A global, observational, cohort study of patients with atopic dermatitis to evaluate tralokinumab real-world clinical use (TRACE): baseline characteristics from the first 100 patients in Germany

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Introduction/Background: Tralokinumab is a high-affinity, fully human IgG4 monoclonal antibody that specifically targets interleukin-13, a key driver of atopic dermatitis (AD) disease progression. Clinical trials have shown that tralokinumab is efficacious in patients with moderate-to-severe AD and has a favorable safety profile, including a low frequency of adverse events such as conjunctivitis. Management of patients in routine clinical practice differs from those enrolled in clinical trials due to strict protocol criteria, and there is a lack of clinical data on tralokinumab use in the real-world setting.

Objectives: TRACE is a real-world study in patients with AD, aiming to better understand the effectiveness, safety, and clinical use of tralokinumab in daily practice. Here, we describe baseline characteristics from the first patients enrolled into TRACE in Germany.

Methods: TRACE is an observational, prospective, single-cohort study of adult patients with moderate-to-severe AD who are treated with tralokinumab, according to national approved labels. Eleven countries are participating in the study across Europe, North America and the Middle East. The primary objective is to assess changes in clinical signs and symptoms of AD in
tralokinumab-treated patients. Secondary objectives are to investigate safety, quality of life, patient-reported outcomes and treatment adherence, among others.

**Results:** Of the first 100 patients initiated on tralokinumab, the mean age (standard deviation [SD]) was 44.7 years (17.9) and 58% were male. Most patients had moderate-to-severe AD with a mean Investigator's Global Assessment (IGA) score of 3.5 (SD 0.7) and mean Eczema Area and Severity Index (EASI) of 22.5 (SD 12.9). Patients reported heavy symptomatic burden of disease; the mean eczema-related sleep numerical rating scale (NRS) was 5.6 (SD 2.9) and mean worst daily pruritus NRS was 6.2 (SD 2.7). Patients also reported a substantial impact on quality of life, demonstrated by a mean Dermatology Life Quality Index of 15.6 (SD 6.9). Overall, 79 patients were biologic-naïve and 19 were biologic-experienced (data missing; n=2). All biologic-experienced patients were previously treated with dupilumab, of whom most experienced one or more treatment failures. Reasons for switching from dupilumab included lack or loss of effectiveness, and adverse events, which most commonly included conjunctivitis.

**Conclusions:** Initial findings showed that most adult patients with moderate-to-severe AD who were treated with tralokinumab were biologic-naïve, indicating tralokinumab is prescribed as first-line systemic treatment in real-world clinical practice, in line with European Dermatology Forum guidelines. The main reasons for switching from dupilumab were lack or loss of effectiveness, and adverse events, such as conjunctivitis, indicating the need for alternative biologic treatments such as tralokinumab.

**Keywords:** tralokinumab, real-world evidence, TRACE, atopic dermatitis, interleukin-13
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