Lebrikizumab-Treated Patients With Atopic Dermatitis Had No Increase in Treatment-Emergent Adverse Events of Facial, Head, and Neck Erythema Compared to Placebo

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BACKGROUND

- Use of some advanced systemic therapies has been associated with the development of facial, head, and neck erythema in patients with AD
- Potential causes include T-cell/T-helper 1 cytokine profile switching, undiagnosed allergic contact dermatitis, reaction to facial Malassezia species, colonization of Demodex mites, resistance of facial AD to therapy, or drug eruption
- 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
- Lebrikizumab has demonstrated a positive benefit-risk profile and efficacy in Phase 2 and Phase 3 clinical trials for AD

OBJECTIVE

- To assess the development of facial, head, and/or neck erythema in patients taking lebrikizumab for moderate-to-severe AD

METHODS

Integrative Safety Analysis Study Design

- Phase 1: 16 weeks of induction + 36 weeks of maintenance
- Phase 2: 12 weeks, single dose, LEBRI 250 mg Q2W and Q4W (ongoing)

PBO-Controlled, Weeks 0-16 All LEBRI

- 2 studies: Adovate1, Adovate2, ADhere, and a Phase 2b study

All LEBRI Analysis Set

- Patients who received 21 dose of LEBRI
- 8 studies: Adovate1, Adovate2, ADhere, ADjoin, ADore, TREBLE, ARBAN, and a Phase 2b study

SUMMARY OF KEY FINDINGS

- Treatment-emergent adverse events of facial, head, or neck not increased in patients with moderate-to-severe AD treated with lebrikizumab compared with placebo
- The IR did not increase with increased number of exposure years to lebrikizumab

CONCLUSIONS

- The development of treatment-emergent adverse events of facial, head, and neck erythema is not more common in patients moderate-to-severe AD taking lebrikizumab than those taking placebo
- IR does not increase with increased number of exposure years to lebrikizumab

Assessments and Statistical Analyses

- Treatment-emergent AEs were analyzed for specified terms related to facial, head, and neck erythema in adults and adolescents with moderate-to-severe AD based on patients who received 21 dose of study treatment, excluding 38 patients from one study site as the patient eligibility criteria could not be confirmed
- Blinded medical review was completed
- For PBO-controlled group, adj % and adj IRs were used to report AEs
- For All LEBRI group, crude % and IRs were reported
- Adj IRs were calculated as the number of patients reporting an event per 100 PYR

RESULTS

Development of Treatment-Emergent Facial, Head, and/or Neck Erythema

- Baseline Patient Demographics and Disease Characteristics

Baseline Patient Demographics and Disease Characteristics

- Table showing the distribution of patient demographics and disease characteristics

Limitations

- These findings need to be confirmed in the real-world setting

REFERENCES

- Format: [Author(s)]. Title of the Article. Journal Name, Year, Volume, Issue: Pages
- For example: [Smith, J. D.] Smith, J. D. The impact of treatment on patient outcomes. J. Pharm. Pract., 2020, 33(2), 123-134
- Other important references

ABBREVIATIONS

- LEBRI: Lebrikizumab
- PBO: Placebo
- IR: Incidence rate
- PYR: Patient-years of exposure
- PYE: Patient-years at risk
- BMI: Body mass index
- AD: Atopic dermatitis
- ADvocate1: A randomized, double-blind, placebo-controlled study
- ADvocate2: A randomized, double-blind, placebo-controlled study
- ADjoin: A Phase 1B/2a study
- ADore: A Phase 2b study
- ADhere: A Phase 3 study
- PBO-Controlled: A placebo-controlled study
- Treatment-Emergent Adverse Events (TEAEs): Adverse events that occur after the establishment of a treatment relationship
- Treatment-Emergent Adverse Events of Facial, Head, and/or Neck Erythema (TEAE-NEE): Adverse events related to facial, head, or neck erythema

DECLARATIONS

- Author(s) declare no competing interests
- Funding and disclosures

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