Press release

Stockholm, 26 May 2026

New analysis shows Tryngolza® (olezarsen) reduced acute pancreatitis by 85% and triglycerides by 66% in severe hypertriglyceridemia

Sobi® (STO: SOBI) today announced results from a new analysis of the pivotal Phase 3 CORE and CORE2 trials, showing Tryngolza® (olezarsen) reduced the relative risk of acute pancreatitis events by 85% (P<0.001) and reduced triglycerides by 66% in patients with severe hypertriglyceridemia (sHTG) after six months.[1]

The pooled subgroup analysis, presented as a late breaking abstract at the European Atherosclerosis Society (EAS) 2026 Congress in Athens, Greece, included 455 patients with baseline triglycerides of ≥880 mg/dL (~10 mmol/L), defined by the EAS as severe hypertriglyceridemia. At six months, patients randomised to receive olezarsen 80 mg showed a placebo-adjusted reduction in triglycerides of 66%, and those on olezarsen 50 mg a 59% reduction (each P<0.001). Overall, 85% of olezarsen-treated patients achieved triglycerides of <10 mmol/L.[1]

“Acute pancreatitis is a painful and potentially life-threatening condition that often requires urgent hospitalisation. People with triglyceride levels above 10 mmol/L have a four times greater risk of acute pancreatitis compared to those with ideal low levels, and this risk increases progressively as triglyceride levels rise[2]. According to EAS/ESC guidelines, triglyceride levels above 10 mmol/L warrant urgent intervention to prevent acute pancreatitis[3],” said Børge Nordestgaard, Professor and Chief Physician at Copenhagen University Hospital. “This new analysis showed that olezarsen reduced acute pancreatitis risk by 85% in patients with baseline triglyceride levels ≥10 mmol/L, while the vast majority of patients achieved triglyceride levels below 10 mmol/L.”

Severe hypertriglyceridemia is the third most common cause of acute pancreatitis.[4] The incidence of acute pancreatitis globally has increased at an average annual rate of 3% since the 1960s, contributing to a growing burden on healthcare systems.[5]

---

[1] Zimmerman A, et al. Olezarsen for acute pancreatitis risk in patients with triglycerides >10 mmol/l. Abstract 1635

[2] Kessler AS, Batra K, Amos Q, *et al*. A real-world study on the risk of acute pancreatitis and cardiovascular events among adults with severe or extreme hypertriglyceridemia. *J Clin Lipidol*. 2026 Apr 11:S1933-2874(26)00102-9.

[3] Mach et al. 2019 European Heart Journal

[4] Bashir B, Ferdousi M, Durrington P, Soran H. Pancreatic and cardiometabolic complications of severe hypertriglyceridaemia. *Curr Opin Lipidol*. 2024 Aug 1;35(4):208-218.

[5] Jordan P. Iannuzzi, James A. King, Jessica Hope Leong, *et al*. Global Incidence of Acute Pancreatitis Is Increasing Over Time: A Systematic Review and Meta-Analysis *Gastroenterology*. 2022 Jan;162(1):122-134.

Swedish Orphan Biovitrum AB (publ) (Sobi®)
SE-112 76 Stockholm, Sweden
Visiting address: Norra Stationsgatan 93A, Stockholm, Sweden
+46 8 697 20 00 | info@sobi.com | sobi.com

“These results add to the collective body of evidence for olezarsen, showing the reduction of acute pancreatitis risk in severe hypertriglyceridemia. As rates of acute pancreatitis continue to increase, olezarsen has the potential to be an important part of a preventative approach to disease management in at-risk patients,” said Lydia Abad-Franch, MD, Research, Development and Medical Affairs, and Chief Medical Officer at Sobi.

The results, presented by Dr Andre Zimerman on behalf of the TIMI Study Group, showed olezarsen 80 mg and 50 mg also reduced remnant cholesterol by 64% and 53%, respectively, and non-HDL-C by 35% and 27%.

The absolute reduction in pancreatitis events with olezarsen was 12 per 100 patient-years, meaning treating nine patients over one year would prevent one acute pancreatitis event in the type of patients included in the study. The safety profile in the subgroup analysis was favourable and similar to the broader trial population.[1]

In March 2026, the European Medicines Agency validated an indication extension application for olezarsen for the treatment of adults with sHTG and triglyceride levels ≥880 mg/dL (~10 mmol/L), aligned with EAS guidelines. In February 2026 the U.S. FDA accepted for Priority Review a supplemental New Drug Application for olezarsen for sHTG (triglyceride levels ≥500 mg/dL), with a target action date of June 30, 2026.

Olezarsen is developed by Ionis Pharmaceuticals. Sobi and Ionis entered into a license agreement under which Sobi has exclusive rights to commercialise Tryngolza in ex-U.S. geographies except 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. Preventing the first pancreatitis event is key. Current standard of care therapies for sHTG and lifestyle modifications (such as diet and exercise) do not sufficiently or consistently lower triglyceride levels or reduce the risks in all patients. 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 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 percent change from baseline in fasting triglycerides at six months compared to placebo.

About olezarsen
Olezarsen is an RNA-targeted medicine being evaluated for the treatment of severe hypertriglyceridemia. Olezarsen is designed to lower the body's production of apoC-III, a protein produced in the liver that regulates triglyceride metabolism in the blood. Olezarsen is approved in the U.S., European Union, and other countries as TRYNGOLZA® for adults with familial chylomicronemia syndrome (FCS).

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.