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OLYMPIA Clinical Trial Program Media Factsheet

The burden of prurigo nodularis

Prurigo nodularis is a debilitating chronic skin condition characterized by thick skin nodules covering large body areas and associated with intense itch (pruritus).[1-3]

It affects an estimated **72 out of every 100,000 adults** aged 18 to 64 in the United States. It is more common in middle-aged women and, disproportionately, people of African descent.[1-4]

Prurigo nodularis severely impacts many aspects of patients' lives, with signs and symptoms including:

- Chronic pruritus (itch)[5]
- Disfiguring skin lesions (nodules)[5]
- Sleep disturbance[5]
- Psychiatric co-morbidities[5]

There is a need for novel, safe, fast-acting, and effective treatments that directly address the underlying disease mechanisms in prurigo nodularis.[1,6]

Introducing nemolizumab

Nemolizumab is a monoclonal antibody specifically designed to target the IL-31 receptor and inhibit IL-31 signaling.

IL-31 plays a key role in multiple disease mechanisms in prurigo nodularis.[1,7-10] It is a **neuroimmune cytokine** that bridges the immune and nervous systems and is the key driver of inflammation and fibrosis.[1, 7-10]

Research to date has indicated that **nemolizumab has the potential to be a key therapeutic solution in the treatment of prurigo nodularis**, effectively improving nodules, itch and nerve function in patients.[11]

Nemolizumab is also being investigated in a **phase III program in atopic dermatitis**, a common and chronic form of eczema characterized by persistent, disruptive itch, inflammatory skin lesions and frequent skin infections, and a **phase II trial** for Chronic Kidney Disease associated pruritus (CKD-aP).

What are the OLYMPIA trials?

OLYMPIA 1 and 2 were two identical phase III clinical trials, designed to evaluate nemolizumab compared with placebo in adults with **moderate to severe prurigo nodularis** after a 16-week treatment period. They investigated nemolizumab in 560 patients with prurigo nodularis.

The trials have **two primary endpoints**:

1. The number of nemolizumab-treated patients who reached clearance or almost-clearance of skin lesions, when assessed using the investigator's global assessment (IGA) score, compared to those treated with placebo.
2. The number of nemolizumab-treated patients who achieved at least a four-point reduction in itching, as measured by the peak-pruritus numerical rating scale (PP-NRS), compared to those treated with placebo.

Secondary endpoints include number of patients with an adverse event in the trial, and the proportion of patients with an improvement of at least four points from baseline in sleep disturbance at week 16.

Trial structure

The two randomized, double-blind, placebo-controlled OLYMPIA trials included 560 patients:

- 286 in OLYMPIA 1
- 274 in OLYMPIA 2

Experimental: Nemolizumab

- Participants weighing less than 90 kg received two subcutaneous (SC) injections of 30 mg nemolizumab (60 mg loading dose) at baseline, then one SC injection once for every four weeks up to 16 weeks.
- Participants weighing 90 kg or more received two SC injections of 60 mg nemolizumab at baseline (no loading dose), and two SC injections once every four weeks up to 16 weeks.

Comparator: Placebo

- Participants weighing less than 90 kg received placebo as two SC injections at baseline, then one SC injection once every four weeks for up to 16 weeks.
- Participants weighing 90 kg or more received placebo as two SC injections at baseline, then two SC injections once every four weeks up to 16 weeks.

Trial results[11-16]

The phase III OLYMPIA 1 and 2 trials **met all primary and key secondary endpoints**. Nemolizumab demonstrated significant improvements in itch, skin clearance and sleep disturbance in adult patients with prurigo nodularis. Nemolizumab demonstrated a favorable benefit-risk balance in these trials.

The OLYMPIA trials further demonstrate that **nemolizumab has the potential to be a key therapeutic solution** for patients suffering from moderate to severe prurigo nodularis.

Regulatory status

Nemolizumab is approved in Japan, where it is being developed by Maruho Co. Ltd., for itch associated with atopic dermatitis.

With Galderma, nemolizumab is under clinical development for the treatment of prurigo nodularis and atopic dermatitis in many countries around the world. Nemolizumab was granted Breakthrough Therapy designation by the FDA in December 2019 for the treatment of itch associated with prurigo nodularis.

Galderma has exclusive rights to the development and marketing of nemolizumab worldwide except in Japan and Taiwan.

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