EA DV CONGRESS
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 6707

Nemolizumab monotherapy improves itch and skin lesions in patients with moderate-to-severe prurigo nodularis: Results from a global phase 3 trial (OLYMPIA 1)

Sonja Ständer*[1], Gil Yosipovitch[2], Franz Legat[3], Adam Reich[4], Carle Paul[5], Dagmar Simon[6], Luigi Naldi[7], Xiaoxiao Chen[8], Zarif Jabbar Lopez[9], Christophe Piketty[9], Shawn Kwatra[10]

[1]Center for Chronic Pruritus, Münster University Hospital, Münster, Germany, [2]Miami Itch Center, Miller School of Medicine Department at the University of Miami, Miami, United States, [3]Medical University of Graz, Department of Dermatology and Venereology, Graz, Austria, [4]University of Rzeszów, Department of Dermatology, Rzeszów, Poland, [5]Medical University of Toulouse, Department of Dermatology, Toulouse, France, [6]Bern University Hospital, Department of Dermatology, Bern, Switzerland, [7]Academic Research Centre, Centro Studi GISED, Bergamo, Italy, [8]Galderma, Research and Development, Dallas, United States, [9]Galderma R&D, Research and Development, Zug, Switzerland, [10]The Johns Hopkins University School of Medicine, Johns Hopkins Itch Center, Baltimore, United States

Introduction & Objectives: Prurigo nodularis (PN) is a chronic and debilitating skin condition, characterized by itch with multiple nodular skin lesions. Nemolizumab, a first-in-class interleukin-31 receptor alpha antagonist, demonstrated clinically and statistically significant improvements in itch and skin nodules in adult patients with moderate-to-severe PN in a phase 3 study OLYMPIA 2 (NCT04501679). Here we report results from another phase 3 study OLYMPIA 1 (NCT04501666), which aimed to assess the efficacy and safety of nemolizumab compared with placebo in adult patients with moderate-to-severe PN after a 16-week treatment period.

Materials & Methods: We conducted a phase 3, multicentre, double-blind study in adults with PN presenting ≥20 nodules, Investigator's Global Assessment (IGA) score ≥3 (range 0-4) and Peak Pruritus Numerical Rating Scale (PP-NRS) score ≥7.0 (range 0-10). The study consisted of screening (up to 4 weeks), a 24-week treatment and an 8-week follow-up periods. Eligible patients were assigned (2:1) to either nemolizumab (N=190) or matching placebo (N=96). Following an initial 60 mg subcutaneous dose, patients received 30 mg or 60 mg (depending on a baseline weight below or ≥90 kg, respectively) every 4 weeks. Topical calcineurin inhibitors (TCI) and topical corticosteroids (TCS) were not allowed during study treatment unless required as a rescue medication. The primary endpoints evaluated were itch response (proportion of patients with a ≥4-point improvement in PP NRS score) and IGA success (proportion of patients with IGA score of 0/1 [clear/almost clear skin] with a reduction of at least 2 points from baseline) at Week 16. We also assessed itch response at Week 4, which was a key secondary endpoint. Prurigo Activity Score (PAS), a secondary endpoint, was evaluated throughout the study. Safety was also assessed all through the study.

Results: All primary and key secondary endpoints were met. At Week 16, a significantly greater proportion of patients receiving nemolizumab vs placebo achieved a ≥4-point improvement in PP NRS (58.4% vs 16.7%; P<0.0001). This ≥4-point improvement in PP-NRS was already achieved as early as Week 4 (41.1% vs 6.3%; P<0.0001). A significantly greater proportion of patients receiving nemolizumab vs placebo achieved significant improvements in skin lesions at Week 16, including IGA success (i.e., IGA 0/1): 26.3% vs 7.3% (P<0.0001) and ≥75% healed lesions (PAS item 5b): 41.1% vs 11.5% (P<0.0001). Improvements in itch and skin lesions were observed up to Week 24. Treatment-emergent adverse events (TEAEs) were reported in 71.7% of nemolizumab- and 65.3% of placebo-treated patients, while serious TEAEs were reported in 8.6% of nemolizumab- and 10.5% of placebo-treated patients. Most of these TEAEs were mild-to-moderate in severity.

Conclusion: Nemolizumab monotherapy administered every 4 weeks without background TCS or TCI was well

tolerated and led to clinically meaningful and statistically significant improvements in core symptoms (itch) and signs (skin lesions) of PN. These results confirm those of the OLYMPIA 2 study, previously reported.