Krystal Biotech Announces European Commission Approval of VYJUVEK® for the Treatment of Dystrophic Epidermolysis Bullosa

April 28, 2025

VYJUVEK approved for the treatment of DEB from birth in Europe

Approval allows for dosing at home or in a healthcare setting, as well as patient or caregiver administration if deemed appropriate by a healthcare professional

PITTSBURGH, April 28, 2025 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS) announced today that on April 23, 2025, the European Commission (EC) granted marketing authorization to VYJUVEK® (beremagene geperpavec-svdt) 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. VYJUVEK is designed to address the genetic root cause of DEB by delivering functional copies of the human *COL7A1* gene to provide wound healing and sustained functional type VII collagen protein expression with redosing. VYJUVEK is the first corrective medicine approved in Europe for the treatment of DEB. The approval granted by the EC allows for flexible VYJUVEK dosing either at home or in healthcare setting, with the option for patient or caregiver administration if deemed appropriate by a healthcare professional.

This EC decision authorizes the marketing of VYJUVEK in all European Union member states, as well as Iceland, Norway and Liechtenstein. The timing for availability of VYJUVEK in individual countries will depend on multiple factors, including the completion of reimbursement procedures. The Company is planning for its first European launch in Germany in mid-2025.

"Today's approval is an exciting milestone for Krystal and the patients we aim to serve. After years of preparation in close coordination with leading DEB treatment centers, we are ready and excited to bring this urgently needed therapy to patients," said Laurent Goux, Senior Vice President and General Manager of Europe at Krystal Biotech. "With already 1,000 DEB patients identified in France and Germany, as well as many more across the continent, our goal is clear – to ensure as many patients as possible are able to benefit from sustainable access to VYJUVEK."

The EC approval follows the positive recommendation issued by the European Medicines Agency's Committee for Medicinal Products for Human Use in February and was based on a comprehensive clinical dataset including results from the Company's Phase 1/2 GEM-1 and Phase 3 GEM-3 studies, which collectively provided clear clinical evidence of successful *COL7A1* gene delivery and durable wound closure following topical administration, and was further supported by results from the Company's open label extension study and real-world experience in the United States.

"We are delighted that VYJUVEK has been approved in Europe as a safe and effective therapy for the many patients across Europe suffering from DEB," said Suma Krishnan, President of Research and Development at Krystal Biotech. "This approval marks a critical milestone in our commitment to improving the lives of DEB patients around the world, and we look forward to providing patients in Europe with the first corrective medicine for this debilitating disease."

VYJUVEK was approved by the FDA in the United States in May 2023 and is also under review for approval by Japan's Pharmaceuticals and Medical Devices Agency with a decision expected in 2H 2025.

EUROPEAN UNION INDICATION

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

For more information, see Summary of Product Characteristics.

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 by the FDA and the EMA for the treatment of dystrophic epidermolysis bullosa (DEB). 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 Company's planned first European commercial launch of VYJUVEK in Germany; the expected timing of Japan's Pharmaceuticals and Medical Devices Agency decision regarding potential marketing approval of VYJUVEK in Japan; 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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