

# Reduction in Tophi Observed in Patients With Chronic Refractory Gout Treated With NASP: Results From Phase 3 DISSOLVE Studies

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## CONCLUSION

Nanoencapsulated sirolimus plus pegadricase (NASP) treatment led to a robust reduction in serum uric acid (sUA) area under the curve (AUC) and significant tophus resolution and/or reduction in tophus size in patients with uncontrolled gout when compared with placebo

## 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 high-dose NASP (HD NASP), low-dose NASP (LD NASP), or placebo (PBO) once every 4 weeks

### Triple read tophus evaluation

Assessments performed by 3 global gout experts from ACR and EULAR

Overall tophus response assessment categories:

Quantitatively applied to measurable “target tophi”

Qualitatively applied to non-measurable “non-target tophi”

One assessment from the majority opinion was selected

### Responses

- Partial response (PR)** was defined as ≥50% and <100% reduction in the area of a tophus without enlargement of any existing tophus and no new tophus
- Complete response (CR)** was defined as 100% reduction in the area or complete disappearance of a tophus without enlargement of any existing tophus and no new tophus

### Primary endpoint

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

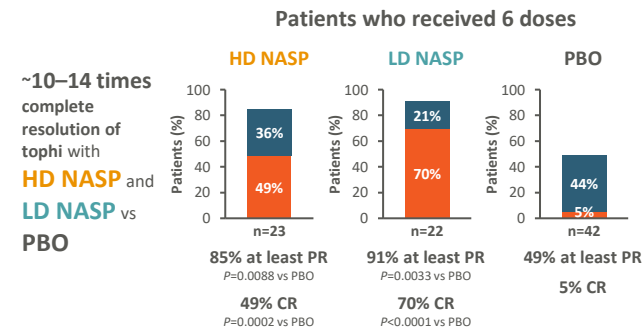
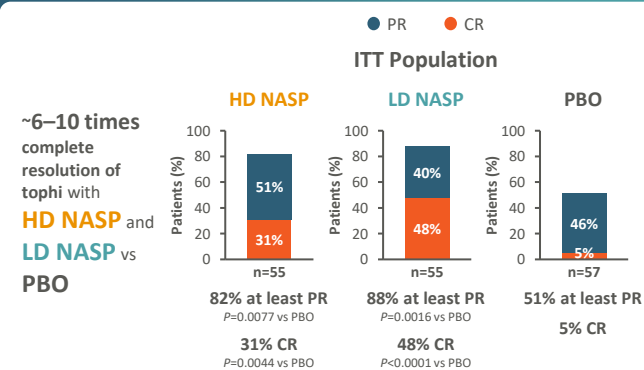
### Key secondary endpoint

- Tophus reduction

## RESULTS

Patients treated with NASP had a significantly greater response in tophus area reduction (weeks 21–24 vs baseline) compared with those who received PBO (≥10-fold CR rate vs PBO with 6 doses)

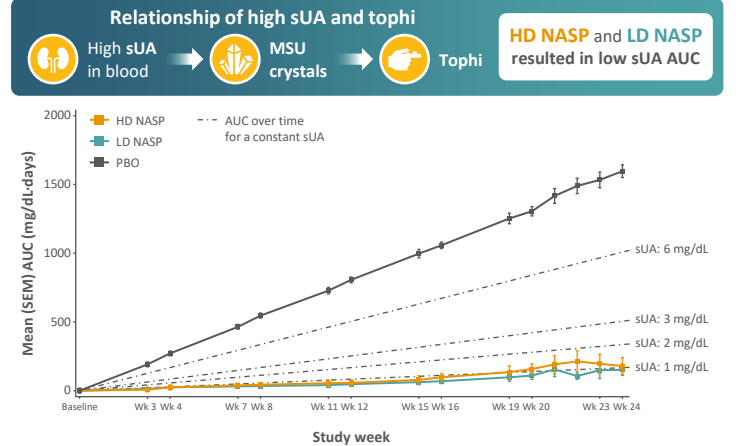
### Tophus response at weeks 21–24



Tophus response in a patient with uncontrolled gout who received 6 doses of HD NASP and had CR at the end of the double-blind phase



Mean sUA remained low throughout the course of treatment in patients who received NASP, which led to a low sUA AUC, whereas patients receiving PBO had consistently higher sUA levels that were reflected in a higher sUA AUC



Adverse events of special interest in patients with tophi at baseline who received 6 doses of HD NASP, LD NASP, or PBO were similar to those in the ITT population<sup>1</sup>

## 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