Jeune Aesthetics Announces Phase 1 Positive Interim Safety and Efficacy Results for KB301 in the Treatment of Lateral Canthal Lines and Dynamic Wrinkles of the Décolleté

August 28, 2024

Décolleté indication selected for Phase 2 study expected to start next year

Conference call to discuss results scheduled for Wednesday, August 28, 2024 at 4:30 p.m. ET

PITTSBURGH, Aug. 28, 2024 (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 address – and reverse – the biology of aging skin, announced today positive interim safety and efficacy results from both Cohorts 3 and 4 of PEARL-1, a Phase 1 study evaluating KB301, an investigational aesthetic treatment designed to deliver the *COL3A1* transgene and increase type III collagen ("COL3") levels in the skin, for the improvement of lateral canthal lines at rest in Cohort 3 and for the improvement of dynamic wrinkles of the décolleté in Cohort 4.

"Today's injectable aesthetics toolbox is limited to toxins and fillers which allow us to manipulate, but not rejuvenate, aging skin," said Steve G. Yoelin, M.D., one of the principal investigators for PEARL-1. "With its unique mechanism of action and compelling early efficacy data, I am excited by the potential for KB301 to change the treatment paradigm in the field of medical aesthetics and meet the growing demand for treatments that fundamentally replenish the skin or delay signs of aging."

Meaningful and sustained improvements in skin aesthetic attributes, assessed using a Global Aesthetic Improvement Scale ("GAIS"), were reported by the study investigators and subjects alike in both the décolleté and lateral canthal regions. Increased subject satisfaction with wrinkle appearance was also reported using a Subject Satisfaction Questionnaire ("SSQ").

Dynamic Wrinkles of the Décolleté Topline Efficacy Results

A total of 20 subjects were enrolled. Two subjects dropped out before completing KB301 treatments. The remaining 18 subjects were assessed for aesthetic improvement out to two months following KB301 injections in the décolleté region. Results included:

- Study investigators reported clinically meaningful improvement in wrinkles both one and two months after treatment, as assessed by GAIS:
  - At two months: 94% of subjects had at least a one point improvement and 28% had a two point improvement - the maximum potential score on the GAIS scale.
  - At one month: 83% of subjects had at least a one point improvement and 28% had a two point improvement.
- Subjects also reported improvements in wrinkles that increased from the first to second follow up month, as assessed by GAIS:
  - At two months: 89% of subjects reported at least a one point improvement and 39% reported a two point improvement.
  - At one month: 61% of subjects reported at least a one point improvement and 28% reported a two point improvement.
- 94% of subjects reported improved satisfaction with their wrinkles' appearance two months after treatment, as assessed by SSQ.
- Improvements were also seen across multiple additional skin attributes, as assessed by GAIS, including crepiness, hydration, and radiance, for which investigators reported improvements of 1 point or better in 89%, 94%, and 94% of subjects, respectively, two months after treatment.

Lateral Canthal Line Topline Efficacy Results

A total of 13 subjects were enrolled. One subject dropped out before completing KB301 treatments. The remaining 12 subjects were assessed for aesthetic improvement out to two months following KB301 injections in the lateral canthal region. Results included:

- Study investigators again reported clinically meaningful improvement in wrinkles both one and two months after treatment, as assessed by GAIS:
  - At two months: 75% of subjects had at least a one point improvement and 50% had a two point improvement.
  - At one month: 92% of subjects had at least a one point improvement and 50% had a two point improvement.
- Subjects also reported improvements in wrinkles, as assessed by GAIS:
  - At two months: 50% of subjects reported at least a one point improvement and 25% reported a two point improvement.
  - At one month: 58% of subjects reported at least a one point improvement and 17% reported a two point improvement.
- 67% of subjects reported improved satisfaction with their wrinkles' appearance two months after treatment, as assessed by SSQ.
- Improvements across multiple additional skin attributes were again reported, as assessed by GAIS, with investigators

reporting one point or greater improvements in at least 75% of subjects for each of crepiness, hydration, and radiance, two months following treatment.

Across both cohorts, the KB301 safety profile was consistent with prior clinical experience in Cohorts 1 and 2 and other injectable aesthetic products. Adverse events were primarily injection associated, mild-to-moderate, and transient. No drug related serious adverse events were reported.

"We are excited to share today's data update in which we continue to see profound aesthetic benefits following KB301 administration in both the lateral canthal region and the décolleté, in line with our earlier findings from PEARL-1 Cohort 2," said September Riharb, Senior Vice President of Jeune. "We are also pleased that, in addition to reporting improvements in fine lines and wrinkles, both study investigators and subjects alike reported high rates of improvement across a variety of key skin attributes, consistent with KB301's paradigm-changing mechanism of delivering *COL3A1* directly to the skin and restoring COL3 levels to more youthful levels. The natural looking results of KB301 rejuvenated skin are exactly what consumers are looking for today. On the basis of the strong results we saw in Cohort 4, we will be progressing KB301 into Phase 2 development for the treatment of dynamic wrinkles of the décolleté, a priority aesthetic site for which no FDA-approved injectables exist, and will be meeting with the FDA in the coming months to enable initiation of the Phase 2 study."

A subset of Cohort 4 subjects opted in to redose at the two month follow up timepoint, after completing the assessments described above. Additional data collection is ongoing in the redosed subjects. Upon completion, detailed results of PEARL-1 Cohorts 3 and 4 will be presented at future scientific conference(s).

Conference Call, Webcast and Presentation Information

Jeune and Krystal will host a conference call and webcast today, Wednesday, August 28, 2024, at 4:30 pm ET, to discuss the PEARL-1 Cohort 3 and Cohort 4 interim results, the KB301 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/3018/51166

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 KB301
KB301 is an investigational aesthetic therapy employing Krystal's novel replication-defective, non-integrating HSV-1-based vector to deliver two copies of the *COL3A1* transgene and increase COL3 levels in skin to address signs of skin aging associated with declining collagen levels and damage of the skin's extracellular matrix. KB301 is formulated as a solution for direct intradermal injection to aesthetic priority areas.

About the PEARL-1 Study
PEARL-1 is a multi-cohort Phase 1 study designed to evaluate the safety, tolerability, initial efficacy and duration of effect of intradermal KB301 injections in adult subjects. Previously disclosed results from Cohorts 1 and 2 revealed that repeat administration of KB301 to various locations on the body was well-tolerated and, in 2022, Jeune announced positive proof-of-concept, safety, efficacy, and nine-month durability data from PEARL-1 Cohort 2 with respect to improvement of fine lines and wrinkles. Building on the results from Cohort 2, Cohorts 3 and 4 of PEARL-1 are open-label, single-arm cohorts designed to evaluate KB301 in two potential target indications for Phase 2, lateral canthal lines at rest and dynamic wrinkles of the décolleté. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.

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 commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK® is the Company's first commercial product, the first-ever redosable gene therapy, and the first medicine approved by the FDA 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 KB301; the potential for KB301 to change the treatment paradigm in the field of medical aesthetics and meet the growing demand for treatments that fundamentally replenish the skin or delay signs of aging; Krystal's and Jeune's plans to progress KB301 into Phase 2 development for the treatment of dynamic wrinkles of the décolleté, including timing of meeting with the FDA and the initiation of the Phase 2 study; Krystal's proprietary, HSV-1 based gene delivery platform; 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: uncertainties associated with regulatory review of clinical trials, the availability or commercial potential of 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 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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