Kymera Therapeutics Receives FDA Orphan Drug Designation for KT-333, a First-in-Class, Investigational STAT3 Degrader for the Treatment of Peripheral T-Cell Lymphoma

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WATERTOWN, Mass., June 01, 2022 (GLOBE NEWSWIRE) -- Kymera Therapeutics, Inc. (NASDAQ: KYMR), a clinical-stage biopharmaceutical company advancing targeted protein degradation to deliver novel small molecule protein degrader medicines, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to KT-333 for the treatment of Peripheral T-cell Lymphoma (PTCL). KT-333 is a first-in-class degrader of the transcriptional regulator STAT3. STAT3 activation has been shown to be a key modulator of disease in PTCL, and there are currently no approved therapies for PTCL that target this pathway.

“The Orphan Drug Designation highlights the potential of this first-in-class heterobifunctional degrader to transform the treatment of PTCL by targeting STAT3, a protein that has historically been undruggable,” said Nello Mainolfi, PhD, Co-Founder, President and CEO, Kymera Therapeutics. “We look forward to working with the lymphoma community to rapidly advance KT-333 as a potential treatment for PTCL while we continue to expand clinical investigation of this novel mechanism in other cancers both in the hematological and in the solid tumor space.”

The FDA's Orphan Drug Designation program provides orphan status to drugs defined as those intended for the treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the United States. Orphan drug designation qualifies the sponsor of the drug for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval.

KT-333 is currently being evaluated in an ongoing Phase 1 trial in adult patients with relapsed/refractory liquid and solid tumors, including aggressive lymphomas. KT-333 is a potent and selective heterobifunctional small molecule protein degrader which can mediate degradation of the STAT3 protein. Normally, the STAT3 protein is activated by cytokines and growth factors, resulting in transcriptional regulation of many important cellular functions. In diseases including cancer, STAT3 activity becomes dysregulated, resulting in persistent activation of STAT3.

About Peripheral T-cell Lymphoma
PTCL, a subtype of non-Hodgkin’s lymphoma, is a heterogenous group of tumors that arise from mature white blood cells (T-cells) in the lymphoid tissues in areas such as the lymph nodes, lungs, gastrointestinal tract and skin. Approximately 13,000 PTCL patients are diagnosed in the U.S. each year, and PTCL accounts for 15% to 20% of aggressive lymphomas in the United States. PTCLs carry a poorer prognosis than other non-Hodgkin’s lymphomas since they are less responsive to standard chemotherapy regimens.

About Kymera Therapeutics
Kymera Therapeutics (Nasdaq: KYMR) 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 therapies that 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 therapeutics designed to address the most intractable pathways and provide new treatments for patients. Kymera’s initial programs target IRAK4, IRAKIMiD, and STAT3 within the IL-1R/TLR or JAK/STAT pathways, providing the opportunity to treat patients with a broad range of immune-inflammatory diseases, hematologic malignancies, and solid tumors. For more information, visit www.kymeratx.com.

Founded in 2016, Kymera is headquartered in Watertown, Mass. Kymera has been named a “Fierce 15” biotechnology company by Fierce Biotech and has been recognized by the Boston Business Journal as one of Boston’s “Best Places to Work.” For more information about our people, science, and pipeline, please visit www.kymeratx.com or follow us on 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 regarding its: strategy, business plans and objectives for the STAT3 degrader program; and plans and timelines for the clinical development of Kymera Therapeutics' product candidates, including the therapeutic potential and clinical benefits thereof. 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 impact of COVID-19 on countries or regions in which we have operations or do business, as well as on the timing and anticipated results of our current preclinical studies and future clinical trials, strategy and future operations; the delay of any current preclinical studies or future clinical trials or the development of Kymera Therapeutics' drug candidates; the risk that the results of current preclinical studies may not be predictive of future results in connection with future clinical trials; Kymera Therapeutics' ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of the Company’s planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in the Quarterly Report on Form 10-Q for the period ended March 31, 2022, filed on May 3, 2022, 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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