Maintenance of efficacy and safety with nemolizumab at week 48: results from two global phase 3 pivotal studies (ARCADIA-1 and ARCADIA-2) in patients with moderate-to-severe atopic dermatitis

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**Background:** Atopic dermatitis (AD) is a common, chronic, and flaring itchy inflammatory skin disease requiring long-term treatment. Nemolizumab significantly improved skin lesions, itch, and sleep through Week (W) 16 in two global phase 3 studies (ARCADIA-1 [NCT03985943] and ARCADIA-2 [NCT03989349]) in adolescents and adults with moderate-to-severe AD.

**Objectives:** To evaluate the efficacy and the safety of maintenance treatment with nemolizumab with background topical therapy for up to 32 weeks in patients (≥12 years) with moderate-to-severe atopic dermatitis.

**Methods:** This analysis pooled 32-week maintenance data from two double-blind, placebo controlled, phase 3 studies (N=507) in moderate-to-severe AD. Clinical responders (IGA 0/1 [clear/almost-clear] or EASI-75 [75% improvement in EASI score]) to nemolizumab at W16 were re-randomized (1:1:1) to receive nemolizumab 30mg every 4 weeks (Q4W), nemolizumab 30mg Q8W, or placebo (nemolizumab withdrawal) Q4W subcutaneously for further 32 weeks in combination with topical corticosteroids of low/medium potency and/or topical calcineurin inhibitors. Safety was assessed throughout the study.

**Results:** At W48, the proportion of patients who maintained IGA success (defined as IGA score of 0 [clear] or 1 [almost clear] and a ≥2-point improvement from baseline) was 61.5% (nemolizumab-Q4W), 60.4% (nemolizumab-Q8W), and 49.7% (placebo); EASI-75 was maintained in 76.3% (nemolizumab-Q4W), 75.7% (nemolizumab-Q8W), and 63.9% (placebo); and itch response (≥4 points improvement in weekly average PPNRS) was achieved in 76.2% (nemolizumab-Q4W), 59.7% (nemolizumab-Q8W), and 41.0% (placebo). Similarly, response in sleep and quality of life was well maintained at W48. The safety profile was consistent across treatment arms; most treatment-emergent adverse events were non-serious and mild/moderate in intensity.

**Conclusions:** Among patients with clinical responses in skin lesions at W16, the majority maintained skin and itch responses at W48 with nemolizumab Q4W/Q8W. Nemolizumab was well-tolerated up to W48, and no safety signals were identified.

**Keywords:** Atopic dermatitis, itch, nemolizumab, quality of life, skin lesion
Reference:


Acknowledgments and Funding Sources:
Research was first presented at American Academy of Dermatology (AAD) Annual Meeting, San Diego, CA held between 08-12 March 2024.

Medical writing/editorial support as provided by Deepika (Galderma), in accordance with the Good Publication Practice 2022 guidelines (https://www.ismpp.org/gpp-2022).

The research was sponsored by Galderma.

Disclosures:

JIS has received honoraria as a consultant and/or advisory board member from AbbVie, Afyx, AOBiome, Arena, Asana, Aslan, BioMX, Bluefin, Bodewell, Boehringer-Ingelheim, Celgene, Connect Biopharma, Dermavant, Dermira, Eli Lilly, Galderma, GlaxoSmithKline, Incyte, Kiniksa, LEO Pharma, Luna, Menlo, Novartis, Pfizer, RAPT, Regeneron, and Sanofi-Genzyme and as a speaker from AbbVie, Eli Lilly, LEO Pharma, Pfizer, Regeneron, and Sanofi-Genzyme; his institution has received grants from Galderma and Pfizer. AW has served as an advisor and/or paid speaker for and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, Beiersdorf, Bioderma, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai, Galapagos, Galderma, Janssen-Cilag, LEO Pharma, L’Oréal, Eli Lilly, Novartis, Pfizer, Pierre Fabre, Regeneron, and Sanofi. FJL has served as an investigator for Galderma and has received consulting fees or honoraria from AbbVie, Almirall, Amgen, Celgene, Eli Lilly, Galderma, LEO Pharma, Menlo Therapeutics, Novartis, Pelpharma, Pfizer, Sanofi Aventis, Trevi Therapeutics, and Vifor Pharma. VTL conducts research for AbbVie, Acelyrin, Acrotech, Amgen, Argenx, Arcutis, Aslan, Biofrontera, Bristol Meyers Squibb, Cara, Dermavant, Eli Lilly, Galderma, Horizon Therapeutics, Incyte, Janssen, LEO Pharma, Novartis, Padagis, Pfizer, Q32, Rapt, Sun, UCB, and Ventyx. AWA has served as an investigator for Galderma and has received research grants and personal fees from Bristol Myers.
Squibb, Eli Lilly, Janssen, LEO Pharma, and Novartis; personal fees from Boehringer Ingelheim/Parexel, Celgene, Dermavant, Genentech, GlaxoSmithKline, Menlo Therapeutics, Merck, Modernizing Medicine, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Science 37, Sun Pharma, and Valeant; and grants from Dermira, Kyowa Hakko Kirin, and UCB, outside the submitted work. **PH** has been an investigator, speaker, and/or consultant for AbbVie, Almirall, Amgen, Bristol Myers Squibb, Janssen, Eli Lilly, Galderma, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi Genzyme, and UCB Pharma. **LN** has served as an investigator for Galderma. **FA**, **LU**, and **CP** are employees of Galderma and hold stocks in the company.