Efficacy of nemolizumab in different subgroups of patients with prurigo nodularis in two randomized, placebo-controlled phase 3 trials

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Abstract

Introduction: It is unknown whether baseline demographics and disease characteristics have an influence on efficacy and safety of nemolizumab in adults with moderate-to-severe prurigo nodularis (PN).

Objectives: To report safety and efficacy of nemolizumab in the phase 3 studies (OLYMPIA-1 [NCT04501666]1 and OLYMPIA-2 [NCT04501679]2) for different subgroups.

Materials & Methods: Data were pooled from the pivotal studies in which adults with moderate-to-severe PN were randomized (2:1) to receive nemolizumab (initial 60mg subcutaneous dose, followed by 30mg/60mg [depending on a baseline weight: <90kg/≥90kg] every 4 weeks) or matching placebo.
**Results:** Comparisons in all subgroups (age, sex, race, weight, disease severity, atopy, prior treatment) identified efficacy of nemolizumab versus placebo consistent with the overall intention-to-treat population. At Week (W) 16, a ≥4-point improvement in weekly average Peak Pruritus Numerical Rating Scale of nemolizumab vs. placebo was found in 18- to 65-year-old/>65-year-old: 58.6%/54.0% vs 20.0%/14.3%; males/females: 54.7%/59.2% vs 21.1%/17.1%; White/Black/Asian/Other race: 60.3%/56.5%/36.4%/40.0% vs 20.8%/11.8%/12.5%/0%, <90kg/≥90kg baseline weight: 55.6%/60.8% vs 17.9%/20.8%, baseline Investigator’s Global Assessment [IGA] score of 3 [moderate]/4 [severe]: 54.9%/60.8% vs 23.6%/11.7%, with/without history of atopy: 53.8%/59.0% vs 23.6%/11.7% and with/without prior systemic treatment for PN: 57.9%/58.8% vs 14.4%/22.7%. An IGA success (score of 0/1 [clear/almost clear skin] with ≥2-point reduction from baseline) was found in 18- to 65-year-old/>65-year-old: 34.8%/24.0% vs 11.0%/2.4%; males/females: 28.0%/34.5% vs 10.5%/8.1%; White/Black/Asian/Other race: 32.2%/26.1%/33.3%/30.0% vs 8.1%/11.8%/18.8%/0%, <90kg/≥90kg baseline weight: 34.3%/27.2% vs 9.0%/9.4%, baseline IGA score of 3 [moderate]/4 [severe]: 34.0%/29.1% vs 12.7%/3.9%, with/without history of atopy: 29.9%/32.8% vs 4.7%/11.4% and with/without prior systemic treatment for PN: 37.2%/26.8% vs 8.9%/9.3%. Similar results were noted for sleep disturbance. No major difference was reported in the safety profile of nemolizumab between the subgroups.

**Conclusion:** Safety and efficacy of nemolizumab monotherapy in itch, skin lesions and sleep disturbance were consistent between the subgroups.

**Keywords:** Efficacy, nemolizumab, Prurigo nodularis, safety, subgroup

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