HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NEMLUVIO safely and effectively. See full prescribing information for NEMLUVIO.

NEMLUVIO® (nemolizumab-ilto) for injection, for subcutaneous use
Initial U.S. Approval: 2024

----------INDICATIONS AND USAGE----------

NEMLUVIO is an interleukin-31 receptor alpha antagonist indicated for the treatment of adults with prurigo nodularis. (1)

----------DOSAGE AND ADMINISTRATION----------

- Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to treatment with NEMLUVIO. (2.1)
- Adult Patients Weighing Less Than 90kg: The recommended dosage is an initial dose of 60 mg (two 30 mg injections), followed by 30 mg given every 4 weeks (Q4W). (2.2)
- Adult Patients Weighing 90kg or More: The recommended dosage is an initial dose of 60 mg (two 30 mg injections), followed by 60 mg given every 4 weeks (Q4W). (2.2)
- Administer NEMLUVIO by subcutaneous injection. (2.4)
- NEMLUVIO must be reconstituted prior to administration. (2.5)

----------DOSAGE FORMS AND STRENGTHS----------

For injection: single-dose prefilled dual-chamber pen containing 30 mg of nemolizumab-ilto lyophilized powder and diluent, water for injection. (3).

----------CONTRAINDICATIONS----------

Known hypersensitivity to nemolizumab-ilto or to any of the excipients in NEMLUVIO. (4)

----------WARNINGS AND PRECAUTIONS----------

- Hypersensitivity: Hypersensitivity reactions have been reported with NEMLUVIO use. If a clinically significant hypersensitivity reaction occurs, immediately institute appropriate therapy and discontinue NEMLUVIO. (5.1)
- Vaccinations: Avoid use of live vaccines during treatment with NEMLUVIO. (5.2)

----------ADVERSE REACTIONS----------

Most common adverse reactions (incidence ≥1%) are headache, dermatitis atopic, eczema, and eczema nummular. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Galderma Laboratories, L.P. at 1-866-735-4137 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 08/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

*** Sections or subsections omitted from the full prescribing information are not listed**

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

NEMLUVIO is indicated for the treatment of adults with prurigo nodularis.

2 DOSAGE AND ADMINISTRATION

2.1 Vaccination Prior to Treatment

Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to treatment with NEMLUVIO [*see Warnings and Precautions (5.2)*].

2.2 Recommended Dosage

Adult Patients Weighing Less Than 90 kg: The recommended subcutaneous 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 (Q4W).

Adult Patients Weighing 90 kg or More: The recommended subcutaneous 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 (Q4W).

2.3 Missed Dose

If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time.

2.4 Important Administration Instructions

- NEMLUVIO is administered by subcutaneous injection.
- NEMLUVIO is intended for use under the guidance of a healthcare provider. Prior to the first injection, provide patients and/or caregivers with proper training on the preparation and administration of NEMLUVIO. Patients may self-inject NEMLUVIO after receiving training on subcutaneous injection techniques.
- For the initial dose, administer each of the two NEMLUVIO injections at different injection sites.
- Administer subcutaneous injection into the front upper thighs or abdomen except for the 2 inches (5 cm) around the navel. Injection in upper arm should only be performed by a caregiver or healthcare professional.
- Alternate the injection site with each injection. Do not inject NEMLUVIO into skin that is tender, inflamed, swollen, damaged or has bruises or scars or open wounds.
- Refer to the Instructions for Use for complete administration instructions with illustrations [*see Instructions for Use*].

2.5 Preparation for Use of NEMLUVIO

- Before injection, remove NEMLUVIO carton from the refrigerator and allow to reach room temperature (30-45 minutes).
- Inspect NEMLUVIO visually prior to reconstitution. NEMLUVIO is supplied in a single-dose pre-filled dual-chamber pen with white powder in one chamber and a clear diluent in the other chamber. Do not use if powder is not white, or if diluent is cloudy or contains visible particles.
- NEMLUVIO must be reconstituted prior to administration.
- Following reconstitution, each pre-filled pen delivers 30 mg/0.49 mL as a clear and colorless to slightly yellow solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the reconstituted solution has discoloration or contains particles.
- Use NEMLUVIO pens within 4 hours after reconstitution. Discard unused reconstituted NEMLUVIO pens after 4 hours.
- Discard any unused portions after administration.
- Refer to the Instructions for Use for complete preparation instructions with illustrations *[see Instructions for Use]*.

3 DOSAGE FORMS AND STRENGTHS

For injection: single-dose pre-filled dual-chamber pen containing 30 mg of nemolizumab-ilto as a white lyophilized powder in one chamber and diluent, water for injection, in the other chamber.

4 CONTRAINDICATIONS

NEMLUVIO is contraindicated in patients who have known hypersensitivity to nemolizumab-ilto or to any of the excipients in NEMLUVIO [*see Warnings and Precautions (5.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Hypersensitivity reactions, such as facial angioedema, have been reported with use of NEMLUVIO. NEMLUVIO is contraindicated in patients with a known hypersensitivity to nemolizumab-ilto or to any of the excipients in NEMLUVIO. If a clinically significant hypersensitivity reaction occurs, immediately institute appropriate therapy and discontinue NEMLUVIO [*see Contraindications (4), Adverse Reactions (6.1)*].

5.2 Vaccinations

Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to treatment with NEMLUVIO. Avoid use of live vaccines in patients during treatment with NEMLUVIO. It is

unknown if administration of live vaccines during NEMLUVIO treatment will impact the safety or effectiveness of these vaccines. No data are available on the response to non-live vaccines.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described in greater details elsewhere in the labeling: Hypersensitivity [*see Warnings and Precautions (5.1)*].

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 508 adult subjects with prurigo nodularis were treated with NEMLUVIO in two placebo-controlled trials and an open label long-term extension trial. Of these, 375 subjects were exposed for at least 1 year in the development program for prurigo nodularis.

Two randomized, double-blind, placebo-controlled, multicenter trials (OLYMPIA 1 and OLYMPIA 2) evaluated the safety of NEMLUVIO in adult subjects with prurigo nodularis. Subjects were treated for up to 24 weeks in OLYMPIA 1 and up to 16 weeks in OLYMPIA 2. In these 2 trials, 370 subjects were treated with subcutaneous injections of NEMLUVIO, and 186 subjects received placebo injections [*see Clinical Studies (14)*].

Subjects weighing less than 90 kg in the NEMLUVIO group received NEMLUVIO 60 mg or placebo at Week 0, followed by 30 mg injections every 4 weeks. Subjects weighing 90 kg or more in the NEMLUVIO group received NEMLUVIO 60 mg or placebo at Week 0 and every 4 weeks.

During the treatment period in NEMLUVIO trials (OLYMPIA 1 and OLYMPIA 2), the proportion of subjects who discontinued treatment because of adverse reactions was 4% in the NEMLUVIO group versus 3% in the placebo group. Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% in the NEMLUVIO group, and for which the rate exceeds the rate in the placebo group through Week 16.

Table 1: Adverse Reactions Occurring in ≥1% of Adult Subjects with Prurigo Nodularis in the NEMLUVIO Group and Greater than Placebo in the OLYMPIA 1 and OLYMPIA 2 Trials through Week 16.

Adverse Reaction	NEMLUVIO N= 370 n (%)	Placebo (N= 186) n (%)
Headache*	23 (6%)	6 (3%)
Dermatitis atopic	16 (4%)	1 (0.5%)
Eczema	14 (4%)	3 (2%)
Eczema nummular	11 (3%)	0

*includes: headache and tension headache

Specific Adverse Reactions

Hypersensitivity reactions

Type 1 hypersensitivity reactions (Ig-E mediated reactions), including one report of discrete facial (peri-ocular) angioedema, were reported in subjects treated with NEMLUVIO [*see Contraindications (4)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data on NEMLUVIO use in pregnant women exposed during clinical trials are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Transport of human IgG antibody across the placenta increases as pregnancy progresses and peaks during the third trimester; therefore, NEMLUVIO may be transferred from the mother to the developing fetus *(see Clinical Considerations)*. In an enhanced pre- and postnatal development study in cynomolgus monkeys, when nemolizumab-ilto was administered subcutaneously during organogenesis to parturition, an increase in early postnatal death was observed at a dose 36 times the maximum recommended human dose (MRHD) *(see Data)*. The clinical significance of this nonclinical finding is unknown.

The background risk of major birth defects and miscarriage for the indicated populations are unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Because nemolizumab-ilto may interfere with immune response to infections, risks and benefits should be considered prior to administering live vaccines to infants exposed to NEMLUVIO in utero. There are no data regarding infant serum levels of nemolizumab-ilto at birth and the duration of persistence of nemolizumab-ilto in infant serum after birth. Although a specific timeframe to delay live virus immunizations in infants exposed in utero is unknown, a minimum of 3 months after birth should be considered because of the half-life of the product.

Data

Animal Data

In an enhanced pre- and postnatal development study, subcutaneous doses up to 25 mg/kg nemolizumab-ilto were administered to pregnant cynomolgus monkeys once every two weeks during organogenesis to parturition. No maternal or embryofetal toxicities were observed at doses up to 25 mg/kg (36 times the MRHD, based on AUC comparison). Early postnatal death occurred in the offspring of one control monkey and 3 monkeys at 25 mg/kg (36 times the MRHD, based on AUC comparison). The clinical significance of this nonclinical finding is unknown. Nemolizumab-ilto was administered subcutaneously to the offspring at doses up to 25 mg/kg (122 times the MRHD, based on AUC comparison), once every 2 weeks for 6 months, starting from postnatal day 35. No adverse effects were noted in the remaining offspring.

8.2 Lactation

Risk Summary

There are no data on the presence of nemolizumab-ilto in human milk, the effects on the breastfed infant, or the

effects on milk production. Nemolizumab-ilto was detected in breast milk of monkeys *(see Data)*. Endogenous maternal IgG and monoclonal antibodies are transferred in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed infant to nemolizumab-ilto are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NEMLUVIO and any potential adverse effects on the breastfed child from NEMLUVIO or from the underlying maternal condition.

Data

Nemolizumab-ilto was detected in breast milk of monkeys in the enhanced pre- and postnatal development study following subcutaneous doses up to 25 mg/kg once every two weeks during organogenesis to parturition. The mean nemolizumab-ilto concentrations in milk were approximately 0.3 – 0.5% of the maternal plasma levels from lactation day 7 to 63. The concentration of nemolizumab-ilto in animal milk does not necessarily predict the concentration of drug in human milk.

8.4 Pediatric Use

The safety and effectiveness of NEMLUVIO have not been established in pediatric patients.

8.5 Geriatric Use

Of the 370 subjects with prurigo nodularis exposed to NEMLUVIO in OLYMPIA 1 AND OLYMPIA 2, 99 (26.8%) subjects were 65 years of age or older. The long-term safety of NEMLUVIO was assessed in 508 subjects, among which 133 (26.2%) were 65 years of age or older. Clinical trials of NEMLUVIO did not include sufficient number of subjects 65 years of age or older to determine whether they respond differently than younger adult subjects. [*see Clinical Pharmacology (12.3)*].

10 OVERDOSAGE

There is no specific treatment for NEMLUVIO overdose. In the event of overdosage, contact Poison Control (1-800-222-1222) for the latest recommendations and monitor the patient for any signs or symptoms of adverse reactions and institute appropriate symptomatic treatment immediately.

11 DESCRIPTION

Nemolizumab-ilto, an interleukin-31 receptor alpha (IL-31RA) antagonist, is a humanized monoclonal modified immunoglobulin G (IgG) antibody with a molecular weight of approximately 144 kDa. Nemolizumab-ilto is produced by recombinant DNA technology in Chinese Hamster Ovary cells.

NEMLUVIO (nemolizumab-ilto) for injection is a sterile, preservative-free, white lyophilized powder in a dual-chamber single-dose, pre-filled pen. One chamber contains 30 mg of nemolizumab-ilto with inactive ingredients arginine hydrochloride (9.5 mg), poloxamer 188 (0.15 mg), sucrose (25.8 mg), trometamol (0.10 mg), and tris hydrochloride for pH adjustment. The diluent, water for injection, is in the other chamber. Following reconstitution, each pre-filled pen delivers 30 mg/0.49 mL of nemolizumab-ilto with a pH of 6.7 to 7.3.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Nemolizumab-ilto is a humanized IgG2 monoclonal antibody that inhibits IL-31 signaling by binding selectively to IL-31 RA. IL-31 is a naturally occurring cytokine that is involved in pruritus, inflammation, epidermal dysregulation, and fibrosis. Nemolizumab-ilto inhibited IL-31-induced responses including the release of proinflammatory cytokines and chemokines.

12.3 Pharmacokinetics

After a single dose, nemolizumab-ilto exposure increased dose proportionally over a dose range of 0.03 and 3 mg/kg following subcutaneous administration. After multiple doses, nemolizumab-ilto systemic exposure increased in an approximately dose-proportional manner across the subcutaneous dose range up to 30 mg. There was a decrease in bioavailability by 9% with the 60 mg subcutaneous dose and by 15% with the 90 mg subcutaneous dose.

Following multiple doses of NEMLUVIO in subjects with prurigo nodularis, the estimated mean (SD) steady-state trough concentrations of nemolizumab-ilto were 3.04 (1.23) µg/mL in subjects with bodyweight less than 90 kg; and 3.66 (1.63) µg/mL in subjects with bodyweight of 90 kg or more. Steady state nemolizumab-ilto concentrations were achieved by week 4 in subjects weighting less than 90 kg and by week 12 in subjects weighing 90 kg or more.

Absorption

Following an initial subcutaneous dose of 60 mg, nemolizumab-ilto reached peak mean (SD) concentrations (C_{max}) of 7.5 (2.31) µg/mL by approximately 6 days post dose.

Distribution

The volume of distribution of nemolizumab-ilto was estimated to be 7.67 L.

Elimination

Nemolizumab-ilto is expected to be degraded in the same manner as endogenous IgG. The terminal elimination half-life (SD) of nemolizumab-ilto was estimated to be 18.9 (4.96) days and systemic clearance was estimated to be 0.263 L/day.

Metabolism

The metabolic pathway of nemolizumab-ilto has not been characterized. Nemolizumab-ilto is expected to be degraded into small peptides by catabolic pathways.

Specific Populations

Geriatric Populations

No clinically significant difference in the pharmacokinetics of nemolizumab-ilto was estimated based on age (subjects 18 to 65 years of age and older than 65 years of age). Dose adjustment in this population is not needed.

Renal or Hepatic Impairment

No clinically significant differences in the pharmacokinetics of nemolizumab-ilto were estimated based on mild to moderate renal or hepatic impairments. The effect of severe renal and severe hepatic impairments on the pharmacokinetics of nemolizumab-ilto is unknown.

Body Weight

The exposure of nemolizumab-ilto decreases with increasing body weight. After a 30-mg dose every 4 weeks, the steady state mean exposure parameters (AUC_{ss}, C_{maxss} and C_{trough}) of subjects with bodyweight of above 87 kg is expected to be 1.7-fold lower than that of subjects weighing below 62 kg.

The variability in systemic exposure due to body weight had a clinically meaningful impact on skin lesion efficacy (IGA response) but not on pruritus improvement.

Drug Interaction Studies

The effects of nemolizumab-ilto on the pharmacokinetics of midazolam (CYP3A4/5 substrate), warfarin (CYP2C9 substrate), omeprazole (CYP2C19 substrate), metoprolol (CYP2D6 substrate), and caffeine (CYP1A2 substrate) were evaluated in a study in 14 subjects with moderate to severe atopic dermatitis receiving an initial subcutaneous dose of 60 mg followed by a 30 mg subcutaneous dose every 4 weeks for 12 weeks. No clinically significant changes in the exposure of CYP450 substrates before and after multiple nemolizumab-ilto injections were observed, with Cmax and AUC ratios ranging from 88.24 to 107.81%.

The concomitant use of nemolizumab-ilto is unlikely to influence the PK profiles of CYP substrates.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of nemolizumab-ilto or other nemolizumab products.

In the Phase 3 trials (OLYMPIA 1, OLYMPIA 2) up to 24 weeks, the incidence of treatment-emergent ADAs was 7%; neutralizing antibodies were seen in 3 % of subjects.

There was no identified clinically significant effect of anti-drug antibodies on the pharmacokinetics, safety or efficacy of nemolizumab-ilto over the treatment duration of 24 weeks.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been conducted to evaluate the carcinogenic or mutagenic potential of NEMLUVIO.

No effects on fertility parameters as reproductive organ morphology, menstrual cycle length, or sperm/testicular analysis were observed in male or female sexually mature cynomolgus monkeys that were administered nemolizumab-ilto at subcutaneous doses up to 25 mg/kg once every two weeks for 6 months (53 times the MRHD, based on AUC comparison). The monkeys were not mated to evaluate fertility.

14 CLINICAL STUDIES

Two randomized, double-blind, placebo-controlled trials (OLYMPIA 1 [NCT04501666] and OLYMPIA 2 [NCT04501679]) enrolled a total of 560 adult subjects with prurigo nodularis (PN). Disease severity was defined using an Investigator's Global Assessment (IGA) in the overall assessment of prurigo nodularis nodules

on a severity scale of 0 to 4. Subjects enrolled in these two trials had an IGA score ≥ 3, severe pruritus as defined by a weekly average of the peak pruritus numeric rating scale (PP-NRS) score of ≥7 on a scale of 0 to 10, and greater than or equal to 20 nodular lesions. OLYMPIA 1 and OLYMPIA 2 assessed the effect of NEMLUVIO on the signs and symptoms of PN, targeting improvement in skin lesions and pruritus over 16 weeks. In OLYMPIA 1, subjects were extended up to 24 weeks of treatment.

Subjects weighing less than 90 kg in the NEMLUVIO group received subcutaneous injections of NEMLUVIO 60 mg at Week 0, followed by 30 mg injections every 4 weeks. Subjects weighing 90 kg or more in the NEMLUVIO group received subcutaneous injections of NEMLUVIO 60 mg at Week 0 and every 4 weeks.

In these trials, at baseline, 60% of subjects were female, 81% were White, 9% were Asian, 7% were Black or African American; for ethnicity, 4% of subjects identified as Hispanic or Latino. Twenty five (25)% of subjects were older than 65 years of age. Thirty-two (32)% of subjects had a history of atopy. The baseline weekly average PP-NRS score was a mean of 8.5. Fifty-eight (58)% of subjects had a baseline IGA score of 3 (moderate PN), and 42% of subjects had a baseline IGA of 4 (severe PN).

The PP-NRS score is a weekly average of daily PP-NRS scores on an 11-point scale from 0-10 that assesses the maximal intensity of pruritus in the last 24 hours with 0 being no itch and 10 being worst itch imaginable. The IGA is a 5-category scale, including "0 = clear", "1 = almost clear", "2 = mild", "3 = moderate" or "4 = severe" indicating the investigator's overall assessment of the pruriginous nodules.

Efficacy was assessed with the proportion of subjects with an improvement of ≥4 from baseline in PP-NRS, the proportion of subjects with an IGA of 0 (Clear) or 1 (Almost Clear) and a ≥2-point improvement from baseline, the proportion of subjects who achieved a response in both PP-NRS and IGA per the criteria described above, and the proportion of subjects with PP-NRS <2.

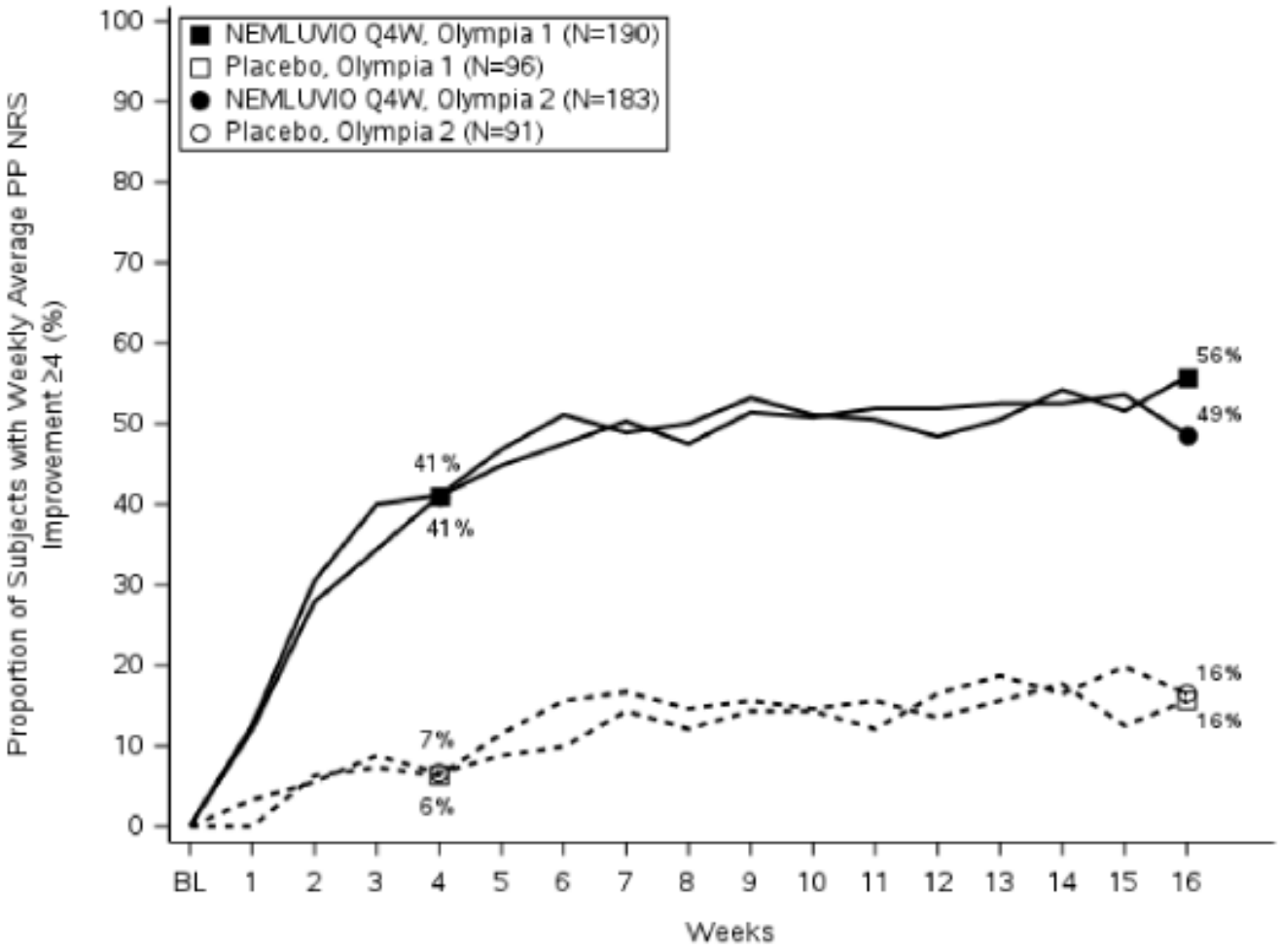
The efficacy results for OLYMPIA 1 and OLYMPIA 2 are presented in Table 2 and Figures 1, 2, and 3.

Table 2: Efficacy Results at Week 16 in Adult Subjects with PN in OLYMPIA 1 and OLYMPIA 2

	OLYMPIA 1			**OLYMPIA 2**		
	NEMLUVIO (N=190)	**Placebo (N=96)**	**Difference from Placebo (95% CI)**	**NEMLUVIO (N=183)**	**Placebo (N=91)**	**Difference from Placebo (95% CI)**
Proportion of subjects with both an improvement (reduction) of ≥4 from baseline in PP-NRS and IGA 0 or 1[a] [b]	22%[a]	2%[a]	15% (8%, 21%)[a]	25%[a]	4%[a]	22% (14%, 30%)[a]
Proportion of subjects with IGA 0 or 1[b]	26%	7%	15% (7%, 23%)	38%	11%	29% (19%, 38%)
Proportion of subjects with an improvement (reduction) of ≥4 from baseline in PP-NRS[b]	56%	16%	38% (27%, 48%)	49%	16%	34% (23%, 45%)
Proportion of subjects with PP-NRS <2[b]	32%	4%	28% (20%, 36%)	31%	7%	26% (18%, 34%)

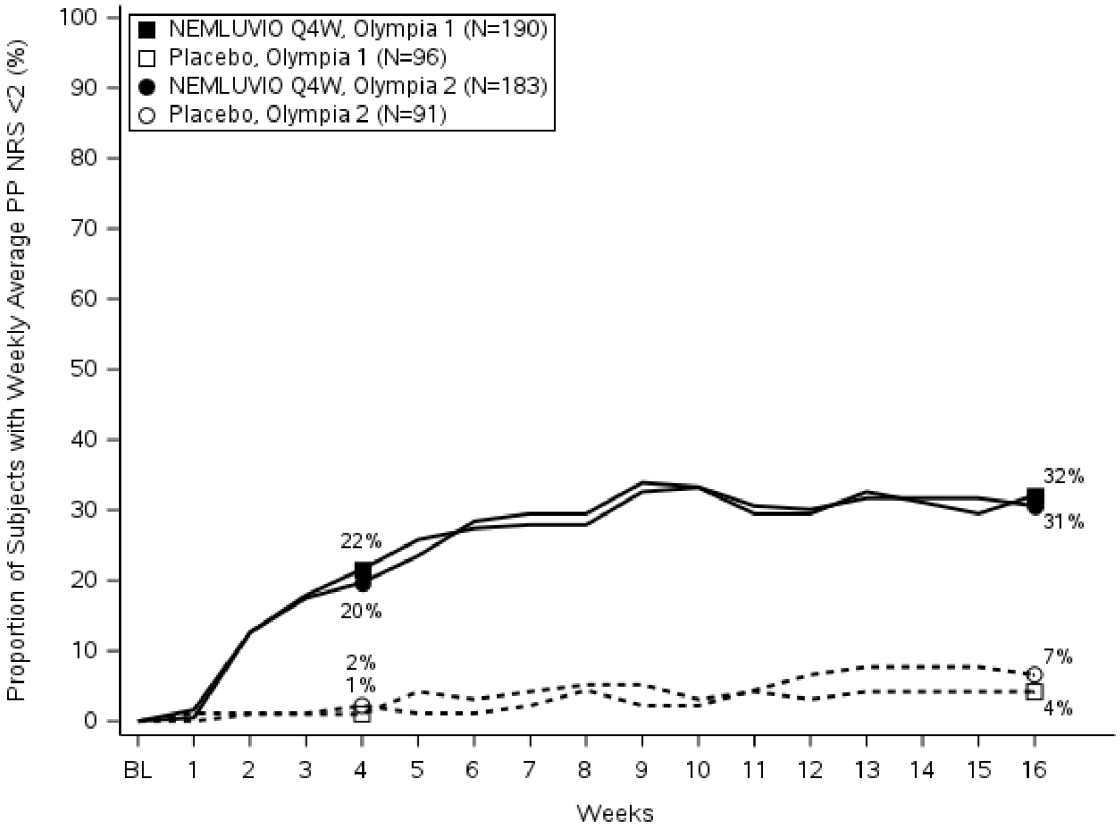
[a] Not adjusted for multiplicity.
[b] Subjects who received rescue therapy or had missing data (fewer than 4 PP-NRS daily diary entries in a 7-day period) were considered non-responders.

Figure 1: Proportion of Adult Subjects with PN with PP-NRS Improvement ≥4 from Baseline Over Time in OLYMPIA 1 and OLYMPIA 2[a]



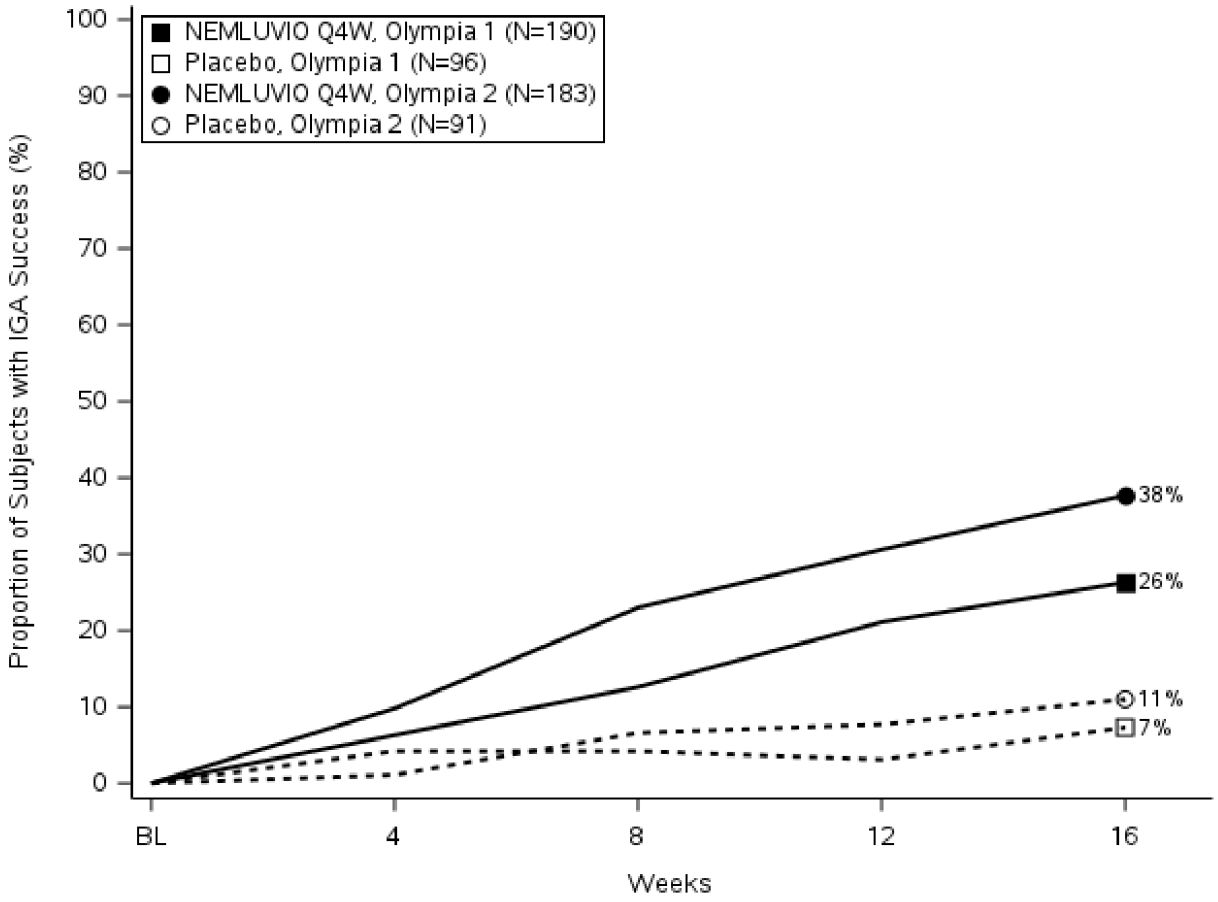
[a] Subjects who received rescue therapy or had missing data (fewer than 4 PP-NRS daily diary entries in a 7-day period) were considered non-responders.

Figure 2: Proportion of Adult Subjects with PN with PP-NRS <2 Over Time in OLYMPIA 1 and OLYMPIA 2[a]



[a] Subjects who received rescue therapy or had missing data (fewer than 4 PP-NRS daily diary entries in a 7-day period) were considered non-responders.

Figure 3: Proportion of Adult Subjects with PN with IGA Response[a] Over Time in OLYMPIA 1 and OLYMPA 2[b]



[a] Response was defined as an IGA of 0 (Clear) or 1 (Almost Clear) and a ≥2-point improvement from baseline.
[b] Subjects who received rescue therapy or had missing data were considered non-responders.

Examination of weight, age, gender, race, history of atopy, and prior treatment did not identify meaningful differences in response to NEMLUVIO among these subgroups at Week 16.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

NEMLUVIO (nemolizumab-ilto) for injection is a sterile, preservative-free, white lyophilized powder available in a single-dose, dual-chamber pre-filled pen containing 30 mg of nemolizumab-ilto in one chamber and the diluent, water for injection, in the other chamber. Following reconstitution, each pre-filled pen delivers 30 mg/0.49 mL of nemolizumab-ilto.

Each carton contains 1 single-dose pre-filled pen.

Presentation	**Pack size**	**NDC #**
Pre-filled Pen	Pack of 1 pen	0299-6220-15

Storage and Handling

Store the NEMLUVIO dual-chamber pre-filled pen in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light until the expiration date. Do not freeze. Do NOT expose to heat or direct sunlight.

Alternatively, the NEMLUVIO carton containing the unused dual-chamber prefilled pen may be stored at room temperature [up to 77°F (25°C)] for up to 90 days. Write the date the NEMLUVIO dual-chamber pre-filled pen is first removed from the refrigerator in the space provided on the inner partition for the pen. Do not use the NEMLUVIO dual-chamber prefilled pen beyond the expiration date or 90 days after the date it was first removed from the refrigerator (whichever is earlier).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Hypersensitivity

Advise patients to seek immediate medical attention and discontinue NEMLUVIO if they experience any symptoms of hypersensitivity reactions [*see Warnings and Precautions (5.1)*].

Vaccinations

Instruct patients to inform their healthcare provider that they are taking NEMLUVIO prior to a potential vaccination [*see Warnings and Precautions (5.2)*].

Administration Instructions:

- Instruct patients and/or caregivers to receive proper training in subcutaneous injection technique prior to self-injection [*see Dosage and Administration (2.4)*]. Inform patients and/or caregivers that Galderma Customer Support may be called toll-free for assistance at 1-866-735-4137.

- Inform patients that NEMLUVIO must be reconstituted prior to administration. Advise patients and/or caregivers to refer to the Instructions for Use that accompanies the NEMLUVIO pen for complete mixing and administration instructions with illustrations [see *Dosage and Administration (2.4, 2.5), Instructions for Use*].

- Inform patients and/or caregivers of proper pen disposal and caution against any reuse of needles. Instruct patients and/or caregivers to discard used pens in an appropriate sharps disposal container following safe needle disposal practices [*see Instructions for Use*].

- Advise patients and/or caregivers of the importance of complying with dosing schedule. If a dose is missed, instruct patients and/or caregivers to administer the injection as soon as possible, and thereafter, resume dosing at the regular scheduled time. [see *Dosage and Administration (2.3)*].

Manufactured by:
Galderma Laboratories, L.P., Dallas, TX 75201
U.S. License No. 2289
NEMLUVIO® is a trademark of Galderma.
© 2024 Galderma Laboratories, L.P. All rights reserved.
Issue Date: August 2024