Krystal Biotech Announces Home Dosing in B-VEC Open Label Extension Study

April 11, 2022

PITTSBURGH, April 11, 2022 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (“Krystal”) (NASDAQ: KRYS), the leader in redosable gene therapies, today announced that it plans to offer patients with dystrophic epidermolysis bullosa (DEB), who are enrolled in the GEM-3 open label extension study, the opportunity to be dosed in their homes by a health care professional (HCP). Krystal is offering this convenience to patients based on feedback from the U.S. Food and Drug Administration (FDA) following review of Krystal’s human factors (HF) validation study report submitted in January 2022.

“We thank the Agency for their consideration and believe that dosing patients in the comfort of their homes relieves them from an undue burden of travel and improves compliance with the therapy,” said Suma Krishnan, Founder and President of Research & Development at Krystal.

Next Steps

Per the FDA’s guidance, Krystal plans to address the convenience of dosing a patient at home of our intend-to-market B-VEC commercial product in its BLA submission that is anticipated in 2Q, 2022.

About the GEM-3 OLE Study

The GEM-3 B-VEC OLE study is a 78-week (approximately a year and a half) open-label extension study of B-VEC for participants diagnosed with DEB who are aged 6 months and older that began in May 2021. The primary endpoint will be to assess long term safety and tolerability of the topical gene therapy. The study will enroll subjects who participated in GEM-3 Phase III study, as well as new participants who were unable to participate in the Phase III study and who meet all enrollment criteria.

About B-VEC

B-VEC is an investigational non-invasive, topical, redosable gene therapy designed to deliver two copies of the *COL7A1* gene when applied directly to DEB wounds. B-VEC was designed to treat DEB at the molecular level by providing the patient’s skin cells the template to make normal COL7 protein, thereby addressing the fundamental disease-causing mechanism.

The FDA and EMA have each granted B-VEC orphan drug designation for the treatment of DEB, and the FDA has granted B-VEC fast track designation and rare pediatric designation for the treatment of DEB. In addition, in 2019, the FDA granted Regenerative Medicine Advanced Therapy (RMAT) to B-VEC for the treatment of DEB and the EMA granted PRIority MEdicines (PRIME), eligibility for B-VEC to treat DEB.

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRYS) is a pivotal-stage gene therapy company leveraging its proprietary, redosable gene therapy platform and in-house manufacturing capabilities to potentially bring life-changing treatment options to patients with serious diseases, including rare diseases in skin, lung, and other areas. For more information, please visit http://www.krystalbio.com, and follow @KrystalBiotech on LinkedIn and Twitter.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including statements about the clinical utility of B-VEC, at home dosing, the timing of Krystal’s BLA submission 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 B-VEC, the sufficiency of cash resources and need for additional financing and such other important factors as are set forth under the caption “Risk Factors” in Krystal’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 Krystal’s views as of the date of this release. Krystal anticipates that subsequent events and developments will cause its views to change. However, while Krystal 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 Krystal’s views as of any date subsequent to the date of this release.

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