Efficacy of Dupilumab in Infants and Preschoolers With Atopic Dermatitis up to 1 Year

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OBJECTIVE

- **To report the impact of treatment with dupilumab and low-potency topical corticosteroids (TCS) for 1 year on efficacy measures in children aged 6 months to 5 years with moderate-to-severe atopic dermatitis (AD)**

METHODS

- Children aged 6 months to 5 years with moderate-to-severe AD who had participated in the 16-week, double-blind, phase 3 LIBERTY AD PRESCHOOL trial (NCT03346434, part B; parent study) were enrolled into an open-label extension (OLE) study (NCT02612454)
- Patients received subcutaneous dupilumab every 4 weeks (q4w) based on weight:
  - 5 to < 15 kg: 200 mg
  - 15 to < 30 kg: 300 mg
- TCS were permitted and may be provided at the discretion of the investigator

CONCLUSIONS

- **Dupilumab treatment for 1 year provides sustained improvement in signs of AD in patients aged 6 months to 5 years with moderate-to-severe AD**
- **Dupilumab was generally well tolerated with an acceptable safety profile**

RESULTS

Table 1. Current study baseline demographics and disease characteristics.

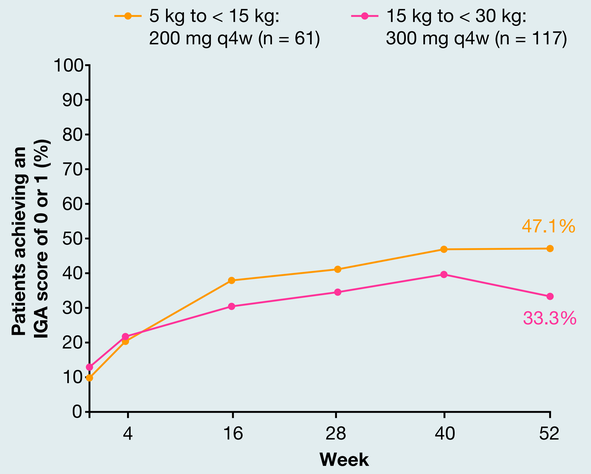
	< 15 kg (n = 61)	15 to < 30 kg (n = 117)
Age (%), years		
≥ 0.5 to < 2 years, n (%)	19 (31.1)	0
≥ 2 to 5 years, n (%)	42 (68.9)	117 (100)
Male sex, n (%)	38 (62.3)	78 (66.7)
Race, n (%)		
White	44 (72.1)	74 (63.2)
Black or African American	8 (13.1)	25 (21.4)
Asian	4 (6.6)	9 (7.7)
Other	5 (8.2)	3 (2.6)
Not reported	0	6 (5.1)
Duration of AD, mean (SD), years	2.4 (1.2)	4.0 (1.0)
Age at AD onset, n (%)		
< 6 months	52 (85.2)	74 (63.2)
≥ 6 months	9 (14.8)	43 (36.8)
IGA score, mean (SD)	3.0 (1.1)	2.7 (1.0)
EASI, mean (SD)	21.3 (15.8)	15.5 (13.3)
BSA affected %, mean (SD)	38.2 (25.0)	28.2 (20.0)
SCORAD score, mean (SD)	51.1(24.3)	45.1 (21.5)

BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; SCORAD, SCORing Atopic Dermatitis; SD, standard deviation.

Table 2. Patient treatment exposure.

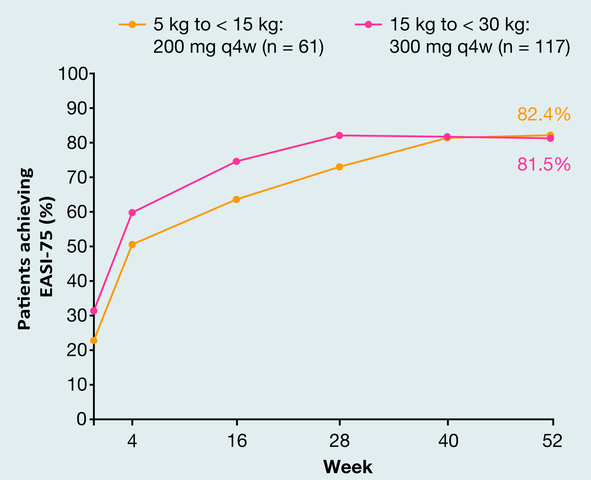
	< 15 kg (n = 61)	15 to < 30 kg (n = 117)
Treatment exposure (weeks), mean (SD)	70.3 (48.3)	61.2 (39.7)
Patients with overall treatment exposure (weeks), n (%)		
1 to < 4 weeks	0	0
4 to < 16 weeks	4 (6.6)	1 (0.9)
16 to < 26 weeks	1 (1.6)	4 (3.4)
26 to < 52 weeks	23 (37.7)	49 (41.9)

Figure 1. Proportion of patients with IGA score of 0 or 1 over time.



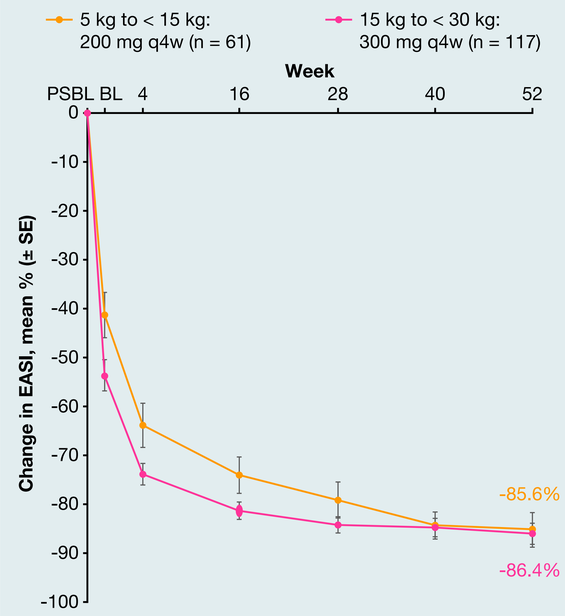
BL, baseline.

Figure 2. Proportion of patients achieving EASI-75 over time.



EASI-75, 75% improvement from BL in EASI.

Figure 3. Percent change in EASI from PSBL at each visit by baseline weight group in children ≥ 6 months to 5 years of age.



PSBL, parent study BL; SE, standard error.

Table 3. Safety summary.

	n (%)	nP/100PY
Patients with any TEAE	143 (79.4)	191.3
Patients with any serious TEAE	11 (6.1)	4.8
Patients with any severe TEAE	8 (4.4)	3.5
Patients with any TEAEs related to treatment	27 (15.0)	12.9
Patients with any TEAEs leading to permanent discontinuation	1 (0.6)[a]	0.4

[a]Severe TEAE of urticaria that was recovered/resolved. nP/100PY, number of patients with at least 1 event per 100 patient-years; TEAE, treatment-emergent adverse event.

*This author has been included to serve as a presenter.

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