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

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Fast Track designation supported by positive results from the KT-621 BroADen Phase 1b atopic dermatitis (AD) patient trial

KT-621 BROADEN2 Phase 2b AD trial ongoing, with data expected to be reported by mid-2027 and BREADTH Phase 2b trial in asthma on track to initiate in 1Q26

WATERTOWN, Mass., Dec. 11, 2025 (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 atopic dermatitis (AD).

“Atopic dermatitis is a chronic, debilitating disease. Far too many patients are currently untreated and are looking for new options. Receiving Fast Track designation will allow us to explore ways to accelerate the development of KT-621 and reflects the immense opportunity to advance a first-in-industry oral therapy that could address significant gaps within the current treatment landscape,” said Nello Mainolfi, PhD, Founder, President and CEO of Kymera Therapeutics. “Our goal with KT-621 is to deliver a once-a-day oral medicine with the activity and safety of injectable biologics, but in a far more convenient format – broadening access and supporting better outcomes for the millions of adults and children affected by AD and other Type 2-driven diseases around the world.”

The Company recently reported positive results from the BroADen Phase 1b AD trial, in which KT-621 demonstrated the potential to provide a once-daily oral treatment for Type 2 inflammatory diseases across every measure evaluated, including STAT6 degradation, biomarker modulation, clinical activity, impact on comorbid Type 2 diseases, and safety. The KT-621 BROADEN2 Phase 2b trial in moderate to severe AD patients is ongoing, with data expected to be reported by mid-2027. The BREADTH Phase 2b trial in asthma is planned to start in the first quarter of 2026. These studies are intended to accelerate KT-621 development and enable dose selection for subsequent parallel Phase 3 registration studies across multiple Type 2 dermatology, gastroenterology and respiratory indications.

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, and currently in Phase 2 clinical testing. In the Phase 1 clinical study in atopic dermatitis 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 paradigms for more than 140 million patients around the world, including children and adults, suffering from Type 2 diseases such as atopic dermatitis (AD), asthma, bullous pemphigoid (BP), chronic obstructive pulmonary disease (COPD), chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic esophagitis (EoE), chronic spontaneous urticaria (CSU), and prurigo nodularis (PN), among others.

About Atopic Dermatitis
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 occurs most frequently in children but also affects adults. 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, such as topical therapies and injectable biologics, there remains a significant unmet need and opportunity to improve treatment options for millions of patients. Learn more about AD 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.

Investor and Media Contact:

Justine Koenigsberg
Vice President, Investor Relations
investors@kymeratx.com
media@kymeratx.com
857-285-5300