Treatment-Emergent Adverse Events in Patients Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis Treated With Dupilumab in an Open-Label Extension Clinical Trial

Amy S. Paller[1,2], Elaine C. Siegfried[3,4], Robert Sidbury[5], Benjamin Lockshin[6], Michael Cork[7], Andreas Pinter[8], Jing Xiao[9], Sarah Stanton[10], Faisal A. Khokhar[9], Ashish Bansal[9], Randy Prescilla[11]

[1]Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [2]Ann and Robert H. Lurie Children's Hospital, Chicago, IL, USA; [3]Saint Louis University, St. Louis, MO, USA; [4]Cardinal Glennon Children's Hospital, St. Louis, MO, USA; [5]Seattle Children's Hospital, Seattle, WA, USA; [6]Georgetown University, Washington, DC, USA; [7]Sheffield Dermatology Research, University of Sheffield, Sheffield, UK; [8]University Hospital Frankfurt am Main, Frankfurt am Main, Germany; [9]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [10]Sanofi, Bridgewater, NJ, USA, [11]Sanofi, Cambridge, MA, USA.

Contact author
TBA

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Objective and methods

OBJECTIVE

- To investigate the safety of dupilumab treatment on patients aged 6 months to 5 years with moderate-to-severe atopic dermatitis (AD) who completed the parent study AD-1539B (NCT03346434).

METHODS

- This ongoing phase 3 open-label extension (OLE; NCT02612454) enrolled patients aged 6 months to 17 years with moderate-to-severe AD

- Patients were treated with dupilumab (weight-based dosing):
  - 200 mg every 4 weeks (q4w; 5 to < 15 kg)
  - 300 mg q4w (15 to < 30 kg), 200 mg q2w (30 to < 60 kg)

- Here we report safety data (cut-off date July 31, 2021) for 180 patients aged 6 months to 5 years who enrolled in the OLE

Patient baseline demographics and disposition

	Total Patients (N = 180)
Age, mean (SD)	3.86 (1.322)
Age group	
>=0.5 to <2 years	19 (10.6%)
>=2 to <6 years	161 (89.4%)
Race	
White	119 (66.1%)
Black or African American	34 (18.9%)
Asian	13 (7.2%)
Other	8 (4.4%)
Not Reported	6 (3.3%)
Sex	
Male	116 (64.4%)
Female	64 (35.6%)
BMI, mean (SD)	16.46 (2.047)

	Total Patients (N = 180)
Patient who completed up to	
Week 16	122 (67.8%)
Week 24	74 (41.1%)
Week 26	68 (37.8%)
Week 52	30 (16.7%)
Week 78	30 (16.7%)
Week 104	29 (16.1%)
Week 156	15 (8.3%)
Patients ongoing	167 (92.8%)
Patients who did not complete study	13 (7.2%)
• Withdrawal by subject	10 (5.6%)
• Adverse Events	1 (0.6%)
• Lost to follow-up	1 (0.6%)
• Lack of efficacy	1 (0.6%)
• Physician Decision	0
• Death	0
• Other	0

BMI, body mass index; SD, standard deviation.

TEAEs in OLE and parent study

	AD-1434 (N = 180)		AD-1539B Placebo+TCS (N = 78)		AD-1539B Dupi 200/300 Q4W+TCS (N = 83)	
Patients with any TEAE	109 (60.6%)		58 (74.4%)		53 (63.9%)	
Patients with any drug related TEAE	15 (8.3%)		5 (6.4%)		9 (10.8%)	
Patients with any TEAE leading to Permanent Study Drug Discontinuation	1 (0.6%)[a]		1 (1.3%)		1 (1.2%)	
Patients with any TEAE with Maximum Intensity						
Mild	50 (27.8%)		22 (28.2%)		30 (36.1%)	
Moderate	56 (31.1%)		26 (33.3%)		21 (25.3%)	
Severe	3 (1.7%)		10 (12.8%)		2 (2.4%)	
Patients with TEAE resulting in Death	0		0		0	
Patients with any Serious TEAE	2 (1.1%) [b]		4 (5.1%)		0	
PT > 5% [c]	**N**	**nP/PY (nP/100 PY)**	**N**	**nP/PY (nP/100 PY)**	**N**	**nP/PY (nP/100 PY)**
Nasopharyngitis	23 (12.8%)	23/109.0 (21.09)	7 (9.0%)	7/23.3 (29.99)	7 (8.4%)	7/25.3 (27.67)
Upper respiratory tract infection	21 (11.7%)	21/116.5 (18.02)	7 (9.0%)	7/23.6 (29.72)	5 (6.0%)	5/25.6 (19.49)
Cough	15 (8.3%)	15/122.9 (12.21)	5 (6.4%)	5/23.5 (21.31)	0	0/26.6
Rhinorrhoea	11 (6.1%)	11/129.3 (8.51)	1 (1.3%)	1/24.3 (4.11)	4 (4.8%)	4/26.0 (15.36)
Urticaria [a]	13 (7.2%)	13/124.7 (10.42)	4 (5.1%)	4/24.2 (16.50)	1 (1.2%)	1/26.2 (3.81)
Dermatitis atopic	12 (6.7%)	12/119.8 (10.02)	25 (32.1%)	25/19.3 (129.69)	12 (14.5%)	12/24.1 (49.69)
Pyrexia	21 (11.7%)	21/111.0 (18.91)	7 (9.0%)	7/23.4 (29.96)	1 (1.2%)	1/26.3 (3.80)
Food allergy	9 (5.0%)	9/128.5 (7.00)	0	0/24.6	1 (1.2%)	1/26.3 (3.80)

[a] Severe Urticaria that lead to treatment discontinuation. [b] Anaphylactic Reaction: 1 (0.6%), Pneumonia mycoplasma: 1 (0.6%). [c] Conjunctivitis was reported in 5 patients (2.8%) (nP/100PY: 3.71) in AD-1434; 0 patients in AD-1539b Placebo + TCS and 3 patients (3.6%) (nP/100PY: 11.40) in AD-1539b Dupi 200/300 Q4W + TCS. Injection site Erythema was reported in 1 patient (0.6%) (nP/100PY: 0.73) in AD-1434; 0 patients in AD-1539B placebo + TCS and 1 patient (1.2%) (nP/100PY: 3.80) in AD-1539B Dupi 200/300 Q4W + TCS.
SD, standard deviation; TEAE, treatment emergent adverse event; PT, preferred term; nP/100PY, number of patients per 100 patient years.

Conclusion

- Dupilumab long term treatment, up to week 156, was generally well tolerated with an acceptable safety profile