Real-world baseline characteristics and persistence in adult patients initiating tralokinumab in the CorEvitas atopic dermatitis registry

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Introduction/Background: Tralokinumab is a high-affinity monoclonal antibody that specifically targets interleukin (IL)-13, a key driver of atopic dermatitis (AD). In clinical trials, tralokinumab demonstrated efficacy and a favorable safety profile for the treatment of moderate-to-severe AD in adults and adolescents. However, data on patients in the real-world setting and persistence to treatment is currently limited.

Objectives: To describe the baseline characteristics and persistence at 6 months of treatment in US adult patients with AD initiating tralokinumab in the CorEvitas AD registry.

Methods: The CorEvitas Atopic Dermatitis Registry is a prospective, non-interventional registry launched in July 2020 for adult AD patients under the care of a licensed dermatologist or qualified dermatology practitioner. Data are collected from both patients and providers approximately every 6 months during routine clinical encounters. This analysis included U.S. patients enrolled in the CorEvitas AD registry who initiated tralokinumab between February 1, 2022 (the commercial launch date) and May 31, 2023 and had baseline data. Baseline demographics and clinical characteristics were summarized using descriptive statistics and stratified by advanced systemic therapy (AST) experience, defined as any previous history of dupilumab, abrocitinib, or upadacitinib for AD
treatment. A 6-month follow-up visit was defined as a visit occurring 5 to 9 months following tralokinumab initiation.

**Results:** Among 259 included patients in this study the mean age was 50.8 years. The majority of patients were female (156/259, 60.2%), White (202/259, 78.0%), worked full-time (143/259, 55.2%), had private health insurance (201/259, 77.6%), and were concomitantly on topical therapy (203/259, 78.4%). Most patients had moderate-to-severe disease, with mean Eczema Area and Severity Index (EASI) of 14.2. Approximately half of patients reported AD involvement of head (face: 121/259, 46.7%; scalp: 80/259, 30.9%; neck: 93/259, 35.9%) and hands (dorsal: 150/259, 57.9%; palmar: 130/259, 50.2%). Patients reported high symptomatic disease burden, demonstrated by mean peak pruritus in past 24 hours numerical rating scale (NRS) of 6.2, and moderate impact on quality of life, as demonstrated by mean Dermatology Life Quality Index (DLQI) of 9.8. At tralokinumab initiation, 87 patients (33.6%) were AST-experienced, of whom 95.4% (83/87) had used dupilumab. Among AST-naïve patients, 80.8% (139/172) had used super potent topical steroids, 36.0% (62/172) topical calcineurin inhibitors, and 10.5% (18/172) topical PDE4 inhibitors. Overall, socio-demographic characteristics were similar between AST-naïve and AST-experienced groups, while AST-naïve patients had higher disease severity at initiation, including mean BSA (29.4% vs. 16.9%) and mean EASI (16.9 vs. 8.8). Among patients with a 6-month follow-up visit (n=81), 74.1% (60/81) remained persistent on tralokinumab. Baseline characteristics of patients with 6-month follow-up, and of persistent patients, were similar to the total population. Among persistent patients, 73.3% (44/60) were AST-Naive and 26.7% (16/60) were AST-experienced, all of whom were dupilumab-experienced. Mean EASI among persistent patients improved from 13.8 at baseline to 3.3 at 6 months. Of the 21 patients who discontinued tralokinumab, 52.4% (11/21) were AST-experienced at initiation, and 42.9% (9/21) switched to another systemic therapy following tralokinumab. Reasons for discontinuation included lack of efficacy (AST-naïve: 30.0%, 3/10; AST-
experienced: 45.5%, 5/11), safety (AST-naïve: 30.0%, 3/10; AST-experienced: 9.1%, 1/11),
insurance (AST-naïve: 10.0%, 1/10; AST-experienced: 9.1%, 1/11), and other (AST-naïve: 30.0%,
3/10; AST-experienced: 36.4%, 4/11).

**Conclusions:** In this US real-world study, adult AD patients initiating tralokinumab were both AST-
naïve and AST-experienced with a high burden of disease. Approximately three-quarters of patients
were persistent with tralokinumab treatment at 6 months. Further real-world evidence studies on
tralokinumab persistence with longer follow-up period are warranted.

**Keywords:** Atopic dermatitis, tralokinumab, IL-13, real-world data, persistence

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