Krystal Biotech Provides Update on EMA's Ongoing Regulatory Review of B-VEC for Dystrophic Epidermolysis Bullosa

December 9, 2024

CHMP opinion now expected in 1Q 2025

No Major Objections outstanding; continue to expect Germany launch in 2Q 2025

PITTSBURGH, Dec. 09, 2024 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a commercial-stage biotechnology company, today announced that the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) cancelled the Oral Explanation regarding the Company's Marketing Authorization Application for beremagene geperpavec-svdt (B-VEC) for the treatment of dystrophic epidermolysis bullosa (DEB) that was scheduled for December 6, 2024, and asked the Company to submit written responses to the remaining outstanding issues.

There are no Major Objections outstanding from the EMA with respect to the full approval of B-VEC.

"We are confident in our ability to address the remaining post-marketing issues, and we believe that this additional exchange with EMA will ultimately maximize benefit and convenience to patients suffering from DEB," said Suma Krishnan, President of Research and Development at Krystal Biotech.

The Company now anticipates a CHMP opinion in 1Q 2025 while the launch timelines remain unchanged with a commercial launch in Germany still planned for Q2 2025.

About Dystrophic Epidermolysis Bullosa (DEB)
DEB is a rare and severe disease that affects the skin and mucosal tissues. It is caused by one or more mutations in a gene called *COL7A1*, which is responsible for the production of the protein type VII collagen (COL7) that forms anchoring fibrils that bind the dermis (inner layer of the skin) to the epidermis (outer layer of the skin). The lack of functional anchoring fibrils in DEB patients leads to extremely fragile skin that blisters and tears from minor friction or trauma. DEB patients suffer from open wounds, which leads to skin infections, fibrosis which can cause fusion of fingers and toes, and ultimately an increased risk of developing an aggressive form of squamous cell carcinoma which, in severe cases, can be fatal.

About B-VEC and VYJUVEK
B-VEC is a non-invasive, redosable gene therapy built to deliver two copies of the *COL7A1* gene to treat DEB at the molecular level by providing the patient's cells the template to make normal COL7 protein, thereby addressing the fundamental disease-causing mechanism. B-VEC was approved by U.S. Food and Drug Agency (FDA) in May 2023 for the treatment of DEB and is marketed and sold in the U.S. under the name VYJUVEK®. For more information on VYJUVEK, see full U.S. Prescribing Information.

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
This press release contains forward-looking statements, including those regarding the EMA's review timeline and approval prospects for B-VEC, and the Company's plans and timeline for its commercial launch of B-VEC in the European Union. Actual outcomes may differ materially based on various factors, including uncertainties associated with regulatory review and marketing approvals 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. 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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