Krystal Biotech Announces Completion of Patient Enrollment in the GEM-3 Pivotal Trial of B-VEC for the Treatment of Dystrophic Epidermolysis Bullosa

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PITTSBURGH, March 30, 2021 (GLOBE NEWSWIRE) -- Krystal Biotech Inc., ("Krystal") (NASDAQ: KRYS), the leader in redosable gene therapies for rare diseases, today announced that enrollment is complete in the pivotal GEM-3 study of B-VEC for dystrophic epidermolysis bullosa (DEB). Based on the timing of this milestone, Krystal expects to report top-line results from the study in the fourth quarter of 2021.

"Completion of enrollment in the GEM-3 study marks a significant milestone for us," said Suma Krishnan, Founder and Chief Operating Officer of Krystal Biotech. "We would like to extend our gratitude to the patients, caregivers, investigators and study staff who, through their commitment during an especially difficult year, have helped bring us closer to potentially providing an easy-to-use topical treatment that addresses the underlying cause of DEB."

About the GEM-3 Pivotal Study
The GEM-3 trial is a randomized, double-blind, intrapatient placebo-controlled multicenter study designed to evaluate the efficacy and safety of B-VEC for the treatment of DEB. The trial enrolled 31 patients ranging in ages from one (1) year to forty-four (44) years old. Sixty-one percent (61%) of the patients enrolled were pediatric patients (18 years old or younger). As anticipated, less than ten percent (10%) of enrolled patients have the dominant form of dystrophic epidermolysis bullosa (DDEB).

In each patient, a primary wound pair(s) was identified by the investigator; one wound was randomized to receive a weekly topical application of B-VEC and the other to placebo. Primary wound pairs selected in the study fell into each of the three wound area segments of <20 cm^2, 20-40 cm^2 and 40-60 cm^2 and were assigned the corresponding doses of 4×10^8 PFU/wound, 8×10^8 PFU/wound or 1.2×10^9 PFU/wound, respectively. Weekly application will be continued until the investigator determines that the wound is completely closed. Re-application may occur at any point throughout the study should the wound re-open. The Primary Outcome Measure is complete wound healing as determined by the Investigator in B-VEC treated wounds versus placebo treated at Weeks 20, 22 and 24.

In addition to the primary target wound pair(s), additional wounds (secondary wounds) may be selected to be treated with B-VEC giving the treating physicians and patients flexibility to treat a larger number of wounds. For more information about the pivotal GEM-3 study, visit www.clinicaltrials.gov (NCT04491604).

Subjects will return to the clinical site 30 days following the last dosing visit (week 24) for safety evaluation by the investigator, and will subsequently have the option to roll into the Open Label Extension (OLE) Study.

About Krystal Biotech
Krystal Biotech, Inc. (NASDAQ:KRYS) is a pivotal-stage gene therapy company leveraging its novel, redosable gene therapy platform and in-house manufacturing capabilities to develop therapies to treat serious rare diseases. For more information, please visit http://www.krystalbio.com.

Forward-Looking Statements
Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including but not limited to statements about the development of Krystal's product candidates, such as plans for the design, conduct and timelines of ongoing clinical trials of beremagene geperpavec ("B-VEC"), KB105, KB104, KB301 and KB407; the clinical utility of B-VEC, KB105, KB104, KB301 and KB407, and Krystal's plans for filing of regulatory approvals and efforts to bring B-VEC, KB105, KB104, KB301 and KB407 to market; the market opportunity for and the potential market acceptance of B-VEC, KB105, KB104, KB301 and KB407; plans to pursue research and development of other product candidates; the sufficiency of Krystal's existing cash resources; the unanticipated impact of COVID-19 on Krystal's business operations, pre-clinical activities and clinical trials; 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: the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or trials will be indicative of the results of ongoing or future trials, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates including B-VEC, KB105, KB104, KB301 and KB407, 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 Krystal'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 Krystal's views as of the date of this release. Krystal anticipates that subsequent events and developments will cause its views to change. However, while Krystal 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 Krystal's views as of any date subsequent to the date of this release.

CONTACTS:

Investors:
Whitney Ijem
wijem@krystalbio.com

Media:
Mary Coyle
TellMed Strategies
mary.coyle@tmstrat.com

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