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

ATOPIC ECZEMA/DERMATITIS

SIGNS, SYMPTOMS, AND QUALITY OF LIFE IN ATOPIC DERMATITIS: EARLY AND SUSTAINED CLINICALLY MEANINGFUL RESPONSES WITH DUPILUMAB AND CONCOMITANT TOPICAL CORTICOSTEROIDS: A PHASE 3 TRIAL POST HOC ANALYSIS

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Introduction: Treatment efficacy in atopic dermatitis (AD) may be assessed using thresholds across various measurements evaluating different aspects of disease burden on patients' health and quality of life (QoL).

Objective: This post hoc analysis describes the proportion of patients with moderate-tosevere AD treated with dupilumab plus concomitant topical corticosteroids (TCS) who achieved clinically meaningful responses in 1 or more of the 3 major AD domains (signs, symptoms, and QoL) using data from a long-term phase 3 trial (CHRONOS: NCT02260986).

Materials and Methods: Patients were randomized 3:1:3 to subcutaneous dupilumab 300mg plus concomitant TCS weekly (qw+TCS), every 2 weeks (q2w+TCS), or placebo+TCS for 52 weeks (Wks). Clinically meaningful responses were defined as: \geq 50% reduction from baseline in the Eczema Area and Severity Index score, or a reduction from baseline of \geq 3 points in weekly average peak daily pruritus Numerical Rating Scale score, or a reduction from baseline of \geq 4 points in the Dermatology Life Quality Index score. Patients were considered non-responders after rescue treatment. Relevant endpoints were assessed at







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16 timepoints from Wk1–Wk52.

Results: 315/106/319 patients were randomized to placebo+TCS/q2w+TCS/qw+TCS, respectively. More patients achieved 1 or more clinically meaningful outcomes with dupilumab+TCS vs placebo+TCS as early as Wk1 (qw+TCS/q2w+TCS vs placebo+TCS: 62.7%/61.3% vs 52.1%; P=0.0067/P=0.0972). At Wk2, 80.6%/81.1% of patients in the qw+TCS/q2w+TCS groups reached 1 or more meaningful outcomes vs 60.3% of patients receiving placebo+TCS. These results were sustained or further improved at Wk52 (qw+TCS/q2w+TCS vs placebo+TCS: 72.1%/79.2% vs 36.2%) (P<0.0001 for all timepoints assessed from Wk2–Wk52). Injection-site reactions and conjunctivitis were more frequent with dupilumab than placebo.

Conclusions: In this long-term phase 3 trial, a higher proportion of patients with moderate-tosevere AD treated with dupilumab+TCS had clinically meaningful improvement in 1 or more key AD domains (signs, symptoms, and QoL) as early as Wk1 and through Wk52.





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