Tralokinumab monotherapy in adult patients with moderate-to-severe atopic dermatitis: regional differences in baseline disease characteristics and prior treatment in ECZTRA 1 and ECZTRA 2 trials

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Prior treatment for AD
The ECZTRA 1 and 2 studies were designed to allow patients who had received previous AD treatment to be included. Therefore, the proportion of patients who had received prior treatment with any immunosuppressant, cyclosporine or biologic, was more than 95% in all regions, but highest in Japan and Australia (Figure 3).

Patient demographics and AD severity at baseline
The proportion of patients with severe AD (IGA=4) was 71.5% and 70.4% for the overall study populations in ECZTRA 1 and 2, respectively. Japan (66.7%) and Australia (63.6%) had the highest proportions of patients with severe (IGA=4) AD compared with Europe (53.1%/52.7%), and North America (48.7%/47.7%) (Figure 2).

Table 1: Demographics and baseline characteristics of all randomized patients

Study design and patients
ECZTRA 1 (n=361) and ECZTRA 2 (n=127) were randomized, double-blind, randomized, placebo-controlled, double-blind, randomized, placebo-controlled studies of tralokinumab monotherapy in patients with moderate-to-severe AD in the regions indicated. The primary objective of both studies was to evaluate the efficacy and safety of tralokinumab in moderate-to-severe AD over a 52-week period compared with placebo. Patients were randomized to receive either tralokinumab 300 mg q2w or placebo q2w in both studies. Tralokinumab 300 mg q2w was administered after an initial loading dose of 600 mg q2w and tralokinumab 300 mg q4w was administered after an initial loading dose of 1200 mg q4w.

Methods
Primary endpoints
The primary objectives were to evaluate the efficacy and safety of tralokinumab in moderate-to-severe AD over a 52-week period. The primary endpoint was the proportion of patients with moderate-to-severe AD achieving IGA-0/1 or EASI-75 at week 16 for the overall study populations in ECZTRA 1 and 2, respectively. Overall, disease characteristics and prior use of AD treatments were more prevalent in patients from Japan and Australia compared with Europe, North America, and Canada. There was high variability in prior use of systemic immunosuppressants. Cyclosporine was the most commonly used systemic immunosuppressant, used in 50.7% of patients in Japan, Europe, and Australia, followed by azathioprine (39.6%, 25.8%, and 20.3%, respectively). More patients in Europe and Australia had received phototherapy for AD compared with Asia and North America, and use of wet wraps was also higher in Australia compared with other regions.

Post hoc analysis
The analysis compared patient demographics, disease characteristics, and prior use of AD treatments in all randomized patients. Disease characteristics were more prevalent in patients from Japan and Australia compared with Europe, North America, and Canada. There was high variability in prior use of systemic immunosuppressants. Cyclosporine was the most commonly used systemic immunosuppressant, used in 50.7% of patients in Japan, Europe, and Australia, followed by azathioprine (39.6%, 25.8%, and 20.3%, respectively). More patients in Europe and Australia had received phototherapy for AD compared with Asia and North America, and use of wet wraps was also higher in Australia compared with other regions.