Real-world effectiveness of persistent tralokinumab use on clinician and patient-reported outcomes in patients with atopic dermatitis in the CorEvitas atopic dermatitis registry

Jonathan Silverberg¹, Sanjeev Balu², C. Jean Choi³, Alvin Li³, Oksana Pugach³, Shannon Schneider², Eric Simpson⁴

¹The George Washington School of Medicine and Health Sciences, Washington, DC, USA; ²LEO Pharma Inc., Madison, NJ, USA; ³CorEvitas, LLC, Waltham, MA, USA; ⁴Department of Dermatology, Oregon Health & Science University, Portland, OR, USA

Introduction/Background: Tralokinumab is a high-affinity monoclonal antibody that specifically targets IL-13, a driver of inflammation in atopic dermatitis (AD). The ECZTRA 1, 2, 3, and 6 trials demonstrated that tralokinumab is efficacious and safe in adults and adolescents; however, real-world evidence on tralokinumab use is limited.

Objectives: To assess the change from baseline in clinician-assessed and patient-reported outcomes (PROs) among US adults with AD following 6 months of persistent tralokinumab use after treatment initiation in the CorEvitas AD registry.

Methods: The CorEvitas AD 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. This analysis includes US patients enrolled in the CorEvitas AD registry who initiated tralokinumab between February 1, 2022 and May 31, 2023, had baseline data, and were persistent on tralokinumab at the 6-month follow-up (defined as a visit occurring 5 to 9 months from tralokinumab initiation). Baseline data were summarized using descriptive statistics and stratified by advanced systemic therapy (AST) experience (defined as any previous history of dupilumab,
abrocitinib, or upadacitinib). Outcome measures collected included: validated Investigator’s Global Assessment for atopic dermatitis (vIGA-AD™), ≥50%/≥75% improvement in Eczema Area and Severity Index (EASI) (EASI-50/75), ≥4-point improvement in Dermatology Life Quality Index (DLQI), ≥3-point improvement in mean weekly pruritis numerical rating scale, and mean change in Work Productivity and Activity Impairment (WPAI).

Results: Among the 60 patients in this analysis, the mean age was 49.1 years and mean AD duration was 15.0 years. The majority of patients were female (34/60, 56.7%), White (51/60, 85.0%), worked full-time (38/60, 63.3%), and AST-naïve (44/60, 73.3%). At baseline, the majority of patients had moderate-to-severe AD based on EASI (EASI≥ 7, 40/60, 67%) and vIGA-AD™ (vIGA-AD™ 3: 50/60, 83.3%; vIGA-AD™ 4: 4/60, 6.7%). Disease severity was lower in AST-experienced patients, all of whom were dupilumab-experienced. A notable proportion of patients experienced improvements in clinician-assessed endpoints and PROs from baseline to 6 months: vIGA-AD™≤1 from 6.7% (4/60) to 55.0% (33/60), EASI≤7 from 33.3% (20/60) to 85.0% (51/60), and DLQI≤5 from 38.3% (23/60) to 66.7% (40/60).

Among patients with EASI≥7.1 at baseline, 85.0% (34/40) achieved EASI-50 (AST-naïve: 90.9%, 30/33; AST-experienced: 57.1%, 4/7) and 77.5% (31/40) achieved EASI-75 (AST-naïve: 84.8%, 28/33; AST-experienced: 42.9%, 3/7) at the 6-month follow-up. In patients with vIGA-AD™ of 3 or 4 at baseline, 79.6% (43/54) achieved EASI-50 (AST-naïve: 83.3%, 35/42; AST-experienced: 66.7%, 8/12) and 66.7% (36/54) achieved EASI-75 (AST-naïve: 76.2%, 32/42; AST-experienced: 33.3%, 4/12) at follow-up. Among patients with baseline DLQI≥4, 71.4% (30/42) achieved ≥4-point improvement at follow-up (AST-naïve: 78.1%, 25/32; AST-experienced: 50.0%, 5/10). Of patients with baseline mean weekly pruritus NRS≥3, 69.8% (37/53) achieved ≥3-point improvement at follow-up (AST-naïve: 70.0%, 28/40; AST-experienced: 69.2%, 9/13). Among the 40 patients
employed at both baseline and follow-up visit, improvements were reported in WPAI. Percent impairment at work due to AD decreased by 14.8% (95% CI: -25.6%; -3.9%) and percent overall work impairment due to AD decreased by 15.7% (95% CI: -26.4%; -5.0%). For all 60 patients, non-work activity impairment due to AD decreased by 14.5% (95% CI: -23.9%; -5.1%).

Conclusions: In this real-world study, patients with AD experienced notable improvements in both clinician-assessed and patient-reported outcomes after 6-months of persistent tralokinumab treatment, regardless of prior AST therapy use. All 16 AST-experienced patients had prior use of dupilumab. These findings support the therapeutic potential of tralokinumab for AD patients, highlighting the need for future studies with longer follow-up period and larger sample size.

Keywords: atopic dermatitis, tralokinumab, IL-13, real-world data, effectiveness

Acknowledgements and Funding Sources:

This study is sponsored by CorEvitas, LLC. CorEvitas has been supported through contracted subscriptions in the last two years by AbbVie, Amgen, Inc., Arena, Boehringer Ingelheim, Bristol Myers Squibb, Chugai, Eli Lilly and Company, Genentech, GSK, Janssen Pharmaceuticals, Inc., LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Inc., Sun Pharmaceutical Industries Ltd., and UCB S.A. This analysis was sponsored by LEO Pharma Inc. (Madison, NJ). Medical writing and editorial support from Alphabet Health (New York, NY) by Michelle Dookwah-Smith, PhD, was funded by LEO Pharma Inc.
Disclosures:

JS: reports honoraria as a consultant/advisory board member from LEO Pharma and has acted as a consultant for and/or received grants/honoraria from AbbVie, AnaptysBio, Asana Biosciences, Galderma Research and Development, GSK, Glenmark, Kiniksa, LEO Pharma, Lilly, MedImmune, Menlo Therapeutics, Pfizer, PuriCore, Regeneron, and Sanofi

ES: reports grants and/or personal fees from AbbVie, Boehringer Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly, FortéBio, Galderma, Incyte, Kyowa Kirin, LEO Pharma, MedImmune, Menlo Therapeutics, Merck, Novartis, Ortho Dermatologics, Pfizer, Pierre Fabre Dermo Cosmetique, Regeneron, Sanofi, Tioga, and Valeant

AL, OP, JC: Employee of CorEvitas, LLC

SB and SS: Employee of LEO Pharma