Krystal Biotech Announces Initiation of Phase 1 Study Evaluating KB301 in Aesthetic Indications

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KB301 is designed to deliver a full-length human type III collagen transgene via intradermal injection

First in-human study will evaluate the safety and efficacy in acne scars and facial wrinkles

Initial data from this study is anticipated in 2021

PITTSBURGH, Aug. 25, 2020 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (Nasdaq:KRYS), today announced the initiation of the PEARL-1 study, a Phase 1 multi-dose, controlled clinical study of KB301 for the treatment of acne scars and facial wrinkles.

The skin is composed of collagen-rich connective tissue composed primarily of types I and III collagen fibrils. Age-related changes in skin are largely due to aberrant collagen homeostasis, caused both by intrinsic (e.g., passage of time, genetics) and extrinsic (e.g., chronic light exposure, pollution) factors, which leads to progressive loss of dermal collagen. KB301 is designed to restore collagen homeostasis locally via directed expression of full-length human type III collagen gene (COL3A1), thereby reconstructing an optimal physiologic environment in the skin to treat wrinkles and other superficial skin defects. KB301 is manufactured in-house at Krystal's fully functional GMP ANCORIS facility, located near corporate headquarters in Pittsburgh.

"I'm excited to be a part of the ground-breaking PEARL-1 study," Dr. Mark Nestor, director of the Center for Clinical and Cosmetic Research and the Center for Cosmetic Enhancement noted. "I believe KB301 holds the potential to provide a truly innovative and differentiated approach to achieve long lasting collagen production in the aesthetics space."

Chairman and CEO Krish Krishnan further added, "The initiation of this trial is an important step forward for Krystal as we look to demonstrate the potential of our platform in broader skin conditions. If ultimately successful, KB301 and any additional aesthetic programs could represent an interesting strategic opportunity through our wholly-owned subsidiary Jeune, Inc."

About the PEARL-1 Trial
The Phase 1 trial will evaluate the safety, tolerability, and initial efficacy of intradermal injections of KB301. Approximately 22 patients will be enrolled across three cohorts. The initial open-label cohort will evaluate the safety and tolerability of two different dose levels of KB301 in healthy buttock skin. Following dose selection enrollment will begin in Cohorts 2 and 3, which are double-blind, placebo-controlled, intra-subject evaluations of the safety and efficacy of KB301 in either shallow-to-moderately deep facial wrinkles or moderate-to-severe atrophic acne scars. In all three cohorts subjects will receive an initial dose on Study Day 0 and a repeat dose on day 30. More information about the PEARL-1 study will be available at clinicaltrials.gov.

About Krystal Biotech
Krystal Biotech, Inc. (NASDAQ:KRYS) is a gene therapy company dedicated to developing transformative medicines to treat diseases caused by protein or gene dysfunction. For more information, please visit http://www.krystalbio.com.

About Jeune, Inc.
Jeune, Inc. is the company's wholly-owned subsidiary, which was incorporated in 2019 for the purpose of undertaking preclinical studies for aesthetic skin conditions.

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.

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