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

Jonathan I. Silverberg,1 Andreas Wollenberg,2 Franz J. Legat,1 Vivian T. Lateur,4 April W. Armstrong,3 Pedro Herranz,3 Luigi Naldi,5 Faiz Ahmad,2 Liliana Ulianov3,3 Christoph Piketty7

1George Washington University School of Medicine and Health Sciences, Washington, DC, USA; 2Department of Dermatology and Allergy, Ludwig Maximilian University, Munich, Germany; 3Department of Dermatology and Venereology, Medical University of Graz, Graz, Austria; 4Division of Dermatology, University of California, Los Angeles, CA, USA; 5Department of Dermatology, University Hospital La Paz, Madrid, Spain; 6Academic Research Centre, Center Studie-QSE, Bergamo, Italy; 7Galderma Laboratories, Dallas, TX, USA.

Objective

Based on data from the ARCADIA 48-week maintenance study of nemolizumab§ in patients with moderate-to-severe AD

SUMMARY OF STUDY FINDINGS

Based on data from the ARCADIA 48-week maintenance study of nemolizumab§ in patients with moderate-to-severe AD

RESULTS

Efficacy

Treatment with nemolizumab§ Q4W/QW was associated with maintenance of clinical response in skin lesions up to 48 weeks (Figures 2A and B).

In improvement in itch (Figure 3A) and itch-free/nearly itch-free state (Figure 3B) response was maintained up to Week 48 with nemolizumab§ QW/QW.

Similarly, response in sleep (Figure 4A) and quality of life (Figure 4B) was well maintained up to Week 48.

SAFETY

Adverse events were consistent with those in the initial treatment period (Table 1).

Table 1. Overall summary of treatment-emergent adverse events over the maintenance period

Key Inclusion Criteria

- Patients (≥12 years old) with chronic AD for ≥2 years
- Eczema Area Severity Index (EASI) score ≥3
- Investigator’s Global Assessment (IGA) score ≥3
- AD involvement > 10% of body surface area
- Peak Pruritus Numeric Rating Scale (NRS) score >4

KEY EXCLUSION CRITERIA

- Any previous treatment completion prior to randomization
- History of chronic obstructive pulmonary disease and/or chronic bronchitis

Maintenance treatment period endpoints

- Proportions of patients maintaining:
  - IGA success (EASI-75 response) and EASI-75 response
  - f-4 point improvement in Peak Pruritus NRS: Sleep Disturbance NRS and Dermatology Life Quality Index
- Peak Pruritus NRS score <2 (itch-free/nearly itch-free state)

*Adverse events were consistent with those in the initial treatment period (Table 1)