Krystal Biotech Announces RMAT Designation Granted by FDA to KB707 for the Treatment of Advanced or Metastatic Non-Small Cell Lung Cancer

February 9, 2026

PITTSBURGH, Feb. 09, 2026 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the “Company”) (NASDAQ: KRYS) announced today that the United States Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation to KB707, the Company’s redosable immunotherapy designed to drive sustained, localized expression of interleukin-2 and interleukin-12 in the tumor microenvironment, for the treatment of advanced or metastatic non-small cell lung cancer (NSCLC).

“The FDA’s decision to grant RMAT designation to KB707 reflects both the urgent unmet need for new NSCLC therapies as well as the promising early clinical evidence of efficacy we have observed with inhaled KB707 in patients with advanced NSCLC,” said Suma Krishnan, President of Research and Development at Krystal Biotech. “This is the second RMAT designation granted to a Krystal program and, as such, we know first-hand the benefits that this designation can provide to accelerate development and shorten the path to a potential approval. We are excited to work closely with the FDA to maximize the potential impact of our KB707 program for patients with NSCLC.”

The FDA’s RMAT designation is intended to support and expedite the development of regenerative medicine therapies, including gene therapies. An investigational regenerative medicine therapy is eligible for the RMAT designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates potential to address unmet medical needs for that disease or condition. The designation provides all the benefits of the FDA's Fast Track and Breakthrough Therapy designations, including potential for rolling review, intensive FDA guidance and interaction, and organizational commitment from senior managers at the FDA, as well as the ability to work more closely and frequently with the FDA to discuss innovative trial designs, surrogate or intermediate endpoints to support potential accelerated approval, and novel approaches to satisfy post-approval requirements.

Data to support the FDA’s RMAT designation included early clinical evidence from the Company’s ongoing KYANITE-1 study that demonstrated consistent and meaningful antitumor activity, including durable responses and clinically significant tumor reductions, in patients with heavily pre-treated advanced NSCLC receiving inhaled KB707. Enrollment in KYANITE-1 is ongoing, and further details will be presented at upcoming scientific conferences. Additional details about the study can be found at www.clinicaltrials.gov under NCT identifier NCT06228326.

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. 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).

CONTACT
Investors and Media:
Stéphane Paquette, PhD
Krystal Biotech
spaquette@krystalbio.com

Source: Krystal Biotech, Inc.