



## Cytokinetics and Royalty Pharma Announce Expanded Strategic Funding Collaboration Totaling Up to \$575 Million to Support Commercial Launch of Aficamten and to Advance R&D Pipeline

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### Deal Provides Cytokinetics with Diversified Access to Capital as Company Advances Its Specialty Cardiology Franchise

SOUTH SAN FRANCISCO, Calif. and NEW YORK, May 22, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) and Royalty Pharma plc (Nasdaq: RPRX) today announced they have entered into a strategic funding collaboration providing capital to support the commercialization of *aficamten* and advance the company's expanding cardiovascular pipeline while diversifying access to capital as the company advances its muscle biology-directed specialty cardiology business.

"We have enjoyed a longstanding relationship with Royalty Pharma and this expanded strategic collaboration reinforces our shared conviction in the value of our cardiac myosin focused pipeline of drug candidates," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "This diversified access to capital from a trusted partner supports our launch of *aficamten* while also fortifying our capital structure and lowering our cost of capital as we become a sustainable company. We believe this deal delivers on stated objectives of advancing our later-stage portfolio of potential medicines alongside our goal of increasing shareholder value."

"We are excited to support Cytokinetics as the company advances towards commercialization of *aficamten*," said Pablo Legorreta, Royalty Pharma's founder and Chief Executive Officer. "This is our third transaction with Cytokinetics and highlights our ability to structure creative, win-win funding solutions and underscores the breadth of our funding capabilities. *Aficamten* has demonstrated an impressive clinical profile in its pivotal Phase 3 study, and we believe it has the potential to significantly improve the lives of patients with HCM, if approved by the FDA."

"Both *omecamtiv mecarbil* and CK-586 represent strategic opportunities to expand our specialty cardiology pipeline in adjacent cardiovascular indications and help underserved patients," said Fady I. Malik, M.D., Ph.D., Cytokinetics' Executive Vice President of Research & Development. "Building on feedback from the FDA and EMA, we have designed a confirmatory Phase 3 clinical trial intended to replicate treatment effects previously observed with *omecamtiv mecarbil* among higher risk patients with heart failure with reduced ejection fraction. In addition, we look forward to advancing CK-586 to Phase 2 to further assess the pharmacology of cardiac myosin inhibition in sicker patients with heart failure with preserved ejection fraction."

The transaction includes funding for planned commercialization, development funding, royalty restructuring and revenue sharing and the purchase of Cytokinetics equity, together, affording Cytokinetics \$250 million on closing and up to a total of \$575 million to support the company's further maturation and corporate development.

The key components of this strategic funding collaboration include:

- 1. Commercial launch funding:** Cytokinetics to receive \$50 million and is eligible to draw an additional \$175 million within 12 months of approval of *aficamten* in oHCM; the capital will be repayable over 10 years in quarterly installments (totaling 1.9x).
- 2. Royalty restructuring:** Royalty Pharma's royalty on *aficamten* was restructured so that Royalty Pharma will now receive 4.5% up to \$5.0 billion of annual net sales of *aficamten* and 1% above \$5.0 billion of annual net sales compared to the prior 4.5% up to \$1.0 billion of annual net sales and 3.5% above \$1.0 billion of annual net sales.
- 3. Development funding:** Cytokinetics will receive \$100 million in upfront capital to fund a confirmatory Phase 3 clinical trial of *omecamtiv mecarbil* in patients with heart failure and reduced ejection fraction. If the Phase 3 clinical trial is positive and FDA approval is received within specified time frames, Royalty Pharma will receive fixed payments totaling \$100 million following approval, as well as an incremental 2.0% royalty on annual net sales and/or fixed quarterly payments. If the Phase 3 trial is not successful or does not lead to FDA approval, Cytokinetics will repay Royalty Pharma up to \$237.5 million over eighteen or twenty-two quarters, in fixed quarterly payments.

**Development funding:** Cytokinetics to receive \$50 million in upfront capital to fund a proof-of-concept Phase 2 clinical trial for CK-586 in patients with heart failure and preserved ejection fraction and Royalty Pharma will have an option to invest up to an additional \$150 million to fund Phase 3 development of CK-586, for which it would be eligible to receive a \$150 million milestone payment upon FDA approval and a 4.5% royalty on annual net sales of CK-586.

If Royalty Pharma does not opt-in to fund Phase 3 development, Royalty Pharma will receive a 1.0% royalty on annual net sales of CK-586.

- 4. Equity Purchase:** Royalty Pharma will purchase \$50 million of Cytokinetics' common stock in a private placement that will be concurrent with the underwritten public offering that Cytokinetics plans to launch today.

From these transactions, Cytokinetics anticipates receipt of up to \$250 million in nearer-term funding. Together with its proforma cash at the end of the first quarter of 2024, this funding from Royalty Pharma enables Cytokinetics extended cash runway based on expected 2024 expenditures, inclusive of planned commercialization activities and expanded pipeline development programs.

#### Advisors

Cooley LLP and Morrison & Foerster LLP acted as legal advisors to Cytokinetics on the transactions. Goodwin Procter LLP, Fenwick & West LLP, Maiwald GmbH, and Wolf, Greenfield & Sacks, P.C., acted as legal advisors to Royalty Pharma. Evercore served as a financial advisor to Cytokinetics on the transactions.

### **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 Understanding of **O**bstruction Impact of *Aficamten* in **H**CM), 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 expects to submit a New Drug Application (NDA) to the FDA in Q3 2024 and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in Q4 2024.

### **About Omecamtiv Mecarbil**

*Omecamtiv mecarbil* is an investigational, selective, small molecule cardiac myosin activator, the first of a novel class of myotropes<sup>1</sup> designed to directly target the contractile mechanisms of the heart, binding to and recruiting more cardiac myosin heads to interact with actin during systole. *Omecamtiv mecarbil* is designed to increase the number of active actin-myosin cross bridges during each cardiac cycle and consequently augment the impaired contractility that is associated with heart failure with reduced ejection fraction (HFrEF). Preclinical research has shown that *omecamtiv mecarbil* increases cardiac contractility without increasing intracellular myocyte calcium concentrations or myocardial oxygen consumption.<sup>2-4</sup>

The development program for *omecamtiv mecarbil* assessed its potential for the treatment of HFrEF. Positive results from GALACTIC-HF 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. Adverse events and treatment discontinuation of study drug were balanced between the treatment arms.

In February 2023, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for *omecamtiv mecarbil*, stating that GALACTIC-HF was not sufficiently persuasive to establish substantial evidence of effectiveness for reducing the risk of heart failure events and cardiovascular death in adults with chronic heart failure with reduced ejection fraction, in lieu of evidence from at least two adequate and well-controlled clinical investigations. In May 2024, Cytokinetics withdrew the Marketing Authorization Application (MAA) from the European Medicines Agency (EMA) for *omecamtiv mecarbil* based on feedback from the Committee for Medicinal Products for Human Use (CHMP) indicating that the Committee would not be able to conclude that the benefits outweigh the risks on the basis of the results from GALACTIC-HF alone. Cytokinetics is planning to start an additional Phase 3 trial of *omecamtiv mecarbil* in Q4 2024 in advanced HFrEF patients with objective to confirm and elaborate on positive results previously observed in GALACTIC-HF.

### **About CK-4021586 (CK-586)**

CK-4021586 (CK-586) is a novel, selective, oral, small molecule cardiac myosin inhibitor designed to reduce the hypercontractility associated with heart failure with preserved ejection fraction (HFpEF). In preclinical models, CK-586 reduced cardiac hypercontractility by decreasing the number of active myosin cross-bridges during cardiac contraction thereby reducing the contractile force, without effect on calcium transients. In some patients, HFpEF is a condition that resembles non-obstructive hypertrophic cardiomyopathy (HCM) in that the patients have higher ejection fractions, thickened walls of their heart, elevated biomarkers, and symptoms of heart failure. In a Phase 2 clinical trial in patients with non-obstructive HCM, *aficamten*, a cardiac myosin inhibitor also developed by the Company, was well tolerated, improved patient reported outcomes (Kansas City Cardiomyopathy Questionnaire (KCCQ) and New York Heart Association (NYHA) Functional Class) and biomarkers, measures that are also relevant to HFpEF, lending support for this mechanism of action in HFpEF.

The Phase 1 study of CK-586 met its primary endpoint and secondary objectives, demonstrating that CK-586 was safe and well-tolerated in healthy participants with linear pharmacokinetics. These data are supportive of advancing CK-586 to a Phase 2 clinical trial in patients with HFpEF which is expected to begin in Q4 2024.

### **About Cytokinetics**

Cytokinetics is a late-stage, specialty cardiovascular 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 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 preparing for regulatory submissions for *aficamten*, its next-in-class cardiac myosin inhibitor, following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial in obstructive hypertrophic cardiomyopathy. *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 2 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. Additionally, Cytokinetics is developing CK-586, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten* for the potential treatment of HFpEF, and CK-136, a cardiac troponin activator for the potential treatment HFrEF and other types of heart failure, such as right ventricular failure resulting from impaired cardiac contractility.

For additional information about Cytokinetics, visit [www.cytokinetics.com](http://www.cytokinetics.com) and follow us on [X](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

### **About Royalty Pharma**

Founded in 1996, Royalty Pharma is the largest buyer of biopharmaceutical royalties and a leading funder of innovation across the biopharmaceutical industry, collaborating with innovators from academic institutions, research hospitals and non-profits through small and mid-cap biotechnology companies to leading global pharmaceutical companies. Royalty Pharma has assembled a portfolio of royalties which entitles it to payments based

directly on the top-line sales of many of the industry's leading therapies. Royalty Pharma funds innovation in the biopharmaceutical industry both directly and indirectly – directly when it partners with companies to co-fund late-stage clinical trials and new product launches in exchange for future royalties, and indirectly when it acquires existing royalties from the original innovators. Royalty Pharma's current portfolio includes royalties on more than 35 commercial products, including Vertex's Trikafta, GSK's Trelegy, Roche's Evrysdi, Johnson & Johnson's Tremfya, Biogen's Tysabri and Spinraza, AbbVie and Johnson & Johnson's Imbruvica, Astellas and Pfizer's Xtandi, Novartis' Promacta, Pfizer's Nurtec ODT and Gilead's Trodelvy, and 17 development-stage product candidates.

### **Cytokinetics 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 timing or availability of additional sale proceeds or loan disbursements from Royalty Pharma; Cytokinetics' research and development and commercialization activities; anticipated cash runway, and the properties and potential benefits of Cytokinetics' 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; 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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### **Royalty Pharma Forward Looking Statements**

The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this document unless stated otherwise, and neither the delivery of this document at any time, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This document contains statements that constitute "forward-looking statements" as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of Royalty Pharma's strategies, financing plans, growth opportunities and market growth. In some cases, you can identify such forward-looking statements by terminology such as "anticipate," "intend," "believe," "estimate," "plan," "seek," "project," "expect," "may," "will," "would," "could" or "should," the negative of these terms or similar expressions. Forward-looking statements are based on management's current beliefs and assumptions and on information currently available to the company. However, these forward-looking statements are not a guarantee of Royalty Pharma's performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, and other factors. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of the company's control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this document are made only as of the date hereof. The company does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law.

Certain information contained in this document relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the company's own internal estimates and research. While the company believes these third-party sources to be reliable as of the date of this document, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this document involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while the company believes its own internal research is reliable, such research has not been verified by any independent source.

For further information, please reference Royalty Pharma's reports and documents filed with the U.S. Securities and Exchange Commission ("SEC") by visiting EDGAR on the SEC's website at [www.sec.gov](http://www.sec.gov).

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### **References:**

1. Psotka MA, Gottlieb SS, Francis GS et al. Cardiac Calcitropes, Myotropes, and Mitotropes. *JACC*. 2019; 73:2345-53.
2. 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.
3. 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.
4. 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.



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