Krystal Biotech Announces Update on Development Plans for Oncology Program KB707 and Prioritization of Inhaled KB707 for the Treatment of Non-Small Cell Lung Cancer

August 21, 2025

PITTSBURGH, Aug. 21, 2025 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the “Company”) (NASDAQ: KRYS), a commercial-stage biotechnology company, today announced an update on development plans for KB707, the Company’s redosable immunotherapy designed to drive sustained, localized expression of interleukin-2 (IL-2) and interleukin-12 (IL-12) in the tumor microenvironment and promote systemic immune-mediated tumor clearance following inhaled or intratumoral delivery to solid tumors.

Based on promising early evidence of efficacy in the treatment of non-small cell lung cancer (NSCLC), the Company was granted an End of Phase 2 meeting with the United States Food and Drug Administration (FDA) in October to discuss potential development pathways to support the registration of inhaled KB707.

“The acceleration of our work on inhaled KB707 is a reflection of both the clear and acute unmet need that exists for new treatments of NSCLC and the promising efficacy profile we have observed to date with inhaled KB707,” said Suma Krishnan, President of Research and Development of Krystal Biotech. “We look forward to meeting with the FDA and bringing another urgently needed therapeutic option to patients.”

Evidence supporting the prioritization of inhaled KB707, including monotherapy activity and durable responses in heavily pre-treated patients with NSCLC, was disclosed by the Company at the 2025 American Society of Clinical Oncology Annual Meeting earlier this year. As of data cut-off of April 15, 2025, the objective response rate in this heavily pre-treated NSCLC patient cohort was 36%. Median duration of response and progression free survival were not reached. Inhaled KB707 continued to be safe and generally well tolerated and amenable to administration in an outpatient setting, with no Grade 4 or 5 adverse events observed.

Enrollment continues in the Company’s KYANITE-1 study, a Phase 1/2 open label, multi-center, dose escalation and expansion study evaluating inhaled KB707 in patients with locally advanced or metastatic solid tumors of the lung. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06228326.

With the prioritization of inhaled KB707, the Company has paused enrollment in OPAL-1, a Phase 1/2 open label, multi-center, dose escalation and expansion study evaluating **intratumoral** KB707 in patients with locally advanced or metastatic solid tumor malignancies. Patients on OPAL-1 continue to be followed and based on safety and efficacy results from OPAL-1, the Company may adjust development plans for intratumoral KB707. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT05970497.

About Krystal Biotech, Inc.
Krystal Biotech, Inc. (NASDAQ: KRYS) is a fully integrated, commercial-stage, global biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK®, the Company’s first commercial product, is the first-ever redosable gene therapy, and the first genetic medicine approved in the United States, Europe, and Japan for the treatment of dystrophic epidermolysis bullosa. The Company is rapidly advancing a robust preclinical and clinical pipeline of investigational genetic medicines in respiratory, oncology, dermatology, ophthalmology, and aesthetics. Krystal Biotech is headquartered in Pittsburgh, Pennsylvania. For more information, please visit http://www.krystalbio.com, and follow @KrystalBiotech on LinkedIn and X (formerly Twitter).

Forward-Looking Statements

This press release contains “forward looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995 based on the Company’s current expectations and beliefs regarding its KB707 program. All statements other than historical facts are or may be deemed to be forward-looking statements and involve known and unknown risks, uncertainties, and assumptions that could cause actual results to differ materially from those indicated by such forward-looking statements as a result of various important factors set forth under the caption “Risk Factors” in the Company’s annual and quarterly reports on file with the U.S. Securities and Exchange Commission. The Company provides this information as of the date of this release and assumes no obligation to update any forward-looking statements.

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Source: Krystal Biotech, Inc.