

A new ERA for global Dermatology 10 - 15 JUNE 2019 MILAN, ITALY

ATOPIC ECZEMA/DERMATITIS

EFFECT OF DUPILUMAB ON HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS (AD): RESULTS FROM TWO IDENTICAL RANDOMIZED PHASE 3 TRIALS (LIBERTY AD SOLO 1 AND 2)

J.p. Lacour⁽¹⁾ - A. Wollenberg⁽²⁾ - T. Werfel⁽³⁾ - Y. Kataoka⁽⁴⁾ - C. Hong⁽⁵⁾ - P. Amerio⁽⁶⁾ - M. Concetta Fargnoli⁽⁷⁾ - K. Kingo⁽⁸⁾ - S.j. Seo⁽⁹⁾ - G. Moretti⁽¹⁰⁾ - A.b. Rossi⁽¹¹⁾ - Z. Chen⁽¹²⁾ - P. Tomondy⁽¹³⁾ - M. Ardeleanu⁽¹²⁾ - A. Gadkari⁽¹⁴⁾ - L. Eckert⁽¹⁵⁾

Centre Hospitalier Universitaire De Nice, Department Of Dermatology, Nice, France (1) - Ludwig-maximilian-university, Department Of Dermatology And Allergology, Munich, Germany (2) - Hannover Medical University, Department Of Dermatology And Allergy, Hannover, Germany (3) - Osaka Habikino Medical Center, Department Of Dermatology, Habikino, Japan (4) - Probity Medical Research, Department Of Dermatology, Surrey, Canada (5) - University (g. D'annunzio" Chieti – Pescara, Dermatologic Clinic, Chieti, Italy (6) - University Of L'aquila, Department Of Dermatology, L'aquila, Italy (7) - Tartu University Hospital, Clinic Of Dermatology, Tartu, Estonia (8) - Chung-ang University Hospital, Department Of Dermatology, Seoul, Republic Of Korea (9) - Papardo Hospital, Department Of Dermatology, Messina, Italy (10) - Sanofi Genzyme, Global Medical Affairs Dermatology, Cambridge, United States (11) - Regeneron Pharmaceuticals, Inc., Medical Affairs, Tarrytown, United States (12) - Sanofi Genzyme, Sanofi Genzyme, Cambridge, United States (13) - Regeneron Pharmaceuticals, Inc., Health Economics And Outcomes Research, Medical Affairs, Tarrytown, United States (14) - Sanofi, R&d, Chilly-mazarin, France (15)

Introduction: Dupilumab, a fully human anti-IL-4Ra mAb, inhibits signaling of IL-4/IL-13, key drivers of type 2-mediated inflammation. Dupilumab is indicated for treatment of moderate-to-severe AD in adult patients who are candidates for systemic therapy. AD has an important impact on patients' HRQoL, commonly assessed with the Dermatology Life Quality Index (DLQI) questionnaire.

Objective: To report the effect of dupilumab treatment on HRQoL by using pooled data from two 16-week phase 3 trials (LIBERTY AD SOLO 1: NCT02277743; LIBERTY AD SOLO 2: NCT02277769).

Materials and Methods: Adults with moderate-to-severe AD were randomized to dupilumab 300 mg weekly (qw), every 2 weeks (q2w), or placebo qw for 16 weeks. Outcomes included











A new ERA for global Dermatology 10 - 15 JUNE 2019 MILAN, ITALY

total DLQI score, as well as its 6 domains: symptoms and feelings, daily activities, leisure, personal relationships (maximum score 6), work and school, and treatment burden (maximum score 3). Patients were considered nonresponders after rescue treatment use (e.g. topical medication, systemic corticosteroids to control intolerable AD symptoms).

Results: 1,379 patients were randomized to dupilumab qw (n=462), q2w (n=457), or placebo (n=460). Baseline characteristics were balanced between treatment groups. Dupilumab treatment resulted in improvements from baseline in all DLQI domains at Week 16 (qw/q2w vs placebo: symptoms and feelings, -2.45/-2.41 vs -1.23; daily activities, -2.16/-2.19 vs -1.04; leisure, -1.86/-1.88 vs -1.02; personal relationships, -1.17/-1.18 vs -0.50; work and school, -0.97/-0.99 vs -0.43; treatment burden, -0.73/-0.72 vs -0.37). Dupilumab treatment also resulted in improvement in total DLQI score at Week 16 (qw/q2w vs placebo): -9.20/-9.30 vs -4.30 (all P values < 0.0001). Dupilumab had an acceptable safety profile.

Conclusions: Adults with moderate-to-severe AD treated with dupilumab monotherapy consistently had improvements in total DLQI score and scores in all its 6 domains compared with placebo at Week 16.





