Nemolizumab fast onset of action in adolescents with moderate-to-severe atopic dermatitis: Results from a pooled subgroup analysis of the ARCADIA Phase 3 Studies

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Acknowledgments and Funding: The authors wish to thank all the investigators and patients involved in the trial. This investigation was funded by Galderma.

Encore Disclosure: Research first presented at European Academy of Allergy and Clinical Immunology (EAACI) Congress 2026; June 12-15, 2026; Istanbul, Türkiye.

Medical Writing: Medical writing support was provided by Kavya Thelakkat (Galderma), in accordance with the Good Publication Practice 2022, guidelines (https://www.ismpp.org/gpp-2022).

Introduction: Itch is the most burdensome symptoms in patients suffering from atopic dermatitis (AD). Nemolizumab, a first-in-class interleukin-31 receptor alpha antagonist, has shown rapid and significant improvements in skin lesions and itch with a favorable safety profile in patients with moderate-to-severe AD. Prior adolescent subgroup analyses reported improvement in skin and itch response comparable to the full population (Week 16: Investigator's Global Assessment success was achieved by 48.9% [nemolizumab] vs 34.4% [placebo] and ≥75% improvement in the Eczema Area and Severity Index by 53.4% vs 43.3% patients) with favorable tolerability. This subgroup analysis of the pivotal studies assessed the early onset of itch and sleep improvement with nemolizumab over the first 14 days in adolescents.

Methods: Data for adolescents (12-17 years old) with moderate-to-severe AD were pooled over Days 1-14 following day of first injection from two double-blind, phase 3 studies (ARCADIA 1 [NCT03985943] & ARCADIA 2 [NCT03989349]). Eligible patients were randomized 2:1 to nemolizumab 30mg (60mg at baseline) or placebo, administered subcutaneously every 4 weeks with concomitant background topical corticosteroids ± topical calcineurin inhibitors. Key endpoints included daily Peak Pruritus Numerical Rating Scale (PP-NRS) response (Least squares [LS] mean percent change from baseline and ≥4-point improvement [PP-NRS4]) and sleep disturbance (≥4-point improvement in Sleep Disturbance Numerical Rating Scale [SD-NRS4]).

Results: A total of 266 adolescents were included. Nemolizumab treatment was associated with rapid itch improvement. By Day 2, the LS mean percent change in PP-NRS from baseline vs placebo was −19.0% vs -6.2% ($p<0.0001$), further improving to −30.2% vs -7.7% ($p<0.0001$) by Day 14. A significantly greater proportion of patients achieved PP-NRS4 at Day 2 (14.2% vs 1.1%; 95% CI: 7.2, 18.4; $p<0.001$), with continued improvement through Day 14 (25.0% vs 7.8%; 95% CI: 8.3, 25.2; $p=0.001$). Sleep disturbance also improved rapidly. At Day 3 (15.9% vs

5.6%; 95% CI: 2.9, 17.2; $p<0.05$) with improvement at Day 14 (24.4% vs 7.8%; 95% CI: 8.0, 24.9; $p<0.01$).

Conclusion: Consistent with findings from the full population, nemolizumab provided rapid clinically meaningful itch relief as early as Day 2 and improved sleep disturbance in adolescents with moderate-to-severe AD inadequately controlled by topical therapies.