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Nemolizumab long-term safety and efficacy up to 56 weeks in ARCADIA open-label extension study in adolescents and adults with moderate-to-severe atopic dermatitis

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Introduction & Objectives: Atopic dermatitis (AD) is a common chronic, flaring neuroinflammatory skin disease, requiring long-term disease control. The ARCADIA long-term extension (LTE), prospective, multicenter, open-label, pooled study (NCT03989206) enrolled patients from ARCADIA-1 and -2 Phase 3 studies and other nemolizumab studies to evaluate long-term safety and efficacy of nemolizumab in adolescents and adults with moderate-to-severe AD.

Materials & Methods: Patients with previous nemolizumab experience [PNE] or nemolizumab-naïve [NN] in lead-in studies received 30 mg subcutaneous nemolizumab every 4 weeks up to Week (W) 200 with background topical corticosteroids of low/medium potency or topical calcineurin inhibitors. Efficacy assessments included proportion of patients achieving Investigator's Global assessment (IGA) score of 0/1 (clear/almost clear) and Eczema area and severity index (EASI)-75 (75% improvement in EASI score), and changes in SCORing Atopic Dermatitis (SCORAD) score (including itch and sleep Visual analog scale [VAS] components) and quality of life (QoL). Results of W56 data cut-off are presented. Efficacy endpoints are summarized using observed data.

Results: Of 1740 patients, 723 patients completed W56 at data cut-off. At baseline, the proportion of PNE and NN patients with IGA 0/1 was 29% and 18% and with EASI-75 was 38% and 24%, respectively. At W56, IGA 0/1 was achieved in 47% and 49% and EASI-75 in 73% and 79% of PNE and NN patients, respectively. Improvements in itch, sleep, and QoL were also observed over time. Safety profile was consistent with that previously reported.

Conclusion: Nemolizumab was well-tolerated up to W56 of treatment. Clinically meaningful improvements in AD signs and symptoms and patient-reported outcomes were observed with continuous treatment with nemolizumab.