Cytokinetics and Bayer Announce Exclusive Licensing Collaboration for Aficamten in Japan

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Approximately €70 Million in Upfront and Near-term Payments to Cytokinetics

Up to €490 Million in Commercial Milestone Payments, with Tiered Royalties on Future Sales

SOUTH SAN FRANCISCO, Calif. and BERLIN, Nov. 19, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) and Bayer today announced they have entered into a collaboration and license agreement for the exclusive development and commercialization of *aficamten* in Japan for the treatment of patients with obstructive and non-obstructive hypertrophic cardiomyopathy (HCM), subject to certain reserved development rights of Cytokinetics. *Aficamten* is a next-in-class cardiac myosin inhibitor for the potential treatment of patients with HCM.

Cytokinetics will receive an upfront payment of €50 million and is eligible to receive up to an additional €90 million upon the achievement of milestones through commercial launch, including €20 million which are near-term. Cytokinetics is also eligible to receive up to €490 million in commercial milestone payments upon the achievement by Bayer of certain sales milestones, and tiered royalties on net sales of *aficamten* in Japan.

This collaboration leverages Cytokinetics' broad development program of *aficamten* and Bayer's regional capabilities and expertise in the development and commercialization of therapies to treat cardiovascular diseases of unmet need for the benefit of patients in Japan.

Under the joint development plan, Bayer will conduct a Phase 3 clinical trial in Japanese patients with obstructive HCM and Cytokinetics will expand ACACIA-HCM, the ongoing Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM, into Japan to support the potential marketing authorization of *aficamten* in Japan and CEDAR-HCM, its ongoing study for a pediatric population of patients with obstructive HCM.

"As we pursue commercialization of *aficamten* in the U.S. and Europe, we are pleased to enter into this partnership with Bayer to leverage their cardiovascular commitment and expertise to potentially bring *aficamten* to an even greater number of patients suffering from HCM," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "This important regional deal follows on our rich history of collaborations to expand potential access to our innovative science."

"We are very excited by the potential of *aficamten* as seen in previous studies and look forward to bringing this treatment option to Japanese patients as soon as possible," said Juergen Eckhardt, M.D., Head of Business Development and Licensing at Bayer's Pharmaceuticals Division. "This collaboration underscores our mission to bring transformative treatments to patients with high unmet cardiovascular needs by leveraging our extensive drug development expertise from early discovery through regulatory approval, life cycle management and commercialization."

For a complete description of the License and Collaboration Agreement detailed in this press release, please refer to our Current Report on Form 8-K filed with the Securities and Exchange Commission on November 19, 2024.

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 (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A****ficamten* 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) as well as the National Medical Products Administration (NMPA) in China. Cytokinetics submitted a New Drug Application (NDA) to the FDA in Q3 2024 and expects to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in Q4 2024.

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, 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 (oHCM), where the thickening of the cardiac muscle leads to left ventricular outflow tract (LVOT) obstruction, while one-third have non-obstructive HCM (nHCM), where 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. Following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial evaluating *aficamten,* a next-in-class cardiac myosin inhibitor, in obstructive hypertrophic cardiomyopathy (HCM), Cytokinetics submitted an NDA for *aficamten* to the U.S. Food & Drug Administration and is progressing regulatory submissions for *aficamten* for the treatment of obstructive HCM in Europe. *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, 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. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac muscle 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 muscle function.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on X, LinkedIn, Facebook and YouTube.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, “Health for all, Hunger for none,” the company’s products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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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 approval of *aficamten* for the treatment of HCM in Japan and Cytokinetics’ receipt of future development milestone payments and royalties in any amount. 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.

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