



Krystal Biotech Announces Approval of VYJUVEK® by Japan's Ministry of Health, Labour and Welfare for the Treatment of Dystrophic Epidermolysis Bullosa

July 25, 2025

VYJUVEK approved for the treatment of DEB from birth with flexible administration options including home dosing and the option for administration by the patient or their family

VYJUVEK is the first and only genetic medicine approved in Japan for the treatment of DEB

PITTSBURGH, July 25, 2025 (GLOBE NEWSWIRE) -- [Krystal Biotech, Inc.](#) (the "Company") (NASDAQ: KRY5) announced today that on July 24, 2025, Japan's Ministry of Health, Labour and Welfare (MHLW) granted marketing authorization to VYJUVEK® (beremagene geperpavec-svdt) for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB), starting from birth. VYJUVEK is the first genetic medicine approved in Japan for the treatment of DEB and is designed to address the root cause of the disease by delivering functional copies of the human *COL7A1* gene to provide wound healing and sustained functional type VII collagen protein expression with redosing. The Japanese approval allows for dosing at home or in a healthcare setting, with the option for administration by patients or their family members.

As per the approval issued by the MHLW, VYJUVEK is intended for use only in patients with a definite diagnosis of dystrophic epidermolysis bullosa. Genetic testing is not a requirement for treatment.

VYJUVEK is the first genetic medicine approved in Japan for home administration after undergoing regulatory evaluation and environmental safety confirmation for type 1 use in accordance with the Cartagena Act. Approval for home administration was granted based on VYJUVEK's favorable safety profile and minimal risk of environmental dissemination when administered appropriately.

The timing for availability of VYJUVEK in Japan will depend on completion of reimbursement procedures currently underway. The Company currently expects to launch in Japan by the end of this year.

"For far too long, DEB patients in Japan have suffered from a lack of corrective therapies to manage their complex and often debilitating disease," said Hiroshi Kasamoto, General Manager of Japan at Krystal Biotech. "The approval of VYJUVEK in Japan is a long-awaited and urgently needed breakthrough, offering the potential to dramatically improve the lives of DEB patients across the country. With this important milestone, we remain on track to commercially launch VYJUVEK in Japan later this year and bring this innovative therapy to the many hundreds of DEB patients in need."

The approval by Japan's MHLW was based on a comprehensive clinical dataset, which included results from an open label extension study conducted in Japanese patients. Results from the Japanese open label extension study closely mirrored prior clinical experience, including the Company's Phase 3 study in the United States, with all four patients that completed the study achieving the primary study endpoint of full wound closure at six months. VYJUVEK was also well tolerated and exhibited a safety profile in Japanese patients that was consistent with previous studies.

"The approval of VYJUVEK in Japan is another important milestone for our organization and the DEB patients we serve," said Suma Krishnan, President of Research and Development at Krystal Biotech. "With recent approvals now in both Japan and Europe, we are making tremendous progress towards our goal of improving outcomes for DEB patients around the world."

The re-examination period for VYJUVEK in Japan is ten years.

VYJUVEK was previously approved by the Food and Drug Administration in the United States in May 2023 and by the European Commission in April 2025.

JAPAN INDICATION

Dystrophic epidermolysis bullosa

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRY5) 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 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).

About Cartagena Act

The Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, also referred to as the Cartagena Act, is a law regulating the use of living and/or genetically modified organisms in Japan, including the use of such organisms as medical products.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects, including statements about the Company's current expectation of launching VYJUVEK in Japan by the end of 2025; 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 related to reimbursement for VYJUVEK; 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. 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.

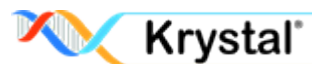
CONTACT

Investors and Media:

Stéphane Paquette, PhD

Krystal Biotech

spaquette@krystalbio.com



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