Tralokinumab real-world use in adults with atopic dermatitis: baseline characteristics of the first 100 patients recruited to the TRACE study in the United States

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Introduction/Background: Tralokinumab is a fully human, high-affinity, monoclonal antibody that specifically neutralizes interleukin-13, a key driver of atopic dermatitis (AD) pathogenesis. Numerous clinical studies have established that tralokinumab is an efficacious treatment for patients with moderate-to-severe AD, along with having a favorable safety profile. However, there is a lack of evidence on tralokinumab use in routine clinical practice, where patient management may differ from that defined by clinical trial protocols.

Objectives: TRACE is a global, real-world study that aims to better understand the effectiveness, safety, and clinical use of tralokinumab in patients with AD in daily practice.

Methods: TRACE is a global, observational, prospective, single-cohort study of tralokinumab-treated adults with moderate-to-severe AD. Overall, 11 countries across Europe, North America and the Middle East are participating. The primary objective of TRACE is to assess changes in clinical signs and symptoms of AD in patients treated with tralokinumab according to the nationally approved labels. Secondary objectives include safety, quality of life, patient-reported
outcomes and treatment adherence. For this interim analysis, the objective was to report the baseline characteristics of the first 100 US patients.

**Results:** Overall, 55% of the first 100 US patients initiated on tralokinumab in the TRACE study were female; the majority (54%) were White, followed by 18% Black or African American and 12% Asian. Mean (standard deviation [SD]) age was 46.4 years (18.2) and body mass index was 28.6 kg/m$^2$ (7.7). Patients had a mean disease duration of 13.9 years (SD 16.5), with 46% being biologic-naïve and 54% biologic-experienced. Most patients (88%) had moderate-to-severe AD, with a mean Investigator’s Global Assessment score of 3.2 (SD 0.8); mean Eczema Area and Severity Index was 15.4 (SD 7.9). A heavy symptomatic burden of disease was evident, with a mean eczema-related sleep numerical rating scale (NRS) of 4.2 (SD 3.3) and mean worst daily pruritus NRS of 6.1 (SD 2.6). Patients also reported a substantial impact of AD on quality of life; mean Dermatology Life Quality Index was 13.2 (SD 8.5). Almost one quarter (24%) of patients reported ≥1 atopic comorbidity, with asthma (12%), cardiovascular disease (8%) and autoimmune disease (6%) being the most frequent; 3% of patients had psychiatric illness.

**Conclusions:** Initial findings showed that tralokinumab is being prescribed as a first-line biologic treatment option in the US in accordance with the label. Treated patients had a heavy burden of disease with considerable impact on quality of life.

**Keywords:** tralokinumab, real-world, baseline, observational, moderate-to-severe
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Tien Nguyen and Jerry Bagel have nothing to declare.

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