Supplement: Dupilumab Provides Clinically Meaningful Responses in Children Aged 6–11 Years with Severe Atopic Dermatitis: Post hoc Analysis Results from a Phase III Trial

Running heading: Dupilumab in Children with Severe Atopic Dermatitis: Post hoc Analysis Results from a Phase III Trial

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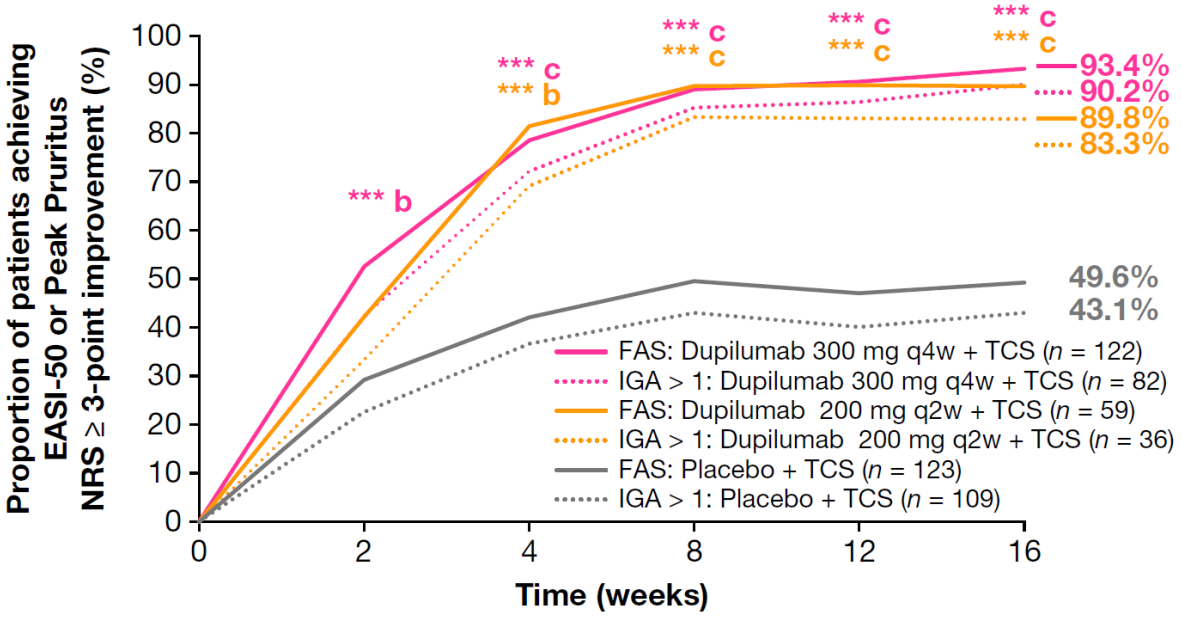
Conflict of interest

Elaine C. Siegfried: Dermavant, Eli Lilly, Pfizer, Regeneron Pharmaceuticals Inc., Verrica Pharmaceuticals – consultant; GlaxoSmithKline, LEO Pharma, Novan – data and safety monitoring board; Eli Lilly, Janssen, Regeneron Pharmaceuticals, Inc., Stiefel, Verrica Pharmaceuticals – Principal Investigator in clinical trials. Michael J. Cork: AbbVie, Astellas Pharma, Boots, Dermavant, Galapagos, Galderma, Hyphens Pharma, Johnson & Johnson, LEO Pharma, L'Oréal, Menlo Therapeutics, Novartis, Oxagen, Pfizer, Procter & Gamble, Reckitt Benckiser, Regeneron Pharmaceuticals Inc., Sanofi – investigator and/or consultant. Norito Katoh: AbbVie, Celgene Japan, Janssen Pharmaceuticals, Kyowa Kirin, LEO Pharma, Lilly Japan, Maruho, Mitsubishi Tanabe Pharma, Sanofi, Taiho Pharmaceutical, Torii Pharmaceutical – speaker/consultant honoraria; A2 Healthcare, AbbVie, Boehringer Ingelheim Japan, Eisai, Janssen Pharmaceuticals, Kyowa Kirin, LEO Pharma, Lilly Japan, Maruho, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical – investigator grants. Haixin Zhang, Ryan B. Thomas, Sonya L. Cyr: Regeneron Pharmaceuticals Inc. − employees and shareholders. Chien-Chia Chuang, Ana B. Rossi, Annie Zhang: Sanofi − employees, may hold stock and/or stock options in the company.

Fig. S1 Proportion of patients achieving EASI-50 or Peak Pruritus NRS ≥ 3-point improvement (FAS and IGA > 1 subgroup)



***$p < 0.0001$ vs placebo (for FAS)

[b]$p < 0.01$ vs placebo, [c]$p < 0.0001$ vs placebo (for IGA > 1 subgroup)

EASI Eczema Area and Severity Index, *EASI-50* improvement from baseline of at least 50% in EASI, *FAS* full analysis set, *IGA* Investigator's Global Assessment, *PP-NRS* Peak Pruritus Numerical Rating Scale, *q2w* every 2 weeks, *q4w* every 4 weeks, *TCS* topical corticosteroids

Table S1. Number of patients with adverse events reported in the overall safety analysis set and IGA > 1 subgroup

Characteristic	IGA > 1 subgroup (*n* = 227)			FAS (*n* = 304)		
	Dupilumab 200 mg q2w + TCS (*n* = 36)	Dupilumab 300 mg q4w + TCS (*n* = 80)	Placebo + TCS (*n* = 106)	Dupilumab 200 mg q2w + TCS (*n* = 59)	Dupilumab 300 mg q4w + TCS (*n* = 120)	Placebo + TCS (*n* = 120)
Patients with ≥ 1 treatment-emergent adverse event, *n* (%)	23 (63.9)	54 (67.5)	77 (72.6)	36 (61.0)	79 (65.8)	88 (73.3)
Patients with ≥ 1 treatment-emergent adverse event leading to discontinuation of study drug, *n* (%)	1 (2.8)	0	2 (1.9)	1 (1.7)	0	2 (1.7)
Patients with ≥ 1 treatment-emergent serious adverse event, *n* (%)	0	2 (2.5)	2 (1.9)	0	3 (2.5)	2 (1.7)
Deaths, *n* (%)	0	0	0	0	0	0

FAS full analysis set, IGA Investigator's Global Assessment, *q2w* every 2 weeks, *q4w* every 4 weeks, *TCS* topical corticosteroids