Dupilumab-treated patients with prurigo nodularis experience improvements in itch and skin pain: 6-month results from the RELIEVE-PN study

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Prurigo nodularis

Conclusion

- **The results from the real-world RELIEVE-PN study demonstrated improvements in patient-reported itch, skin pain, and skin burning or stinging/tingling in dupilumab treated PN patients, which were observed as early as 1 month and sustained over the 6 months post treatment.**

Objective

- **To evaluate improvements in itch, skin pain, and skin burning or stinging/tingling in US adult patients with PN treated with dupilumab in the real-world setting**

Background

- Patients with prurigo nodularis (PN) experience significant itch, skin pain, and skin burning/stinging/tingling.[1]
- Dupilumab, a fully human VelocImmune®-derived monoclonal antibody, was the first approved treatment for adults with PN in the United States.[2]
- Dupilumab demonstrated a significant improvement in multiple measures of symptoms (such as itch and skin pain) in the pivotal phase 3 clinical trials—LIBERTY PN-PRIME (NCT04183335) and PRIME2 (NCT04202679).[3] However, the effectiveness of dupilumab in real-world settings is yet to be established.

Methods

- RELIEVE-PN (eaRly rEal-worLd patIent EValuation for DupixEnt in Prurigo Nodularis) is an ongoing longitudinal prospective patient survey study assessing the real-world effectiveness of dupilumab in the treatment of adult patients with PN.

RELIEVE-PN study design

Study design and population

- Pre-post longitudinal, prospective survey study
- Inclusion criteria
  - Adult patients with PN enrolled into the dupilumab patient support program
  - Provided informed consent
  - Completed the baseline survey[a]
  - Initiated dupilumab
- Exclusion criteria
  - Have used dupilumab before baseline
  - Enrolled in clinical trials over past 6 months
  - Not initiating dupilumab within 8 weeks post the baseline survey

Data collection time points

Pre Dupilumab baseline survey

↓

Weekly emails for up to 8 weeks to identify dupilumab initiation

↓

Post Dupilumab initiation surveys

M1 | M2 | M3 | M6 | M9 | M12 | M18 | M24

Assessments

- **Patient characteristics**
  - Demographics and clinical characteristics
  - Treatment history and comorbidities
- **Assessment of itch severity**
  - WI-NRS and average itch NRS
  - 7 days recall period; 0 (no itch) to 10 (worst itch imaginable)
- **Assessment of pain**
  - Average skin pain-NRS and skin burning/stinging /tingling-NRS
  - 7 days recall period; range 0 (no pain) to 10 (worst imaginable pain)

Statistical analysis

- Descriptive analyses were conducted to summarize the study outcomes.
- Continuous variables were summarized using means and standard deviations (SD), whereas categorical variables were summarized using frequency counts and percentages .
- The mean scores based on outcomes were compared to baseline values using t-tests.
- A subgroup analysis was conducted on patients who indicated they continued taking dupilumab at the time of each follow-up survey.

[a]The baseline survey collected data on socio-demographic characteristics, disease characteristics, medical history, PN sign/symptoms, prior treatment history and experiences, psychological wellbeing, health-related quality of life, employment status, treatment satisfaction, and patient global assessments.
NRS, Numeric Rating Scale; PN, prurigo nodularis; SD, standard deviation; WI-NRS, Worst Itch-Numeric Rating Scale.

Results

- Of the 181 patients who completed the baseline survey and initiated dupilumab, 156, 130, and 85 patients completed the Month 1, 3, and 6 surveys, respectively; 149, 125 and 67 patients remained on dupilumab at the respective time points.
- The most commonly reported reasons for stopping dupilumab therapy were: experienced side effects, dupilumab did not seem to work, my doctor told me to stop taking it, worried about potential side effects, and issue with health insurance coverage.

Demographic and medical history at baseline

Overall cohort ***N*=181**

Mean age (SD): **57.9 (14.5)** years

78.5% female

Mean (SD) time since diagnosis: **1.1 (4.1)** years[a]

[a]Calculated among 158 initiators that remembered when they were diagnosed of prurigo nodularis.

Table 1. Demographic at baseline

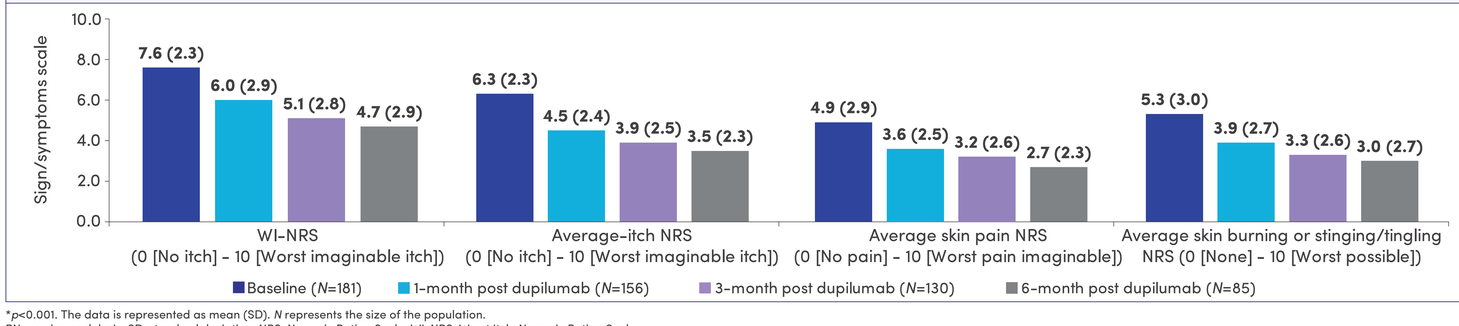
	Enrollment (*N*=181)	Patients who completed survey at		
		Month 1 (*N*=156)	Month 3 (*N*=130)	Month 6 (*N*=85)
Race, *n* (%)				
White or Caucasian	155 (85.6)	133 (85.3)	109 (83.9)	70 (82.4)
Black or African American	14 (7.7)	14 (9.0)	12 (9.2)	9 (10.6)
Asian or Pacific Islander	4 (2.2)	4 (2.6)	3 (2.3)	3 (3.5)
Native American/American Indian or Alaska Native	2 (1.1)	1 (0.6)	2 (1.5)	1 (1.2)
Multiple races or other	2 (1.1)	1 (0.6)	2 (1.5)	0 (0)
Prefer not to answer	4 (2.2)	3 (1.9)	2 (1.5)	2 (2.4)
Ethnicity, *n* (%)				
Hispanic or Latino	9 (5.0)	6 (3.9)	7 (5.4)	2 (2.4)
Not Hispanic or Latino	166 (91.7)	148 (94.9)	122 (93.9)	82 (96.5)
Prefer not to answer	6 (3.3)	2 (1.3)	1 (0.8)	1 (1.2)

N represents the size of the population. *n* represents the sample size.

Real-world effectiveness of dupilumab

a. Overall population

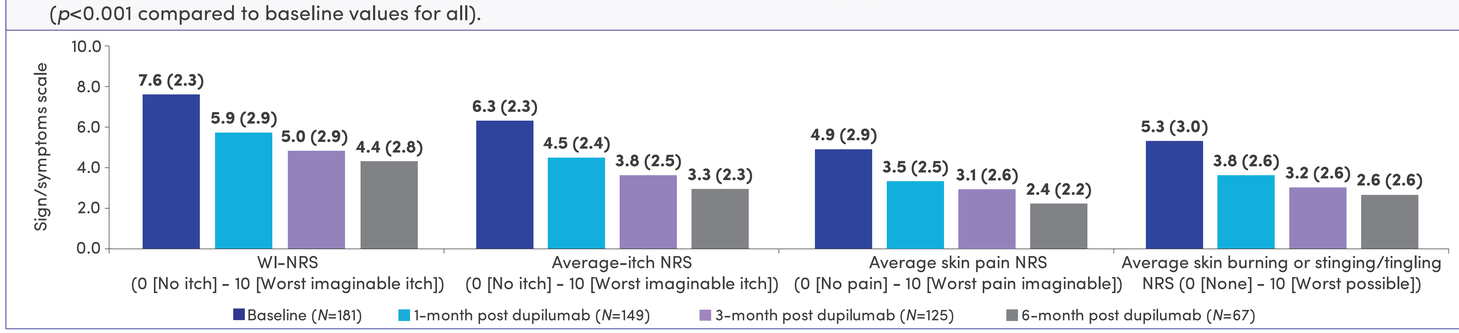
- The WI-NRS, average itch-NRS, skin pain NRS and skin burning or stinging/tingling NRS scores at months 1, 3, and 6 after dupilumab initiation all showed a significant reduction compared to baseline values ($p<0.001$).



*$p<0.001$. The data is represented as mean (SD). *N* represents the size of the population.
PN, prurigo nodularis; SD, standard deviation; NRS, Numeric Rating Scale; WI-NRS, Worst Itch-Numeric Rating Scale.

b. Persistent dupilumab subgroup

- The reduction in the WI-NRS, average itch NRS, skin pain NRS, and skin burning/tingling NRS scores were consistent with the overall population ($p<0.001$ compared to baseline values for all).



*$p<0.001$. The data is represented as mean (SD). *N* represents the size of the population.
PN, prurigo nodularis; SD, standard deviation; NRS, Numeric Rating Scale; WI-NRS, Worst Itch-Numeric Rating Scale.

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