Kymera Therapeutics Receives U.S. FDA Fast Track Designation for KT-333, a First-in-Class, Investigational STAT3 Degrader for the Treatment of Relapsed/Refractory Cutaneous T-Cell Lymphoma and Relapsed/Refractory Peripheral T-Cell Lymphoma

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KT-333 Phase 1 oncology trial ongoing with an update including initial evaluation of its clinical antitumor activity in patients expected in the fourth quarter of 2023

Fast Track designation can potentially accelerate KT-333's development path for the treatment of R/R Cutaneous T-Cell Lymphoma and R/R Peripheral T-Cell Lymphoma

WATERTOWN, Mass., Sept. 18, 2023 (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 Fast Track designation to KT-333 for the treatment of R/R Cutaneous T-cell Lymphoma (CTCL) and R/R Peripheral T-cell Lymphoma (PTCL).

KT-333 is a highly selective degrader of STAT3 in development for the treatment of multiple STAT3-dependent pathologies, including hematological malignancies and solid tumors. STAT3 is a transcriptional regulator that has been linked to numerous cancers as well as to inflammatory and autoimmune diseases. In 2022, KT-333 received FDA orphan drug designation for the treatment of both CTCL and PTCL.

"The KT-333 Fast Track designation highlights the promise of degrading STAT3, a protein that has historically been undruggable, for the treatment of patients with CTCL and PTCL," said Jared Gollob, MD, Chief Medical Officer, Kymera Therapeutics. "We look forward to providing an update on the KT-333 Phase 1 clinical trial later this year, including initial evaluation of its antitumor activity in the target patient populations, and to working with the lymphoma community to rapidly advance this first-in-class heterobifunctional degrader in CTCL and PTCL in addition to exploring its potential in other cancers."

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 the KT-333 Clinical Program
The Phase 1 clinical trial of KT-333 is designed to evaluate the safety, tolerability, PK/PD and clinical activity of KT-333 dosed weekly in adult patients with relapsed and/or refractory lymphomas, leukemias and solid tumors. In June at the International Conference on Malignant Lymphoma (ICML), with a data cutoff date of May 1, 2023, Kymera presented data on thirteen patients who received a mean of five doses across the first four dose levels (DL1-4) of the trial, including patients with solid tumors, CTCL and PTCL. With DL4 still open to accrual at the time of the presentation, data reported from DL1-3 found plasma exposure increased with dose, reaching levels close to those predicted to be efficacious, and demonstrated dose-dependent STAT3 degradation with up to 88% mean maximum reduction in peripheral blood mononuclear cells and degradation profiles at DL3 near levels of knockdown that led to antitumor activity in preclinical models. We shared at ICML that there were no dose-limiting toxicities observed in the study. The Phase 1a dose escalation stage is ongoing, recruiting broadly across solid and liquid tumors, and more information can be found at www.clinicaltrials.gov, identifier NCT05225584.

About Cutaneous T-Cell Lymphoma
Cutaneous T-cell lymphoma (CTCL) is a general term for non-Hodgkin's T-cell lymphomas that are primarily characterized by an abnormal accumulation of T-cells in the skin and can involve the blood, lymph nodes and other internal organs. Approximately 3,000 CTCL patients are diagnosed in the U.S. each year, and CTCL accounts for 25% of T-cell lymphomas in the U.S. CTCL is a typically slow-growing cancer, with symptoms such as dry skin, potentially severe itching, rashes and enlarged lymph nodes. Since symptoms and skin biopsy findings are similar to other skin conditions, early-stage diagnosis can be difficult.

About Peripheral T-cell Lymphoma
PTCL, a subtype of non-Hodgkin's lymphoma, is a heterogenous group of tumors that arise from mature T-cells in the lymphoid tissues in areas such as the lymph nodes, lungs, gastrointestinal tract and skin. Approximately 4,000-8,000 PTCL patients are diagnosed in the U.S. each year, and PTCL accounts for 15% to 20% of aggressive lymphomas in the U.S. PTCL carries a poorer prognosis than other non-Hodgkin's lymphomas since it is less responsive to standard chemotherapy regimens.

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, IRAKIMiD, 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 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 the IRAK4, IRAKIMiD, STAT3, and MDM2 degrader 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), KT-333, KT-413 and KT-253; 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 Annual Report on Form 10-K for the period ended December 31, 2022 and 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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