Amlitelimab (an anti-OX40 Ligand antibody) vs placebo in patients with moderate-to-severe atopic dermatitis: Study design of OCEANA phase 3 trials COAST 1/2, SHORE, AQUA, and ESTUARY

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Introduction

OX40L–OX40 Signaling: A Therapeutic Target in Atopic Dermatitis

- Anti-OX40L therapy has been shown to induce a range of immunological effects, including the inhibition of Th2-driven allergic inflammation.
- Blocks OX40L–OX40 signaling, which is an essential costimulatory pathway for T-cell activation.

Methods

Phase 3 Trials in AD for Patients with Inadequate Response to Biologic or Oral JAK Inhibitor Therapy
- Randomized, double-blind, placebo-controlled, parallel-group, 3-arm, multinational, multicenter study to evaluate the efficacy and safety of SC amlitelimab in patients on background topical corticosteroid (TCS) plus/or topical calcineurin inhibitor (TCI) who have had an inadequate response to prior biologic therapy or oral JAK inhibitor treatment.
- Key Secondary Gradients: USA/USA reference countries; vIGA AD 0/1 and a reduction from baseline of ≥4 points - EU/CIPA/SO reference countries; vIGA AD 0/1 and ≥5 points.
- Timepoint of primary and secondary endpoints: Week 16.

References

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Footnotes
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