Krystal Biotech Announces EMA Validation of Marketing Authorization Application for VYJUVEK for the Treatment of Dystrophic Epidermolysis Bullosa

November 27, 2023

- *If approved, ~3,000 people with DEB in the European Union could receive VYJUVEK to treat the underlying cause of the disease for the first time*

- *VYJUVEK received Orphan Drug Designation and PRIME designation from the EMA*

PITTSBURGH, Nov. 27, 2023 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs, today announced that the Company's Marketing Authorization Application (MAA) to the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) for VYJUVEK (beremagene geperpavec-svdt, also known as B-VEC) for the treatment of dystrophic epidermolysis bullosa (DEB) has been validated and is now under CHMP review. A CHMP opinion is anticipated in the second half of 2024.

"The validation of our MAA for review by CHMP is an important step toward our goal to bring VYJUVEK to patients in the EU who are living with DEB," said Suma Krishnan, President, Research & Development, Krystal Biotech, Inc. "We look forward to working closely with EMA through the MAA review process, as VYJUVEK has the potential to fulfil an unmet medical need for DEB patients and their families."

In September 2023, Krystal Biotech received a positive opinion from the EMA Pediatric Committee on the Pediatric Investigation Plan for VYJUVEK for the treatment of DEB. Based on this positive opinion, the Company would be eligible for up to an additional two years of marketing exclusivity in the EU, on top of the ten-year EU market exclusivity after market approval in the EU. Previously, VYJUVEK received Orphan Drug Designation and PRIority Medicines (PRIME) eligibility from the EMA.

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 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.

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.

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 only 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 Twitter.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including statements about the timing of a potential CHMP opinion anticipated in the second half of 2024 for VYJUVEK and prospects regarding the timing of the approval and the commercial availability of VYJUVEK in Europe 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 regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates, the sufficiency of cash resources and need for additional financing 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. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this 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 release.

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