Tralokinumab Real-World Patient-Reported Outcomes in Moderate-to-Severe Atopic Dermatitis Adult Patients in the United States: 6-Month Interim Analysis

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Objectives

- The objective of this 6-month interim analysis from an ongoing study (February 2022 – December 2024) was to evaluate the real-world impact of tralokinumab on Patient-Reported Outcomes (PROs) of adult atopic dermatitis patients.

Results

Treatment History

Baseline (tralokinumab initiation)

- The duration of atopic dermatitis/eczema was 16.8 years at baseline, with the dupilumab-experienced group having atopic dermatitis/eczema for longer.
- At baseline, patients reported having used an average of 3.2 medications (excluding tralokinumab) to treat their atopic dermatitis/eczema. The dupilumab-experienced group reported a greater number of medications used compared to the dupilumab-naïve group.
- There were fewer concomitant medications used at 6 months in both groups when compared to baseline.

Table 1. Treatment History at Baseline and Current Treatment at 6 Months

Baseline (tralokinumab initiation)		Total N=102		Dupilumab-experienced N=54		Dupilumab-naïve N=48	
*Duration of atopic dermatitis/eczema (years)**	Mean, Median	16.84	12.00	21.28	19.00	11.85	2.50
Number of additional medications ever taken to treat AD/eczema	Mean, Median	3.22	3.00	4.19	4.00	2.13	2.00
Number of concomitant medications currently taking to treat AD/eczema	Mean, Median	1.09	1.00	1.17	1.00	1.00	1.00
6 Months							
Number of concomitant medications currently taking to treat AD/eczema	Mean, Median	0.79	1.00	0.89	1.00	0.69	1.00

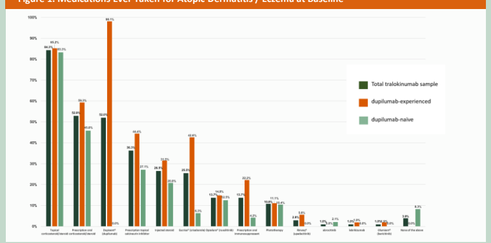
**Year of birth is approximated based on age at the time of study, so age at diagnosis is an approximation based on year of diagnosis and approximate year of birth*

Medication Ever Taken

Atopic dermatitis/eczema (baseline)

- Most patients had used a topical corticosteroid/steroid in the past (84.3%).
- Many patients had also used a prescription oral corticosteroid/steroid (52.9%).
- Some dupilumab-experienced patients were also previously on JAK inhibitors, including 5.6% previously on upadacitinib.

Figure 1. Medications Ever Taken for Atopic Dermatitis / Eczema at Baseline

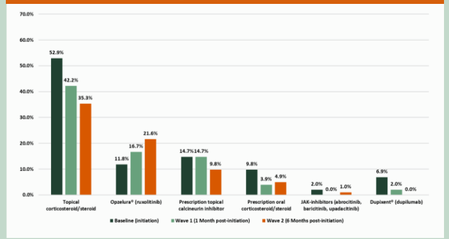


Current Concomitant Medications

Atopic dermatitis/eczema (baseline)

- At 6 months, only 35.3% of patients used a topical corticosteroid/steroid compared to 52.9% at baseline.
- There is a decrease in listed concomitant medication use at 6 months compared to baseline.

Figure 2. Medications Currently Taking for Atopic Dermatitis/Eczema



Improvement in Humanistic Burden at 6 Months

Sleep NRS and itch NRS

- Patients had an approximately 2-point improvement in mean sleep, average weekly itch, and worst weekly itch NRS (Table 2). Score improvement was greater in the dupilumab-naïve group for all three measures.
- Of the total population, 57.1% showed a median meaningful improvement in sleep NRS, 48.4% in the dupilumab-experienced group and 65.6% in the dupilumab-naïve group.
- Of the total population, 51.7% showed a median meaningful improvement in average weekly itch NRS, 44.4% in the dupilumab-experienced group and in the 59.5% of dupilumab-naïve group.
- Of the total population, 50.0% showed a median meaningful improvement in worst weekly itch NRS, 39.6% of dupilumab-experienced and 61.4% of dupilumab-naïve.

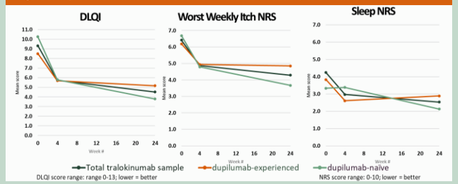
DLQI and PO-SCORAD

- Patients had an average score improvement of 4.8 points and 15.4 points for DLQI and PO-SCORAD, respectively (Table 2).
- From baseline to 6 months, 68.7% of patients had a median meaningful improvement in DLQI scores (Table 2). The dupilumab-experienced group had a lower proportion of meaningful improvement than the dupilumab naïve group.
- From baseline to 6 months, 47.4% of patients had a median meaningful improvement in PO-SCORAD scores (Table 2). The dupilumab-experienced group had a lower proportion of meaningful improvement than the dupilumab naïve group.
- All three treatment satisfaction measures showed a greater improvement in the dupilumab-naïve group compared to the dupilumab-experience group (Figure 3).
- Convenience showed little to no improvement from baseline to 6 months among dupilumab-experience patients (Table 2).

Table 2. Improvement in Humanistic Burden - Baseline (initiation) to 6 Months

	Total N=102		Dupilumab-experienced N=54		Dupilumab-naïve N=48	
	Mean	Med	Mean	Med	Mean	Med
Sleep Interference NRS [range 0-10; lower is better]						
Baseline Score	4.24	3.50	3.83	3.00	4.69	5.00
6 Month Score	2.53	2.00	2.89	2.00	2.13	1.50
Improvement from Baseline	1.71	1.00	0.94	0.50	2.56	2.00
Average Weekly Itch NRS [range 0-10; lower is better]						
Baseline Score	5.25	5.00	4.96	5.00	5.56	6.00
6 Month Score	3.22	3.00	3.63	3.00	2.75	2.50
Improvement from Baseline	2.03	2.00	1.33	2.00	2.81	3.00
Worst Weekly Itch NRS [range 0-10; lower is better]						
Baseline Score	6.42	7.00	6.19	6.50	6.69	7.00
6 Month Score	4.29	4.00	4.85	4.00	3.67	3.00
Improvement from Baseline	2.13	2.00	1.33	1.50	3.02	3.00
DLQI [range 0-30; lower is better]						
Baseline Score	9.33	8.50	8.50	8.00	10.27	9.00
6 Month Score	4.52	3.00	5.17	3.00	3.79	3.00
Improvement from Baseline	4.81	4.00	3.33	3.00	6.48	6.00
PO-SCORAD [range 0-103.6; lower is better]						
Baseline Score	41.59	40.45	40.16	37.05	43.19	46.15
6 Month Score	26.18	23.90	27.98	26.55	24.15	
Improvement from Baseline	15.41	12.20	12.18	11.00	19.04	17.60
TSQM Global Satisfaction [range 0-100; higher is better]						
Baseline Score	56.58	57.14	53.39	57.14	53.42	53.57
6 Month Score	67.65	71.43	61.51	71.43	74.55	78.57
Improvement from Baseline	11.06	7.14	2.12	7.14	21.13	21.43
TSQM Convenience [range 0-100; higher is better]						
Baseline Score	60.57	58.33	62.65	61.11	58.22	50.00
6 Month Score	64.49	61.11	60.70	61.11	68.75	72.22
Improvement from Baseline	3.92	0.00	-1.95	-5.56	10.53	21.11
TSQM Effectiveness [range 0-100; higher is better]						
Baseline Score	51.20	50.00	50.93	50.00	51.50	50.00
6 Month Score	65.80	66.67	59.98	63.89	72.34	72.22
Improvement from Baseline	14.60	13.89	9.05	11.11	20.83	22.22

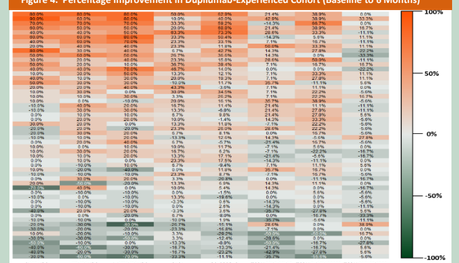
Figure 3. Improvement in Humanistic Burden - Baseline (initiation) to 6 Months



Percentage Improvement in Outcomes from Baseline to 6 Months in Dupilumab-Experienced Patients

- Figure 4 shows patients who have an improvement in one outcome tend to show improvement in additional outcomes.
- Even if there is deterioration in one outcome, there may be improvement in multiple other outcomes.
- There are few dupilumab-experienced patients who have multiple deteriorating outcomes.

Figure 4. Percentage Improvement in Dupilumab-Experienced Cohort (Baseline to 6 Months)



NOTE: Positive values indicate an improved outcome from baseline to 6 months; negative values indicate a worse outcome from baseline to 6 months.

Conclusions

- This 6-month interim analysis conducted in a real-word setting shows that patients diagnosed with moderate-severe atopic dermatitis reported improved quality of life outcomes related to sleep, itch, and treatment satisfaction when treated with tralokinumab, both when used in either dupilumab-naïve or in dupilumab-experienced patients.
- Within the dupilumab-experienced cohort, there were differences in treatment response, with many patients experiencing meaningful improvements across endpoints, while others did not see improvement
- There is a downward trend in the use of concomitant medications among moderate-severe atopic dermatitis patients treated with tralokinumab.
- In a real word setting tralokinumab presents as an effective option for patients to manage their atopic dermatitis disease, regardless of their previous experience with dupilumab.

Background

- Atopic dermatitis (AD), often referred to as eczema, is a chronic (long-lasting) disease that causes inflammation, redness, and irritation of the skin and can have an enduring negative impact on quality of life (QoL).
- Tralokinumab, an IL-13 targeted biologic approved in the United States (US) for moderate-to-severe atopic dermatitis (AD), improved patient-reported outcomes (PROs) in clinical trials and after one month of use in the real-world setting.
- In this study we assessed the changes in PROs at 6 months amongst patients that were treated with tralokinumab.

Methods

Study Design

- U.S. adult patients were recruited through the Adbry™ Advocate™ Program and eligible patients were asked to complete a series of mandatory and pulse online surveys at baseline, 2 weeks post-initiation, 1 month post-initiation, 2 months post-initiation, 3 months post-initiation, 4 months post-initiation, 5 months post-initiation, and 6 months post-initiation.
- The 6-month interim analysis includes 102 participants who have completed the mandatory surveys at baseline, 1 month and 6 months.
- The survey respondent base for this interim analysis includes patients who received their initial survey invitation and completed the baseline survey by December 17, 2022.
- Patients will continue to be followed for up to 52 weeks of treatment with tralokinumab

Endpoints

- In this study patients completed several Patient Reported Outcomes (PROs) questionnaires: Dermatology Life Quality Index (DLQI), average weekly itch numeric rating scale (NRS), worst weekly itch NRS, AD-related weekly sleep NRS, Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) index, and Treatment Satisfaction Questionnaire for Medication (TSQM-9).
- PRO results were reported as the change in score or percentage change in score from baseline to 6 months.
- A meaningful improvement among patients was represented by a 3-point reduction in the NRS[4], a 15-point reduction in PO-SCORAD[5], and a 4-point reduction in the DLQI[6].

References

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Disclosures

SB is an employee of LEO Pharma, Inc; YK was a previous employee of LEO Pharma, Inc.; DB, CR, HC are employees of Cerner Enviza, an Oracle Company and have served in a consulting or advisory role for LEO Pharma and have received research funding from Leo Pharma Inc.; PL and IS have served in a consulting or advisory role for LEO Pharma, Inc.; AL is a patient with atopic dermatitis

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Patient Characteristics

Baseline (tralokinumab initiation)

- There are 102 patients who completed baseline, one month, and 6-month surveys. Of this population, 52.9% were dupilumab-experienced.
- Most patients were female (59.8%), white (82.4%), and 85.3% reported having private insurance.
- The dupilumab-experienced group was younger and more likely to be female, compared to the dupilumab-naïve group.
- The average age at diagnosis of atopic dermatitis/eczema was 27.3 years (SD = 23.8), with the dupilumab-experienced group diagnosed at a younger age.
- The dupilumab-experienced group had more patients with anxiety, asthma, depression, and a history of conjunctivitis.

Table 3. Patient Characteristics

Baseline *(tralokinumab initiation)*		Total N=102		Dupilumab-experienced N=54		Dupilumab-naïve N=48	
Current age (years)	Mean, Median	44.23	44.50	39.89	36.50	49.10	51.50
Age at diagnosis of atopic dermatitis/ eczema (years)*	Mean, Median	27.38	22.00	18.61	10.00	37.25	24.13
Sex at birth, n (%)	Female	61	59.8%	36	66.7%	25	52.1%
	Male	41	40.2%	18	33.3%	23	47.9%
Ethnicity, n (%)	Hispanic or Latino	7	6.9%	4	7.4%	3	6.3%
Race, n (%) *[select all that apply]*	Asian or Asian American	13	12.7%	6	11.1%	7	14.6%
	Black or African American	6	5.9%	4	7.4%	2	4.2%
	White	84	82.4%	45	83.3%	39	81.3%
	Other race or origin	3	2.9%	2	3.7%	1	2.1%
	Decline to answer	4	3.9%	1	1.9%	3	6.3%
Region of residence	Northeast	21	20.6%	13	24.1%	8	16.7%
	Midwest	19	18.6%	13	24.1%	6	12.5%
	South	49	48.0%	24	44.4%	25	52.1%
	West	13	12.7%	4	7.4%	9	18.8%
Current health insurance, n (%) *[select all that apply]*	Private health insurance	87	85.3%	47	87.0%	40	83.3%
	Public health insurance	14	13.7%	4	7.4%	10	20.8%
	Other	3	2.9%	2	3.7%	1	2.1%
	Uninsured	3	2.9%	1	1.9%	2	4.2%
Diagnosed medical conditions, n (%)	Allergies	55	53.9%	30	55.6%	25	52.1%
	Anxiety	32	31.4%	20	37.0%	12	25.0%
	Asthma	30	29.4%	21	38.9%	9	18.8%
	Depression	22	21.6%	15	27.8%	7	14.6%
	History of conjunctivitis	6	5.9%	5	9.3%	1	2.1%
	None of the above	28	27.5%	10	18.5%	18	37.5%

Abbreviations

%, percentage; AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; Max, maximum; Min, minimum; n, number of patients; NRS, Numeric Rating Scale; PO-SCORAD, Patient-Oriented SCORing Atopic Dermatitis; PRO, patient-reported outcomes; TSQM-9, Treatment