Long-term safety and efficacy (up to 152 weeks) of nemolizumab in ARCADIA open-label long-term extension study in adults and adolescents with moderate-to-severe atopic dermatitis

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Introduction: Long-term clinical data are essential to establish sustained efficacy and safety of atopic dermatitis (AD) treatment. The ARCADIA long-term extension study (NCT03989206; 200-week duration) aimed to evaluate the safety and efficacy of nemolizumab in adults and adolescents with moderate-to-severe AD. Previously presented data suggested that nemolizumab showed continuous improvements in itch, skin lesions and sleep through week (W)104 with a favourable safety profile in patients with moderate-to-severe AD. Herein, we report safety data in all treated patients and efficacy data up to W152 at the time of the new data cut-off (July 2025).

Materials and Methods: This prospective, multicentre, open-label, long-term extension study enrolled nemolizumab-previously experienced [NPE] or nemolizumab-naïve [NN] participants from ARCADIA 1&2 phase 3 and other nemolizumab studies. Participants received nemolizumab 30mg every 4 weeks alongside background topical corticosteroids (low/medium potency) with or without topical calcineurin inhibitors. Efficacy endpoints included Investigator's Global Assessment (IGA) score of 0/1 (clear/almost clear), ≥50%/≥75%/≥90% improvement from baseline in the Eczema Area and Severity Index (EASI-50/EASI-75/EASI-90), ≥4-point improvement from lead-in baseline in visual analogue scale (VAS) Pruritus and in VAS Sleep loss of SCORing Atopic Dermatitis (SCORAD) score, SCORAD VAS Pruritus score <2, ≥4-point improvement from lead-in baseline in Dermatology Life Quality Index (DLQI) score, and DLQI score of 0/1. Efficacy outcomes are presented using as-observed (AO; observed cases [OC]; no imputations were made for missing data) analyses, and multiple imputation (MI) under a missing-at-random (MAR) assumption was conducted as a sensitivity analysis.

Results: Of 1901 treated participants, 1268 (67%) had completed W104 and 995 (52%) had completed W152 at the time of data cut-off. Of 1164 NPE participants and 737 NN participants, 72 (6%) and 39 (5%) respectively discontinued the study due to adverse events. At W152, the proportion of NPE and NN participants achieving efficacy outcomes (OC analysis) was 65% and 67% for IGA 0/1, 97% and 97% for EASI-50, 88% and 91% for EASI-75, and 72% and 75% for EASI-90, respectively; 88% and 86% achieved a ≥4-point improvement from lead-in baseline in SCORAD VAS Pruritus, 73% and 68% achieved a SCORAD VAS Pruritus score <2, 92% and 90% achieved a ≥4-point improvement from lead-in baseline in DLQI, and 57% and 59% achieved a DLQI score of 0/1, respectively. At W152, the proportion of NPE and NN participants achieving efficacy outcomes (MI analysis for MAR data) was 57% and 56% for IGA 0/1, 74% and 70% for EASI-50, 61% and 59% for EASI-75 and 46% and 46% for EASI-90, respectively. Improvements in sleep parameters mirrored those observed in itch parameters. The most frequently reported adverse events were nasopharyngitis, COVID-19, and dermatitis atopic. Exposure-adjusted incidence rates for any treatment emergent adverse events were 105 participants/100 person years (NPE) and 111 participants/100 person years (NN). Safety results corroborated those previously reported.

Conclusions

Long-term nemolizumab treatment was effective through W152 and well tolerated with a low study discontinuation rate due to adverse events. Sustained and continuous improvements were observed in skin lesions, itch relief, sleep disturbance and quality of life.