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): January 20, 2021

EVELO BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38473**	**46-5594527**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

620 Memorial Drive
Cambridge, Massachusetts 02139
(Address of principal executive offices) (Zip Code)

(617) 577-0300
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	EVLO	Nasdaq Global Select Market

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 8.01. Other Events.

Evelo Biosciences, Inc. (the "Company") recently updated its business information as follows:

Updated Data from Phase 1b Trial of 1815

On January 20, 2021, the Company announced updated data following completion of the mild and moderate atopic dermatitis cohort in its Phase 1b clinical trial, which updates the interim data announced on December 9, 2020. The Company previously reported interim data in 23 evaluable patients. These new results now include patient-reported outcomes, as well as all of the physician-reported outcomes for all 24 patients in the cohort. The primary endpoint of the Phase 1b trial was safety and tolerability. EDP1815 was well tolerated in this study with no treatment-related adverse events of moderate or severe intensity, and no serious adverse events.

Treatment with EDP1815 resulted in clinically meaningful improvement in the Dermatology Life Quality Index ("DLQI") and Patient-Oriented Eczema Measure (POEM). These patient-reported outcomes capture the important impact of the disease on patients, including the domains of itch and sleep, both of which saw improvements in patients receiving EDP1815 in the study. All five measures of itch within the Pruritus-Numerical Rating Scale (Pruritus-NRS), SCORing Atopic Dermatitis ("SCORAD"), POEM, and DLQI showed greater improvements in the treated group at day 56 compared with placebo.

The full results also reinforce the positive interim data released on December 9, 2020. Additional physician- reported outcomes of Investigator's Global Assessment ("IGA") and SCORAD were consistent with the previously reported Eczema Area and Severity Index ("EASI") and IGA times Body Surface Area ("IGAxBSA") measures. Table 1 shows the treatment difference between patients receiving EDP1815 and placebo as measured by percentage change of these well-established efficacy endpoints at day 56.

Table 1

Clinical Measure	**Treatment Difference between EDP1815 and Placebo Percentage Change at Day 56***
EASI	52% (p=0.062)
IGA*BSA	65% (p=0.022)
SCORAD	55% (p=0.043)

*Least Squares Mean Percentage Change From Baseline

Although this Phase 1b study was not powered to evaluate statistical significance on efficacy measures, the data showed consistent improvements in percentage change from baseline compared to placebo for all three clinical scores: EASI, IGA*BSA, and SCORAD. In addition, 7 out of 16 (44%) patients treated with EDP1815 achieved an outcome of a 50% improvement from baseline in EASI score ("EASI50") by day 70, compared with 0% in the placebo group, showing sustained improvement in those patients responding to EDP1815. As noted in Table 1 above, at the 95% confidence interval, EASI was not statistically significant, whereas IGA*BSA and SCORAD were.

About the EDP1815 Phase 1b Clinical Trial – EDP1815-101 is a double-blind, placebo-controlled Phase 1b trial designed to evaluate the safety and tolerability of EDP1815 in healthy volunteers and patients with psoriasis or atopic dermatitis. The atopic dermatitis cohort enrolled 24 patients with mild and moderate atopic dermatitis, randomized 2:1 to receive oral administration of the enteric capsule formulation of EDP1815 or placebo once daily, for 56 days, with follow-up off treatment at day 70. Patients were not allowed to use active topical treatments and were not required to use emollients. The primary endpoint was safety and tolerability. Secondary endpoints included a range of established markers of atopic dermatitis.

Corporate Slide Presentation

On January 20, 2021, the Company hosted a corporate update conference call and live webcast. A copy of the slide presentation from the webcast is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Forward-Looking Statements

This Current Report on Form 8-K (the "Current Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements concerning the development of EDP1815, the promise and potential impact of EDP1815 and the Company's other product candidates, and the timing of and plans for future clinical trials of EDP1815.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the impact of the COVID-19 pandemic on the Company's operations, including the Company's preclinical studies and clinical trials, and the continuity of the Company's business; the Company has incurred significant losses, is not currently profitable and may never become profitable; the Company's need for additional funding; the Company's limited operating history; the Company's unproven approach to therapeutic intervention; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; the Company's reliance on third parties and collaborators to expand its microbial library, conduct its clinical trials, manufacture its product candidates, and develop and commercialize its product candidates, if approved; the Company's lack of experience in manufacturing, selling, marketing, and distributing its product candidates; failure to compete successfully against other drug companies; protection of the Company's proprietary technology and the confidentiality of its trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of its intellectual property; the Company's patents being found invalid or unenforceable; risks associated with international operations; the Company's ability to retain key personnel and to manage its growth; the potential volatility of the Company's common stock; the Company's management and principal stockholders have the ability to control or significantly influence its business; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against the Company. These and other important factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as may be updated in the Company's other filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, the Company disclaims any obligation to do so, even if subsequent events cause its views to change. 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 Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Slide Presentation, dated January 20, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

EVELO BIOSCIENCES, INC.

Date: January 20, 2021

By: /s/ Daniel S. Char
Daniel S. Char
General Counsel & Secretary

EVELO BIOSCIENCES

Complete Phase 1b Dataset: EDP1815 in Atopic Dermatitis

January 20, 2021

Legal disclaimer

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation that do not relate to matters of historical fact should be considered forward-looking statements, including statements concerning the development of EDP1815, the promise and potential impact of EDP1815 and our product candidates, the timing of and plans to initiate clinical studies of EDP1815 and our other product candidates, and the timing and results of any clinical studies or readouts. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our cash runway; our limited operating history; our unproven approach to therapeutic intervention; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; our reliance on third parties and collaborators to expand our microbial library, conduc our clinical trials, manufacture our product candidates, and develop and commercialize our product candidates, if approved; our lack of experience in manufacturing, selling, marketin and distributing our product candidates; failure to compete successfully against other drug companies; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; our patents being found invalid unenforceable; risks associated with international operations; our ability to retain key personnel and to manage our growth; the potential volatility of our common stock; our management and principal stockholders have the ability to control or significantly influence our business; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against us.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward looking statement represent management's estimates as of the date of this presentation. While we may elect to update such forward-looking statements at some point in the future, except as required law, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and we make no representation as to the adequacy, fairness, accuracy or completeness of any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

Phase 1b clinical trial design

Trial Summary

- Double-blind, placebo-controlled trial of 24 patients
- Mild and moderate atopic dermatitis*, randomized 2:1 (active : placebo)
- 56 days of oral administration of enteric capsule formulation, follow-up at day 70
- Once daily
- No active topical treatments, no requirement to use emollients

*Baseline Disease Severity

Inclusion criteria:

- IGA 2 or 3
- BSA 5-40%

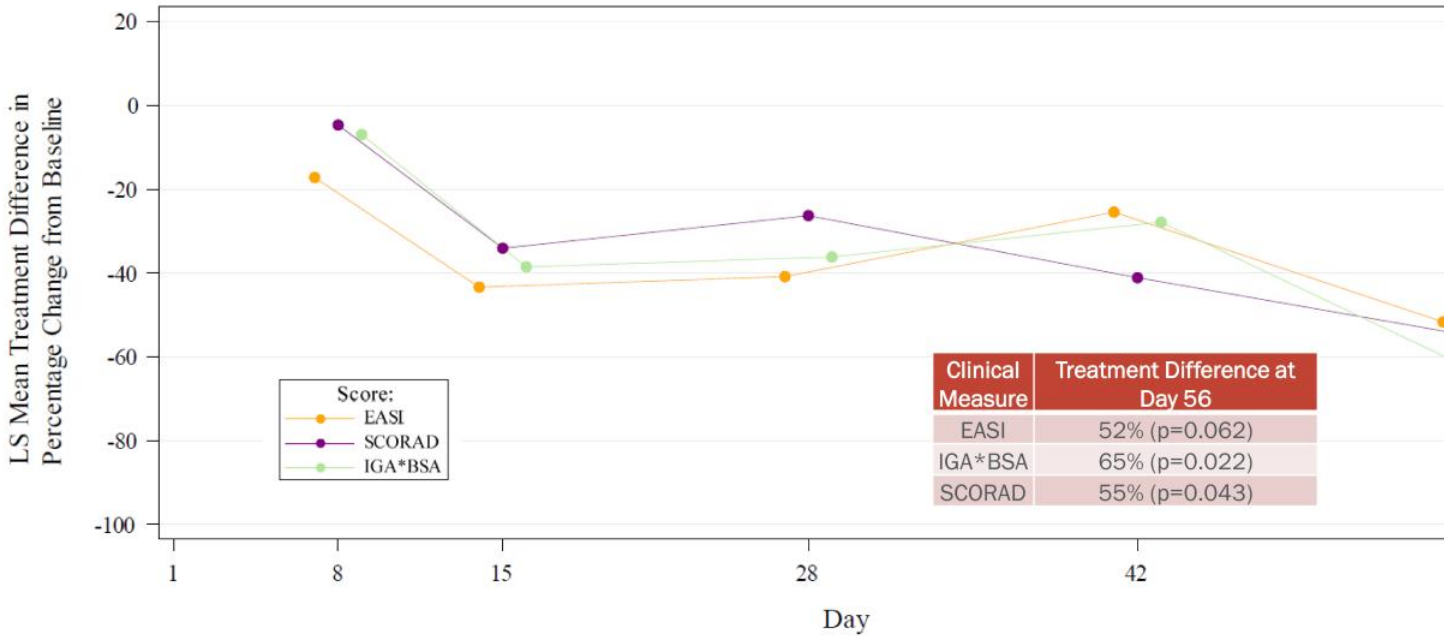
Mean baseline characteristics	EDP1815 (n=16)	Placebo (n=8)
EASI	8.31	9.31
IGA	2.63	2.75

No topical therapies required for patients for >8 weeks

- No topical steroids permitted at any point
- Topical emollients permitted to be used only if the patient was already using regularly prior to entry into trial
- Low rate of topical emollients use:
  - Placebo: 2 of 8 (25%) applied emollient regularly
  - EDP1815: 4 of 16 (25%) applied emollient regularly
- Phase 2 and 3 trials would include at least daily emollient use

EVELO

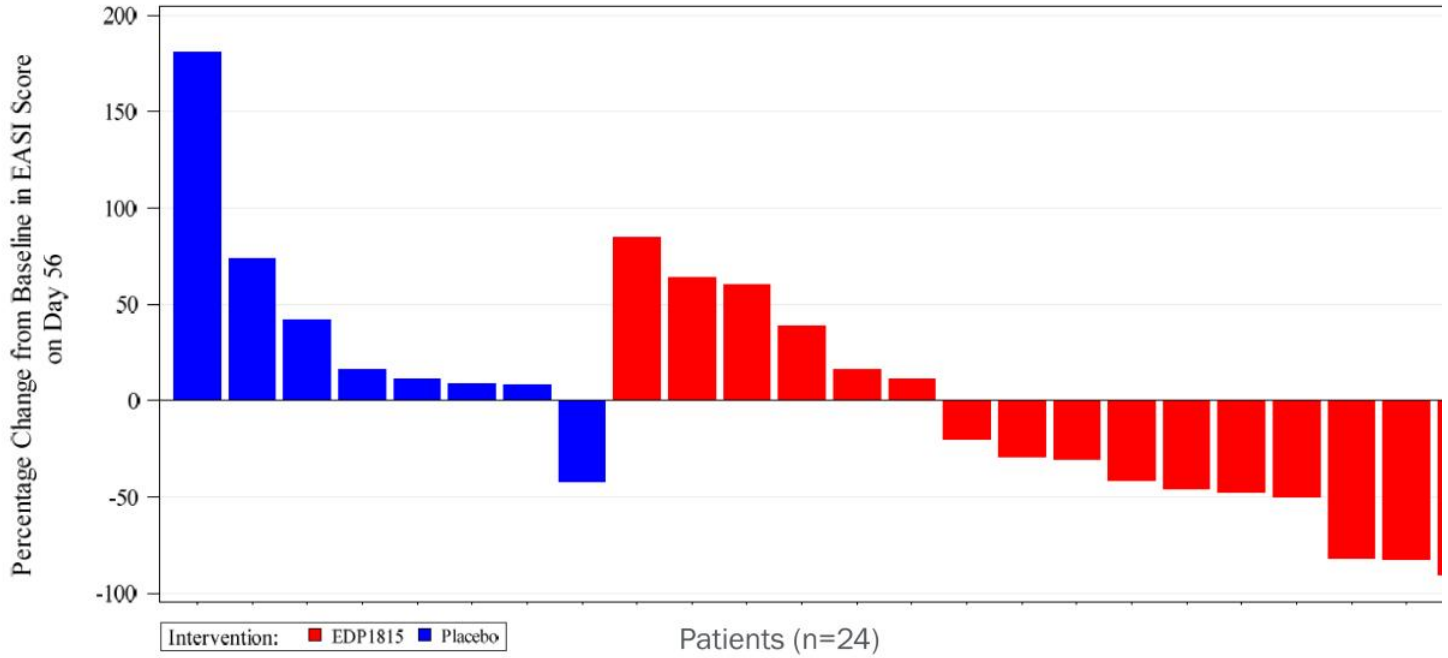
Improvements in EASI, IGA*BSA, and SCORAD at day 56



Clinical Measure	Treatment Difference at Day 56
EASI	52% (p=0.062)
IGA*BSA	65% (p=0.022)
SCORAD	55% (p=0.043)

EVELO

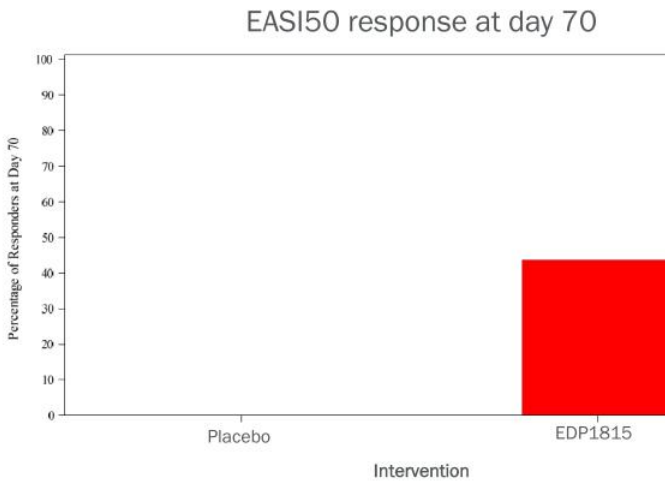
EASI: 10/16 patients on EDP1815 improved at day 56



EVELO

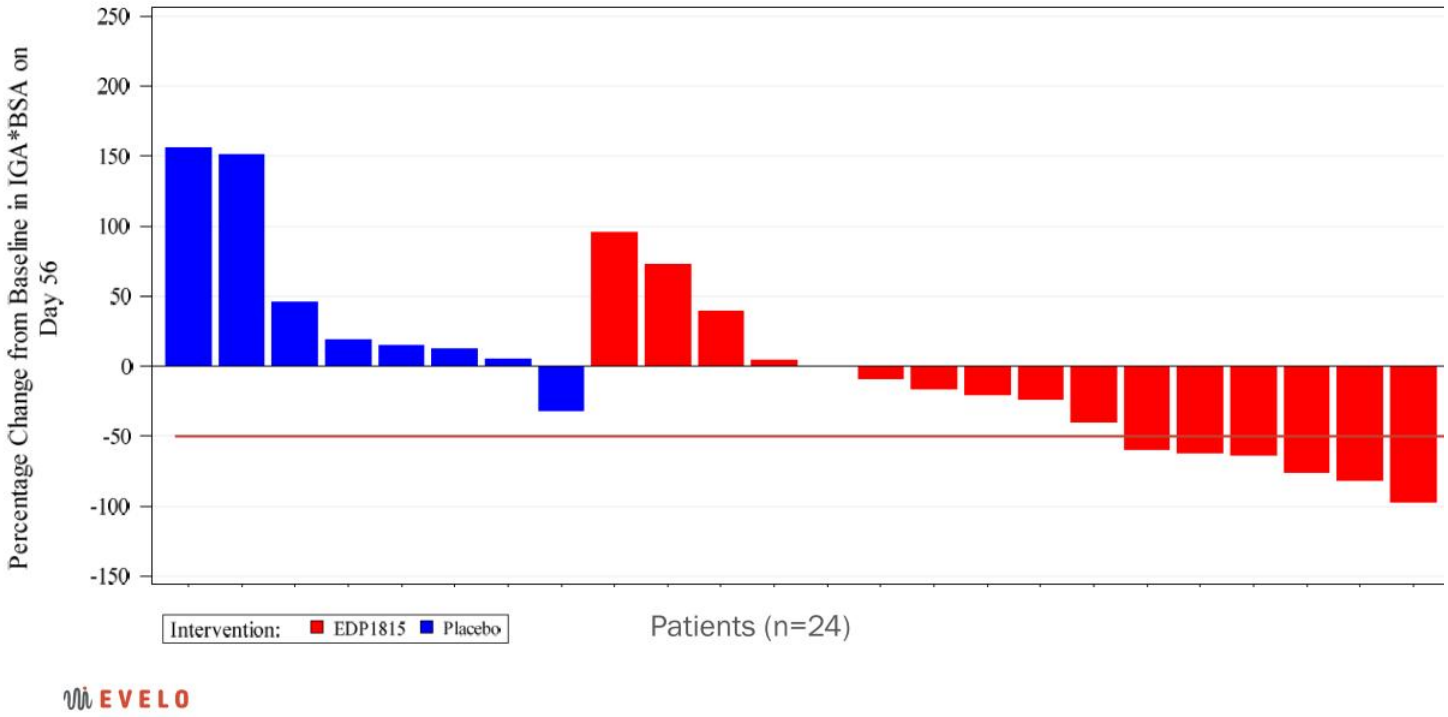
44% of EDP1815 patients achieved EASI50

Clinical Measure	Placebo	EDP1815
EASI50 day 56	0/8 (0%)	4/16 (25%)
EASI50 day 70	0/8 (0%)	**7/16 (44%)**



EVELO

IGA*BSA: 6 patients achieved a >50% improvement at day 56 with EDP1815



EVELO

Clinically meaningful improvements in Patient-Reported Outcomes a day 56, including itch and sleep

Patient-Reported Outcome	EDP1815 Mean change, day 56 (mean % change per patient)	Placebo Mean change, day 56 (mean % change per patient)
DLQI (Dermatology Life Quality Index)	–3.6* (-35%)	–0.3 (+46%)
POEM (Patient-Oriented Eczema Measure)	–4.1* (-21%)	+1.6 (+22%)

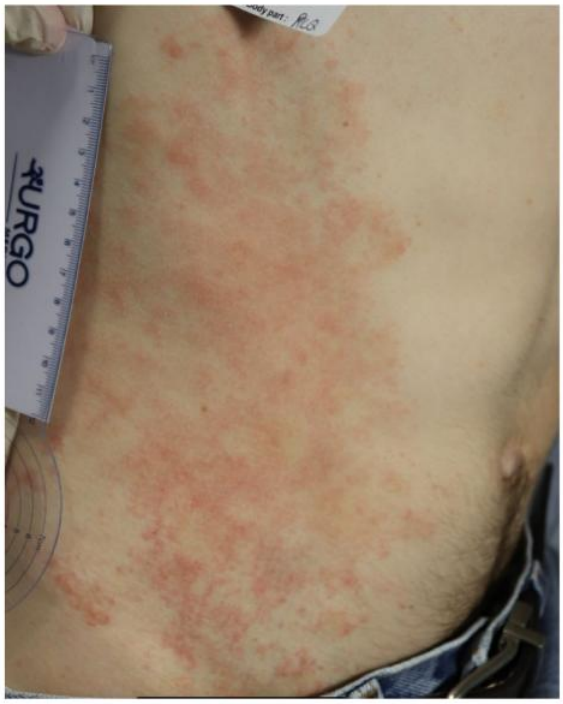
*Mean improvement exceeded the minimally clinically important difference[1,2]

- EDP1815 led to improvement in itch across all measured scores at day 56
- EDP1815 led to improvement in sleep across all measured scores at day 56

1. Basra MK, Salek MS, Camilleri L, Sturkey R, Finlay AY. Determining the minimal clinically important difference and responsiveness of the Dermatology Life Quality Index (DLQI): further data. Dermatology. 2015;2 doi: 10.1159/000365390. Epub 2015 Jan 20. PMID: 25613671.
2. Schram ME, Spuls PI, Leeflang MM, Lindeboom R, Bos JD, Schmitt J. EASI, (objective) SCORAD and POEM for atopic eczema: responsiveness and minimal clinically important difference. Allergy. 2012 Jan;67(1):9 doi: 10.1111/j.1398-9995.2011.02719.x. Epub 2011 Sep 27. PMID: 21951293.

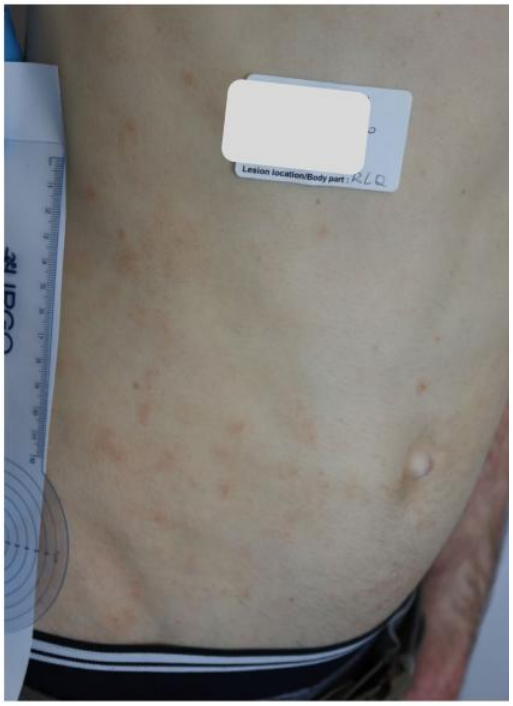
EVELO

Efficacy of oral EDP1815 in atopic dermatitis



EVELO Before, day 0

Patient on once daily oral EDP1815 and no topical treatments: before and after (patient achieved EASI50 score)



After, day 56

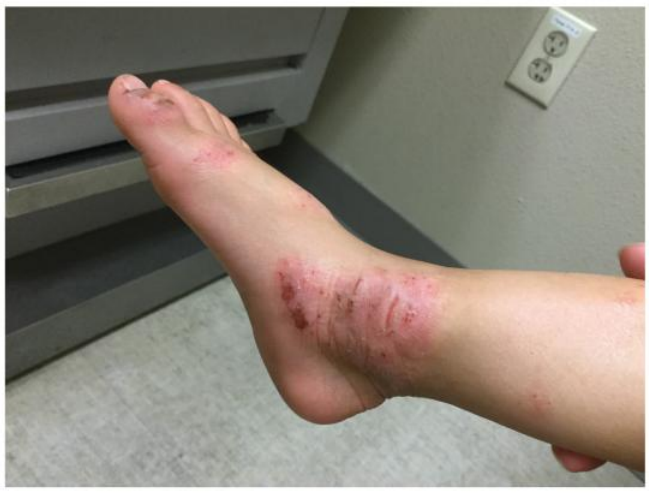
Conclusions

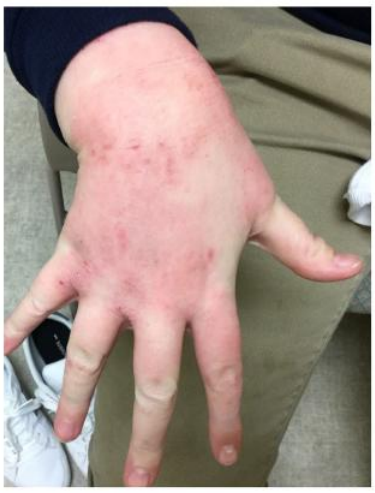
1. Consistent results observed across all atopic dermatitis measures

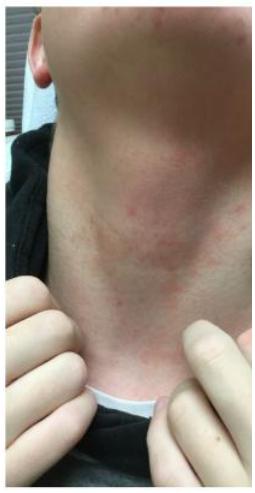
2. Progressing into Phase 2 clinical trial in atopic dermatitis

3. EDP1815 has now shown clinical activity in both psoriasis and atopic derma patients

Patient need in mild and moderate atopic dermatitis



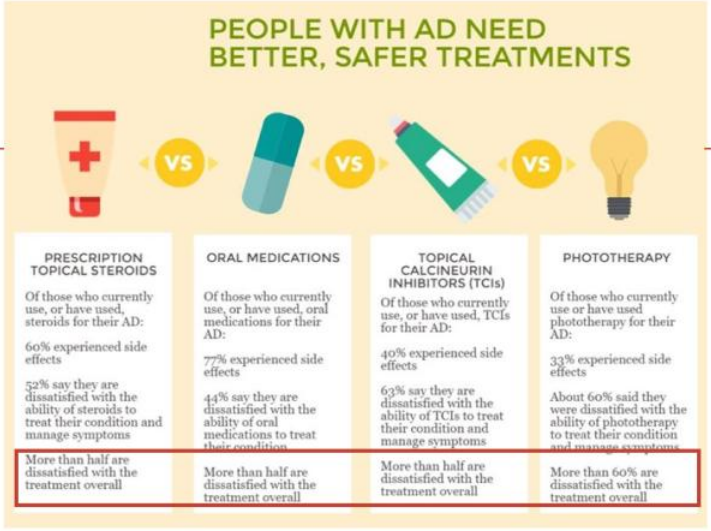




Hundreds of millions of patients worldwide live with atopic dermati most with no meaningful treatments

15-20% of children and 3-6% of adults worldwide[1] are estimated to suffer from atopic dermatiti

"1 in 3 takes one or more hours per day to treat their AD"



"Lack of safe and effective treatments"

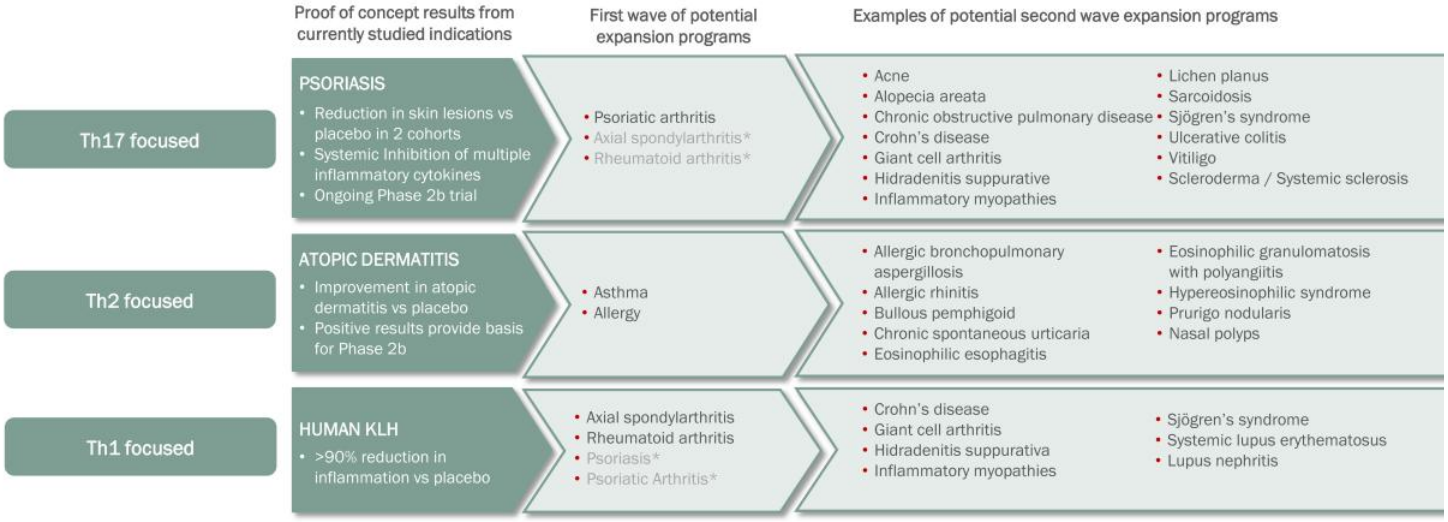
[1] Datamonitor Healthcare; DaVeiga, 2
2018; Nutten, 2015, National Eczem

1

EVELO

Atopic Dermatitis: Survey of 192 patients from the National Eczema Association, 2016
https://nationaleczema.org/in-your-words-survey-series

SINTAX medicines potentially applicable across spectrum of inflammatory diseases- plan to capture full breadth in staged manne



**Simplified and non-exhaustive view of inflammation. Many inflammatory diseases are complex and involve multiple arms of the immune system*

EVELO

Pipeline is rich in anticipated near-term clinical catalysts

Candidate	Catalyst
EDP1815 Psoriasis	**1Q 2021:** Phase 1b tablet formulation trial initiation **3Q 2021:** Phase 1b tablet formulation data **2Q 2021:** Phase 2 interim data **2H 2021:** Full Phase 2 dataset **1H 2022:** Phase 3 initiation*
EDP1815 Atopic dermatitis	**3Q 2021:** Phase 2 initiation **1Q 2022:** Phase 2 interim data **2022:** Phase 3 initiation*
EDP1815–TACTIC-E COVID-19	**2Q 2021:** Phase 2/3 interim safety data and futility analysis
EDP1815–Rutgers University COVID-19	**2Q 2021:** Phase 2 data
EDP1867 Atopic dermatitis	**1Q 2021:** Phase 1b initiation **4Q 2021:** Phase 1b data
EDP2939 Inflammation	**2022:** Phase 1b initiation
EDP1908 Oncology	**2022:** Phase 1 initiation

*Progression to Phase 3 dependent on positive Phase 2 data