Kymera Therapeutics Announces FDA Clearance of Investigational New Drug Application for KT-621, a First-in-Class, Oral STAT6 Degrader

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KT-621 has demonstrated dupilumab-like activity and was well tolerated in a wide variety of preclinical models of TH2 diseases

KT-621 is expected to start Phase 1 in October, with Phase 1 data in the first half of 2025

WATERTOWN, Mass., Oct. 09, 2024 (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 the clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) for KT-621, a potent, selective, oral degrader of STAT6. The Company expects to initiate dosing in a Phase 1 clinical trial in healthy volunteers in October 2024 and to report data from the Phase 1 study in the first half of 2025.

“FDA clearance of the KT-621 IND is a significant milestone for Kymera, patients, and the whole industry, allowing Kymera to be the first company to advance a STAT6 targeted medicine into clinical evaluation,” said Nello Mainolfi, PhD, Founder, President and CEO, Kymera Therapeutics. “Unlike traditional oral small molecule inhibitors, we believe that our oral STAT6 degrader, KT-621, has the potential to combine the complete pathway blockade of upstream biologics with the convenience of oral administration and in doing so has the opportunity to transform the current treatment paradigm for atopic and allergic diseases. We are excited to advance KT-621 into Phase 1 clinical testing and look forward to sharing updates on this program in the near future.”

The Phase 1 trial will evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of KT-621 compared to placebo.

About STAT6 Degrader
STAT6 is a historically undrugged essential transcription factor in the IL-4/IL-13 signaling pathways and the central driver of T helper type 2 (TH2) inflammation in allergic diseases. Multiple gain of function mutations of STAT6 were identified to cause severe allergic diseases in humans. Dupilumab, an injectable monoclonal antibody that blocks IL-4/IL-13 signaling, is an approved therapy for multiple allergic and atopic diseases. STAT6 targeting is therefore supported by both human genetics and clinical pathway validation. STAT6 functions through protein-protein and protein-DNA interactions, and it has been challenging to selectively and potently inhibit STAT6 with small molecule inhibitors. However, we believe it is well suited for a targeted protein degradation approach, where a binding event is sufficient to drive degradation. KT-621 is an investigational first-in-class once daily, oral STAT6 degrader with dupilumab-like activity in preclinical models and the potential to address multiple allergic and atopic diseases including atopic dermatitis, asthma, and chronic obstructive pulmonary disease, among others. Kymera intends to initiate Phase 1 testing for KT-621 in October 2024 and expects data from the Phase 1 trial to be reported in the first half of 2025.

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 delivering oral small molecule degraders to provide a new generation of convenient, highly effective therapies for patients with these conditions. Kymera is also progressing degrader oncology programs that target undrugged or poorly drugged proteins to create new ways to fight cancer. 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 clinical development of KT-621. 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 any forward-looking statements contained in this press release, including, without limitation, risks associated with: the risk that the results of preclinical studies and clinical trials may not be predictive of future results in connection with current and future clinical trials, uncertainties inherent in the initiation of future clinical trials, the timing and anticipated results of current and future clinical trials, whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to successfully demonstrate the safety and efficacy of drug candidates, the timing and outcome of planned interactions with regulatory authorities, 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 Securities and Exchange Commission. 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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