
Olympia 1 was a phase 3 randomized controlled trial that compared nemolizumab 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 nemolizumab experienced significantly greater itch reduction and skin clearance than patients treated with placebo. Among the secondary outcomes, significantly more patients treated with nemolizumab achieved a 4-point itch reduction (PP-NRS) at week 4. Nemolizumab 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.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Nemolizumab</th>
<th>Placebo</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-point itch reduction (PP-NRS)</td>
<td>58.4%</td>
<td>16.7%</td>
<td>&lt;0.0001</td>
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<tr>
<td>Complete or almost complete skin clearance (IGA 0/1)</td>
<td>26.3%</td>
<td>7.3%</td>
<td>&lt;0.0001</td>
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<tr>
<td>4-point itch reduction at week 4 (PP-NRS)</td>
<td>41.1%</td>
<td>6.3%</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

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)


Olympia 2 was a phase 3 double-blind, multicenter, randomized controlled trial of nemolizumab 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 pruritis 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 nemolizumab vs placebo groups. Significantly faster itch reduction was achieved with nemolizumab. Rescue therapy (topical or systemic glucocorticoids or immunosuppressants) was needed in 4.9% of patients assigned to nemolizumab, compared to 15.4% assigned to placebo. The most common adverse events that occurred in ≥5% of patients treated with nemolizumab, and reported at a higher rate than placebo, were (nemolizumab vs placebo) atopic dermatitis (5.5% vs 0%) and headache (6.6% vs 4%). Serious adverse events occurred more frequently in the placebo group.
% 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)