Efficacy and Safety of Amlitelimab, an Anti-OX40 Ligand Antibody, in Patients With Moderate-to-Severe Atopic Dermatitis (AD): A Phase 2b Trial (STREAM-AD)

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Background
- Amlitelimab is a fully human, non-depleting, anti-OX40L monoclonal antibody.
- Blocks upregulation (GHR) on antigen-presenting cells and
- Inhibits T-cell-dependent inflammation without T-cell depletion
- Immunomodulation of the AD pathway
- Potential for a sustained and durable clinical response both on and off treatment observed in Part 2b study

Methods
- STREAM-AD (NCT01314177): A two-part, randomized, placebo-controlled, double-blind, Phase 2b trial for adults (≥18 to ≤75 years; n=390)
  Part 1: 24-week monotherapy treatment period. Participants were randomized 1:1:1 to:
  - 250 mg with Q12W dosing (n=125) – 250 mg without LD (n=125)
  - 250 mg with Q12W dosing (n=125) – 250 mg without LD (n=125)
  Part 2: 22-week extension/withdrawal phase (n=140). At week 24, patients with loss of response were randomized to continue with the plaformer (n=61), while clinical responders were re-randomized in a 3:1 ratio to:
    - Withdraw from treatment (plaformer) or
    - Continue their pre-week 24 admlitelimab (Q12W dosing) (n=63)

Key Results

1. In Part 1, admlitelimab demonstrated efficacy, safety, and tolerability across all coQ12W doses, with improvements through Week 24

2. Part 2 showed durable clinical and biomarker response across all doses, which supports the viability of a weekly extended-dosing regimen

3. Admlitelimab demonstrated an acceptable safety profile

4. Ongoing OCEANA AD Phase 3 program in adults and adolescents will confirm the efficacy and safety of admlitelimab, moving on and off treatment

Results (continued)

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Figure 1. D404 Ligand-OX40 axis: a secondary co-stimulatory pathway

Figure 2. STREAM-AD met key primary and secondary endpoints in Part 1

Figure 3. Durable clinical response on and off-amlitelimab was observed regardless of how rescue medications were statistically handled

Figure 4. Durable clinical response was maintained following drug withdrawal despite serum admlitelimab reaching negligible levels

References

Disclosures

Acknowledgments

Presented at Revolutionizing Atopic Dermatitis (RAD): Chicago, Illinois, United States; June 8–10, 2024.

Note from the moderator: please stay on this topic and refer to the abstract for additional information about the trial and the available medications.