Long-term Dupilumab Efficacy Is Sustained in Adults With Moderate-to-Severe Atopic Dermatitis Transitioning From Weekly to Every Other Week Dosing: Results From an Open-Label Extension Trial

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BACKGROUND

- Atopic dermatitis (AD) is a chronic systemic inflammatory disease requiring long-term management
- Systemic immunosuppressive treatments for moderate-to-severe AD may not be recommended for continuous use due to safety concerns
- Data from an open-label extension (OLE) study (NCT01949311) have previously demonstrated favorable safety and sustained efficacy in adult patients for up to 172 weeks with weekly dosing

OBJECTIVE

- **To evaluate long-term maintenance of efficacy in the subgroup of patients with moderate-to-severe AD switching from weekly (qw) to every other week (q2w) dupilumab treatment in a phase 3 multicenter, OLE study (NCT01949311)**

METHODS

Study design

- Adult patients aged ≥ 18 years with moderate-to-severe AD who had previously participated in any dupilumab parent study (phase 1–3) were enrolled in this long-term, multicenter, OLE study with a maximum treatment period of 5 years
- In 2019, 226 ongoing patients transitioned from 300 mg qw to 300 mg q2w to align with approved dosage
- Concomitant treatments for AD, including topical corticosteroids and topical calcineurin inhibitors, were permitted
- Data shown are for the full population switching from dupilumab 300 mg qw to q2w

RESULTS

Table 1. Patient OLE demographics and baseline disease characteristics for patients switching from qw to q2w.

	N = 226
Age, mean (SD), years	34.3 (11.68)
Sex, male, n (%)	139 (61.5)
Race, n (%)	
White	226 (100)
BMI, mean (SD), kg/m^2	24.9 (4.17)
Duration of AD in years, mean (SD)	26.4 (12.79)
OLE baseline EASI Total Score, mean (SD)	15.4 (15.02)
OLE baseline IGA Total Score, mean (SD)	2.4 (1.00)

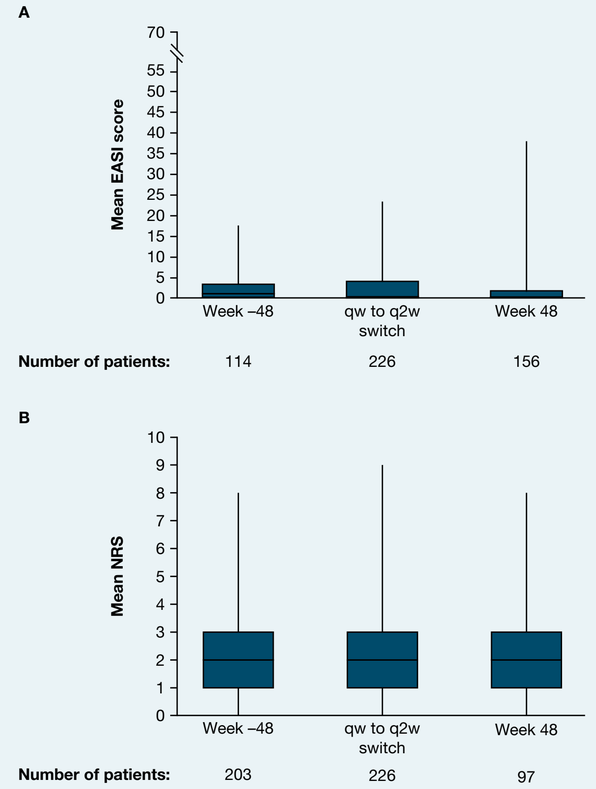
BMI, body mass index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; SD, standard deviation.

Table 2. Summary of treatment exposure for patients transitioning from qw to q2w.

	Treatment exposure with qw	Treatment exposure with q2w	Treatment exposure with qw + q2w
Treatment exposure (Weeks)			
N	226	226	226
Mean (SD)	195.03 (19.20)	46.65 (7.34)	241.68 (16.37)
Number (%) of patients with Treatment exposure (Weeks)			
1 to < 4 weeks	0	0	0
4 to < 12 weeks	0	1 (0.4%)	0
12 to < 16 weeks	0	1 (0.4%)	0
16 to < 24 weeks	0	2 (0.9%)	0
24 to < 52 weeks	0	175 (77.4%)	0
52 to < 76 weeks	0	47 (20.8%)	0
76 to < 100 weeks	0	0	0
100 to < 124 weeks	0	0	0
124 to < 148 weeks	0	0	0
148 to < 156 weeks	0	0	0
156 to < 182 weeks	67 (29.6%)	0	0
182 to < 208 weeks	99 (43.8%)	0	5 (2.2%)
208 to < 234 weeks	56 (24.8%)	0	70 (31.0%)
234 to < 260 weeks	4 (1.8%)	0	112 (49.6%)
≥ 260 weeks[a]	0	0	39 (17.3%)

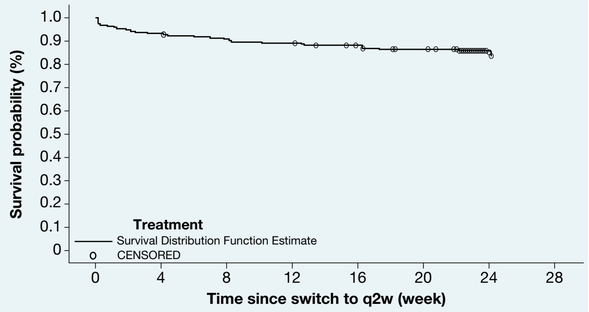
For the overall OLE study population (N = 2677), 59.4% of patient withdrawals were due to regulatory approval and commercialization of dupilumab, whereas 8.4% and 4.3% withdrew due to adverse events or lack of efficacy, respectively
SD, standard deviation. [a]Patients receive treatment at Week 260 resulting in treatment exposure > 260 weeks in some patients.

Figure 1. (A) Mean EASI 48 weeks before and after q2w transition; (B) Mean Pruritus Numerical Rating Scale (NRS) score 48 weeks before and after q2w transition.



Middle horizontal lines indicate medians. Top and bottom of each box represents Q3 and Q1, respectively. The upper and lower vertical bars represent Q4 (maximum) and Q0 (minimum).
Dose switch baseline defined as visit date after qw and before q2w; BL, baseline; EASI, Eczema Area and Severity Index; SE, standard error; NRS, Numerical Rating Scale; IGA, Investigator's Global Assessment.

Figure 2. Continuous maintenance of NRS score ≤ 4 or EASI ≤ 7 following dupilumab dose switch from 300 mg qw to 300 mg q2w.



Number at risk	221	206	200	196	189	183	81	0

Dose switch baseline defined as visit date after qw and before q2w.

CONCLUSIONS

- **In this long-term, open-label study, dupilumab showed sustained efficacy following dose regimen transition from 300 mg qw to q2w, with stable signs and symptoms 48 weeks post switch**
- **Continuous maintenance of disease control, defined as EASI ≤ 7 or NRS score ≤ 4, for 24 weeks following qw to q2w change without rebound or exacerbation was observed in the majority of patients who achieved this response at the time of switch**
- **The subgroup of patients who transitioned doses represent the longest treated cohort of OLE patients, with a mean total duration of drug exposure of over 4.5 years**
- **Safety for the overall population was consistent with the known dupilumab safety profile previously observed in controlled studies**

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