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): October 15, 2018

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 October 15, 2018, Krystal Biotech, Inc. (the "Company") issued a press release announcing positive interim results from its placebo-controlled Phase 1/2 clinical trial of KB103 (the "Interim Results"). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In addition, on October 15, 2018, the Company presented the Interim Results by a telephone conference. A copy of the presentation used in connection with this telephone conference is furnished herewith as Exhibit 99.2. An audio archive of the telephone conference will be made available on the Company's website.

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 (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated October 15, 2018
99.2	Presentation, dated October 15, 2018

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: October 15, 2018

KRYSTAL BIOTECH, INC.

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

Krystal Biotech Announces Positive Interim Results from Placebo-Controlled Phase 1/2 Clinical Trial of KB103

KB103 is Krystal's first "off-the-shelf", topical, gene therapy candidate to treat patients suffering from Dystrophic Epidermolysis Bullosa.

Results on 2 patients met all primary efficacy (presence of functional COL7 expression, observation of NC1 and NC2 reactive anchoring fibrils and continued expression following repeat administration) and safety endpoints (no adverse events, inflammation or irritation) in topically administered KB103 wounds.

With respect to secondary endpoints – topically administered KB103 wounds closed in 2 weeks and continue to stay closed to date. Topically administered placebo administered wounds took 10 weeks to close in patient 1 and did not completely close throughout the study in patient 2.

KB103 when administered intradermally to intact skin shows presence functional COL7 expression and anchoring fibrils in both patients.

The Phase 1/2 study is anticipated to be complete in 1H 2019 and a pivotal Phase 3 study is anticipated to commence in 2H 2019.

Management and the Principal Investigator to host a webcast at 8:45 AM EST – webcast/conference call details below.

PITTSBURGH, October 15, 2018 — Krystal Biotech, Inc. (Nasdaq:KRYS), a gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from dermatological diseases, today announced positive interim results from its ongoing placebo-controlled Phase 1/2 clinical trial of KB103.

GEM Study Status update

Two adult Recessive Dystrophic Epidermolysis Bullosa ("RDEB"), NC1[+] patients aged 35 and 28 years old have completed treatment with topical KB103 to date. The patients were re-dosed during the study. In each patient, two wounds with an approximate surface area of 10 cm^2 were randomized to receive either topical KB103 or placebo (for a total of 4 wounds evaluated). KB103 was also injected intradermally in both patients to intact skin to evaluate the mechanism of action of KB103 and validate molecular correction. Both KB103-treated wounds and intradermally injected intact skin were biopsied to assess functional COL7 expression and anchoring fibril formation. KB103-treated wounds were also evaluated for clinically relevant healing compared to placebo-treated wounds and to baseline. They were also monitored for general and recombinant viral infection and autoimmune response at each evaluation.

"Results on 2 patients demonstrate a meaningful clinical benefit and suggest that KB103 can afford a simple, convenient, painless way to administer treatment for patients suffering with this debilitating disease," said Dr. Peter Marinkovich, MD, Associate Professor of Dermatology, Stanford University and Principal Investigator in the GEM study. "These early data are encouraging and we look forward to continuing the study in pediatric populations."

Interim Data Update

Results on 2 patients met all primary efficacy (presence of functional COL7 expression, observation of NC1 and NC2 reactive anchoring fibrils and continued expression following repeat administration) and safety endpoints (no adverse events, inflammation or irritation) in topically administered KB103 wounds.

1. Analysis of KB103-treated wounds demonstrates clearly detectable robust functional COL7 expression by immunofluorescence (IF) in the biopsy samples from the two treated patients as early as Day 2 of treatment. Functional COL7 was determined by staining the tissue samples with NP185 and LH24 antibodies that bind to NC1 and NC2 domains of the COL7 protein respectively. Both of the patients were NC1 positive at baseline. The tissues from the skin biopsies show the presence of both the NC1 and NC2 domains demonstrating production of functional COL7 that has linearly deposited along the Basement Membrane Zone (BMZ).
2. NC1 and NC2 reactive anchoring fibrils were observed by immunoelectron microscopy (IEM) as early as Day 14 and up to the last biopsy for both patients.
3. *Safety data from both patients show that KB103 was well tolerated. No serious adverse events, and no product-related adverse events* were reported. No inflammation or irritation was observed at KB103-treated wounds. In addition, no antibody response was noted for type VII collagen (COL7)
4. Repeat administration of KB103 in both patients demonstrated continued expression of COL7 expression with no immune or safety concerns.

With respect to secondary endpoints – topically administered KB103 wounds closed in 2 weeks and continue to stay closed to date. Topically administered placebo wounds took 10 weeks to close in patient 1 and did not completely close throughout the study in patient 2.

5. In Patient 1, the wounds administered with KB103 closed in 2 weeks while wounds administered with placebo closed in 10 weeks. In Patient 2, the wounds administered with KB103 closed in 2 weeks also - demonstrating a faster rate of wound closure on KB103-administered wounds to date compared to placebo. Patient 2's placebo-administered wound did not fully close throughout the study.
6. To date, both of the patient's KB103-treated wounds remain closed, representing 4.5 months of total closure for Patient 1 and 3.5 months of total closure for Patient 2. Patient 1 has chosen to discontinue bandaging on the KB103-treated wound that previously required regular bandaging.

KB103 when administered intradermally to intact skin on both patients shows presence functional COL7 expression and anchoring fibrils.

7. Analysis of KB103-treated intact skin revealed clearly detectable functional COL7 expression by immunofluorescence in biopsy samples collected from the intradermal injection sites.
8. Clinical data from two patients were submitted to the FDA. FDA acknowledges molecular correction as evidenced by expression of COL7 and anchoring fibrils. Consequently, the protocol has been amended to remove the intradermal arm for patients in the Phase 1/2 trial going forward.
9. Per discussion with the FDA, the amended protocol will now enroll pediatric patients and will focus on evaluating durability of wound closure in preparation for selecting endpoints for Phase 3 clinical trial. With safety and molecular correction established, the revised Phase 1/2 protocol allows for increased dosing and KB103 administration to larger wound areas.

Conference Call

Management, along with the Principal Investigator on the Study – Dr. Peter Marinkovich, MD, Stanford University, will elaborate on the clinical data during a webcasted conference call today at 8:45 am EST. The dial-in details of the call are +1-877-524-6431 or +1-786-815-8673, conference ID: 4487935. The live webcast can be accessed at https://edge.media-server.com/m6/p/5d7wxq73

About Krystal Biotech

Krystal Biotech, Inc. (NASDAQ:KRYS) is a gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from dermatological diseases. For more information, please visit http://www.krystalbio.com.

About KB103

KB103 is Krystal's lead product candidate that seeks to use gene therapy to treat dystrophic epidermolysis bullosa, or DEB, an incurable skin blistering condition caused by a lack of collagen in the skin. KB103 is a replication-defective, non-integrating viral vector that has been engineered employing Krystal's STAR-D platform to deliver functional human COL7A1 genes directly to the patients' dividing and non-dividing skin cells. HSV-1 is Krystal's proprietary vector that can penetrate skin cells more efficiently than other viral vectors. Its high payload capacity allows it to accommodate large or multiple genes and its low immunogenicity makes it a suitable choice for direct and repeat delivery to the skin.

About Dystrophic Epidermolysis Bullosa

Dystrophic epidermolysis bullosa, or DEB, is an incurable, often fatal skin blistering condition caused by a lack of collagen protein in the skin. It is caused by mutations in the gene coding for type VII collagen, or COL7, a major component of anchoring fibrils, which connect the epidermis to the underlying dermis, and provide structural adhesion between these skin layers in a normal individual. The lack of COL7 in DEB patients causes blisters to occur in the dermis as a result of separation from the epidermis. This makes the skin incredibly fragile, leading to blistering or skin loss at the slightest friction or knock. It is progressive and incredibly painful.

The most severe form of DEB is recessive DEB, or RDEB, which is caused by null mutations in the COL7A1 gene. DEB also occurs in the form of dominant DEB, or DDEB, which is considered to be a milder form of DEB. There are no known treatments affecting the underlying cause of either form of the disease, and the current standard of care for DEB patients is limited to palliative treatments. Krystal is developing KB103 for the treatment of the broad DEB population, including both recessive and dominant forms of the disease.

Forward-Looking Statements

This press release on announcing positive interim data from Krystal's phase 1/2 trial evaluating KB103 in patients suffering from Dystrophic epidermolysis bullosa, or DEB, contains "forward-looking statements" regarding matters that are not historical facts, including statements relating to the Company's clinical trials, including plans to commence a pivotal Phase 3 study in 2H 2019. There can be no assurance that the data contained in these results will be replicated in additional current and future patients enrolled in this or any future trial or that these results will prove clinically meaningful in the development of KB103 as a potential drug. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "anticipates," "plans," "expects," "intends," "will," "potential," "hope" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon current expectations of the Company and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release relating to the Company may be found in the Company's periodic filings with the Securities and Exchange Commission, including the factors described in the section entitled "Risk Factors" in its annual report on Form 10-K for the fiscal year ended December 31, 2017, and supplemented from time to time and the Company's Quarter Reports on Form 10-Q and other filings submitted by the Company to the SEC, copies of which may be obtained from the SEC's website at www.sec.gov. The parties do not undertake any obligation to update forward-looking statements contained in this press release.

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Source: Krystal Biotech, Inc.

Exhibit 99.2

Krystal

Gene Therapy for **Dermatological Diseases**

KB103: Gem Study
Interim Phase 1/2 Clinical Update
October 15, 2018

Forward-Looking Statements

This webcast and the slides accompanying it regarding positive interim data from Krystal's phase 1/2 trial evaluating KB103 in patients suffering from Dystrophic epidermolysis bullosa, or DEB, contains "forward-looking statements" regarding matters that are not historical facts, including statements relating to the Company's clinical trials, including plans to commence a pivotal Phase 3 study in 2H 2019. There can be no assurance that the data contained in these results will be replicated in additional current and future patients enrolled in this or any future trial or that these results will prove clinically meaningful in the development of KB103 as a potential drug. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "anticipates," "plans," "expects," "intends," "will," "potential," "hope" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon current expectations of the Company and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in the webcast and slides relating to the Company may be found in the Company's periodic filings with the Securities and Exchange Commission, including the factors described in the section entitled "Risk Factors" in its annual report on Form 10-K for the fiscal year ended December 31, 2017, and supplemented from time to time and the Company's Quarter Reports on Form 10-Q and other filings submitted by the Company to the SEC, copies of which may be obtained from the SEC's website at www.sec.gov. The parties do not undertake any obligation to update forward-looking statements contained in this webcast and slides.

KB103 Phase I/II Interim Clinical Update

Dystrophic Epidermolysis Bullosa (DEB)

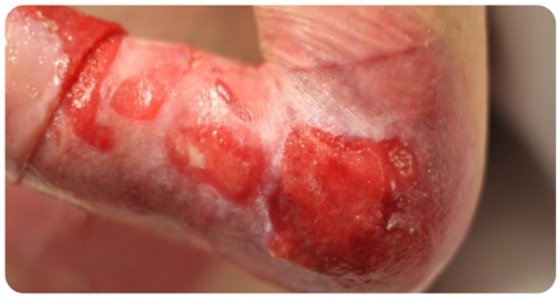
"Butterfly Children" is used to describe young DEB patients because their skin is as fragile as a butterfly's wings

Dystrophic Epidermolysis Bullosa

A rare, genetic connective tissue disease that causes skin to tear or blister from minor contact

Caused by a mutation in the COL7A1 gene that codes for the COL7 protein

Without COL7 the epidermis does not anchor to the dermis



Epidemiology

Prevalence: Up to 125,000 people are affected by DEB worldwide[1]

Incidence: The incidence of DEB is 6.5 per million births in the US[2]

Current Standard of Care

There are no approved treatments for DEB

Existing therapies limited to expensive and time-consuming palliative treatments

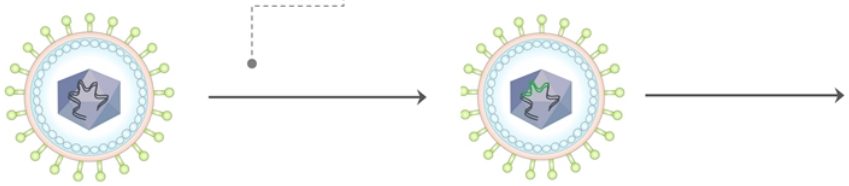
Palliative treatments cost $200k – $400k annually[3,4]

1. DEBRA International, http://www.debra-international.org/epidermolysis-bullosa/causes-and-subtypes.html; http://www.debra-international.org/what-is-eb/causes-and-subtypes/deb.html
2. Pfendner EG, Lucky AW. Dystrophic Epidermolysis Bullosa. 2006 Aug 21 [Updated 2015 Feb 26]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet].
3. Rashidghamat E., Mellerio J.E., Management of chronic wounds in patients with dystrophic epidermolysis bullosa: challenges and solutions, Chronic Wound Care Management and Research Volume 2017:4, 45-54
4. GENEGRAFT Report Summary. (2015, February 16). Retrieved December 13, 2016, from http://cordis.europa.eu/result/rcn/156078_en.html

Krystal's Approach

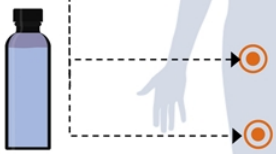
"Off-the-shelf", repeat-administration therapy

Specific modifications using our proprietary STAR-D platform to modify wild type HSV-1 into a suitable vector to introduce genes and effectors to treat skin disease



Wild type HSV-1 virus

Modified non-replicating/ non integrating virus with gene(s) and effectors of interest inserted



Topical gel or Intradermal formulation

Phase 1/2 Trial Design

A Phase I/II Study of KB103, a Non-Integrating, Replication-Incompetent HSV Vector Expressing the Human Collagen VII Protein, for the Treatment of Dystrophic Epidermolysis Bullosa (DEB)

- Key objectives: Demonstrate efficacy and safety of KB103
- Primary Objectives: Expression of COL7, presence of anchoring fibrils, and safety
- Secondary Objectives: Change in wound area, duration of wound closure, time to wound closure
- Principal investigator: Dr. Peter Marinkovich, MD, Dermatologist, Stanford University
- Trial Design:
  - Randomized, open-label, placebo controlled
  - 2 wounds treated topically: 1 placebo, 1 active
  - 1 intact site treated intradermally
  - Patients were evaluated for COL7 expression by immunofluorescence and for the presence of anchoring fibrils by electron microscopy
  - Initial dosing at Day 0 and a repeat dose a month later. Patient 2 was additionally dosed on Day 14 and Day 42 by PI to understand impact of incremental dose escalation.

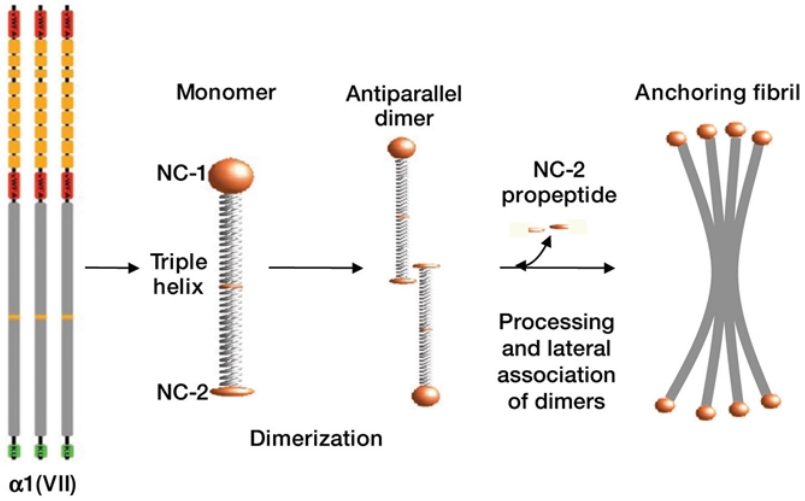
Patient Characteristics

Two patients have completed the study per Phase 1/2 protocol

Characteristic	Patient 01	Patient 02
Age, y	35	28
Sex	Male	Male
Clinical and genetic diagnosis	Recessive DEB	Recessive DEB
Type VII collagen expression		
By immunofluorescence of skin biopsy	Trace NC1 detected NC2 undetected	Trace NC1 detected NC2 undetected
By Western blot	Positive for NC1	Positive for NC1
Electron microscopy of skin biopsy	No mature anchoring fibrils; sublamina densa split	No mature anchoring fibrils; sublamina densa split
Circulating autoantibodies	Negative	Negative

KB103 Pharmacology

Detection of both NC1 and NC2 domains confirms expression of full length COL7



Molecular Therapy 2009 17, 6-7DOI: (10.1038/mt.2008.262)

KB103 Safety Update in Wounds with Topical Application

Summary

KB103 continues to be well tolerated to date following first and repeat dose

- No treatment-related adverse events (serious or otherwise) were reported.
- No immune response or blistering observed around the sites of administration following first and repeat dose.
- Blood and urine samples collected throughout the study revealed:
  - No systemic viral shedding
  - No adverse events associated with routine labs (chemistry and hematology)
  - No antibodies to COL7 were detected

KB103 Efficacy Update in Wounds with Topical Application

Summary

- Results to date on 2 patients met all primary efficacy (presence of functional COL7 expression as early as Day 2 of treatment, observation of NC1 and NC2 reactive anchoring fibrils and continued expression following repeat administration) and safety endpoints (no adverse events, inflammation or irritation) in topically administered KB103 wounds.

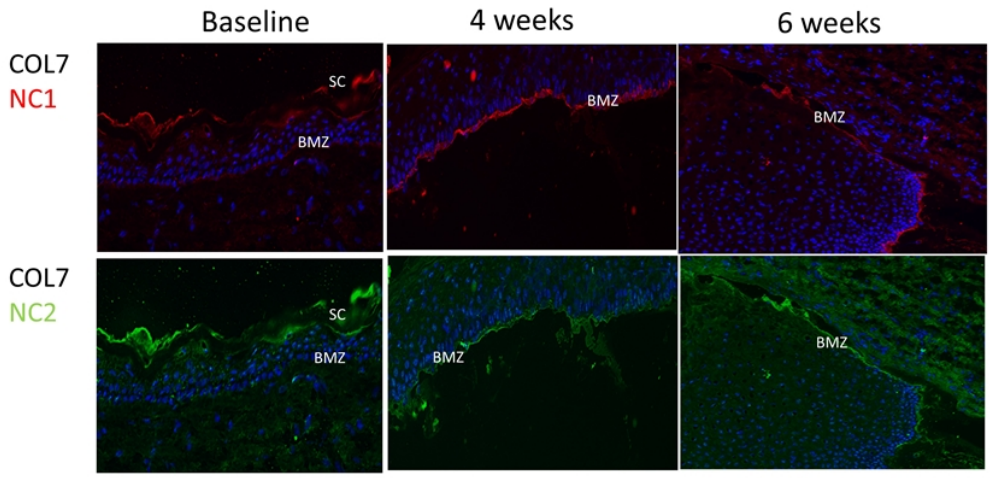
- With respect to secondary endpoints – topically administered KB103 wounds closed in 2 weeks and continue to stay closed to date. Topically administered placebo administered wounds took 10 weeks to close in patient 1 and has not completely closed to date in patient 2. Placebo treated wound in Patient 1 is beginning to get compromised.

- KB103 when administered intradermally to intact skin shows presence functional COL7 expression and anchoring fibrils in both patients.

- Empirical observation that one patient discontinued use of bandages at the site of a KB103-treated area, an area which had required bandages for several months prior to administration.

Patient 01: COL7 Immunofluorescence

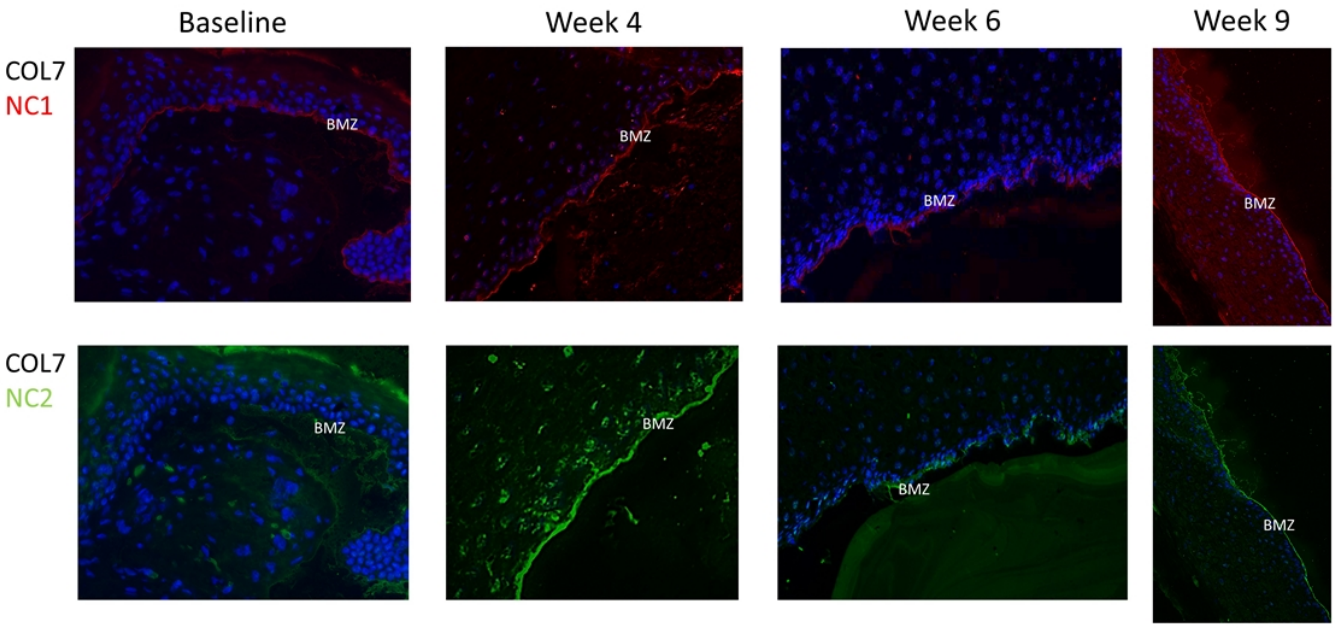
Full length COL7 (NC1 and NC2) was detected at week 4 and week 6



SC: stratum corneum; BMZ: basement membrane zone

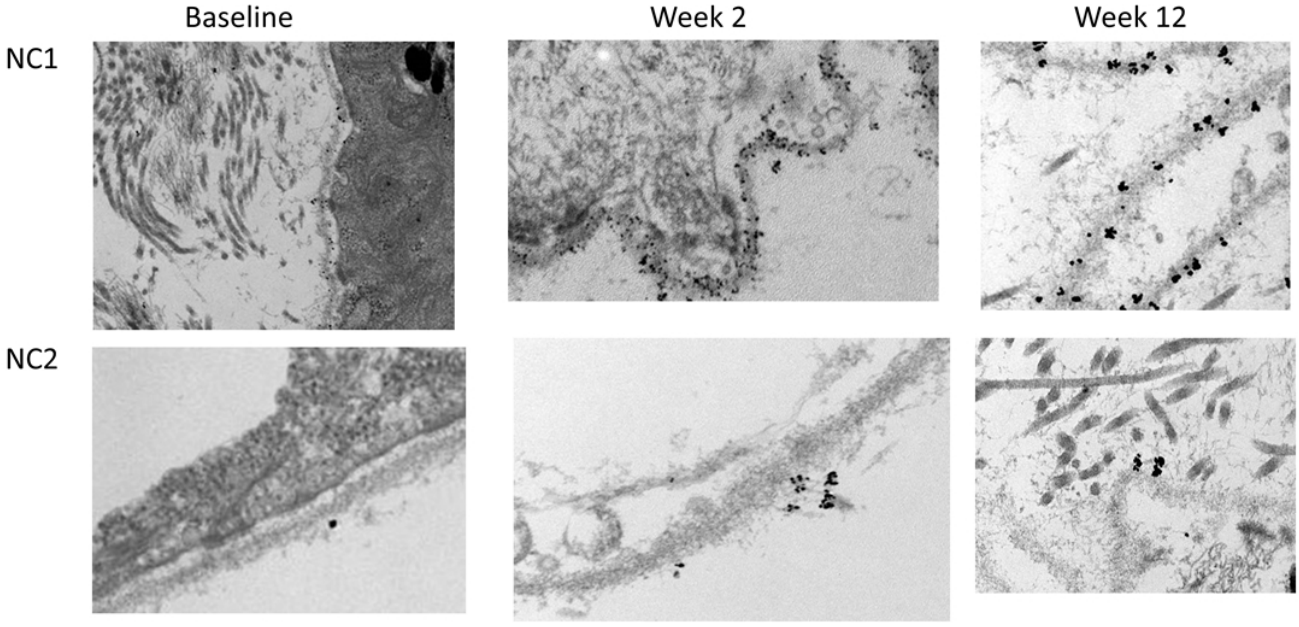
Patient 02: COL7 Immunofluorescence

Full length COL7 (NC1 and NC2) was detected at week 4 and week 6



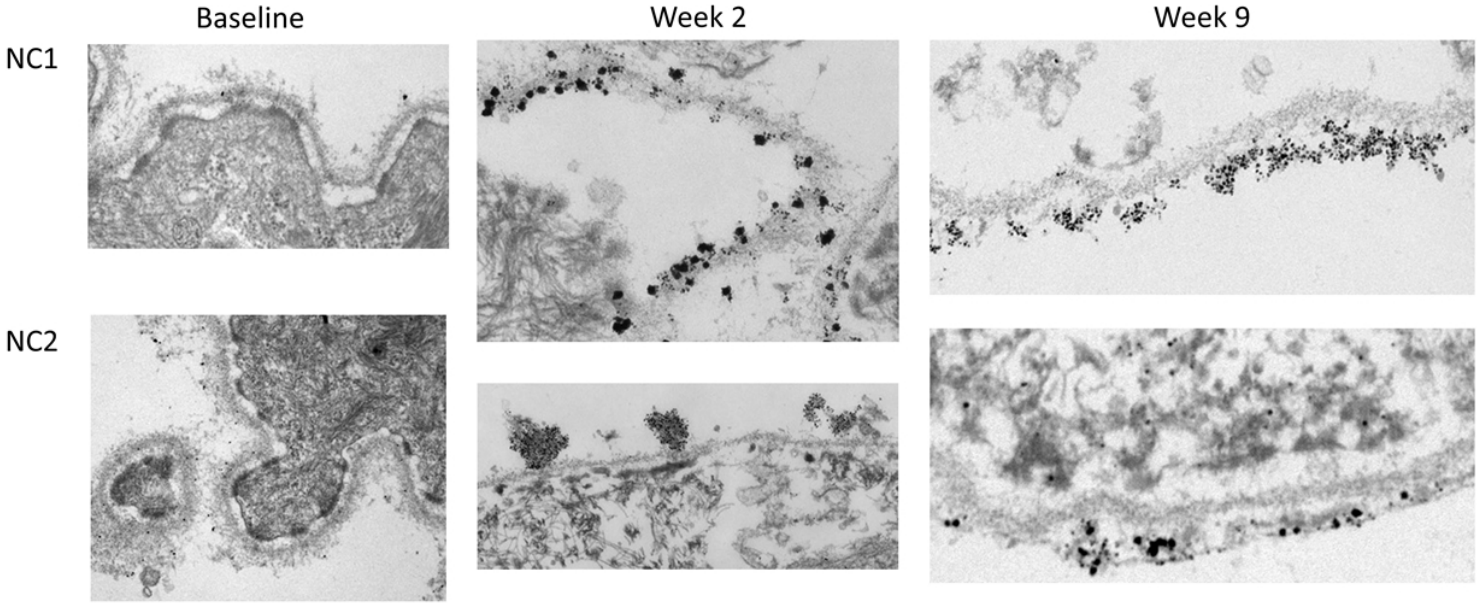
Patient 1: Anchoring Fibrils using Immunoelectron Microscopy

NC1 and NC2 reactive anchoring fibrils were detected as early as Week 2, and throughout the study



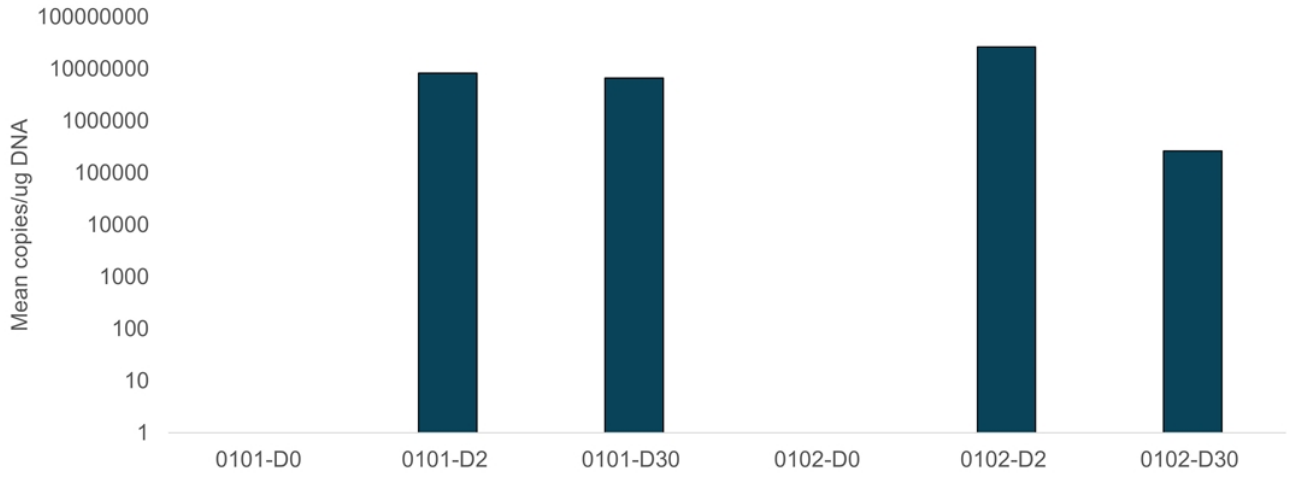
Patient 2: Anchoring Fibrils using Immunoelectron Microscopy

NC1 and NC2 reactive anchoring fibrils were detected as early as Week 2, and throughout the study



Patients 01 and 02: Vector DNA Copies by qPCR

Post-dose KB103 DNA copies



- Dosing on Days 0 and 28. Measurements at Days 2 and 30.
- The ability to re-administer KB103 was confirmed.

Wound Monitoring

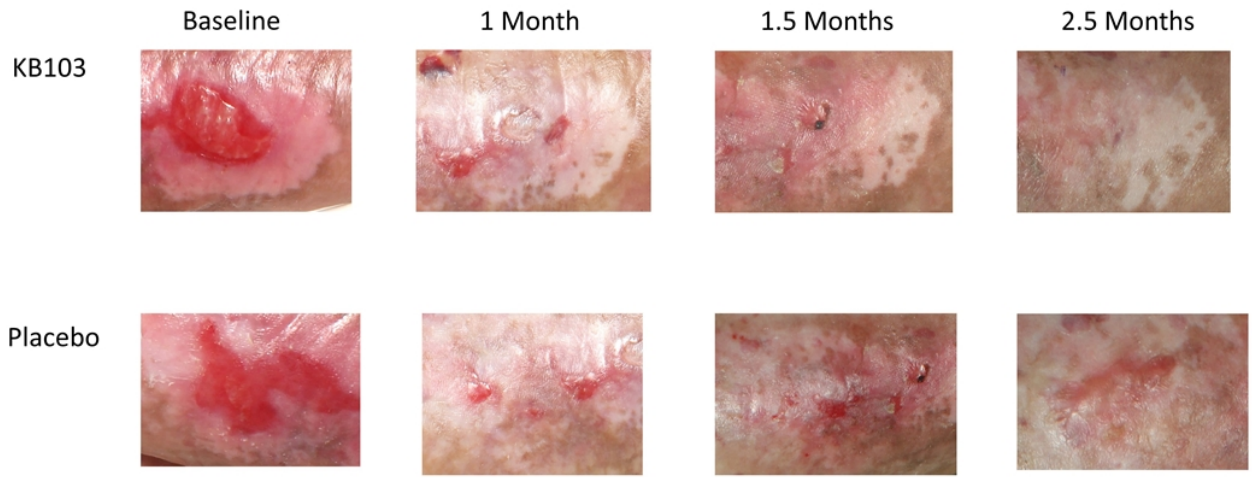
KB103-treated wounds closed by week 2 and continued to remain closed to date

Parameters	Patient 01		Patient 02	
Number of wounds treated	KB103	Placebo	KB103	Placebo[1]
	1	1	1	1
Time to complete wound closure (weeks)	2.0	10	2	-
Duration of wound closure (months)	4.5[2]	2.5	3.5[2]	-
% wound closure at 1 month	100%	85%	100%	34%

[1]Patient 02's placebo wound did not fully close throughout the study
[2]To date both wounds treated with KB103 continue to remain closed

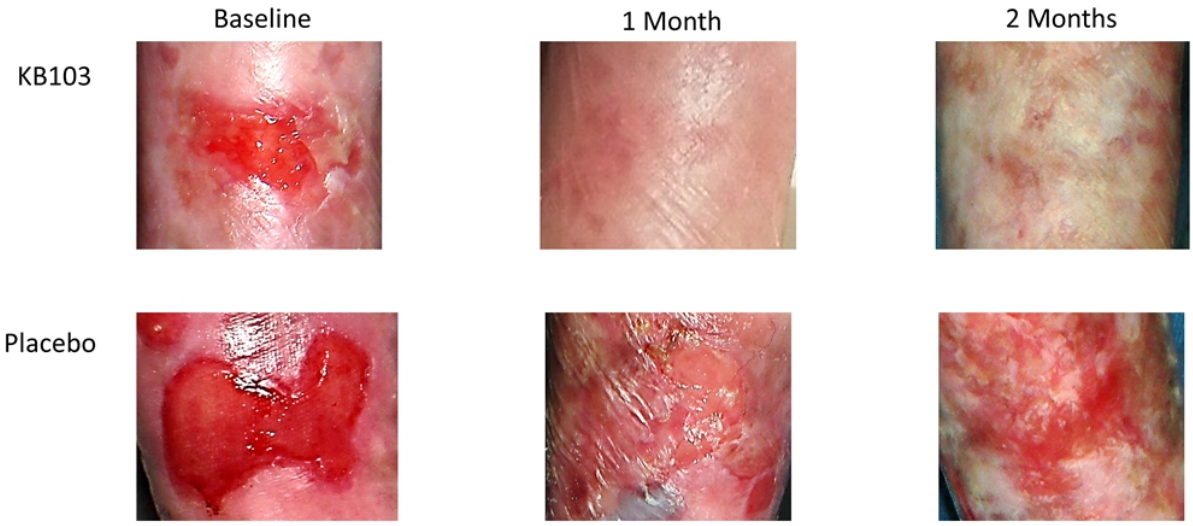
Patient 1: Wound Closure Images

Patient 1, KB103- and Placebo-Randomized Wounds



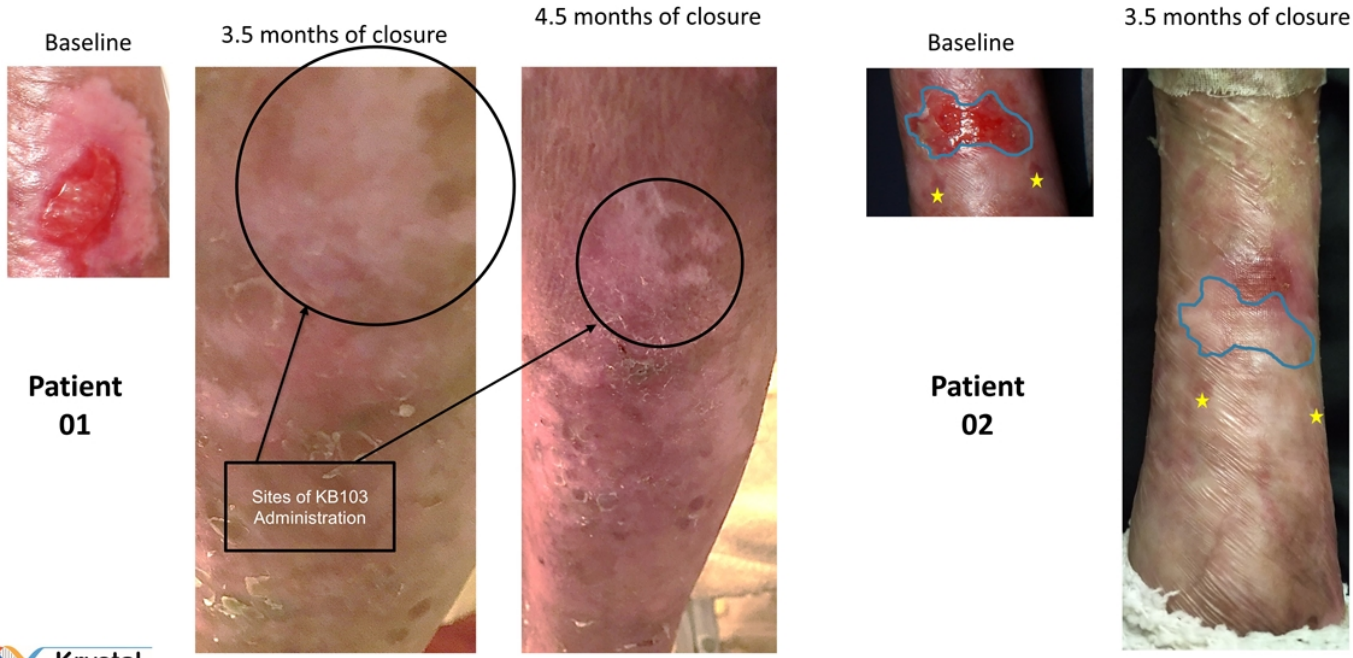
Patient 2: Wound Closure Images

Patient 2, KB103- and Placebo-Randomized Wounds



Patients 1 and 2: Long-term Wound Closure Images

Post-Study, At-Home Wound Imaging of the KB103-Administered site



KB103 Efficacy Update in Wounds with Topical Application

Summary

- Results to date on 2 patients met all primary efficacy (presence of functional COL7 expression, observation of NC1 and NC2 reactive anchoring fibrils and continued expression following repeat administration) and safety endpoints (no adverse events, inflammation or irritation) in topically administered KB103 wounds.

- With respect to secondary endpoints – topically administered KB103 wounds closed in 2 weeks and continue to stay closed to date. Topically administered placebo administered wounds took 10 weeks to close in patient 1 and has not completely closed to date in patient 2. Placebo treated wound in Patient 1 is beginning to get compromised.

- KB103 when administered intradermally to intact skin shows presence functional COL7 expression and anchoring fibrils in both patients.

- Empirical observation that one patient discontinued use of bandages at the site of a KB103-treated area, an area which had required bandages for several months prior to administration.

Next Steps in KB103 Development

- Complete Phase 1/2 trial in adults and pediatric patients by 1H 2019
  - Clinical data from two patients submitted to FDA
  - FDA acknowledges molecular correction as evidenced by expression of COL7 and anchoring fibrils
  - Amended protocol allows for:
    - Removal of the intradermal arm for patients in the ongoing Phase 1/2 trial
    - The enrollment of pediatric patients and a focus on the durability of wound closure
    - Increased dosing and KB103 administration to larger wound areas
- Initiate pivotal Phase 3 study in 2H 2019
  - The study is anticipated to be ~ 6 months in duration
  - File the BLAin US for KB103 following successful completion of Phase 3 study
  - Anticipated review time by Agency ~ 6 months based on Fast Track Designation
- GMP facility in Pittsburgh is expected to be complete by end of 2018 produce clinical materials for pivotal batch and commercialization
- Efforts underway to initiate clinical trials in Europe and Australia in 2019