Krystal Biotech Receives Positive CHMP Opinion for VYJUVEK® for the Treatment of Dystrophic Epidermolysis Bullosa

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EC approval decision anticipated in second quarter of 2025

PITTSBURGH, Feb. 28, 2025 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a commercial-stage biotechnology company, today welcomed the European Medicines Agency's (EMA's) announcement that its Committee for Medicinal Products for Human Use (CHMP) has issued a positive recommendation for the European Commission (EC) to approve VYJUVEK® (beremagene geperpavec-svdt, or B-VEC) for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB) who have mutations in the collagen type VII alpha 1 chain (*COL7A1*) gene, starting from birth. The CHMP's positive opinion includes support for administration of VYJUVEK in either a health care setting (e.g., a clinic) or at home. If deemed appropriate by a healthcare professional, trained patients or caregivers may also apply VYJUVEK.

The final EC decision is anticipated in the second quarter of 2025. The decision will be applicable to all European Union member states, as well as Iceland, Norway and Liechtenstein.

"We are excited to be able to provide DEB patients with the first treatment that corrects the genetic defect and makes a true difference in their lives," said Cristina Has, M.D., Professor and Head of the Genodermatoses Clinic in the Department of Dermatology at the University of Freiburg in Germany. "By addressing the very first stage in the complex pathophysiology of DEB, VYJUVEK is a landmark. It is amazing how simple and non-invasive its use is, even in infants."

"We are very pleased that our patients, from birth, will have a simple, topical treatment that promotes durable wound closure, something that until now has been beyond the reach of any therapy," added Christine Bodemer, M.D., PhD, Professor and Head of the Department of Dermatology at the Necker Enfants Malades Hospital in Paris. "This is a remarkable advance for DEB patients and a new approach to gene therapy for genodermatoses, revolutionary and remarkably innovative."

The positive opinion issued by the CHMP is based on a comprehensive clinical dataset including results from the Company's Phase 1/2 GEM-1 and Phase 3 GEM-3 studies, published in Nature Medicine and the New England Journal of Medicine, respectively, which collectively provided clear clinical evidence of successful *COL7A1* gene delivery and durable wound closure following topical administration. The long-term safety and efficacy of B-VEC is further supported by results from the Company's open label extension study completed in the United States as well as real-world experience with VYJUVEK since launching the United States in 2023.

"The CHMP's recommendation for approval of VYJUVEK is an exciting step towards our goal of delivering the first ever corrective therapy to DEB patients across Europe," said Suma Krishnan, President of Research and Development at Krystal Biotech. "The CHMP's support for a broad label, including treatment of patients from birth and the option of patient or caregiver administration at home, are also fantastic outcomes for the DEB patients we aim to serve, broadening access and reducing barriers to starting on and staying on therapy."

If approved by the EC, the Company expects to market B-VEC under the registered European trademark, VYJUVEK.

"Our team in Europe has been working tirelessly in preparation for Krystal's first commercial launch outside of the United States and with the CHMP's positive opinion we remain on track to launch in Germany around the middle of this year," said Laurent Goux, Senior Vice President and General Manager of Europe at Krystal Biotech. "This will be the first of many launches in Europe, including a launch in France planned for later in 2025, as we advance diligently to ensure as many patients as possible benefit from access to VYJUVEK."

About VYJUVEK
VYJUVEK is a non-invasive, topical, redosable gene therapy designed to deliver two copies of the *COL7A1* gene when applied directly to DEB wounds. VYJUVEK 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. VYJUVEK was approved in the United States by the U.S. Food and Drug Agency (FDA) in May 2023 for the treatment of wounds in patients six months of age or older with DEB.

The use of VYJUVEK in the European Union remains investigational.

U.S. INDICATION

VYJUVEK is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients six months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene.

U.S. IMPORTANT SAFETY INFORMATION

Adverse Reactions
The most common adverse drug reactions (incidence >5%) were itching, chills, redness, rash, cough, and runny nose. These are not all the possible side effects with VYJUVEK. Call your healthcare provider for medical advice about side effects.

To report SUSPECTED ADVERSE REACTIONS, contact Krystal Biotech, Inc. at 1-844-557-9782 or FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

Contraindications
None.

Warnings and Precautions

VYJUVEK gel must be applied by a healthcare provider.

After treatment, patients and caregivers should be careful not to touch treated wounds and dressings for 24 hours.

Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from the first dressing change with a virucidal agent, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste. Dispose of the subsequent used dressings in a sealed plastic bag in household waste.

Patients should avoid touching or scratching wound sites or wound dressings.

In the event of an accidental exposure flush with clean water for at least 15 minutes.
For more information, 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
Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including statements about the expected timing of the European Commission approval of VYJUVEK, the expectation that the Company will market B-VEC in the European Union under the registered European trademark, VYJUVEK, the timing of expected commercial launches in Germany and France, 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 applications for marketing approvals and 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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