UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 17, 2022

KRYSTAL BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38210**	**82-1080209**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

2100 Wharton Street, Suite 701
Pittsburgh, Pennsylvania 15203
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (412) 586-5830

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On November 17, 2022, Jeune Aesthetics, Inc. (the "Company"), a wholly owned subsidiary of Krystal Biotech, Inc., issued a press release announcing positive durability results for KB301 in the PEARL-1 Extension Cohort, an investigational gene-based treatment for improvement of fine lines and wrinkles. In addition, the press release indicated that the Company and Krystal Biotech, Inc. would host an investor conference call at 8:30 a.m. ET on November 17, 2022, to discuss the PEARL-1 durability results and the KB301 clinical development program. For purposes of the call, the Company provided an investor slide presentation (the "Investor Slide Presentation"), which is available on the "Investors" section of Krystal Biotech, Inc.'s website at www.krystalbio.com. Copies of the press release and the Investor Slide Presentation are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated by reference herein.

This information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 17, 2022
99.2	Investor Slide Presentation, dated November 2022
104	Cover Page Interactive Data file (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 17, 2022

KRYSTAL BIOTECH, INC.

By: /s/ Krish S. Krishnan
Name: Krish S. Krishnan
Title: Chairman and Chief Executive Officer

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

November 17, 2022

- 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, November 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.

CONTACT:

Investors and Media:
Meg Dodge
Krystal Biotech
mdodge@krystalbio.com

Source: Krystal Biotech, Inc.


A GENE-BASED
AESTHETICS COMPANY
November 2022
JEUNE
PEARL-1 Durability Results

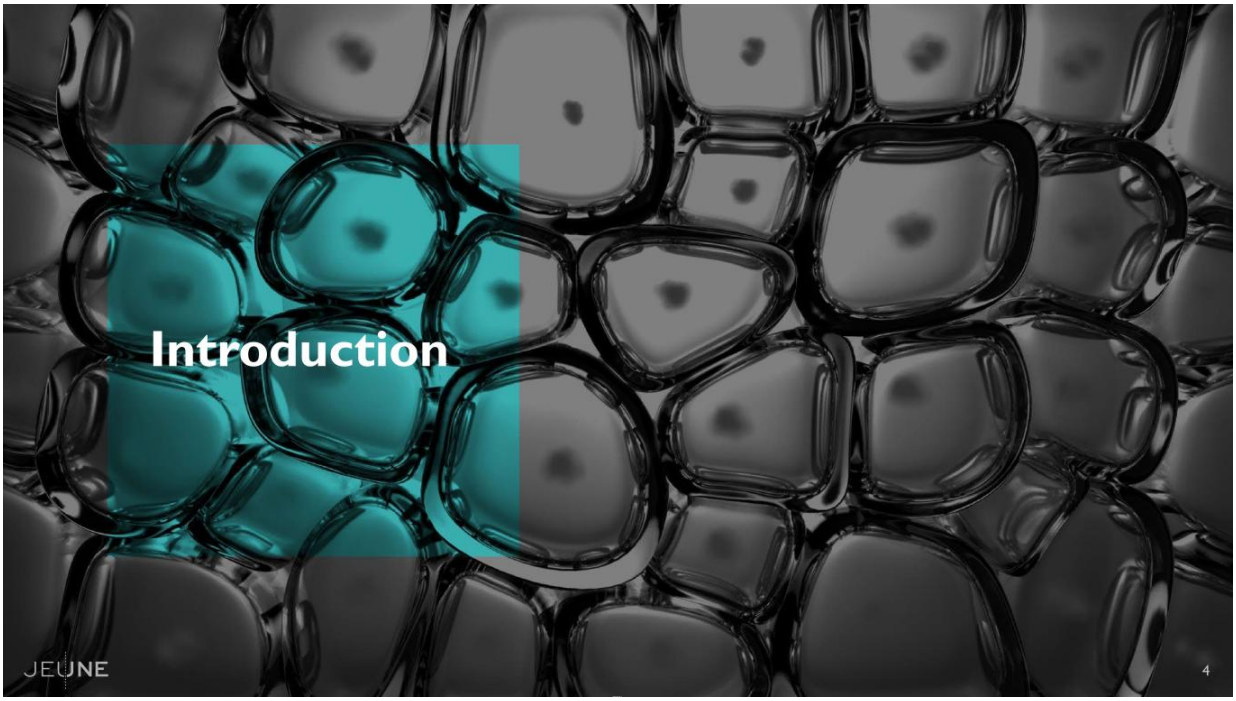
Forward Looking Statement

This presentation contains forward-looking statements that involve substantial risks and uncertainties. Any statements in this presentation about future expectations, plans and prospects for Krystal Biotech, Inc. and its wholly-owned subsidiary, Jeune Aesthetics, Inc. (collectively, the "Company"), including but not limited to statements about the development of the Company's product candidates, such as the development or commercialization of KB301; conduct and timelines of preclinical and clinical trials, the clinical utility of KB301; the market opportunity for and the potential market acceptance of KB301; 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 content and timing of decisions made by the U.S. Food and Drug Administration, European Medicines Agency and other regulatory authorities; 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; the ability to retain and hire key personnel; the sufficiency of cash resources and need for additional financing; and such other important factors as are set forth in Krystal Biotech Inc.'s annual and quarterly reports and other filings on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this presentation represent the Company's views as of the date of this presentation. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company 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 the Company's views as of any date subsequent to the date of this presentation.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Agenda

1. **Introduction**
   - September Riharb, SVP, Jeune Aesthetics, Inc.
2. **PEARL - 1 Durability Trial Results**
   - Dr. Hubert Chen, SVP Clinical Development
4. **Next Steps / PEARL-2 Study**
   - September Riharb, SVP, Jeune Aesthetics, Inc.
5. **Q&A**


Introduction
JEUNE
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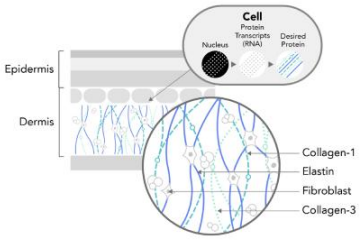
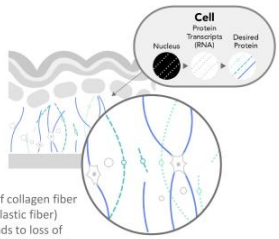
Aging Skin is Caused by Declining Levels of Collagen and Elastin

- Skin aging is caused, in part, by a reduction of the skin's key proteins: collagen and elastin
- Impaired collagen and elastin synthesis leads to the degradation of the extracellular matrix, affecting overall skin quality and function
- The primary function of the extracellular matrix is to give skin its mechanical and biochemical properties

YOUNGER / HEALTHY



AGED / PHOTODAMAGED



Declining levels of collagen fiber and elastin (elastic fiber) production leads to loss of extracellular matrix integrity

KB301 is Designed to Increase Production of Type III Collagen

- Collagen 3 provides tensile strength, and influences other functions such as cell adhesion, migration, proliferation, and differentiation through its interaction with integrins, which are cell surface receptors[1]

	Type I Collagen	Type III Collagen	Elastin
Percentage in the skin	70-80%	20-30%	2-3%
Aging alteration	declines with aging	Abundant in baby skin, declines thereafter	Abundant in baby skin, declines thereafter

1 Kim JK, Xu Y, Xu X, Keene DR, Gurusiddappa S, Liang X, Wary KK and Hook M, 2005. A novel binding site in collagen type III for integrins alpha1beta1 and alpha2beta1. J Biol Chem 280, 32512–20.

KB301 Key Product Differentiation

Feature	Benefit
Novel MOA naturally produces patient's own Collagen-3	Reduced wrinkles and improved skin quality attributes
Applicable for all skin types	Can be added to every patient's skin care program
Physician (injector) controlled placement	Targeted application to specific cheek skin concerns
Injected with 33-gauge microneedle	No painkillers required
Collagen response (onset) within days	No pre-event planning required
Expected 9-month (or longer) duration	Lasting "Jeune Glow"

KB301 Treatment

A universally appealing treatment because it does not alter the face shape or features, it simply returns the skin to a natural looking youthful state.

"KB301 holds the promise to fundamentally change the way we age."

Jeune Scientific Advisor

Market Uptake Beyond the Current Aesthetic Market

Non-Aesthetic Consumers

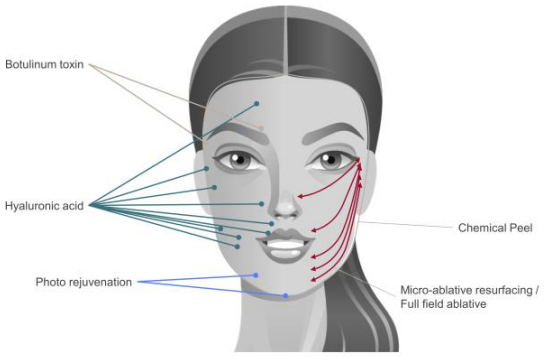
Stage 1: Aging Skin Concerns → **Stage 2:** Retinol and Sunscreen Usage → **Stage 3:** **Genetic Skin Rejuvenation with KB301 Treatments**

Aesthetic Consumers

Stage 1: Aging Skin Concerns Despite Current Treatments with Dermal Fillers, Neuromodulators and Lasers → **Stage 2:** Inclusion of **KB301 Treatments for Genetic Skin Rejuvenation**

Improvement in Skin Quality had Potential Beyond the Face

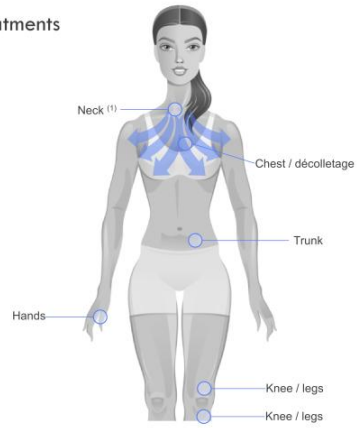
Significant opportunity in areas with no FDA-approved indications or treatments available.



Global Facial Rejuvenation Market[1]

$19B → $44B

2019 by 2026



Global Skincare Devices Market[2]

$18B → $50B

2018 by 2028

Sources: ISAPS International Survey on Aesthetic/Cosmetic Procedures Note: Not all products or indications approved in the US.
1. September 2020 – insightSLICE - Global Facial Rejuvenation Market Share, Trends, Analysis and Forecasts, 2020-2030. 2. November 2020 – Research and Markets - Global Skincare Devices Market (2020 to 2030) - by Product, Distribution Channel, Application and End-user.

Robust Pipeline Addresses Multiple Aspects of Skin Quality

PROGRAM	INDICATION	GENE	PRE-CLINICAL	CLINICAL
KB301	Improved Skin Quality Attributes	type III collagen (COL3)		
KB303	TBD	elastin (ELN)		
KB302	TBD	COL3 + ELN		
KB304	TBD	Type 1 collagen (COL1)		
KB305	TBD	type IV collagen (COL4)		

KB301 Leverages Experience with Vector and Manufacturing Infrastructure

- KB301 uses same HSV-1 vector backbone as B-VEC, Krystal's rare skin disease product currently under FDA review for licensure
- Preclinical and clinical data generated for B-VEC, as well as manufacturing infrastructure, de-risks and accelerates KB301 development

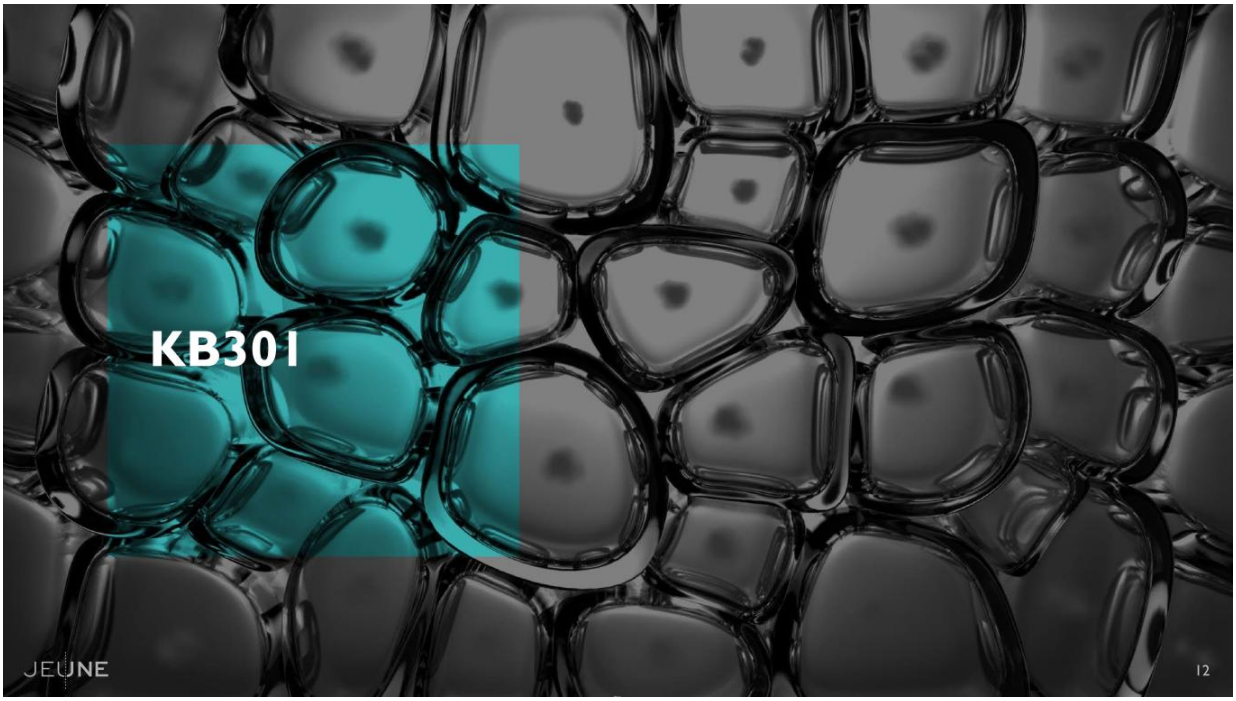
CLINICAL EXPERIENCE

- Vector backbone extensively studied during B-VEC clinical development program
- Vector data package includes B-VEC Phase 1/2 and Phase 3 studies, two clinical stage programs, and multiple preclinical candidates
- Favorable preclinical and clinical safety profile across all products and routes of administration to date
- Jeune leverages data generated on other Krystal programs to inform KB301 clinical strategy and support interactions with regulators

GMP MANUFACTURING

- GMP manufacturing already established with additional near-term capacity anticipated
  - **Ancoris:** Fully operational 10,000 sq ft GMP manufacturing facility has produced over 20 GMP batches to date
  - **Astra:** 150,000 sq ft GMP manufacturing facility to be operational by H2 2022 with capacity to support Krystal and Jeune portfolios
- Infrastructure and in-house vector manufacturing expertise to accelerate KB301 development and launch

Astra Manufacturing Facility
Expected H2 2022
Close proximity to Pittsburgh International Airport


KB301
JEUNE
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PEARL-1: KB301 Phase 1 Program Overview

- Phase 1 study (KB301-01) was conducted in 3 parts:

Safety (Cohort 1/1a)

Objectives

- Establish preliminary safety
- Evaluate for *COL3A1* transgene expression

Design

- Open-label treatment of buttocks
- Skin biopsies

Efficacy (Cohort 2)

Objectives

- Demonstrate preliminary efficacy
- Dose exploration
- Evaluate scales

Design

- Double-blind, placebo-controlled, randomized, split-face design
- Different doses explored in upper cheek, lower cheek, neck, and above knees

Durability (Cohort 2E)

Objectives

- Assess durability in subjects previously treated with high dose in lower cheeks
- Correct unevenness in lower cheeks that previously received placebo

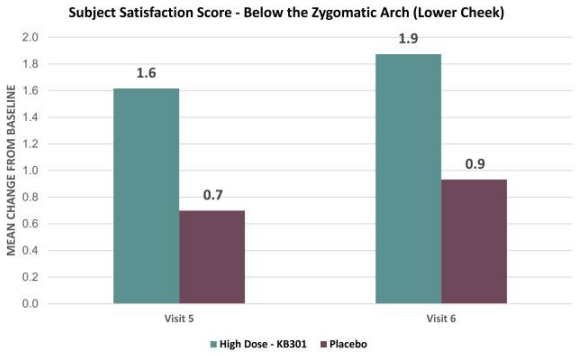
Design

- Open-label extension with observation of previously treated lower cheeks
- Treatment of lower cheeks that previously received placebo

PEARL-1: Cohort 2 Efficacy Results

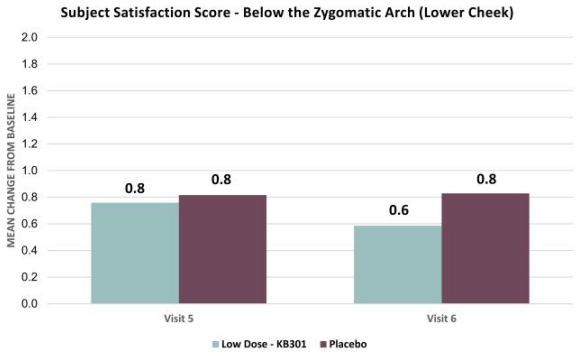
Difference in Mean Change from Baseline between High Dose KB301 and Placebo is Clinically Meaningful

High Dose



N for High Dose = 19 for KB301| N = 9 for Matching Placebo*

Low Dose



N for Low Dose = 12 for KB301| N = 6 for Matching Placebo*

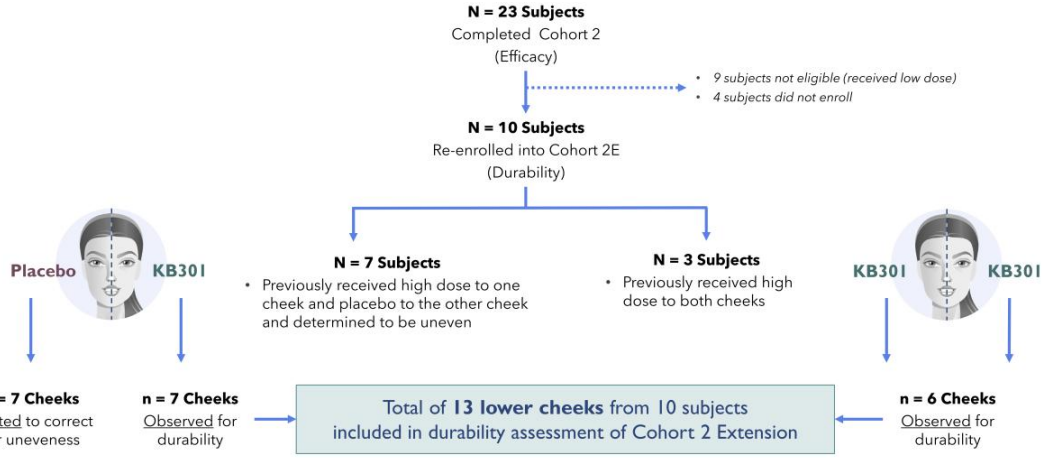
Results previously presented by Jeune in March 2022

JEUNE

** Assessment was done on 23 subjects.*
Visit 5 and 6 correspond to 2 to 4 weeks after the last dose, depending on whether the subject received 3 or 4 doses.

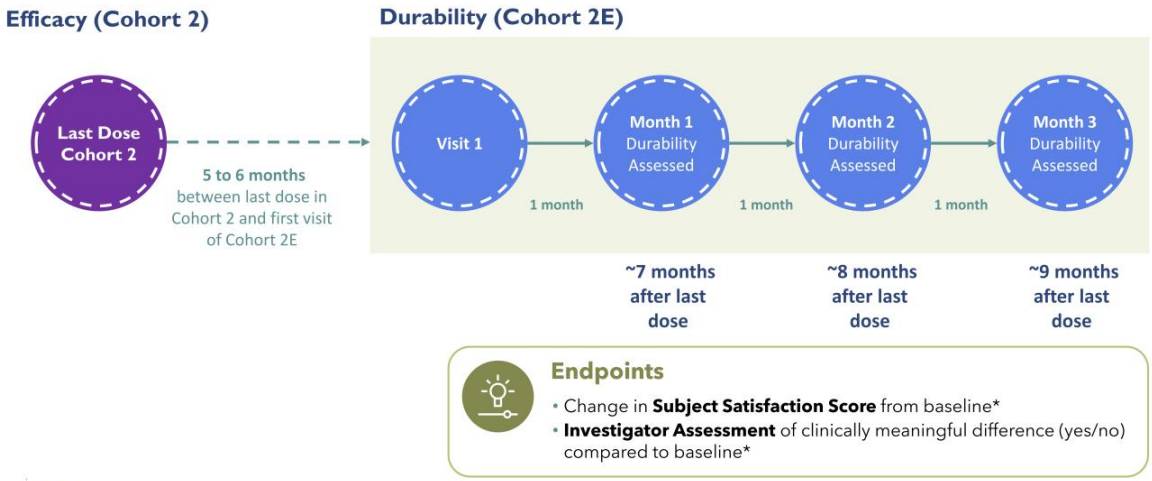
PEARL-1: Cohort 2 Extension Study for Assessment of Durability

- 10 of 23 subjects who completed the **Cohort 2 (Efficacy)** re-enrolled into **Cohort 2E (Durability)**



Assessment of Durability in Cohort 2 Extension

- Open-label extension to evaluate durability of high dose KB301 following unblinding of Cohort 2



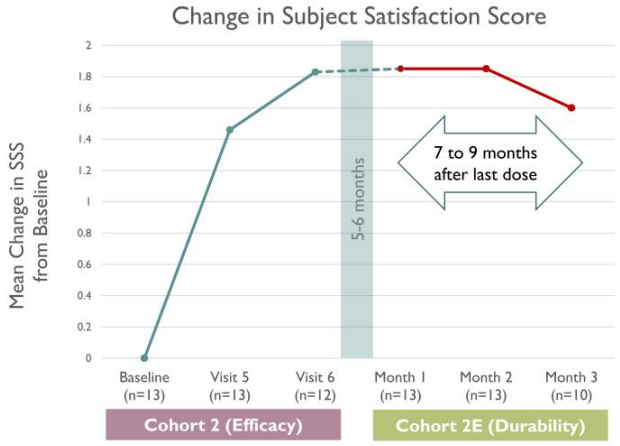
Endpoints

- Change in **Subject Satisfaction Score** from baseline*
- **Investigator Assessment** of clinically meaningful difference (yes/no) compared to baseline*

** Baseline defined as the beginning of Cohort 2 prior to any treatment with KB301*

Mean Change in Subject Satisfaction Scores during Cohort 2 Extension

- Subject Satisfaction Scores (SSS) collected in Cohort 2E indicate persistent treatment effect out to 9 months after the last dose of KB301

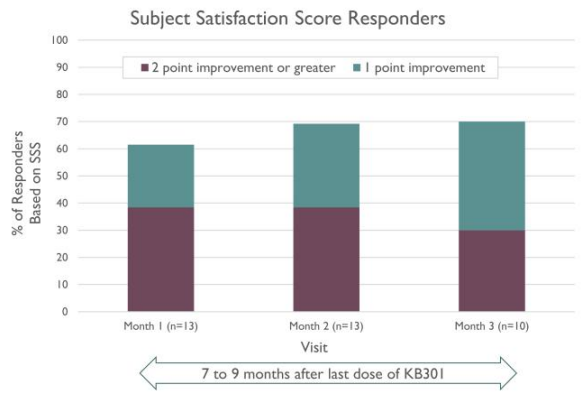


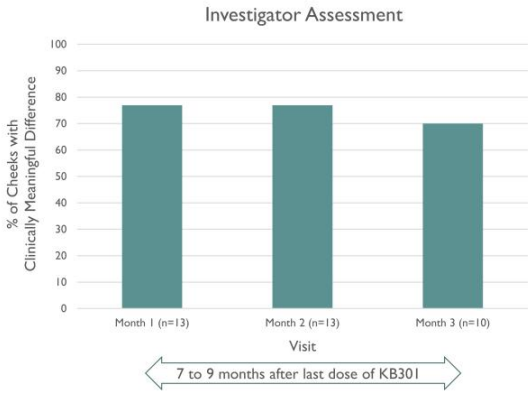
Subject Satisfaction Scores remain elevated from baseline approximately 7-9 months after the last dose in Cohort 2

Change in SSS compared to baseline (defined as the beginning of Cohort 2 prior to any treatment with KB301)
Visit 5 and 6 correspond to 2 to 4 weeks after the last dose, depending on whether the subject received 3 or 4 doses
Missing data at Visit 6 and Month 3 are due to missed study visits.

Sustained Treatment Response during Cohort 2 Extension

- Subject Satisfaction Score shows high proportion of responders up to 9 months after last dose
- Investigator Assessment shows high proportion of cheeks with a clinically meaningful difference up to 9 months after last dose

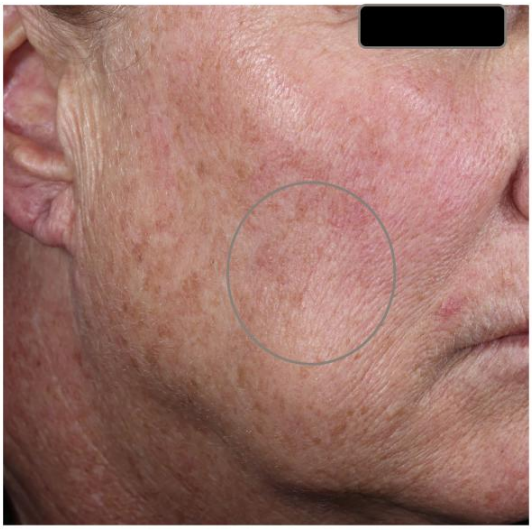




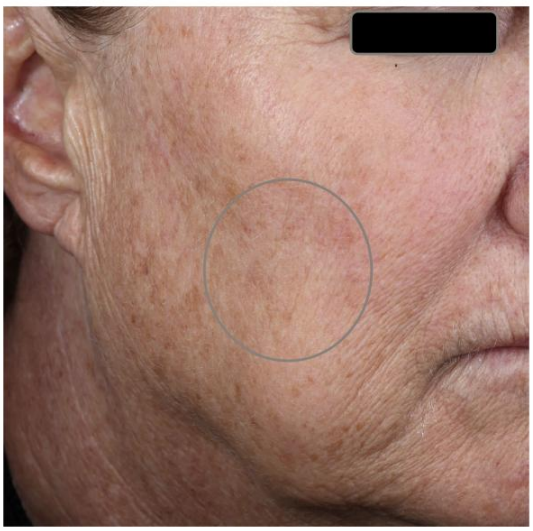
Change in SSS and Investigator Assessments compared to baseline (defined as the beginning of Cohort 2 prior to any treatment with KB301)
Missing data at Month 3 are due to missed study visits.

Lower Cheek Observation Arm: Cohort 2 Baseline and Nine Month Extension Assessment

Subject Age: 65



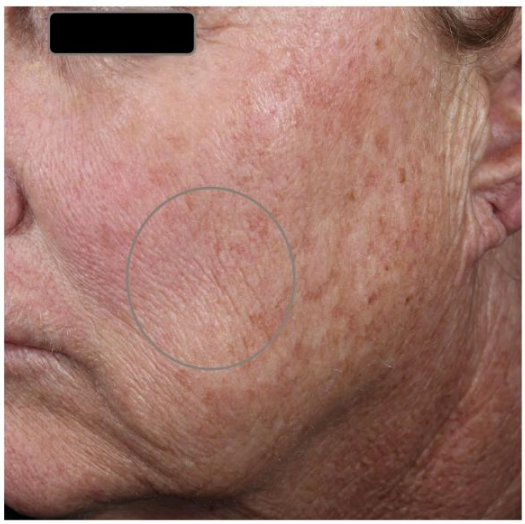
Baseline



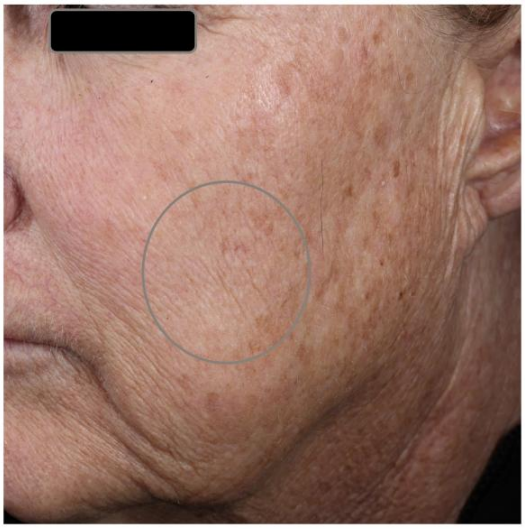
9 Months

Lower Cheek Observation Arm: Cohort 2 Baseline and Nine Month Extension Assessment

Subject Age: 65



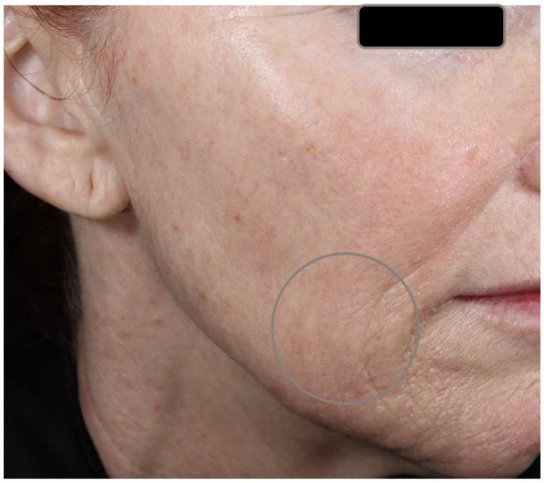
Baseline



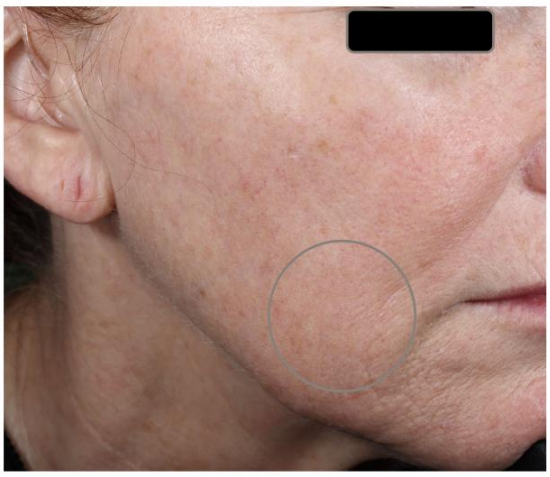
9 Months

Lower Cheek Observation Arm: Cohort 2 Baseline and Nine Month Extension Assessment

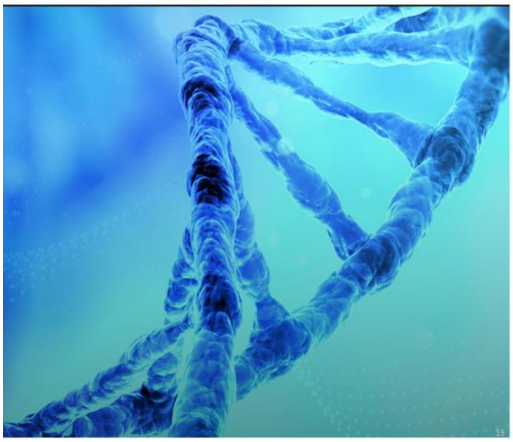
Subject Age: 61



Baseline

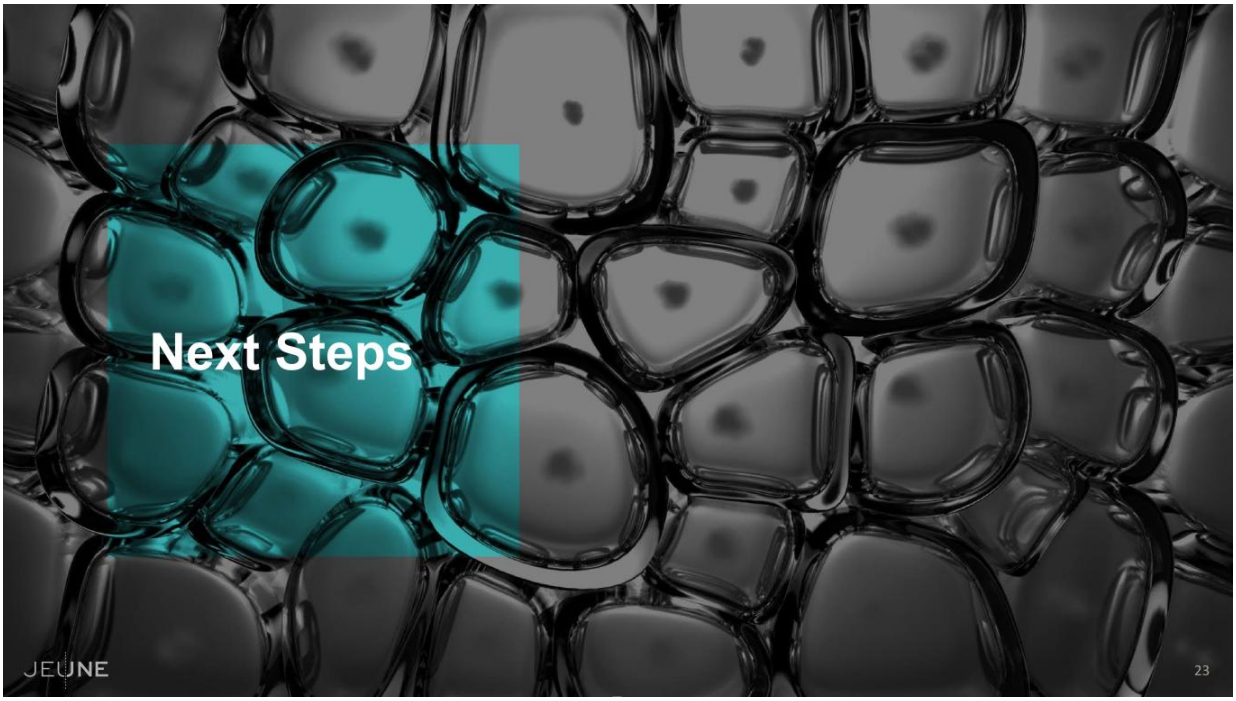


9 Months



Conclusions

- Results from open-label PEARL-1 Cohort 2 Extension demonstrate evidence of durable treatment response approximately 7, 8, and 9 months after last dose as indicated by:
  - Sustained change in Subject Satisfaction Scores compared to pre-treatment
  - Percent of responders by Subject Satisfaction Score
  - Percent of cheeks demonstrating clinically meaningful change from baseline based on Investigator Assessment


Next Steps
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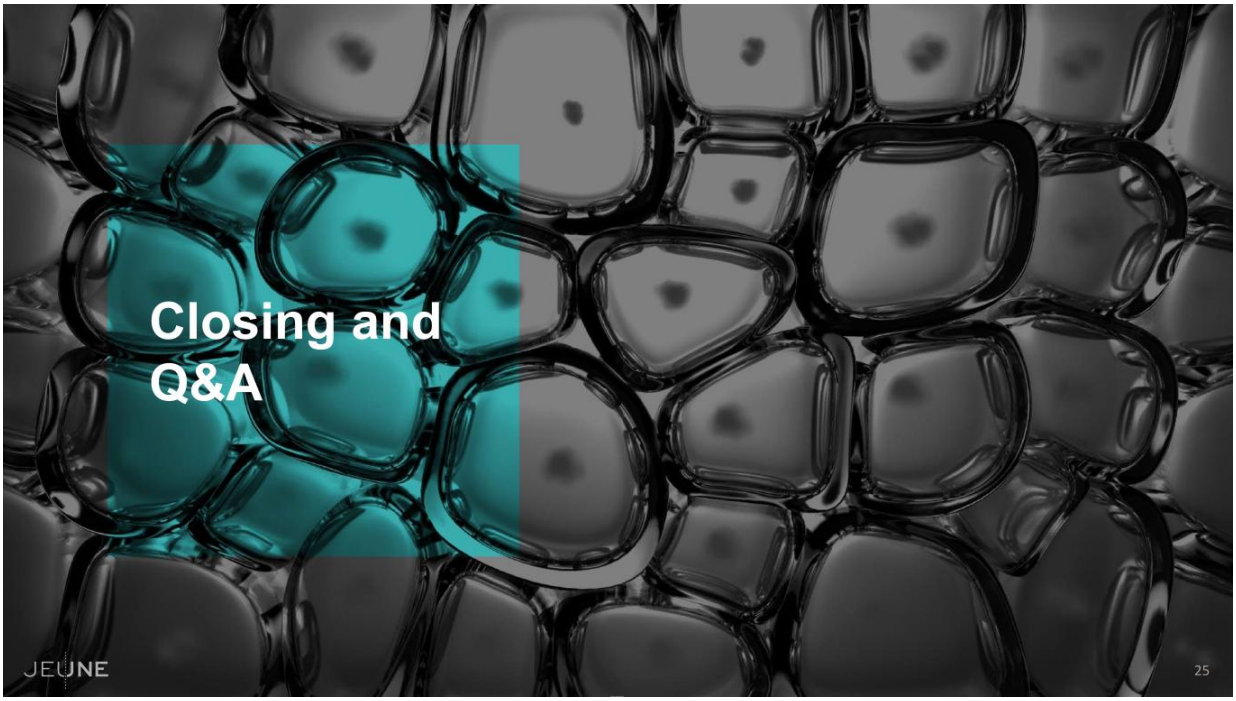
Next Steps: PEARL-2 Study

Design

- PEARL-2 study design is based on positive results from PEARL-1 Study and FDA guidance on KB301 fine lines and wrinkles scale
- Study design will be a prospective, multicenter, randomized, double-blind, placebo-controlled study to assess improvement of fine lines in target facial regions
- KB301 dose will be optimized in phase 2a cohort

Endpoints

- Safety and tolerability of KB301
- Primary efficacy endpoint will be a composite endpoint in which a subject is defined as a responder if both the subject and the investigator independently agree
- KB301 specific scale(s) for fine lines and wrinkles will be utilized as well as other subject and investigator exploratory endpoints


Closing and
Q&A
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