



Press release

Stockholm, 26 June 2026

Sobi receives complete response letter from FDA for NASP (nanoencapsulated sirolimus plus pegadricase)

The FDA has requested additional data related to chemistry, manufacturing, and controls (CMC) and contract manufacturing facilities; no clinical safety or efficacy concerns were identified that impact approvability

Sobi to meet with FDA to discuss next steps for resubmission

Sobi® (STO: SOBI) today announced that the Company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the Company's Biologics License Application (BLA) for NASP (nanoencapsulated sirolimus plus pegadricase) for the treatment of adult patients with uncontrolled gout.

In the CRL, the FDA required that the Company provide additional data mainly related to manufacturing control strategy of the biological component of NASP and to address contract manufacturing facility deficiencies. The FDA identified no concerns regarding the clinical efficacy or safety of NASP that impact approvability. Sobi will request a meeting with the FDA to discuss the feedback, determine the appropriate steps toward resubmission and work with the contract manufacturing organisations to address the deficiencies.

“We continue to believe strongly in NASP’s potential to address the significant unmet need faced by people living with uncontrolled gout,” said Lydia Abad-Franch, MD, MBA, Chief Medical Officer at Sobi. “The clinical data generated to date have demonstrated meaningful reductions in serum uric acid levels in patients with uncontrolled gout. The FDA’s feedback provides a clear and actionable path forward and we will work closely with them towards a resubmission. We remain committed to bringing NASP to patients.”

About uncontrolled gout

Gout is the most common form of inflammatory arthritis with more than 12 million people in the United States having been diagnosed.¹ Gout is caused by high levels of uric acid in the body that accumulate around the joints and other tissues and can result in flares that cause intense pain.² Approximately 200,000 people in the United States suffer from uncontrolled gout, with serum uric acid (sUA) levels above 6 mg/dL and persistent, debilitating flares and/or tophi despite treatment with oral urate-lowering therapies.^{3,4} Elevated sUA levels have also been associated with diseases of the heart, vascular system, metabolism, kidney and joint damage.

About NASP (nanoencapsulated sirolimus plus pegadricase)

NASP is a novel, investigational medicine designed to reduce serum uric acid (sUA) levels in people living with uncontrolled gout. By lowering uric acid, it may help reduce harmful urate deposits in tissues, which, when left untreated, can lead to irreversible joint damage, increased cardiometabolic and renal comorbidities, and substantial quality-of-life burden. NASP is administered every 4 weeks as a sequential, two-component, infusion

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therapy with a built-in immunomodulator, consisting of tolerogenic nanoencapsulated sirolimus (NAS) which mitigates the formation of anti-drug antibodies (ADAs) and a uricase, pegadricase (P), which reduces serum uric acid.

About Sobi®

Sobi is a global biopharma company unlocking the potential of breakthrough innovations, transforming everyday life for people living with rare diseases. Sobi has approximately 2,000 employees across Europe, North America, the Middle East, Asia and Australia. In 2025, revenue amounted to SEK 28 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and [LinkedIn](#).

Contacts

For details on how to contact the Sobi Investor Relations Team, please click [here](#). For Sobi Media contacts, click [here](#).

This information is information that Sobi is obliged to make public pursuant to the EU Market Abuse Regulation and/or the Swedish Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out below, on 26 June 2026 at 21:15 CEST.

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Head of Investor Relations

¹ FitzGerald JD. Gout. *Annals of Internal Medicine*. 2025;178(3):ITC33-ITC48. doi:10.7326/ANNALS-24-03951.

² Mayo Clinic. *Gout – Symptoms and causes*. Available at: <https://www.mayoclinic.org/diseases-conditions/gout/symptoms-causes/syc-20372897>.

³ Chen-Xu M, et al. *Arthritis Rheumatol*. 2019;71(6):991–999.

⁴ McAdams MA, et al. *J Rheumatol*. 2011;38(1):135–141.