



Jeune Announces Positive Results and Significant Aesthetic Improvements from Phase 1 Study of KB304 for Moderate to Severe Wrinkles of the Décolleté

July 24, 2025

KB304 designed to deliver collagen and elastin to restore skin naturally

Conference call to discuss results scheduled for Thursday, July 24, 2025 at 4:30pm ET

PITTSBURGH, July 24, 2025 (GLOBE NEWSWIRE) -- Jeune Aesthetics, Inc. ("Jeune"), a wholly owned subsidiary of Krystal Biotech, Inc. ("Krystal") (NASDAQ: KRYS) leveraging Krystal's clinically validated gene-delivery platform to fundamentally reverse the biology of aging skin, announced today positive safety and efficacy results, including significant improvements in key skin aesthetic attributes such as wrinkles and elasticity, in PEARL-2, a randomized, double-blind, placebo-controlled Phase 1 study evaluating KB304, for the treatment of wrinkles of the décolleté.

Meaningful aesthetic improvements were reported following KB304 treatment with clear and statistically significant advantages over placebo as evaluated by both the investigator and subjects using the Global Aesthetic Improvement Scale (GAIS). GAIS assesses the overall aesthetic change in appearance as a result of a treatment. Subjects also reported increased satisfaction with the appearance of wrinkles, as measured by the Subject Satisfaction Questionnaire (SSQ). The SSQ is a tool to gather subject-reported outcomes providing valuable insights on the impact of treatment beyond clinical observations.

Topline Efficacy Results

A total of 19 subjects were enrolled, 12 were randomized to KB304 and seven to placebo. One subject dropped out before completing KB304 treatments. The remaining 18 subjects were assessed for aesthetic improvement out to three months following KB304 injections in the décolleté.

The study investigator and subjects reported a clinically meaningful improvement in wrinkles one, two, and three months after treatment, as assessed by GAIS among KB304-treated subjects.

	Investigator Reported: At Least One-Point Improvement for Subjects Receiving:		Subject Reported: At Least One-Point Improvement for Subjects Receiving:	
	KB304	Placebo	KB304	Placebo
At Three Months	100%	28.6%	72.7%	14.3%
At Two Months	100%	28.6%	90.9%	14.3%
At One Month	100%	14.3%	72.7%	14.3%

As assessed by SSQ, 81.8% of subjects receiving KB304 reported improved satisfaction with their wrinkles' appearance three months after treatment, compared to 14.3% of subjects receiving placebo.

Improvements in subjects receiving KB304 were also seen across multiple additional skin attributes, as assessed by GAIS, including elasticity, crepiness, hydration, and radiance, for which the investigator reported that 100% of subjects demonstrated an improvement of at least 1 point in each of these attributes at one, two, and three months following treatment.

"We are very excited to share today's data update. We are pleased that both the investigator and subjects reported high rates of improvements across a variety of skin attributes when treated with KB304. We believe that KB304 has the potential to revolutionize the treatment of wrinkles and skin quality by directly addressing the underlying biology of aging skin. KB304 is a truly unique product candidate, which we think will address a massive gap in the market two ways...being the first product candidate to directly address elastin and by doing so in the décolleté where there are no injectable products approved. Consumers are yearning for a solution that delivers natural looking results, and KB304 has the potential to restore the skin to a more youthful appearance," said Marc Forth, Chief Executive Officer of Jeune.

The KB304 safety profile was consistent with prior clinical experience in KB301. Adverse events were mild-to-moderate and mostly reported after the first dose but substantially tapered off with subsequent doses. No severe or drug-related serious adverse events were reported.

"We are extremely excited by the promising data from the Pearl-2 study," said Suma Krishnan, President of Research & Development at Krystal Biotech. "We believe KB304 has the potential to be a first-in-class treatment to deliver collagen and elastin directly to the skin. This study is the first randomized, double-blind, placebo-controlled trial to investigate the potential combinatorial benefits of COL3 and elastin supplementation when produced by the body's own skin cells. On the basis of the strong results and broad improvements across multiple skin aesthetic attributes, we will be progressing KB304 into Phase 2 development for the treatment of wrinkles in the décolleté, a priority aesthetic site for which no FDA-approved injectables exist. We plan to prioritize the development of KB304 and will be meeting with the FDA in the coming months to enable initiation of the Phase 2 study."

Jeune has recently completed development and validation of a décolleté-specific photometric scale ("JDWS"). Jeune intends to submit the JDWS to the FDA and align on the Phase 2 study protocol in the second half of 2025 with the goal of initiating the Phase 2 study in the first half of 2026.

Conference Call and Webcast

Jeune and Krystal will host a conference call and webcast today, Thursday, July 24, 2025, at 4:30pm ET, to discuss the results of the PEARL-2 study, the KB304 clinical development program, Jeune's pipeline product candidates, and the strategic vision for Jeune.

Investors and the general public can access the live webcast at: <https://www.webcaster4.com/Webcast/Page/3018/52758>.

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

About KB304

KB304 is an investigational aesthetic therapy employing Krystal's novel replication-defective, non-integrating HSV-1-based vector to deliver two copies of the gene encoding COL3 transgene and one copy of the gene encoding elastin to increase their levels in skin and address signs of skin aging associated with damage to the skin's extracellular matrix. KB304 is formulated as a solution for direct intradermal injection to aesthetic priority areas.

About the PEARL-2 Study

PEARL-2 is a Phase 1 Study of KB304, a replication-defective, non-integrating vector expressing human type III collagen (COL3) and elastin for the treatment of moderate to severe wrinkles of the décolleté. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT06724900.

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: KRY5) is a fully integrated, commercial-stage, global biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK®, the Company's first commercial product, is the first-ever redosable gene therapy, and the first genetic medicine approved by the FDA and EMA 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 X (formerly 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 statements about the clinical utility of KB304; KB304's ability to deliver collagen and elastin to restore the skin naturally to a more youthful appearance and potentially revolutionize the treatment of wrinkles and skin quality; KB304's potential to address a massive gap in the market; Krystal's and Jeune's plans to prioritize the development of KB304 and progress KB304 into a Phase 2 study for the treatment of wrinkles of the décolleté, including timing of meeting with the FDA and the goal of initiating the Phase 2 study in the first half of 2026; 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: preliminary clinical data from a Phase 1 trial with a small sample size and limited follow-up may not predict results in later-stage studies; uncertainties associated with regulatory review of clinical trials, the availability or commercial potential of KB304, 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 press 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 press release.

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