PRESS RELEASE

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FDA Accepts Biologics License Application for Sobi's NASP for Patients with Uncontrolled Gout

- *Submission includes results of the pivotal DISSOLVE I and II studies*
- *NASP PDUFA date set for 27 June 2026*

Sobi® (STO: SOBI), a global biopharmaceutical company dedicated to delivering innovative treatments for patients with rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) seeking approval for Nanoecapsulated Sirolimus plus Pegadricase (NASP), formerly SEL-212, for the treatment of uncontrolled gout. NASP is a novel, every 4-week infusion therapy consisting of nanoencapsulated sirolimus, which has a targeted immunomodulating effect, and pegadricase, a pegylated uricase. The FDA has set a Prescription Drug User Fee Act (PDUFA), or target action date of 27 June 2026.

NASP potentially offers a significant advancement to this patient population for which there is a high unmet need and limited treatment options.

"There is a significant unmet need for patients living with uncontrolled gout," said Lydia Abad-Franch, MD, MBA, Head of Research, Development, and Medical Affairs, and Chief Medical Officer at Sobi. "People living with uncontrolled gout experience chronic inflammation, often resulting in severe gout flares and a buildup of uric acid, leading to the formation of painful tophi. These clinical manifestations not only affect a patient's physical and mental quality of life but also their comorbid conditions. We believe NASP has the opportunity to provide a novel option for patients who are inadequately controlled with conventional treatment and look forward to working closely with the FDA to bring this important uricase-based therapy to patients as quickly as possible."

The submission included results from the Phase 3 DISSOLVE I & II placebo controlled randomized clinical trials evaluating safety and efficacy of two different dose levels of NASP in adult patients with uncontrolled gout. Both studies met their primary endpoint of achieving and maintaining reduction in serum uric acid (sUA) <6mg/dL for at least 80% of the time during month six. In DISSOLVE I and II, the pooled response rates were 51% and 43% in the high dose and low dose of NASP, respectively.

In addition to achieving the primary endpoint, NASP treatment resulted in rapid and sustained reductions in serum uric acid (sUA) levels following the first treatment and throughout the study duration. Improvements in key clinical manifestations were also observed, including the resolution of tophi, a reduction in gout flares over time, and improved patient-reported quality of life. In the clinical trials, NASP was observed to be generally well tolerated across both doses.

In May 2024, the US FDA granted NASP Fast Track designation, recognizing its potential to address a serious condition with high unmet need and limited treatment options.

About uncontrolled gout

Gout is the most common form of inflammatory arthritis with more than 8.3 million people in the United States having been diagnosed. 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. Approximately 200,000 people in the United States suffer from uncontrolled gout, with serum uric acid (sUA) levels above 6 mg/dL despite treatment with oral urate lowering therapies. This leads to debilitating flares and tophi. Elevated sUA levels have also been associated with diseases of the heart, vascular system, metabolism, kidney and joints.

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About NASP, formerly SEL-212
NASP is a novel investigational medicine designed to reduce serum uric acid (sUA) levels in people living with uncontrolled gout, potentially reducing harmful tissue urate deposits which when left untreated can lead to debilitating gout flares and joint deformity. NASP is administered every 4-weeks as a sequential, two-component, infusion therapy 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. ADAs develop due to unwanted immune responses to biologic medicines, reducing their efficacy and tolerability, which remains an issue across multiple therapeutic modalities and disease states including uncontrolled gout.

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 1,900 employees across Europe, North America, the Middle East, Asia and Australia. In 2024, revenue amounted to SEK 26 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.