Jeune Aesthetics Announces Positive Durability Results for KB301 in the PEARL-1 Extension Cohort, an Investigational Gene-based Treatment for Improvement of Fine Lines and Wrinkles

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- Up to nine months durability of effect observed in patients aged 55 to 76 in the extension cohort following administration of high dose KB301
- Mean change in Subject Satisfaction Scores from baseline ranged from 1.6 to 1.85 points up to nine months after dosing
- Company plans on initiating a Phase 2 trial in fine lines and wrinkles in 1H 2023

PITTSBURGH, Nov. 17, 2022 (GLOBE NEWSWIRE) -- Jeune Aesthetics, Inc. ("Jeune"), a wholly owned subsidiary of Krystal Biotech, Inc. ("Krystal") (NASDAQ: KRYS) today announced nine-month durability of effect in the extension cohort of the PEARL-1 study of KB301, an investigational gene-based treatment designed to address the underlying biology of aging skin for improvement of fine lines and wrinkles.

"We are pleased to see the sustained durability of effect supporting the clinical benefits afforded by KB301," said September Riharb, SVP of Jeune. "Treatment of superficial fine lines has been a challenge for aesthetic physicians, and as one of the first signs of skin aging, fine lines represent a significant unmet need. Replenishment of the skin's key proteins through targeted gene-delivery holds promise for this significant market segment. We look forward to including a younger patient population in our future Phase 2 study."

About the PEARL-1 Durability Cohort Design

Previously, the PEARL-1 study evaluated the safety, tolerability, and initial efficacy of intradermal dose-ranging injections of KB301 in adult subjects. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900. On March 22, 2022, Jeune announced positive proof-of-concept, safety and efficacy data with respect to improvement of fine lines and wrinkles in the upper cheek, lower cheek, and above the knee from the efficacy cohort of the PEARL-1 study.

Ten subjects from the PEARL-1 efficacy cohort were enrolled in the PEARL-1 extension cohort, an open-label study to assess duration of effect below the zygomatic arch (the lower cheek area). The extension cohort enrolled subjects who had received the high dose regimen of KB301 during the efficacy cohort in one or both of their lower cheeks. Subject Satisfaction Scores and Investigator Assessments were measured monthly for three consecutive visits that correspond to timepoints up to nine-months following administration of the last dose of KB301. In addition, subjects with placebo-treated lower cheeks were dosed with KB301 during the open-label extension cohort to normalize their appearance.

About the PEARL-1 Extension Cohort Results

Overall, data from the PEARL-1 extension cohort showed up to nine-month durability of effect following administration of high dose KB301. The mean change in Subject Satisfaction Scores from baseline ranged from 1.6 to 1.85 points approximately seven to nine months after dosing. Alternatively, a responder analysis based on Subject Satisfaction Scores was performed. The percentage of responders, defined as a lower cheek with a Subject Satisfaction Score of ≥1 point change from baseline, ranged from 62% to 70%.

In addition, Investigator Assessments for a clinically meaningful difference were also evaluated with 70-76% of treated cheeks demonstrating a clinically meaningful difference approximately seven to nine months after KB301 dosing.

All reported adverse events associated with the extension cohort KB301 treatment to the placebo treated lower cheeks, to normalize the subjects' appearance, were injection site-related and the reported events were transitory and rated as mild or moderate.

Next Steps, Initiation of the PEARL-2 Study

Based on the positive results from the PEARL-1 study and feedback from the U.S. Food and Drug Administration on newly developed internal scales, Jeune is planning to initiate a Phase 2 study in 1H 2023. The Phase 2 study, called the PEARL-2 study, will be a prospective, multicenter, randomized, double-blind, placebo-controlled study to assess improvement of fine lines and wrinkles in challenging areas of the face.

Investor Conference Call, Webcast and Presentation Information

Jeune and Krystal will host a 30-minute investor conference call and webcast today, Thursday, November 17, at 8:30 am ET, to discuss the PEARL-1 extension cohort results and the KB301 clinical development program. To register and participate in the conference call, please go to: https://www.netroadshow.com/events/login?show=644d1cca&confId=44638.

For those unable to listen to the live conference call, a replay will be available on the Investor's section of the Krystal website at www.krystalbio.com.

About Jeune Aesthetics, Inc.

Jeune Aesthetics, Inc., a wholly-owned subsidiary of Krystal Biotech, Inc., is a biotechnology company leveraging a clinically validated gene-delivery platform to fundamentally address – and reverse – the biology of aging skin. For more information, please visit http://www.jeuneinc.com.

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRYS) is a biotechnology company focused on developing and commercializing genetic medicines for patients with rare diseases. The Company's wide-ranging pipeline is based on its proprietary redosable HSV vector. Headquartered in Pittsburgh, Pennsylvania, the Company is led by an experienced management team, is fully-integrated and has core capabilities in viral vector design, vector optimization, gene therapy manufacturing and commercialization. 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., or its wholly-owned subsidiary, Jeune Aesthetics, Inc., including but not limited to statements about the clinical utility of KB301, Jeune's plan to initiate a Phase 2 study of KB301 in 1H 2023, 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 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 KB301 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 and Jeune's views as of the date of this release. Krystal and Jeune anticipate that subsequent events and developments will cause their views to change. However, while Krystal and Jeune may elect to update these forward-looking statements at some point in the future, they specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing Krystal's and Jeune's views as of any date subsequent to the date of this release.

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