Kymera Therapeutics Announces First Patient Dosed in Phase 2 Atopic Dermatitis Clinical Trial of KT-474 (SAR444656), a First-in-Class, Investigational IRAK4 Degrader, Generating a $15 Million Payment from Sanofi

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Atopic Dermatitis (AD) trial is the second KT-474 Phase 2 clinical trial to begin enrolling patients this quarter following trial in Hidradenitis Suppurativa (HS)

Topline Phase 2 data from both the AD and HS trials expected in the first half of 2025

WATERTOWN, Mass., Dec. 07, 2023 (GLOBE NEWSWIRE) -- Kymera Therapeutics, Inc. (NASDAQ: KYMR), a clinical-stage biopharmaceutical company advancing a new class of small molecule medicines using targeted protein degradation (TPD), today announced that the first patient has been dosed in the randomized Phase 2 clinical trial (ADVANTA) evaluating KT-474 (SAR444656) in AD, generating a $15 million milestone payment under its collaboration with Sanofi. The Phase 2 study will evaluate the efficacy and safety of KT-474, a first-in-class, investigational IRAK4 degrader, compared with placebo in adult patients with moderate to severe AD. Sanofi is conducting Phase 2 KT-474 studies in both AD and HS, and dosed the first HS patient in October 2023, which generated a $40 million milestone payment under the terms of the collaboration. Study completion dates for both trials are projected in the first quarter of 2025.

“The initiation of dosing in the second Phase 2 trial of KT-474 reinforces the potential of degrading IRAK4 in the treatment of multiple immunological and inflammatory diseases, and the promise of TPD to offer patients with complex inflammatory diseases a new way to manage their disease,” said Nello Mainolfi, PhD, Founder, President and CEO, Kymera Therapeutics. “Our focus has always been on genetically validated targets within pathways with clear clinical validation and where TPD offers the best or the only path to creating an effective treatment, and we believe our IRAK4 degrader has the potential to offer AD patients a well-tolerated, effective, and convenient oral medicine. We look forward to sharing updates as our partner Sanofi progresses this program.”

“While we’ve made great strides in the treatment of AD, there continues to be an opportunity to advance a diverse range of solutions that address unmet needs across the spectrum of patients suffering from this chronic condition,” said Naimish Patel, MD, Head of Global Development, Immunology and Inflammation, Sanofi. “We are pleased to be working with Kymera to explore the potential of IRAK4 degradation to treat a variety of inflammatory conditions, including in our recently initiated Phase 2 AD and HS trials.”

About KT-474

KT-474 is an oral IRAK4 degrader, in development for the treatment of IL-1R/TLR-driven complex inflammatory diseases where there is an opportunity to significantly advance the standard of care, including HS and AD. The Phase 1 clinical trial results were recently published in Nature Medicine and showed evidence of robust IRAK4 degradation in the blood and active skin lesions of HS and AD patients and a favorable safety profile. Treatment with KT-474 was associated with a systemic anti-inflammatory response and improvement in skin lesions and symptoms in both HS and AD patients, with internal consistency between the effect on inflammatory biomarkers and impact on clinical endpoints. KT-474 was generally safe and well-tolerated, with no serious adverse events, no drug-related infections, and no dose interruptions or discontinuations due to adverse events.

The safety and efficacy of KT-474 (SAR444656) is currently being evaluated in double blind, placebo-controlled, randomized Phase 2 clinical trials in adult patients with moderate to severe HS and AD. Sanofi, which is collaborating with Kymera on the development of KT-474 outside of the oncology and immune-oncology fields, is conducting the Phase 2 studies.

More information on the Phase 2 studies in HS (NCT06028230) and AD (NCT06058156) can be found at www.clinicaltrials.gov.

About Atopic Dermatitis
AD is the most common form of eczema, a chronic inflammatory disease that causes the skin to become inflamed and irritated, making it extremely pruritic (itchy). AD is a common condition that usually begins in childhood; however, anyone can get the disease. It can affect a patient’s quality of life and lead to additional complications, such as infections and sleep loss. While there are currently available medicines for AD, there is a significant opportunity to improve treatment for patients not effectively treated with currently available options.

About Kymera Therapeutics
Kymera is a biopharmaceutical company pioneering the field of targeted protein degradation, a transformative approach to address disease targets and pathways inaccessible with conventional therapeutics. Kymera’s Pegasus platform is a powerful drug discovery engine, advancing novel small molecule programs designed to harness the body’s innate protein recycling machinery to degrade dysregulated, disease-causing proteins. With a focus on undrugged nodes in validated pathways, Kymera is advancing a pipeline of novel therapeutic candidates designed to address the most promising targets and provide patients with more effective treatments. Kymera’s initial programs target IRAK4 and STAT3 within the IL-1R/TLR or JAK/STAT pathways, and the MDM2 oncoprotein, providing the opportunity to treat patients with a broad range of immune-inflammatory diseases, hematologic malignancies, and solid tumors.

Founded in 2016, Kymera is headquartered in Watertown, Mass. Kymera has been named a “Fierce 15” company by Fierce Biotech and has been recognized by both the Boston Globe and the Boston Business Journal as one of Boston’s top workplaces. For more information about our people, science and pipeline, please visit www.kymeratx.com or follow us on X (formerly Twitter) or LinkedIn.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements by Kymera Therapeutics regarding its: strategy, business plans and objectives for its clinical programs; plans and timelines for the preclinical and clinical development of its product candidates, including the therapeutic potential, clinical benefits and safety thereof; expectations regarding timing, success and data announcements of current ongoing preclinical and clinical trials; the ability to initiate new clinical programs; and Kymera’s financial condition and expected cash runway into the second half of 2025. The words "may," “might,” "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," “expect,” "estimate," “seek,” "predict," “future,” "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations

and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the timing and anticipated results of our current and future preclinical studies and clinical trials, supply chain, strategy and future operations; the delay of any current and future preclinical studies or clinical trials or the development of Kymera Therapeutics' drug candidates; the risk that the results of current preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical and clinical trials, including those for KT-474 (SAR444656); Kymera Therapeutics' ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of the Kymera Therapeutics' planned interactions with regulatory authorities; obtaining, maintaining and protecting its intellectual property; the risks associated with pandemics or epidemics; and Kymera Therapeutics' relationships with its existing and future collaboration partners. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in the most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in Kymera Therapeutics' subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Kymera Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. Kymera Therapeutics explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements

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