Optum Rx®

Nemluvio® (nemolizumab-ilto) – New drug approval

- On August 13, 2024, Galderma announced the FDA approval of Nemluvio (nemolizumab-ilto), for the treatment of adults with prurigo nodularis.

- Prurigo nodularis is a chronic neuroimmune skin disease characterized by the presence of intense itch and thick skin nodules covering large body areas.

    — Prurigo nodularis affects up to 181,000 people in the U.S.

- Nemluvio is a novel interleukin-31 (IL-31) receptor antagonist. IL-31 is a naturally occurring cytokine that is involved in pruritus, inflammation, epidermal dysregulation, and fibrosis.

- The efficacy of Nemluvio was established in two randomized, double-blind, placebo-controlled studies (OLYMPIA 1 and OLYMPIA 2) in a total of 560 adult patients with prurigo nodularis. Patients were randomized to Nemluvio or placebo. Efficacy was assessed with the proportion of patients with an improvement of ≥ 4 from baseline in peak pruritus numeric rating scale (PP-NRS), the proportion of patients with an Investigator's Global Assessment (IGA) of 0 (Clear) or 1 (Almost Clear) and a ≥ 2-point improvement from baseline, the proportion of patients who achieved a response in both PP-NRS and IGA per the criteria described above, and the proportion of subjects with PP-NRS < 2.

OLYMPIA 1 Results

Endpoint	Nemluvio	Placebo	Difference from placebo (95% CI)
Proportion of patients with both an improvement (reduction) of ≥ 4 from baseline in PP-NRS and IGA 0 or 1	22%	2%	15% (8, 21)
Proportion of patients with IGA 0 or 1	26%	7%	15% (7, 23)
Proportion of subjects with an improvement (reduction) of ≥ 4 from baseline in PP-NRS	56%	16%	38% (27, 48)
Proportion of subjects with PP-NRS < 2	32%	4%	28% (20, 36)

OLYMPIA 2 Results

Endpoint	Nemluvio	Placebo	Difference from placebo (95% CI)
Proportion of patients with both an improvement (reduction) of ≥ 4 from baseline in PP-NRS and IGA 0 or 1	25%	4%	22% (14, 30)
Proportion of patients with IGA 0 or 1	38%	11%	29% (19, 38)
Proportion of subjects with an improvement (reduction) of ≥ 4 from baseline in PP-NRS	49%	16%	34% (23, 45)
Proportion of subjects with PP-NRS < 2	31%	7%	26% (18, 34)

- The FDA has also accepted the Biologics License Application for Nemluvio for the treatment of moderate-to-severe atopic dermatitis, with a decision anticipated in December of this year.

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- Warnings and precautions for Nemluvio include hypersensitivity and vaccinations.
- The most common adverse reactions (≥ 1%) with Nemluvio use were headache, atopic dermatitis, eczema, and nummular eczema.
- The recommended subcutaneous (SC) dosage of Nemluvio for adult patients weighing less than 90 kg is an initial dose of 60 mg (two 30 mg injections), followed by 30 mg given every 4 weeks.
- The recommended SC dosage of Nemluvio for adult patients weighing 90 kg or more is an initial dose of 60 mg (two 30 mg injections), followed by 60 mg given every 4 weeks.
- Nemluvio is intended for use under the guidance of a healthcare provider. Prior to the first injection, patients and/or caregivers should be provided with proper training on the preparation and administration of Nemluvio. Patients may self-inject Nemluvio after receiving training on SC injection techniques.
- Galderma's launch plans for Nemluvio are pending. Nemluvio will be available as a single-dose prefilled dual chamber pen containing 30 mg of Nemluvio lyophilized powder and diluent, water for injection.

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