Jeune Aesthetics Announces Initiation of Dosing in Efficacy Cohort of KB301 Phase 1 trial to Assess Improvement in Skin Quality

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- *KB301 is designed to deliver a full-length human type III collagen transgene via intradermal injection*
- *Initial data from this efficacy cohort of the PEARL-1 study is anticipated in 4Q21*

PITTSBURGH, Aug. 02, 2021 (GLOBE NEWSWIRE) -- Jeune Aesthetics, Inc., a wholly-owned subsidiary of Krystal Biotech, Inc., ("Krystal") (NASDAQ: KRYS) today announced the initiation of dosing in the efficacy cohort of the PEARL-1 trial, a Phase 1 multi-dose, controlled clinical study of KB301 to assess improvement of skin quality.

"The initiation of dosing in this cohort represents an important milestone for Jeune," noted Dr. Bhushan Hardas, President of Jeune Aesthetics. "While other modalities artificially address the 'symptoms' of aging skin or make use of controlled injury to indirectly stimulate collagen, KB301 is designed to directly restore production of collagen."

Age-related changes in the skin are caused by intrinsic (e.g., the passage of time, genetics) and extrinsic (e.g., chronic light exposure, pollution) factors, leading to progressive loss of dermal collagen and other extracellular matrix proteins, which ultimately leads to changes in the structure and appearance of skin. KB301 is designed to restore collagen locally by enabling cells to produce full-length human type III collagen (*COL3A1*), thereby fundamentally addressing the biology of aging skin. Initial data from Cohort 1 of the PEARL-1 study showed the safety and tolerability of repeat KB301 injections. Cohort 2 will assess the improvement in skin quality, as assessed by changes in skin roughness, fine lines, and skin thickness from baseline.

"I am thrilled to be among the first to apply this innovative gene-delivery technology to aesthetics as part of the PEARL-1 study," said Steve G. Yoelin, M.D., an ophthalmologist with a medical aesthetics private practice in Newport Beach, California, and a distinguished researcher, clinician, and speaker. "The ability to controllably produce normal collagen has potential to change the paradigm in skin-quality management."

About the PEARL-1 Trial
The Phase 1 dose-ranging trial is evaluating the safety, tolerability, and initial efficacy of intradermal injections of KB301 in adult subjects aged 18-75 (NCT04540900). Complete results from the initial safety Cohort were presented at the 2021 Society for Investigative Dermatology (SID) Annual Meeting.

Cohort 2 is a randomized, double-blind, saline-controlled trial to evaluate the safety and efficacy of KB301 for the improvement of skin quality attributes such as fine lines, texture, and skin thickness. This cohort will enroll approximately 30 subjects across two trial sites. Bilateral treatment areas on the neck behind the ear, on the cheek below and above the zygomatic arch, and around the knee will be chosen on Day 0 and randomized 2:1 to receive low dose KB301, high dose KB301, or saline. KB301 or saline will be injected in multiple micro depot injections over the selected treatment area.

Subjects will be treated twice in the selected areas 2 weeks apart and evaluated for efficacy 2 and 4 weeks after the last treatment. Change in skin quality from baseline will be assessed via the Skin Roughness Score (SRS)[1], Fine Lines Score (FLS)[2], and the Subject Satisfaction Score (SSS). Skin calipers will be used to measure the change in skin thickness over the knee.

Skin quality measurements for this study will also make use of Canfield Scientific's VISIA-CR, which includes micron resolution surface topography using the Primos 3D system, which is now fully integrated into each set of captures. "We are very excited to objectively evaluate the measures for skin quality in this important study using our latest most advanced facial imaging solution," said Doug Canfield, President of Canfield Scientific, Inc.

Initial data from this efficacy cohort of the PEARL-1 study is anticipated in 4Q21.

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

About Krystal Biotech, Inc.
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., or its wholly-owned subsidiary, Jeune Aesthetics, Inc., including but not limited to statements about the development of Jeune's product candidates, such as plans for the design, conduct and timelines of ongoing clinical trials of KB301, the clinical utility of KB301, the ability of KB301 to fundamentally address and potentially reverse the biology of aging or damaged skin, 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 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 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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[1] Carruthers J, Donofrio L, Hardas B, et al. Development and Validation of a Photonumeric Scale for Evaluation of Facial Fine Lines. Dermatol Surg. 2016;42 Suppl 1(Suppl 1):S227-S234. doi:10.1097/DSS.0000000000000847

[2] Donofrio L, Carruthers A, Hardas B, et al. Development and Validation of a Photonumeric Scale for Evaluation of Facial Skin Texture. Dermatol Surg. 2016;42 Suppl 1(Suppl 1):S219-S226. doi:10.1097/DSS.0000000000000852