

Prurigo Nodularis: Recognizing, Diagnosing and Treating a Rare but Debilitating Disease



Clinical Update

Stander S, et al. Nemozumab monotherapy improves itch and skin lesions in patients with moderate-to-severe prurigo nodularis: Results from a global phase 3 trial (OLYMPIA 1). Late-breaking abstract presented at European Academy of Dermatology and Venereology Congress, Berlin, Germany, October 11-14, 2023.

Olympia 1 was a phase 3 randomized controlled trial that compared nemozumab to placebo in adults (N=286) with moderate-to-severe prurigo nodularis (PN). Patients were required to have ≥ 20 nodules, Investigator Global Assessment (IGA) score ≥ 3 , and Peak Pruritus Numeric Rating Scale (PP-NRS) score ≥ 7 . The patients did not use concomitant topical steroids or calcineurin inhibitors. After 16 weeks, patients treated with nemozumab experienced significantly greater itch reduction and skin clearance than patients treated with placebo. Among the secondary outcomes, significantly more patients treated with nemozumab achieved a 4-point itch reduction (PP-NRS) at week 4. Nemozumab was well tolerated. The safety events were consistent with those reported in the Olympia 2 trial, which showed headache and atopic dermatitis as the most common.

Outcome	Nemozumab	Placebo	P
4-point itch reduction (PP-NRS)	58.4%	16.7%	<0.0001
Complete or almost complete skin clearance (IGA 0/1)	26.3%	7.3%	<0.0001
4-point itch reduction at week 4 (PP-NRS)	41.1%	6.3%	<0.0001

IGA, Investigator Global Assessment (0 to 4, with 0 indicating clear, 1 almost clear)

PP-NRS, peak pruritus numerical rating scale (0 to 10, with higher score indicating more severe itch)

Kwatra SG, Yosipovitch G, Legat FJ, et al. Phase 3 trial of nemozumab in patients with prurigo nodularis. *N Engl J Med.* 2023;389(17):1579-1589. doi:10.1056/NEJMoa2301333.

Olympia 2 was a phase 3 double-blind, multicenter, randomized controlled trial of nemozumab monotherapy compared to placebo in adults (N=286) with moderate-to-severe prurigo nodularis (PN). Patients were required to have a disease duration of at least 6 months, severe pruritus defined by a Peak Pruritus Numeric Rating Scale (PP-NRS) score ≥ 7 , ≥ 20 nodules, and an Investigator Global Assessment (IGA) score ≥ 3 . Significantly greater reductions in the 2 primary endpoints, as well as 5 key secondary endpoints, were observed in the nemozumab vs placebo groups. Significantly faster itch reduction was achieved with nemozumab. Rescue therapy (topical or systemic glucocorticoids or immunosuppressants) was needed in 4.9% of patients assigned to nemozumab, compared to 15.4% assigned to placebo. The most common adverse events that occurred in $\geq 5\%$ of patients treated with nemozumab, and reported at a higher rate than placebo, were (nemozumab vs placebo) atopic dermatitis (5.5% vs 0%) and headache (6.6% vs 4%). Serious adverse events occurred more frequently in the placebo group.

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% Patients achieving	Nemolizumab (n=183)	Placebo (n=91)	P
≥ 4-point reduction on PP-NRS at week 16*	56%	21%	<0.001
IGA score ≤1 at week 16*	38%	11%	<0.001
≥4-point reduction on PP-NRS at week 4	41%	8%	<0.001
PP-NRS <2 at week 4	20%	2%	<0.001
PP-NRS <2 at week 16	35%	8%	<0.001
≥4-point reduction on SD-NRS at week 4	37%	10%	<0.001
≥4-point reduction on SD-NRS at week 16	52%	21%	<0.001

*Primary endpoints

SD-NRS, sleep disturbance numerical rating scale (0, no sleep loss to 10, unable to sleep at all)