Efficacy and Safety of Dupilumab in Children Aged 6–11 Years With Inadequately Controlled Severe Atopic Dermatitis: Results From an Open-Label Extension Trial up to 1 Year

Amy S. Paller[1,2], Michael J. Cork[3], Elaine C. Siegfried[4,5], Emma Guttman-Yassky[6,7], Eric L. Simpson[8], Weily Soong[9], Jing Xiao[10], Zhixiao Wang[10], Chien-Chia Chuang[11], John T. O'Malley[11], Ashish Bansal[10]

[1]Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [2]Ann and Robert H. Lurie Children's Hospital, Chicago, IL, USA; [3]Sheffield Dermatology Research, University of Sheffield, Sheffield, UK; [4]Saint Louis University, St. Louis, MO, USA; [5]Cardinal Glennon Children's Hospital, St. Louis, MO, USA; [6]Icahn School of Medicine at Mount Sinai Medical Center, New York, NY, USA; [7]Rockefeller University, New York, NY, USA; [8]Oregon Health and Science University, Portland, OR, USA; [9]Alabama Allergy & Asthma Center, Birmingham, AL, USA; [10]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [11]Sanofi, Cambridge, MA, USA

INTRODUCTION

- Atopic dermatitis (AD), a common chronic inflammatory type 2 systemic disease, is characterized by pruritus, disruption of skin barrier function and eczematous lesions
- Treatment options are limited, especially for children with AD.
- Dupilumab has previously demonstrated efficacy and an acceptable safety profile in patients with type 2 inflammatory diseases such as AD, asthma and chronic rhinosinusitis with nasal polyps[1-3]

OBJECTIVE

- **To report the long term efficacy and safety of dupilumab in patients aged 6-11 years with severe AD who enrolled in the phase 3 multicenter, open-label extension (OLE) LIBERTY AD PED OLE study (NCT02612454)**

METHODS

- Children aged 6–11 years with severe AD who had previously participated in the 16 week, double-blind, phase 3 LIBERTY AD PEDS study (NCT03345914; parent study), were enrolled into the long-term, multicentre OLE study
- Patients enrolled in the OLE were treated with 300 mg dupilumab every four weeks
- If the treatment response was inadequate, defined as failure to achieve an Investigator's Global Assessment (IGA) score of 0/1 within 16 weeks of treatment initiation, treatment could be up-titrated to 200 mg or 300 mg every 2 weeks (for patients weighing < 60 kg or ≥ 60 kg, respectively) at the discretion of the physician
- Patients were permitted to receive concomitant topical treatments.
- Data are presented as observed

CONCLUSIONS

- **Dupilumab treatment resulted in substantial and sustained long-term reduction in AD signs and symptoms and improvement in health-related quality of life in patients aged 6–11 years with inadequately controlled severe AD**
- **The long-term safety profile of dupilumab was favorable and consistent with that previously seen in shorter term, placebo-controlled studies**

RESULTS

Table 1. Demographics and baseline characteristics.

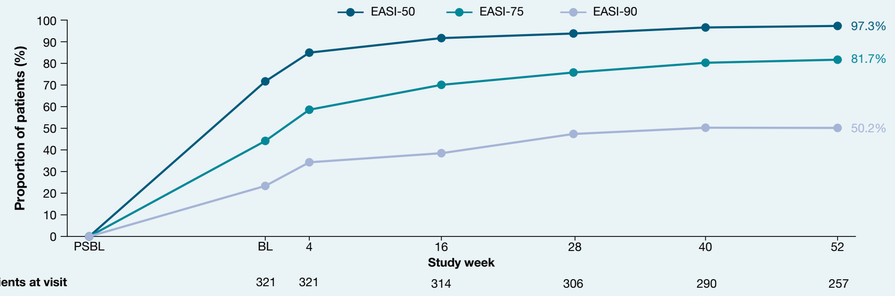
	N = 321
Age, mean (SD), years	8.6 (1.7)
Sex, male, n (%)	159 (49.5)
Race, n (%)	
White	230 (71.7)
Black or African American	51 (15.9)
Asian	25 (7.8)
American Indian or Alaska native	1 (0.3)
Other	12 (3.7)
Not reported	2 (0.6)
Weight, mean (SD), kg	31.4 (8.6)
Duration of AD, mean (SD), years	7.4 (2.2)
IGA, n (%)	
0	7 (2.2)
1	55 (17.1)
2	113 (35.2)
3	89 (27.7)
4	57 (17.8)
EASI, mean (SD)	14.5 (15.1)
BSA affected by AD, mean (SD), %	26.9 (24.8)
SCORAD score, mean (SD)	40.0 (21.8)
CDLQI, mean (SD)	6.8 (6.6)

BMI, body mass index; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; SCORAD, SCORing Atopic Dermatitis; SD, standard deviation.

Table 2. Treatment exposure and patient disposition.

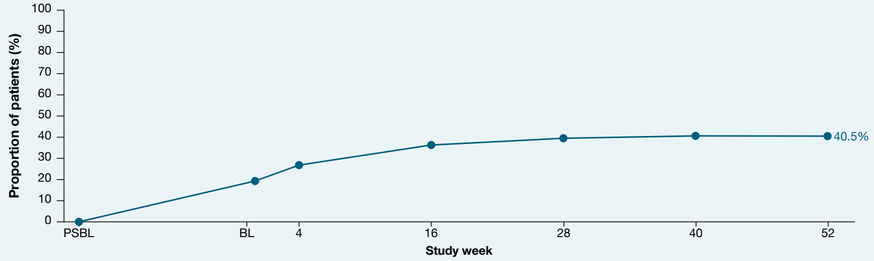
	N = 321
Overall treatment exposure, mean (SD), weeks	64 (20.0)
Overall treatment exposure, median (IQR), weeks	64 (52.0 – 78.1)
Patients who completed up to Week 16, n (%)	315 (98.1)
Patients who completed up to Week 24, n (%)	310 (96.6)
Patients who completed up to Week 26, n (%)	310 (96.6)
Patients who completed up to Week 52, n (%)	254 (79.1)
Patients who completed up to Week 78, n (%)	115 (35.8)
Patients who completed up to Week 104, n (%)	4 (1.2)
Patients who completed study, n (%)	5 (1.6)
Patients ongoing, n (%)	255 (79.4)
Patients who did not complete study, n (%)	61 (19.0)
Adverse Event	3 (0.9)
Physician Decision	6 (1.9)
Withdrawal by Subject	11 (3.4)
Lack of Efficacy	4 (1.2)
Lost to Follow-up	3 (0.9)
Protocol Deviation	2 (0.6)
Death	0
Drug Commercially Available	32 (10.0)

Figure 1. Proportion of patients achieving EASI-50/75/90 relative to the PSBL.



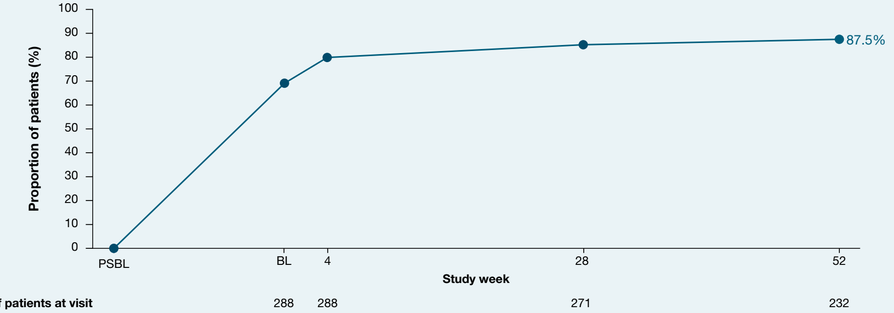
BL, baseline; EASI-50/75/90, 50%/75%/90% improvement from baseline in EASI; PSBL, parent study baseline.

Figure 2. Proportion of patients achieving IGA score 0/1.



BL, baseline; IGA, Investigator's Global Assessment; NRS, numerical rating scale; PSBL, parent study baseline.

Figure 3. Proportion of patients with ≥ 6-point improvement in CDLQI relative to PSBL.



CDLQI, Children's Dermatology Life Quality Index; PSBL, parent study baseline.

Table 3. Safety summary

	n (%)	nP/100PY
Patients with any TEAE	255 (79.4)	172.0
Patients with any serious TEAE	15 (4.7)	3.7
Patients with any severe TEAE	13 (4.0)	3.2
Patients with any TEAEs related to treatment	59 (18.4)	16.6
Patients with any TEAEs leading to permanent discontinuation	3 (0.9)	0.7

nE/100PY, number of events per 100 patient-years; TEAE, treatment-emergent adverse event.

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