Kymera Therapeutics Outlines Key 2025 Objectives and Strategy to Advance Industry Leading Portfolio of Oral Immunology Programs

January 14, 2025

KT-621 (STAT6) Phase 1 healthy volunteer trial ongoing, with data expected in 2Q25

Kymera plans to initiate a KT-621 Phase 1b trial in atopic dermatitis (AD) patients in 2Q25 with data in 4Q25 and plans to initiate parallel Phase 2b trials in AD and asthma in late 2025 and early 2026, respectively

KT-295 (TYK2) to advance into Phase 1 testing in 2Q25 with data expected in late 2025

KT-474/SAR444656 (IRAK4) Phase 2b dose-ranging studies in hidradenitis suppurativa (HS) and AD ongoing, with completion expected in 1H26 and mid-2026, respectively

Novel oral immunology program with a first-in-class development candidate to be disclosed in 1H25

Well-capitalized with $850[1] million in cash and runway into mid-2027

Kymera to present its 2025 outlook at J.P. Morgan Annual Healthcare Conference on Tuesday, January 14, 2025, at 9:00 a.m. PT/12:00 p.m. ET

WATERTOWN, Mass., Jan. 14, 2025 (GLOBE NEWSWIRE) -- Kymera Therapeutics, Inc. (NASDAQ: KYMR), a clinical-stage biopharmaceutical company advancing a new class of oral small molecule degrader medicines with biologics-like activity for immunological diseases, today announced its corporate goals for 2025, including anticipated progress on its clinical pipeline of immunology programs.

“We expect 2025 to be another year of significant progress and accomplishments, and likely our busiest year to date. After unveiling our broader immunology strategy and new pipeline last year, we are poised to demonstrate the clinical potential of our first-in-class, wholly owned STAT6 and TYK2 oral degrader programs,” said Nello Mainolfi, PhD, Founder, President and CEO, Kymera Therapeutics. “Our vision is to leverage the power of targeted protein degradation to deliver, for the first time in industry, oral drugs with biologics-like activity that have the potential to revolutionize the treatment of many inflammatory diseases with significant unmet needs. We are rapidly progressing the development of our first-in-industry oral STAT6 degrader, KT-621, and will have Phase 1 healthy volunteer data, Phase 1b atopic dermatitis data, as well as initiate the first Phase 2b study, all in 2025.”

Dr. Mainolfi continued, “In addition to the significant progress we expect with our disclosed immunology programs, we look forward to expanding our immunology pipeline with a new program disclosure in the first half of 2025, continuing to build what we believe is the best oral immunology portfolio in industry.”

Additional details around Kymera's pipeline, including its development plans for KT-621, will be presented today at the J.P. Morgan Healthcare Conference.

Program updates on the company's disclosed programs and platform include:

STAT6 Degrader Program
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 Th2 inflammation. Currently in Phase 1 testing, KT-621 has demonstrated dupilumab-like activity and very good safety data in preclinical models. Recruiting for the KT-621 Phase 1 heathy volunteer trial is ongoing, with multiple single ascending dose (SAD) and multiple ascending dose (MAD) cohorts completed. KT-621 has the potential to address numerous Th2 diseases including AD, asthma, chronic obstructive pulmonary disease (COPD), chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic esophagitis (EoE), chronic spontaneous urticaria (CSU) and prurigo nodularis (PN), among others. Kymera intends to develop KT-621, an oral drug with potential for biologics-like efficacy, with the goal of transforming the treatment paradigm for the more than 130 million patients (children and adults) in the world suffering from Th2 diseases.

Key upcoming KT-621 milestones:

- **Complete KT-621 Phase 1 healthy volunteer clinical trial and report data in the second quarter of 2025.**
- **Advance KT-621 into a Phase 1b clinical trial in AD patients in the second quarter of 2025 and report data in the fourth quarter of 2025.**
- **Initiate KT-621 Phase 2b clinical trial in AD in the fourth quarter of 2025, followed by a Phase 2b clinical trial in asthma in early 2026.**

TYK2 Degrader Program
KT-295 is an investigational, first-in-class, once daily, oral degrader of TYK2, a member of the Janus kinase (JAK) family required for Type I IFN, IL-12 and IL-23 signaling. Given KT-295’s ability, observed in preclinical studies, to replicate the human genetic loss of function profile of TYK2, and to block the pathway to the level of upstream biologics (e.g., anti-IL-23), KT-295 has the potential to be the first oral therapy to deliver biologics-like activity in diseases such as IBD, psoriasis and others.

Key upcoming KT-295 milestones:

- **File KT-295 IND and initiate dosing in the Phase 1 healthy volunteer clinical trial in the second quarter of 2025, with Phase 1 data expected in the fourth quarter of 2025.**

IRAK4 Degrader Program
KT-474 (SAR444656) is an investigational, first-in-class, once daily, oral degrader of IRAK4, a key protein involved in TLR/IL-1R-driven inflammation. Given IRAK4's ability to block IL-1 family cytokine and TLR signaling, KT-474 holds promise to be superior to individual upstream cytokines blockers (e.g., anti-IL-1, anti-IL-33) as an oral drug. Initial Phase 2b clinical trials for HS and AD, in collaboration with Sanofi, are currently ongoing with potential in the future to expand beyond these two indications.

Key upcoming KT-474 milestones:

- **Collaborate with Sanofi to advance the KT-474/SAR444656 (IRAK4) Phase 2b dose-ranging clinical trials in HS and AD, with primary completion expected in the first half of 2026 for HS and mid-2026 for AD.**

Research Platform
Leveraging its proven small molecule discovery capabilities, deep expertise, and unique target selection strategy, Kymera is building an industry leading portfolio of innovative oral immunology medicines addressing high value undrugged or poorly-drugged targets for areas of significant need.

Key upcoming pipeline disclosures:

- **Kymera plans to announce the next immunology program, a first-in-class development candidate addressing an undrugged transcription factor, in the first half of 2025, and initiate clinical testing in early 2026.**

For more information on Kymera's pipeline visit our website.

J.P. Morgan Healthcare Conference Webcast

Kymera will present its 2025 outlook at the 43rd Annual J.P. Morgan Healthcare Conference on Tuesday, January 14, at 9:00 a.m. PT (12:00 p.m. ET). A live webcast of the presentation and Q&A session will be available under "News and Events" in the Investors section of the Company's website at www.kymeratx.com. A replay of the webcast and the presentation will be archived on Kymera's website following the event.

[1]Unaudited, estimated cash as of December 31, 2024.

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 clinical development of clinical and preclinical pipeline, including the therapeutic potential, clinical benefits and safety thereof, Sanofi's expansion of the Phase 2 clinical trials of KT-474/SAR444656, the Phase 1 data readout of KT-621 in the first half of 2025, the advancement of KT-295 into Phase 1 clinical testing, the declaration of its next clinical candidate and filing of an IND in second half of 2025, and Kymera's financial condition and expected cash runway into 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: 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, whether preliminary 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, 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 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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