Krystal Biotech Announces FDA Approval of Updated VYJUVEK® Label

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Revised label allows treatment of DEB patients from birth

VYJUVEK can now be applied by patients and caregivers

PITTSBURGH, Sept. 15, 2025 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS) announced today that the United States Food and Drug Administration (FDA) approved a label update for VYJUVEK® (beremagene geperpavec-svdt) that expands the VYJUVEK eligible patient population to include dystrophic epidermolysis bullosa (DEB) patients from birth and provides patients full flexibility with respect to VYJUVEK application and managing wound dressings.

"We believe these changes further reinforce VYJUVEK's leadership position as the most flexible, convenient, and disease modifying medicine to treat DEB patients in the United States," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "Moreover, by providing patients and their caregivers the ability to apply VYJUVEK themselves, we have made it easier for patients to integrate VYJUVEK into their daily routines and lifestyle. Overall, we believe that these advancements solidify VYJUVEK as the standard of care for all DEB wounds, regardless of wound size and severity, and will further improve compliance."

In addition to allowing DEB patients and their caregivers to apply VYJUVEK at home on their own, today's label update also affords patients greater flexibility in managing wound dressings. Wound dressings are now permitted to be removed as part of the next dressing change rather than waiting 24 hours, further integrating VYJUVEK into existing wound care routines.

"The updates to the VYJUVEK label are yet another significant and impactful step forward for all those living with DEB" said Brett Kopelan, Executive Director of debra of America. "Enabling caretakers to apply VYJUVEK during their standard of care regimen is an enormous positive change allowing for increased convenience without sacrificing safety. The Krystal team has always prioritized patient safety and convenience when it comes to the use of VYJUVEK and them advocating for these updates is not surprising given Krystal's patient centric approach. This aspect of the update to the label will only increase the quality of life of those living with this challenging disorder and that is exactly what our community needs."

This label update is based on real-world data collected since VYJUVEK launch in the United States, as well as results from the open label extension study conducted in the United States and published earlier this year, which collectively reinforce the long-term safety and efficacy of VYJUVEK across patients of all ages, including in cases of patient or caregiver application.

About VYJUVEK
VYJUVEK is a non-invasive, topical, redosable genetic medicine 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 is approved in the United States, Europe, and Japan.

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

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 may be applied by a healthcare provider, a caregiver, or the patient.

After treatment, patients and caregivers should be careful not to touch treated wounds and dressings until the next dressing change.

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 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).

Forward-Looking Statements

This press release contains "forward looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 based on the Company's current expectations and beliefs regarding the recent FDA approved label update for VYJUVEK. All statements other than historical facts are or may be deemed to be forward-looking statements and involve known and unknown risks, uncertainties, and assumptions that could cause actual results to differ materially from those indicated by such forward-looking statements as a result of various important factors 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 Company provides this information as of the date of this release and assumes no obligation to update any forward-looking statements.

CONTACT
Investors and Media:
Stéphane Paquette, PhD
Krystal Biotech
spaquette@krystalbio.com

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