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

September 15, 2022

Cutaneous T-Cell Lymphoma is the second orphan drug designation for KT-333

WATERTOWN, Mass., Sept. 15, 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 Cutaneous T-cell Lymphoma (CTCL).

KT-333 is a first-in-class degrader of the transcriptional regulator STAT3. Deregulation of STAT3 signaling has been implicated in the pathogenesis of a variety of cancers, including CTCL. There are currently no approved therapies for CTCL that target this pathway. KT-333 received orphan drug designation for the treatment of Peripheral T-cell Lymphoma (PTCL) earlier this year.

“This second orphan drug designation reinforces the potential of KT-333 to impact the lives of a broad range of patients with hematological and solid tumors by targeting STAT3, a protein that has been considered undruggable,” said Nello Mainolfi, Co-Founder, President and CEO of Kymera Therapeutics. “We have a significant opportunity to deliver an important new medicine with this first-in-class heterobifunctional degrader, and we look forward to working with the lymphoma community to rapidly advance KT-333 in CTCL and exploring its potential in other cancers.”

The safety, tolerability and PK/PD of escalating doses of KT-333 are currently being evaluated in an ongoing Phase 1 clinical trial in adult patients with relapsed/refractory liquid and solid tumors, including aggressive lymphomas.

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.

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 which account for approximately 25 percent of T-cell lymphomas in the U.S. CTCL can involve the blood, lymph nodes and other internal organs. CTCL is a rare and 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 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 Annual Report on Form 10-K for the period ended December 31, 2021 and most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in Kymera’s 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.

Investor Contact:
Bruce Jacobs
Chief Financial Officer
investors@kymeratx.com
857-285-5300

Chris Brinzey
Managing Director, Westwicke
chris.brinzey@westwicke.com
339-970-2843

Media Contact:
Todd Cooper
Senior Vice President, Corporate Affairs
media@kymeratx.com
857-285-5300