The TCS/TCI-Free Rate Remains High and Stable While on Lebrikizumab for Treatment of Moderate-to-Severe Atopic Dermatitis Over 1 Year

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BACKGROUND
- Lebrikizumab is a monoclonal antibody that binds with high affinity and slow off-rate to IL-13, thereby blocking the downstream effects of IL-13 with high potency.
- Phase 3 randomized, double-blind, placebo-controlled trials in patients with moderate-to-severe AD in which lebrikizumab demonstrated efficacy and safety.
- Lebrikizumab demonstrated clinical benefit in patients with moderate-to-severe AD after 16 and 52 weeks of treatment.
- TCS and TCI are commonly used as concomitant treatments for AD.
- Long-term use of TCS or TCI has challenges with large areas of BSA involvement or more diffuse involvement, and may lead to side effects and increased burden.

OBJECTIVES
- To determine the proportion of patients without TCS or TCI usage by study visit during the maintenance period from Week 16 to Week 52.
- To assess the proportion of patients without TCS or TCI usage by study visit during the maintenance period.

METHODS

Study Design: ADVocate 1 and ADVocate 2

Key Eligibility Criteria
- Adults or adolescents (12 to <18 years; weight ≥40 kg).
- Diagnosis of AD, as defined by the American Academy of Dermatology Consensus Criteria, for ≥1 year before screening.
- Moderate-to-severe AD, as defined by all of the following at the baseline visit:
  - EASI ≥16
  - BSA ≥23
  - BSA involvement ≥20%
  - Candidate for systemic therapy
  - Biologic naïve

Analysis Population
- POOLED mNPP of ADVocate 1 & 2 (lebrikizumab responders at Week 16) who entered the maintenance period through Week 52.
-ADVocate efficacy and safety analyses were performed on a modified population, excluding 17 patients who entered the maintenance period (from a single study site) whose eligibility could not be confirmed.

Statistical Methodology
- The proportions of patients summarized across the maintenance period or by study visit from Week 16 to Week 52 were based on descriptive analyses of observed data, reported for patients not using TCS, TCI, or either TCS or TCI.
- The time to the first use of TCS, TCI, or either TCS or TCI was analyzed using the Kaplan-Meier method, and the survival time among groups was compared with the log-rank test.

RESULTS

Most Patients did not use TCS or TCI During the Maintenance Period

Baseline Demographics and Disease Characteristics

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REFERENCE

DISCLOSURES
- All authors provided significant contributions to the research and writing of the manuscript.
- The authors declare no conflicts of interest.

Abbreviations
- AD: Atopic dermatitis
- TCS: Topical corticosteroids
- TCI: Topical immunomodulators
- EASI: Eczema Area and Severity Index
- IGA: Investigator’s Global Assessment
- EMA: European Medicines Agency
- FDA: US Food and Drug Administration
- NR: Not reached
- NRSc: Not reached—scored
- NRcs: Not reached—scored
- NRsc: Not reached and scored
- %: Percent
- kg: Kilograms
- cm: Centimeters
- lb: Pounds
- mm: Millimeters