Dupilumab Monotherapy for 1 Year Provides Sustained Improvement in DLQI in Adults With Moderate-to-Severe Atopic Dermatitis Optimally Responding at Week 16

Jerry Bagel[1], Servando E. Marron[2,3], Jean-Philippe Lacour[4], Andreas Pinter[5], Marco Romanelli[6], Chih-ho Hong[7,8], Hiroshi Mitsui[9], Chun Wook Park[10], Haixin Zhang[11], Ryan B. Thomas[11], Gaëlle Bégo-Le Bagousse[12], Genevieve Wortzman-Show[11], Ana B. Rossi[13]

[1]Eczema Treatment Center of New Jersey, East Windsor, NJ, USA; [2]Aragon Psychodermatology Research Group (GAI+PD) partnered with Aragon Health Sciences Institute (IACS), University Hospital Miguel Servet, Zaragoza, Spain. [3]University of Zaragoza, Zaragoza, Spain; [4]University Hospital of Nice, Nice, France; [5]University Hospital Frankfurt am Main, Frankfurt am Main, Germany; [6]University of Pisa, Pisa, Italy; [7]University of British Columbia, Vancouver, BC, Canada; [8]Probity Medical Research, Surrey, BC, Canada; [9]University of Yamanashi, Yamanashi, Japan; [10]Kangnam Sacred Heart Hospital, Hallym University College of Medicine, Seoul, Korea; [11]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [12]Sanofi Genzyme, Paris, France; [13]Sanofi Genzyme, Cambridge, MA, USA

BACKGROUND

- The Dermatology Life Quality Index (DLQI; range 0–30, higher score indicates worse quality of life) is a 10-item self-reported validated questionnaire reflecting the impact of skin disease on patient quality of life over a 1-week period, including symptoms, self-consciousness, work/school, daily tasks and leisure activities, relationships, and impact of treatment[1]

OBJECTIVE

- **To evaluate the effect of dupilumab monotherapy over 1 year on quality of life as assessed by DLQI in adults with moderate-to-severe atopic dermatitis who achieved an optimal response after 16 weeks of dupilumab treatment**

METHODS

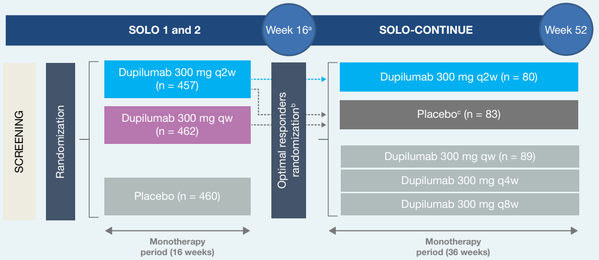
- SOLO-CONTINUE (NCT02395133) was a phase 3 clinical trial to assess the efficacy and safety of long-term dupilumab monotherapy treatment in patients who had earlier achieved a 75% reduction from baseline in Eczema Area and Severity Index (EASI-75) and/or an Investigator's Global Assessment (IGA) score of 0–1 after 16 weeks of dupilumab treatment in SOLO 1 and 2[2]

Analysis

- This analysis included only these treatment groups: approved dupilumab dose 300 mg every 2 weeks (q2w) and placebo from SOLO-CONTINUE
- Baseline demographics and disease characteristics have been previously reported[2,3]

METHODS (CONT.)

Figure 1. Study design.



[a]Week 16 of SOLO 1 and 2 is baseline of SOLO-CONTINUE.
[b]Only patients achieving either IGA score of 0–1 or EASI-75 were eligible to continue treatment in SOLO-CONTINUE.
[c]Placebo patients in SOLO-CONTINUE had been treated with either dupilumab q2w or qw in SOLO 1 and 2.
q4w, every 4 weeks; q8w, every 8 weeks; qw, weekly.

RESULTS

Table. Proportions of patients reporting total DLQI score 0–1 by visit.

Visit, n(%)	Dupilumab 300 mg q2w optimal responders continuing q2w (n = 80)	Dupilumab 300 mg qw/ q2w optimal responders randomized to placebo at Week 16 (n = 83)
Baseline	0 (0)	1 (1.2)
Week 16	31 (38.8)	37 (44.6)
Week 52	37 (46.3)**	22 (26.5)

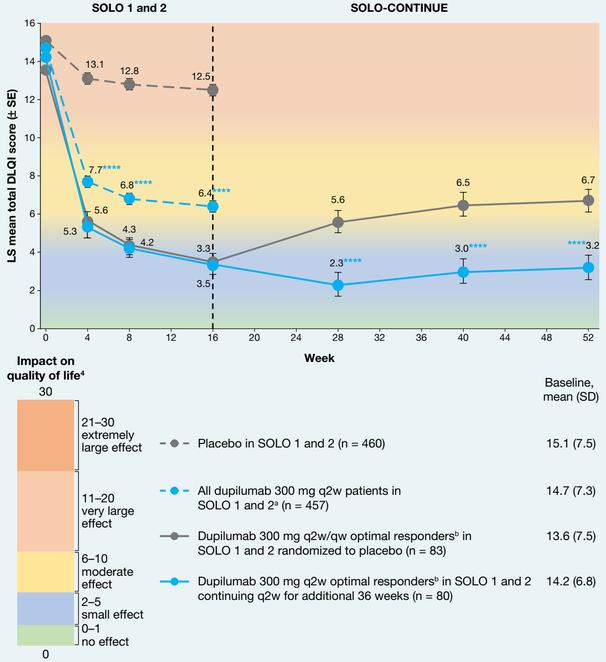
**P (dupilumab vs placebo) ≤ 0.01. LOCF method with censoring after rescue treatment use. LOCF, last observation carried forward.

Safety

- Dupilumab was generally well tolerated with a favorable safety profile[2]

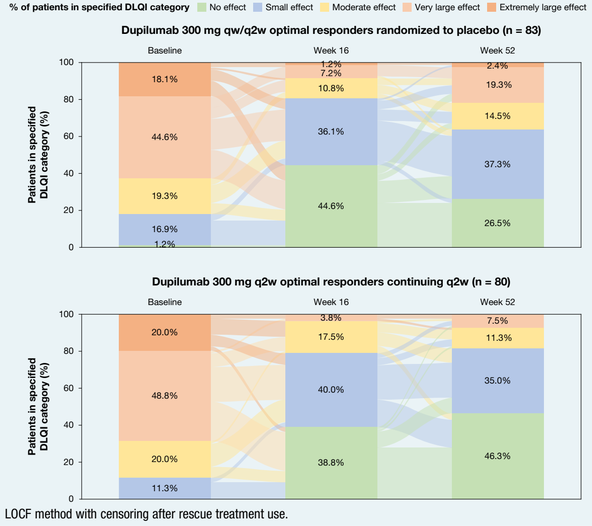
RESULTS (CONT.)

Figure 2. LS mean (± SE) total DLQI score, at each visit through Week 52.



[a]All patients in the SOLO 1 and 2 dupilumab 300 mg q2w trial arms.
[b]Patients achieving either IGA 0–1 or EASI-75 in SOLO 1 and 2.
****$P \leq 0.0001$. LOCF method with censoring after rescue treatment use.
LS, least squares; SD, standard deviation; SE, standard error.

Figure 3. Proportion of patients shifting DLQI impact categories over time.



LOCF method with censoring after rescue treatment use.

CONCLUSIONS

- **Dupilumab-treated patients experienced rapid improvement in quality of life, and improvements were sustained over a year in patients who achieved IGA 0–1 or EASI 75 at Week 16**
- **Patients switching to placebo after 16 weeks of dupilumab treatment partially lost the DLQI benefit of treatment in a slow and progressive manner**

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