# Real-World Baseline Characteristics and Early Patient-Reported Outcomes in Adult Patients with Moderate-to-Severe Atopic Dermatitis Treated with Tralokinumab

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## Introduction

- **Atopic dermatitis (AD) is characterized mainly by widespread skin lesions and itch, and is associated with a substantial disease burden and decreased quality of life[1-3]**
- **Tralokinumab-ldrm (Adbry™) was approved in the US in December 2021 for the treatment of moderate-to-severe AD in adult patients**
- **Currently, there is very little data on the real-world experience or outcomes associated with tralokinumab utilization**
- **This study will provide insights into the impact of tralokinumab on adult patients in the real world (non-clinical trial) setting**
- **Goal of this study is to have at least 250 patients complete the study from baseline to 52 weeks**

## Objective

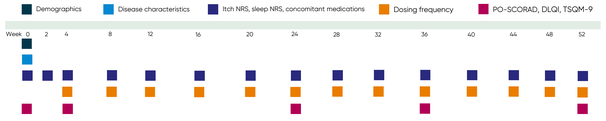
The objective of this interim analysis from this ongoing prospective study is to report the baseline characteristics and evaluate the early (4-week) real-world impact on patient-reported outcomes (PROs) of patients treated with tralokinumab for moderate-to-severe atopic dermatitis

## Materials and Methods

### *Study Design and Patient Cohort*

- Patients were asked to participate in this study through the Adbry™ Advocate™ Program (Hub) within 1 week of their tralokinumab initiation
- Full-length web-based surveys will be completed at baseline, 4 weeks, 24 weeks, 36 weeks, and 52 weeks, with shorter pulse surveys conducted in between **(Figure 1)**
- This interim analysis include patients who were evaluated via web-based surveys at baseline and after 4 weeks
- The demographic and disease characteristics are presented in this poster

**Figure 1.** Study data collection




### *Endpoints and Analyses*

- PRO endpoints included the Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) index, Dermatology Life Quality Index (DLQI), average weekly itch numeric rating scale (NRS), worst weekly itch NRS, AD-related weekly sleep NRS, 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 week 4
- DLQI and NRS items are also presented as the proportion achieving a 4-point improvement from baseline to week 4 (wave 1)
- Results are presented descriptively for the total population and by use of dupilumab at any time (at the time of completion of the baseline survey)

## Results

### *Demographics and Disease Characteristics*

- As of August 2022, 96 adult patients completed the baseline and week 4 surveys
- Patients were mainly female (59.4%) and white (82.3%) with a mean age of 44.4 (SD=15.0) years **(Table 1)**
- Their mean age at AD diagnosis was 26.8 (SD=22.0) years and most patients were diagnosed 17.6 (SD=17.8) years ago **(Table 1)**

**Table 1.** Baseline demographic and disease characteristics

| | Baseline (tralokinumab initiation) | | |
|---|---|---|---|
| | Total patients on tralokinumab (n=96) | Ever taken dupilumab (n=52) | Never taken dupilumab (n=44) |
| **Current age (years)** | | | |
| Mean (SD) | 44.40 (15.01) | 41.54 (14.89) | 47.77 (14.60) |
| Median (Min; Max) | 44.5 (18; 71) | 38.5 (18; 71) | 51.0 (20; 69) |
| **Sex at birth** n (%) | | | |
| Female | 57 (59.4) | 34 (65.4) | 23 (52.3) |
| Male | 38 (39.6) | 17 (32.7) | 21 (47.7) |
| Decline to answer | 1 (1.0) | 1 (1.9) | 0 (0.0) |
| **Ethnicity** n (%) | | | |
| Hispanic or Latino | 6 (6.3) | 4 (7.7) | 2 (4.5) |
| Not Hispanic or Latino | 87 (90.6) | 46 (88.5) | 41 (93.2) |
| Decline to answer | 3 (3.1) | 2 (3.8) | 1 (2.3) |
| **Race** n (%) | | | |
| White | 79 (82.3) | 45 (86.5) | 34 (77.3) |
| Asian or Asian American | 12 (12.5) | 5 (9.6) | 7 (15.9) |
| Black or African American | 6 (6.3) | 3 (5.8) | 3 (6.8) |
| Other race or origin | 3 (3.1) | 3 (5.8) | 0 (0.0) |
| Decline to answer | 3 (3.1) | 0 (0.0) | 3 (6.8) |
| **Diagnosed medical conditions** n (%) | | | |
| Allergies | 54 (56.3) | 30 (57.7) | 24 (54.5) |
| Anxiety | 37 (38.5) | 23 (44.2) | 14 (31.8) |
| Asthma | 26 (27.1) | 16 (30.8) | 10 (22.7) |
| Depression | 25 (26.0) | 17 (32.7) | 8 (18.2) |
| History of conjunctivitis (pink eye) | 7 (7.3) | 5 (9.6) | 2 (4.5) |
| **Age at diagnosis of AD/eczema (years)*** | | | |
| Mean (SD) | 26.76 (22.04) | 19.38 (20.27) | 35.48 (21.02) |
| Median (Min; Max) | 23.5 (0; 69) | 10.5 (0; 64) | 38.5 (0; 69) |
| **Duration of AD/eczema (years)*** | | | |
| Mean (SD) | 17.64 (17.85) | 22.15 (16.93) | 12.30 (17.60) |
| Median (Min; Max) | 12 (0; 68) | 21 (0; 56) | 3 (0; 68) |

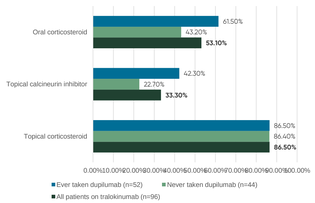
*Age at diagnosis is an approximation based on year of diagnosis and approximate year of birth (based on age at the time of study)

### *Summary of Concomitant Medication Use*

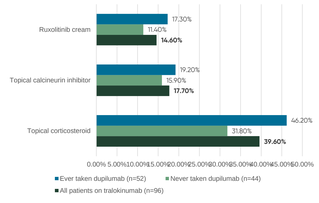
- Patients were generally treatment experienced at baseline, with 86.5% previously treated with topical corticosteroids (prescription or non-prescription), 54.2% previously treated with dupilumab, 33.3% previously treated with topical calcineurin inhibitor, and 53.1% previously treated with a prescription oral corticosteroid **(Figure 2a)**
- Topical treatments were generally taken as concomitant medications at week 4, with 39.6% of patients using topical corticosteroids (prescription or non-prescription), 17.7% using a topical calcineurin inhibitor (prescription), and 14.6% using ruxolitinib **(Figure 2b)**
- Patients who reported having ever taken dupilumab at baseline report a greater use of prior and concomitant medications compared to those who had never taken dupilumab at baseline

**Figure 2.** Top 3 medications taken for atopic dermatitis/eczema

**2.a.** Previously or at time of taking baseline survey




**2.b.** At Week 4 (wave 1 survey)




### *Summary of PO-SCORAD and TSQM-9*

- After 4 weeks of tralokinumab use, patients saw improvements in their PO-SCORAD (13.6%, SD=62.6%) and average weekly itch (22.3%, SD=48.8%) scores **(Table 2)**
- Patients also saw improvements in their mean TSQM-9 global satisfaction (6.0 points, SD=23.3), TSQM-9 convenience (9.8 points, SD=20.7), and TSQM-9 effectiveness (5.1 points, SD=18.3) scores **(Table 2)**
- Improvements were seen in both 'ever taken dupilumab' and 'never taken dupilumab' groups in PO-SCORD and TSQM-9 outcomes **(Table 2)**

**Table 2.** Improvement in patient reported outcomes

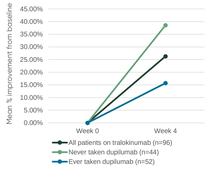
| | Wave 1 *(4-weeks post-initiation)* from Baseline *(initiation)* | | |
|---|---|---|---|
| | Total patients on tralokinumab (n=96) | Ever taken dupilumab (n=52) | Never taken dupilumab (n=44) |
| **PO-SCORAD** | | | |
| N | 96 | 52 | 44 |
| Mean score at baseline (SD) | 46.01 (22.15) | 45.67 (21.46) | 46.41 (23.19) |
| Mean % improvement at week 4 (SD) | 13.56 (62.56) | 2.37 (74.64) | 26.79 (41.33) |
| Median % improvement at week 4 (Min; Max) | 22.08 (-443.90; 100.00) | 21.79 (-443.90; 71.38) | 26.80 (-78.31; 100.00) |
| **Average Weekly Itch NRS** (% improvement) | | | |
| N | 92 | 49 | 43 |
| Mean score at baseline (SD) | 5.53 (2.58) | 5.35 (2.72) | 5.75 (2.42) |
| Mean % improvement at week 4 (SD) | 22.33 (48.78) | 14.71 (50.88) | 31.02 (45.30) |
| Median % improvement at week 4 (Min; Max) | 25.00 (-200; 100.00) | 25.00 (-200; 100.00) | 25.00 (-66.67; 100.00) |
| **Average Weekly Itch Meaningful Improvement** | | | |
| Meaningful improvement (3-points), n (%) | 32 (33.3) | 16 (30.8) | 16 (36.4) |
| **Worst Weekly Itch NRS** | | | |
| N | 96 | 52 | 44 |
| Mean score at baseline (SD) | 6.66 (2.78) | 6.56 (2.85) | 6.77 (2.73) |
| Mean % improvement at week 4 (SD) | 18.54 (59.50) | 10.39 (63.42) | 27.83 (53.93) |
| Median % improvement at week 4 (Min; Max) | 22.22 (-300; 100) | 22.22 (-300, 80) | 22.22 (-150; 100) |
| **Sleep Interference NRS** | | | |
| N | 96 | 52 | 44 |
| Mean score at baseline (SD) | 4.20 (3.43) | 3.96 (3.43) | 4.48 (3.44) |
| Mean % improvement at week 4 (SD) | 21.03 (55.28) | 12.31 (60.58) | 31.80 (46.57) |
| Median % improvement at week 4 (Min; Max) | 25 (-100; 100) | 13.39 (-100; 100) | 29.29 (-50; 100) |
| **DLQI** | | | |
| N | 96 | 52 | 44 |
| Mean score at baseline (SD) | 10.50 (6.45) | 9.58 (5.89) | 11.59 (6.98) |
| Mean % improvement at week 4 (SD) | 26.29 (52.42) | 15.70 (59.14) | 38.56 (40.67) |
| Median % improvement at week 4 (Min; Max) | 33.33 (-250; 100) | 25 (-250; 100) | 42.48 (-100; 100) |
| **DLQI Meaningful Improvement** | | | |
| Meaningful improvement (4-points), n(%) | 41 (42.7) | 17 (32.7) | 24 (54.5) |
| **TSQM-9: Global Satisfaction** | | | |
| Mean score improvement (SD) | 5.95 (23.36) | 4.40 (21.60) | 7.79 (25.21) |
| Median score improvement (Min; Max) | 3.57 (-50.00; 71.43) | 0.00 (-50.00; 71.43) | 7.14 (-50.00; 64.29) |
| **TSQM-9: Convenience** | | | |
| Mean score improvement (SD) | 9.78 (20.70) | 10.04 (21.08) | 9.47 (20.49) |
| Median score improvement (Min; Max) | 8.33 (-55.56; 66.67) | 5.56 (-55.56; 66.67) | 11.11 (-33.33; 61.11) |
| **TSQM-9: Effectiveness** | | | |
| Mean score improvement (SD) | 5.09 (18.27) | 2.78 (18.69) | 7.83 (17.58) |
| Median score improvement (Min; Max) | 5.56 (-44.44; 50.00) | 0.00 (-44.44; 50.00) | 11.11 (-38.89; 44.44) |

### *Summary of DLQI and NRS*

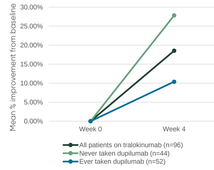
- Improvement on DLQI, average weekly itch NRS, and sleep interference NRS was seen in the total population; improvements were seen in both the 'ever taken dupilumab' and the 'never taken dupilumab' groups **(Table 2, Figure 3)**
  - The 'ever taken dupilumab' group improved at a lower rate compared to the 'never taken dupilumab' group, as this group may be a more difficult-to-treat population
- The mean percentage improvement in DLQI and worst weekly itch NRS were 26.3% (SD=52.4%) and 18.5% (SD=59.5%)
- Clinically meaningful improvement was experienced by 33.3% of patients on the average weekly itch NRS and 42.7% of patients on the DLQI
- The improvement in these outcomes is similar or was at a lower proportion than what was seen in the ECZTRA clinical trials at the same time point, although the differences in study designs and the small sample size of this study are not conducive for a comparison with the clinical trials[4]

**Figure 3.** Mean percentage improvement in score from baseline to week 4

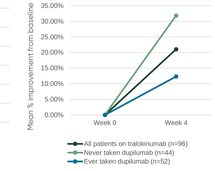
**3.a.** DLQI




**3.b.** Worst Weekly Itch NRS




**3.c.** Sleep NRS




## Conclusions

- This interim real-world analysis of the ongoing study describes the baseline characteristics of patients who were prescribed tralokinumab in the US
- After 4 weeks of tralokinumab use, patients saw improvements in itch, sleep, quality of life, and treatment satisfaction; additionally, over a third of patients experienced clinically important improvements in these outcomes
- From baseline to week 4, there was a reduction in patients using topical corticosteroids (86.5% to 39.6%) and topical calcineurin inhibitors (33.3% to 17.7%)
- There were improvements seen in both the dupilumab-experienced and the dupilumab-naïve groups from baseline to week 4, although lower rates were seen in the dupilumab-experienced group as this group may be a more difficult-to-treat population
- The interim data show promising early improvements, but longer-term data are needed as tralokinumab clinical trials have shown that improvements continue and maintain over a longer period of time

## 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 Satisfaction Questionnaire for Medication.

## References

**1.** Bieber T. *N Engl J Med.* 2008;358(14):1483-1494; **2.** Weidinger S, Novak N. *Lancet.* 2016;387(10023):1109-1122; **3.** Kiebert G et al. *Int J Dermatol.* 2002;41(3):151-158; **4.** Simpson EL, et al. *Ann Allergy Asthma Immunol.* 2022;129:592-604

## Disclosures

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