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News Release

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Bayer strengthens cardiovascular portfolio with Cytokinetics' aficamten in Japan

- Exclusive license agreement with Cytokinetics to develop and commercialize aficamten in Japan
 - Aficamten is designed to reduce hypercontractility associated with hypertrophic cardiomyopathy (HCM), the most common monogenic inherited cardiovascular disorder
 - Aficamten has received Breakthrough Therapy designations in the US and China for treatment of symptomatic obstructive HCM
 - Cytokinetics will receive approximately €70 million in upfront and near-term payments and is eligible to receive up to €490 million in commercial milestone payments with tiered royalties on future sales
 - Highly strategic fit adding to Bayer's commercial footprint in specialty cardiology
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Berlin, Germany, and South San Francisco, Calif., USA, November 19, 2024 – Bayer and Cytokinetics, Incorporated (Nasdaq: CYTK), a late-stage specialty cardiovascular biopharmaceutical company, today announced they have entered into a collaboration and license agreement for the exclusive development and commercialization of aficamten in Japan, subject to certain reserved development rights of Cytokinetics. Aficamten is a cardiac myosin inhibitor for the potential treatment of patients with obstructive and non-obstructive hypertrophic cardiomyopathy (HCM).

This collaboration agreement leverages Cytokinetics' broad development program for aficamten and Bayer's regional capabilities and expertise in the development and commercialization of specialty cardiology diseases of unmet need for the benefit of patients in Japan.

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

Earlier this year, aficamten has received Breakthrough Therapy designations 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.

“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.”

“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.”

Under the terms of the agreement, 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.

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. 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 III 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 plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in Q4 2024.

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. The patients with HCM have obstructive HCM (oHCM), where the thickening of the cardiac muscle leads to left ventricular outflow tract (LVOT) obstruction, while 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.¹ 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.² 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 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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References

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2. Hong Y, Su WW, Li X. Risk factors of sudden cardiac death in hypertrophic cardiomyopathy. Current Opinion in Cardiology. 2022 Jan 1;37(1):15-21