

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: Tralokinumab is a high-affinity, fully human IgG4 monoclonal antibody that specifically inhibits interleukin-13 (IL-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 (AEs) such as conjunctivitis. However, management of patients in routine clinical practice differ from those enrolled in clinical trials due to strict inclusion/exclusion criteria, and there is currently a lack of clinical data on tralokinumab use in the real-world setting. TRACE is an observational cohort study of patients with AD, which aims to better understand the effectiveness, safety, and clinical use of tralokinumab in the real-world setting.

Objectives: To describe baseline characteristics and initial insights from the first 100 patients enrolled into TRACE in Germany.

Methods: TRACE is a longitudinal, prospective, new user, non-comparative, observational, single-cohort study, with primary data collection of adult patients with AD who are treated with tralokinumab, according to national approved labels. The study is taking place across countries

in 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 adherence, among others. This analysis includes the first 100 patients enrolled from 39 sites across Germany.

Results. Of the first 100 patients in TRACE initiated on tralokinumab in Germany, the majority were male. Most patients had moderate-to-severe disease as indicated by their mean Investigator's Global Assessment score (IGA) and mean Eczema Area and Severity Index (EASI). Patients reported heavy symptomatic burden of disease, as demonstrated by their mean eczema-related sleep numerical rating scale (NRS) and mean worst daily pruritus NRS. Patients also reported a substantial impact on quality of life, as demonstrated by mean Dermatology Life Quality Index (DLQI). Overall, approximately $\frac{4}{5}$ of the patients were biologic-naïve. 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 efficacy, and AEs which included mainly conjunctivitis.

Conclusions: Initial findings from the first 100 patients from TRACE in Germany showed that the majority of adult patients with moderate-to-severe AD treated with tralokinumab were biologic-naïve, indicating that tralokinumab is prescribed as first-line systemic treatment in the real world, in line with European Dermatology Forum guidelines. Of patients who switched from dupilumab, the main reasons for switching were lack or loss of efficacy, and conjunctivitis, indicating the need for an alternative biologic treatment such as tralokinumab.

Keywords (up to 5): atopic dermatitis, tralokinumab, IL-13, TRACE, real-world data

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