Nanoencapsulated Sirolimus Plus Pegadricase (NASP) Demonstrates a Reduction in Gout Flares: Results From the Phase 3 DISSOLVE Studies

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CONCLUSION

Over 95% of patients who received 6 doses of high-dose NASP (HD NASP) were flare-free at weeks 21–24, highlighting the potential of NASP as an effective therapy for improving a key clinical manifestation of uncontrolled gout

INTRODUCTION

- NASP, a novel, every 4-week, sequential infusion therapy designed to reduce serum uric acid (sUA) levels in patients with uncontrolled gout, consists of targeted immunomodulating, nanoencapsulated sirolimus (NAS; formerly SEL-110) co-administered with pegadricase, a pegylated uricase (formerly SEL-037)

METHODS

- Adults with uncontrolled gout (≥3 gout flares within 18 months prior to screening or ≥1 tophus or current gouty arthritis diagnosis), treatment-resistant non-normalized sUA levels, and screening sUA level ≥7 mg/dL were randomized 1:1:1 to receive HD NASP, low-dose NASP (LD NASP), or placebo (PBO) once every 4 weeks
- This post hoc analysis focused on patients who received 6 doses of NASP or PBO in the pooled DISSOLVE I and II trial data

Primary endpoint

- Percentage of patients with an sUA response (sUA levels <6 mg/dL for ≥80% of time during weeks 21–24 of therapy)

Key secondary endpoint

- Incidence of gout flares

RESULTS

Patients with uncontrolled gout experienced a high disease burden prior to treatment

42 Patients (HD NASP) + 35 Patients (LD NASP) + 67 Patients (PBO) — Received 6 doses of treatment

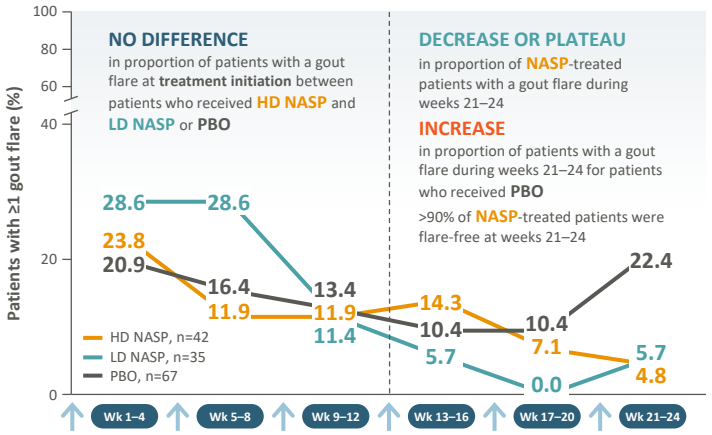
Mean duration of gout diagnosis: **11.7–13.3 years**

Mean baseline sUA levels: **8.5 mg/dL (HD and LD NASP)** **8.7 mg/dL (PBO)**

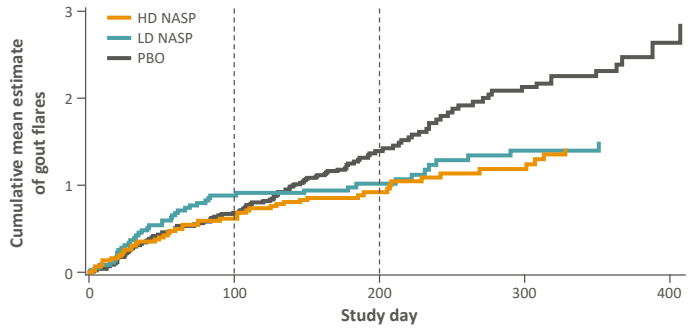
Prior to treatment, patients experienced a mean number of:

Tender joints			Swollen joints		
5.8 (HD NASP)	6.1 (LD NASP)	7.7 (PBO)	2.9 (HD NASP)	3.5 (LD NASP)	5.2 (PBO)

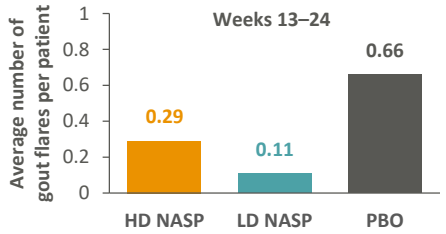
At treatment initiation, no difference in the proportion of patients with gout flares was seen between NASP and PBO; during weeks 13–24, a decrease in gout flares was seen with NASP



From day 100, gout flares plateaued in NASP-treated patients and increased with PBO



During weeks 13–24, the average number of gout flares per patient was substantially reduced with NASP



Average number of gout flares per patient was **2.3** and **5.7** times fewer with **HD NASP** and **LD NASP**, respectively, vs **PBO** in weeks 13–24

Adverse events of special interest, including gout flares and infusion-related adverse events within 24 hours, were generally similar to those observed in the overall DISSOLVE I and DISSOLVE II intent-to-treat population[1]

REFERENCE

1. Baraf HSB, et al. Congress of Clinical Rheumatology (CCR) – East; May 9–12, 2024; Destin, FL, USA.

Presented at the Congress of Clinical Rheumatology (CCR) – East; May 1–4, 2025; Destin, FL, USA