additional undisclosed payments in connection with the execution of the agreement between Sanofi and CORXEL.

"We have enjoyed a productive collaboration with CORXEL and appreciate all they have done to advance *aficamten* in Greater China," said Robert I. Blum, Cytokinetics' President and CEO. "We now look forward to partnering with Sanofi with shared objective to leverage their cardiovascular expertise and expand the reach of *aficamten* to patients suffering from HCM throughout Greater China."

About *Aficamten*

Aficamten is an investigational selective, small molecule cardiac myosin inhibitor discovered following an extensive chemical optimization program that was conducted with careful attention to therapeutic index and pharmacokinetic properties and as may translate into next-in-class potential in clinical development. *Aficamten* was designed to reduce the number of active actin-myosin cross bridges during each cardiac cycle and consequently suppress the myocardial hypercontractility that is associated with hypertrophic cardiomyopathy (HCM). In preclinical models, *aficamten* reduced myocardial contractility by binding directly to cardiac myosin at a distinct and selective allosteric binding site, thereby preventing myosin from entering a force producing state.

The development program for *aficamten* is assessing its potential as a treatment that improves exercise capacity and relieves symptoms in patients with HCM as well as its potential long-term effects on cardiac structure and function. *Aficamten* was evaluated in SEQUOIA-HCM (Safety, Efficacy, and Quantitative Understanding of Obstruction Impact of *Aficamten* in HCM), a positive pivotal Phase 3 clinical trial in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* received Breakthrough Therapy Designation for the treatment of symptomatic obstructive HCM from the U.S. Food & Drug Administration (FDA). The FDA recently accepted the company's New Drug Application (NDA) for aficamten, for the treatment of obstructive hypertrophic cardiomyopathy and assigned the NDA a Prescription Drug User Fee Act target action date of September 26, 2025. Cytokinetics also recently submitted a Marketing Authorization Application for *aficamten* to the European Medicines Agency.

Aficamten is also currently being evaluated in MAPLE-HCM, a Phase 3 clinical trial of *aficamten* as monotherapy compared to metoprolol as monotherapy in patients with obstructive HCM, ACACIA-HCM, a Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM, and CEDAR-HCM, a clinical trial of *aficamten* in a pediatric population with obstructive HCM, and FOREST-HCM, an open-label extension clinical study of *aficamten* in patients with HCM.

About Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a disease in which the heart muscle (myocardium) becomes abnormally thick (hypertrophied). The thickening of cardiac muscle leads to the inside of the left ventricle becoming smaller and stiffer, and thus the ventricle becomes less able to relax and fill with blood. This ultimately limits the heart's pumping function, resulting in reduced exercise capacity and symptoms including chest pain, dizziness, shortness of breath, or fainting during physical activity. HCM is the most common monogenic inherited cardiovascular disorder, with approximately 280,000 patients diagnosed, however, there are an estimated 400,000-800,000 additional patients who remain undiagnosed in the U.S.[1,2,3] Two-thirds of patients with HCM have obstructive HCM, in which the thickening of the cardiac muscle leads to left ventricular outflow tract obstruction, while one-third have non-obstructive HCM, in which blood flow isn't impacted, but the heart muscle is still thickened. People with HCM are at high risk of also developing cardiovascular complications including atrial fibrillation, stroke and mitral valve disease.[4] People with HCM are at risk for potentially fatal ventricular arrhythmias and it is one of the leading causes of sudden cardiac death in younger people or athletes.[5] A subset of patients with HCM are at high risk of progressive disease leading to dilated cardiomyopathy and heart failure necessitating cardiac transplantation.

About Cytokinetics

Cytokinetics is a late-stage, specialty cardiovascular biopharmaceutical company focused on discovering, developing and commercializing muscle biology-directed drug candidates as potential treatments for debilitating diseases in which cardiac 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 myocardial muscle function and contractility. Cytokinetics is readying for the potential commercialization of *aficamten,* a next-in-class cardiac myosin inhibitor following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial in patients with obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in additional clinical trials enrolling patients with obstructive and non-obstructive HCM.

Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac myosin activator, in patients with heart failure with severely reduced ejection fraction (HFrEF), CK-586, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten,* for the potential treatment of heart failure with preserved ejection fraction (HFpEF) and CK-089, a fast skeletal muscle troponin activator with potential therapeutic application to a specific type of muscular dystrophy and other conditions of impaired skeletal muscle function.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on X, 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. 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; patient enrollment for or conduct of clinical trials may be difficult or delayed; Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' ability to conduct clinical trials; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; 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. 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.

References

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