

Press release

Stockholm, 16 October 2026

Sobi receives positive CHMP opinion for TRYNGOLZA® (olezarsen) for the treatment of severe hypertriglyceridemia (sHTG)

- **Positive CHMP opinion based on Phase 3 CORE and CORE2 results, demonstrating a statistically significant placebo-adjusted mean reduction of up to 72% in triglyceride levels and a significant 85% reduction in the rate of acute pancreatitis events with TRYNGOLZA (olezarsen) compared with placebo**
- **Approximately 700,000 people in the EU5 are estimated to have triglyceride levels ≥ 880 mg/dL (≥ 10 mmol/L)ⁱ**

Sobi® today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the indication extension for TRYNGOLZA® (olezarsen) as an adjunct to diet, in combination with other lipid-lowering therapies, for the treatment of adult patients with severe hypertriglyceridemia (sHTG, fasting levels of ≥ 880 mg/dL [≥ 10 mmol/L]). If confirmed by the European Commission (EC), TRYNGOLZA would be the first and only RNA-targeted therapy authorised in the EU for adults with sHTG and triglyceride levels ≥ 880 mg/dL (≥ 10 mmol/L). The positive CHMP opinion comes ahead of Sobi's previously anticipated timeline, with a final EC decision expected in the fourth quarter of 2026.

The positive CHMP opinion is based on results from the pivotal Phase 3 CORE and CORE2 studies, which were sponsored by Ionis Pharmaceuticals and conducted in collaboration with the TIMI Study Group. These studies met their primary endpoint, with TRYNGOLZA demonstrating a statistically significant placebo-adjusted mean reduction in fasting triglyceride levels of up to 72% at six months, sustained through 12 months. In a pooled analysis across the two studies, TRYNGOLZA demonstrated a statistically significant 85% reduction in adjudicated acute pancreatitis events over 12 months compared with placebo. The efficacy and safety results from CORE and CORE2 were presented at the American Heart Association (AHA) Scientific Sessions 2025 and published simultaneously in [The New England Journal of Medicine \(NEJM\)](#).

"The CHMP's positive opinion reflects the strength of the clinical evidence and brings us one step closer to offering TRYNGOLZA as a new treatment option to help reduce the risk of acute pancreatitis in patients with sHTG in the EU," said Lydia Abad-Franch, MD, Head of R&D and Medical Affairs and Chief Medical Officer at Sobi. "Acute pancreatitis is a potentially life-threatening complication of sHTG that can place a significant burden on patients through frequent hospitalisations, intensive care treatment, irreversible complications and reduced quality of life. We look forward to the final decision from the EC."

sHTG is commonly defined by triglyceride levels of ≥ 500 mg/dL (≥ 5.65 mmol/L). At triglyceride levels ≥ 880 mg/dL (≥ 10 mmol/L), the risk of acute pancreatitis becomes clinically significant, and clinical guidelines recommend intervention to reduce this riskⁱⁱ. Acute pancreatitis is a

potentially life-threatening medical emergency often requiring admission to intensive care unit, prolonged hospitalisation and that can lead to persistent organ damage.

“Today’s positive CHMP opinion marks an important step towards making TRYNGOLZA available to patients with sHTG in the EU,” said Brett P. Monia, Ph.D., Chief Executive Officer of Ionis. “The recommendation builds on the clinical evidence from the CORE and CORE2 studies and reflects the continued collaboration between Ionis and Sobi as we work towards a potential European approval.”

TRYNGOLZA was discovered and developed by Ionis, which also commercialises the medicine in the US. Sobi and Ionis entered into a licence agreement under which Sobi has exclusive rights to commercialise TRYNGOLZA outside the US, excluding Canada and China.

About severe hypertriglyceridemia (sHTG)

Severe hypertriglyceridemia (sHTG) is defined by severely high triglyceride levels ≥ 500 mg/dL (≥ 5.65 mmol/L) and triglyceride levels ≥ 880 mg/dL (≥ 10 mmol/L) are often associated with the increased accumulation of chylomicrons in the blood and with an increased risk of acute pancreatitis and other morbidities. Considered a medical emergency, acute pancreatitis causes debilitating abdominal pain that often requires prolonged hospitalisation, can lead to permanent organ damage and can become life-threatening. Approximately 2 million people are living with sHTG in the EU5, including approximately 700,000 with TG levels ≥ 880 mg/dL (≥ 10 mmol/L).

About the CORE and CORE2 studies

CORE (NCT05079919; n=617) and CORE2 (NCT05552326; n=446), conducted in collaboration with the TIMI Study Group, were Phase 3 global, multicentre, randomised, double-blind, placebo-controlled trials investigating the safety and efficacy of olezarsen for sHTG. Participants aged 18 years and older with triglyceride levels ≥ 500 mg/dL (≥ 5.65 mmol/L) were enrolled. Participants were required to be on standard of care therapies for elevated triglycerides. At baseline, 43% of participants had fasting triglycerides ≥ 880 mg/dL (≥ 10 mmol/L). Participants were randomised to receive 50 mg or 80 mg of olezarsen or placebo every 4 weeks via subcutaneous injection for 12 months. The primary endpoint was the percentage change from baseline in fasting triglycerides at six months compared to placebo.

About TRYNGOLZA® (olezarsen)

TRYNGOLZA® (olezarsen) is an RNA-targeted medicine designed to lower the body’s production of apolipoprotein C-III, a protein produced in the liver that is a key regulator of triglyceride metabolism. TRYNGOLZA is approved in the UK, the United States, the European Union and Canada for adults with familial chylomicronaemia syndrome (FCS) and in the United States as an adjunct to diet to reduce triglycerides (TG) and the risk of acute pancreatitis in adults with severe hypertriglyceridaemia (sHTG: TG greater than or equal to 500 mg/dL). TRYNGOLZA is administered as a subcutaneous injection once monthly using a pre-filled autoinjector.

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](https://www.linkedin.com/company/sobi).

Contacts

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

ⁱ Hegele RA, et al. *Lancet Diabetes Endocrinol.* 2020;8(1):50–67. doi:10.1016/S2213-8587(19)30264-5.

ⁱⁱ Mach F, Baigent C, Catapano AL, et al. 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk. *Eur Heart J.* 2020;41(1):111–188. doi: [10.1093/eurheartj/ehz455](https://doi.org/10.1093/eurheartj/ehz455). doi:10.1016/j.atherosclerosis.2019.08.014