Krystal Biotech Receives FDA Fast Track Designation for Inhaled Oncology Candidate KB707 to Treat Solid Tumors of the Lung

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• FDA clears IND and Phase 1 (KYANITE-1) clinical trial expected to be initiated in 1H 2024

PITTSBURGH, Feb. 13, 2024 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a commercial-stage biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for inhaled KB707 for the treatment of patients with solid tumors with pulmonary metastases that are relapsed or refractory to standard of care therapy.

"The lung is often the predominant site of metastasis for many different cancers, most of which have limited or no standard of care immunotherapy treatment options" said Daniel Johnson, MD, Director of the Center for Innovative Cancer Therapies at the Ochsner MD Anderson Cancer Center Medical Center in New Orleans, LA. "The therapeutic benefits of cytokine therapy for the treatment of solid tumors have long been recognized, but difficult to harness due to toxicities when given systemically. Intra-tumoral injection of potent immunotherapies can avoid systemic toxicities, but many sites of disease, particularly the lung, are not accessible for direct injection. We are excited about the possibility of bringing cytokine therapy to this patient population via localized, sustained cytokine expression in the lung itself."

KB707 is a modified HSV-1 vector designed to deliver genes encoding both human interleukin-12 (IL-12) and interleukin-2 (IL-2) to the tumor microenvironment and promote systemic immune-mediated tumor clearance. In January 2024, the FDA cleared an amendment to the Company's Investigational New Drug application to evaluate inhaled KB707 in a clinical trial to treat patients with locally advanced or metastatic solid tumors of the lung. The Company expects to dose the first patient in the open-label, multi-center, monotherapy, dose escalation and expansion Phase 1 clinical study (KYANITE-1) in the first half of 2024. Details of the study can be found at www.clinicaltrials.gov under NCT identifier: NCT06228326.

This is the second Fast Track Designation granted for KB707. In July 2023, the FDA granted intratumoral KB707 Fast Track Designation for the treatment of anti-programmed cell death protein-1 relapsed/refractory locally advanced or metastatic melanoma.

"The FDA's decision to grant inhaled KB707 Fast Track Designation is a reflection of both the urgent unmet need that exists for patients with lung metastases and the robust preclinical data we have generated to date in stringent syngeneic mouse models of checkpoint inhibitor refractory metastatic disease," said Suma Krishnan, President, Research & Development, Krystal Biotech. "We look forward to the first patient being dosed with inhaled KB707 later this year."

About Fast Track Designation
Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and treat a serious or unmet medical need, enabling drugs to reach patients sooner. Clinical programs with Fast Track Designation may benefit from early and frequent communication with the FDA throughout the regulatory review process, and such clinical programs may be eligible to apply for Accelerated Approval and Priority Review if relevant criteria are met.

About KB707
IL-2 and IL-12 are secreted cytokines with complementary functions promoting cell-mediated immunity in humans. Both IL-2 and IL-12 have been shown to elicit anti-tumor immune responses in preclinical or clinical models and have been extensively studied for their potential in cancer immunotherapy. Despite promising signs of efficacy, it has proven difficult to effectively harness IL-2 and IL-12 for therapeutic benefit, as systemic administration is often poorly tolerated, and their inherently short half-lives necessitate high dose levels and extremely frequent dose intervals. KB707 is a modified HSV-1 vector designed to deliver genes encoding both human IL-12 and IL-2 directly to a patient's tumor(s) and promote systemic immune-mediated tumor clearance. KB707 targets solid tumors that are accessible via intratumoral injection or inhalation.

About Krystal Biotech, Inc.
Krystal Biotech, Inc. (NASDAQ: KRYS) is a commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK® is the Company's first commercial product, the first-ever redosable gene therapy, and the first medicine approved by the FDA 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
Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including the Company's beliefs about the clinical utility of KB707 and its potential therapeutic capabilities, the Company expectations regarding the timing of a Phase 1 clinical study of inhaled KB707, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates, including KB707, and such other important factors as are 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. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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