Real-World Dupilumab Continuation in US Children and Adolescents With Atopic Dermatitis Over a 24-Month Period

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Digital poster

Introduction

AD is a chronic, remitting-relapsing inflammatory dermatitis characterized by dryness, intense itching, erythema and lichenification[1]

Topical corticosteroids are a first-line anti-inflammatory therapy for patients with AD;[1] however, for patients with moderate-to-severe disease, more advanced therapies may be necessary[2]

Alongside topical and systemic treatments, biologic treatments have been developed as an alternative treatment option for patients with moderate-to-severe AD[1,3]

- Dupilumab, a monoclonal antibody, is a FDA-approved[3] treatment for adolescent patients aged 12–17 years (since March 2019)[4] and children aged 6–11 years (since May 2020)[5], and was approved in June 2022 for patients aged 6 months to 5 years[6]

Although real-world rates of dupilumab treatment persistence have been reported among adults,[7,8] data on treatment persistence among children and adolescents are limited

Objectives

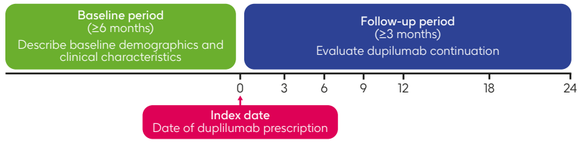
- To describe baseline demographic and clinical characteristics of children and adolescent patients with AD who have initiated dupilumab treatment
- To evaluate the real-world utilization of dupilumab among children and adolescent patients with AD by assessing treatment continuation over time
- To characterize the time to treatment discontinuation of dupilumab using KM curves among children and adolescent patients with AD

Methods

Study design

- This retrospective cohort analysis assessed US children (4–12 years) and adolescent (13–17 years) patients with AD in the OM1 PremiOM™ dataset
- The dataset comprised patients from the American Academy of Dermatology's DataDerm™ Registry with linked EHR and claims data from the OM1 Real-World Data Cloud
- Patients had initiated dupilumab treatment between March 2017 and September 2021, with follow-up through to December 2021 and had ≥6 months of data prior to, and ≥3 months of data after the first date of dupilumab prescription (index date; **Figure 1**)
- Continuation was defined by ≥1 prior prescription with an end-date falling within 90 days of a subsequent prescription
  - Discontinuation-free time was estimated for each patient for a maximum of 24 months from initiation until discontinuation or censoring

Figure 1 **Study design**



Patient eligibility

- Eligible patients in the DataDerm™ registry met the following conditions:
  - One of the following:
    - At least two diagnosis codes for AD, at least 30 days apart, from a dermatologist/dermatology specialty data source
    - At least one inpatient visit with an AD diagnosis code
    - At least two outpatient records for an AD diagnosis, at least 30 days apart and within a year, regardless of physician specialty
  - AND
    - At least two clinical notes from a dermatologist/dermatology specialty data source, at least 30 days apart
  - AND one of the following:
    - At least one observation of an AD-specific outcome
    - At least one record for a non-steroidal systemic medication
- In addition, patients were required to have:
  - Received dupilumab treatment as prescribed by a dermatologist in routine clinical care
  - At least one diagnosis code for AD during the six months prior to the index date
  - Available EHR or claims data for at least six months prior to and three months after index

Analyses

- Analyses were stratified by age group: children (4–12 years) or adolescents (13–17 years)
- Time-to-treatment discontinuation was estimated using KM methods

Conclusions

- This study observed that, among children and adolescent patients with AD, over three-quarters continued dupilumab 12 months after initiation, consistent with previous adult results[6,7]
- By 24 months of follow-up, approximately two-thirds of children and adolescent patients assessed at index continued dupilumab
- Strengths of this study include the large cohort of children and adolescent patients and follow-up of up to 24 months after index, enabling stable continuation estimates
- Study limitations include the lack of data on reasons for discontinuation and loss to follow-up

Results

Baseline characteristics

- In total, 208 children and 430 adolescent patients were eligible and included in the study
- Baseline demographics and clinical characteristics were similar between children and adolescents (**Table 1**)

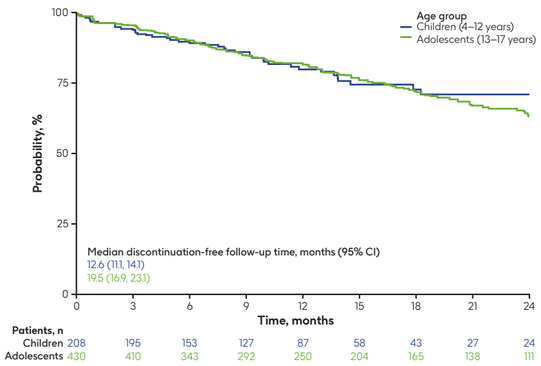
Table 1 **Baseline demographics and clinical characteristics of children and adolescent patients with AD (N=638)**

	Children (4–12 years), N=208	Adolescents (13–17 years), N=430
Age (years), mean (SD)	**9.4 (2.2)**	**15.2 (1.4)**
Females, n (%)	**110 (53)**	**243 (57)**
Race, n (%)		
White	83 (40)	233 (54)
Black	77 (37)	85 (20)
Other	13 (6)	37 (9)
Unknown/missing	35 (17)	75 (17)
Time since AD diagnosis (months), mean (SD)	**37.5 (24.3)**	**37.3 (27.5)**
Treatment history, n (%)		
Any corticosteroid	179 (86)	395 (92)
Any topical therapy other than corticosteroids	174 (84)	372 (87)
Any systemic therapy (excluding dupilumab)	50 (24)	82 (19)
Select comorbidities, n (%)		
Allergic rhinitis	60 (29)	119 (28)
Asthma	49 (24)	70 (16)
Psoriasis	3 (1)	11 (3)
Malignancies	1 (<1)	9 (2)
Dyslipidemia	1 (<1)	4 (1)

Dupilumab continuation

- Dupilumab continuation decreased consistently over 24 months of follow-up (**Figure 2**)
- The median (95% CI) discontinuation-free follow-up time was 12.6 (11.1, 14.1) and 19.5 (16.9, 23.1) months for children and adolescent patients, respectively

Figure 2 **KM curves of the probability of dupilumab continuation among children and adolescent patients with AD**



- Dupilumab continuation at 12 and 24 months was 79.8% and 70.8% in children and 81.9% and 63.1% in adolescents, respectively (**Table 2** and **Table 3**)

Table 2 **Probability of continuing dupilumab over time among child patients with AD (n=208)**

Time interval (post-index), months	Patients receiving dupilumab at start of time interval, n	Discontinued, n (%)	Censored*, n (%)	Estimated KM probability for cumulative continuance, % (95% CI)
0–3	208	13 (6)	0†	93.8 (89.5, 96.3)
3–6	195	8 (4)	34 (17)	89.7 (84.6, 93.1)
6–9	153	6 (4)	20 (13)	85.9 (80.0, 90.1)
9–12	127	8 (6)	32 (25)	79.8 (72.7, 85.2)
12–18	87	6 (7)	38 (44)	72.6 (63.8, 79.7)
18–24	43	1 (2)	18 (42)	70.8 (61.4, 78.4)

*Patients were censored (ended follow-up without discontinuing) on December 31, 2021 or after 90 days of follow-up without an encounter (lost to follow-up). Patients whose treatment extended beyond their last encounter, or whose dupilumab prescription ended within 90 days of their last encounter, were censored as of their last encounter date
†All patients completed follow-up during the first 3 months per the inclusion criterion

Table 3 **Probability of continuing dupilumab over time among adolescent patients with AD (n=430)**

Time interval (post-index), months	Patients receiving dupilumab at start of time interval, n	Discontinued, n (%)	Censored*, n (%)	Estimated KM probability for cumulative continuance, % (95% CI)
0–3	430	20 (5)	0†	95.3 (92.9, 97.0)
3–6	410	22 (5)	45 (11)	89.9 (86.6, 92.4)
6–9	343	18 (5)	33 (10)	85.0 (81.0, 88.1)
9–12	292	10 (3)	32 (11)	81.9 (77.7, 85.4)
12–18	250	27 (11)	58 (23)	72.0 (66.7, 76.6)
18–24	165	18 (11)	36 (22)	63.1 (57.0, 68.6)

*Patients were censored (ended follow-up without discontinuing) on December 31, 2021 or after 90 days of follow-up without an encounter (lost to follow-up). Patients whose treatment extended beyond their last encounter, or whose dupilumab prescription ended within 90 days of their last encounter, were censored as of their last encounter date
†All patients completed follow-up during the first 3 months per the inclusion criterion

Abbreviations

AD, atopic dermatitis; CI, confidence intervals; EHR, electronic health record; FDA, Food and Drug Administration; KM, Kaplan–Meier; SD, standard deviation; US, United States

References

1. Galli E, et al. *Acta Biomed.* 2020;91(11-S):e2020011
2. Lobefaro F, et al. *Biomedicines* 2022:10(11):2927.
3. Regeneron. Dupilumab prescribing information. October 2023 https://www.regeneron.com/downloads/dupixent_fpi.pdf (Accessed: January 16, 2024)
4. Sanofi Press Release. March 2019. https://www.news.sanofi.us/2019-03-11-FDA-approves-Dupixent-R-dupilumab-for-moderate-to-severe-atopic-dermatitis-in-adolescents (Accessed: January 16, 2024)
5. Sanofi Press Release. May 2020 https://www.sanofi.com/assets/dotcom/pressreleases/2020/2020-05-26-15-40-00-2038798-en.pdf (Accessed: January 16, 2024)
6. Sanofi Press Release. June 2022. https://www.sanofi.com/en/media-room/press-releases/2022/2022-06-07-20-45-00-2458243 (Accessed: January 16, 2024)
7. Silverberg J, et al. *Ann Allergy Asthma Immunol.* 2021;126(1):40–45.
8. Strober B, et al. *JAMA Dermatol.* 2022;158(2):142–150.

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Disclosures

JMS, **UK**, **SN**, and **DSP** are employed by GSK. **JB** is an independent contractor for OM1, and **SGS**, and **SW** are employees of OM1

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