Kymera Therapeutics Announces U.S. FDA Fast Track Designation for KT-621, a First-in-Class, Oral STAT6 Degrader for the Treatment of Moderate to Severe Asthma

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KT-621 BREADTH Phase 2b asthma trial ongoing, with data expected to be reported in late 2027

KT-621 BROADEN2 Phase 2b atopic dermatitis (AD) trial ongoing, with data expected by mid-2027

Fast Track designation previously granted for KT-621 for moderate to severe AD

WATERTOWN, Mass., April 13, 2026 (GLOBE NEWSWIRE) -- Kymera Therapeutics, Inc. (NASDAQ: KYMR), a clinical-stage biopharmaceutical company advancing a new class of oral small molecule degrader medicines for immunological diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to KT-621, its first-in-class oral STAT6 degrader, for the treatment of moderate to severe eosinophilic asthma. KT-621 is currently being studied in two global Phase 2b studies, including for the treatment of moderate to severe eosinophilic asthma. While several therapies are approved for asthma, including inhalers and injectable biologics, there remains a significant unmet need for effective, safe, convenient oral therapies.

“Asthma is a chronic lung condition that can significantly disrupt daily life and, in severe cases, be life-threatening. Many patients with moderate to severe asthma have inadequately controlled disease despite available therapies, underscoring the need for novel treatment approaches,” said Jared Gollob, MD, Chief Medical Officer, Kymera Therapeutics. “As a once-daily oral therapy, KT-621 has the potential to reach more patients, reduce treatment burden, and improve disease control, while addressing persistent gaps in today’s treatment landscape. Receiving Fast Track designation provides an opportunity to work closely with the FDA and explore ways to potentially accelerate the development of KT-621, supporting the promise of this program.”

After demonstrating compelling efficacy in preclinical asthma models, KT-621 demonstrated substantial reductions in fractional exhaled nitric oxide (FeNO), a biomarker of Type 2 inflammation in the lungs, as well as improvement in asthma disease control (ACQ-5) in a subset of patients with comorbid asthma in the BroADen Phase 1b trial in atopic dermatitis patients. These early preclinical and clinical findings support systemic STAT6 degradation and modulation of Type 2 inflammation in the lungs and validate KT-621’s mechanistic breadth and potential to benefit patients across Type 2-driven diseases, including asthma. The KT-621 BREADTH Phase 2b trial in moderate to severe eosinophilic asthma is ongoing, with data expected to be reported in late 2027. Additionally, the KT-621 BROADEN2 Phase 2b trial in moderate to severe atopic dermatitis is ongoing, with data expected to be reported by mid-2027. These studies are intended to support accelerated development of KT-621 and enable dose selection for subsequent parallel Phase 3 registration studies across multiple Type 2 inflammatory diseases.

The FDA’s Fast Track process is designed to get important new medicines to patients more quickly, facilitating the development and expediting the review of therapies intended to treat serious conditions and address unmet medical needs. Companies whose programs are granted Fast Track designation are eligible for more frequent interactions with the FDA during clinical development and potentially accelerated approval and/or priority review, if relevant criteria are met. For more information on the Fast Track process, please visit the FDA’s official website .

About KT-621
KT-621 is an investigational, first-in-class, once daily, oral degrader of STAT6, the specific transcription factor responsible for IL-4/IL-13 signaling and the central driver of Type 2 inflammation. KT-621 is currently in Phase 2 clinical testing in atopic dermatitis (AD) and asthma. In the Phase 1 clinical study in AD patients, KT-621 demonstrated deep STAT6 degradation in blood and skin, robust reductions in disease-relevant Type 2 inflammatory biomarkers, meaningful improvements on clinical endpoints and patient-reported outcomes in AD and comorbid asthma and allergic rhinitis, and was well tolerated with a favorable safety profile. KT-621, the first STAT6-directed drug to enter clinical evaluation, has the potential to transform treatment for more than 140 million patients around the world living with Type 2 inflammatory diseases such as AD, asthma, chronic obstructive pulmonary disease (COPD), eosinophilic esophagitis (EoE), chronic rhinosinusitis with nasal polyps (CRSwNP), chronic spontaneous urticaria (CSU), prurigo nodularis (PN), and bullous pemphigoid (BP), among others.

About Asthma
Asthma is a chronic inflammatory lung disease characterized by airway swelling and narrowing, which can make breathing difficult and can be potentially life threatening. Symptoms can include shortness of breath, coughing, wheezing, and chest tightness or pain. While there are currently available medicines for asthma, such as inhalers and injectable biologics, there remains a significant unmet need and opportunity to improve treatment options for millions of patients. Learn more about asthma on Kymera’s website .

About Kymera Therapeutics
Kymera is a clinical-stage biotechnology company pioneering the field of targeted protein degradation (TPD) to develop medicines that address critical health problems and have the potential to dramatically improve patients’ lives. Kymera is deploying TPD to address disease targets and pathways inaccessible with conventional therapeutics. Having advanced the first degrader into the clinic for immunological diseases, Kymera is focused on building an industry-leading pipeline of oral small molecule degraders to provide a new generation of convenient, highly effective therapies for patients with these conditions. Founded in 2016, Kymera has been recognized as one of Boston’s top workplaces for the past several years. For more information about our science, pipeline and people, please visit www.kymeratx.com or follow us on X 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 about our expectations regarding strategy, business plans and objectives on the development of KT-621, including the therapeutic potential, clinical benefits and safety thereof, the Phase 1b results providing further validation of KT-621 in AD and the potential clinical benefits of KT-621 in dermatology, gastroenterology and respiratory indications, the initiation of Phase 2b study of KT-621 in patients with asthma in the first quarter of 2026, the effect of initial parallel development of Phase 2b studies in AD and asthma patients on acceleration of late parallel development and dose selection across multiple indications, Phase 2b data readout of KT-621 in patients with moderate to severe AD expected by mid-2027. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target," “upcoming” 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 any forward-looking statements contained in this press release, including, without limitation, risks associated with: that the results from the Phase 2b KT-621 trial may differ from the Phase 1/1b KT-621 data, that preclinical and clinical data, including the results from the Phase 1/1b trial of KT-621, is not predictive of, may be inconsistent with, or more favorable than, data generated from future or ongoing clinical trials of the same product candidate, uncertainties inherent in the initiation, timing and design of future clinical trials, the availability and timing of data from ongoing and future clinical trials and the results of such trials, the ability to successfully demonstrate the safety and efficacy of drug candidates, the timing and outcome of planned interactions with and submissions to regulatory authorities, the availability of funding sufficient for our operating expenses and capital expenditure requirements and other factors. These risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in the most recent Quarterly Report on Form 10-Q and in subsequent filings with the SEC. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim 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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