Press release

Stockholm, 17 November 2026

Tryngolza™ (olezarsen) approved in the EU for severe hypertriglyceridaemia (sHTG)

- **Tryngolza is now the first and only RNA-targeted therapy indicated in the EU for sHTG ≥880 mg/dL (≥10 mmol/L)**
- **EC decision is based on Phase 3 CORE and CORE2 results, demonstrating a statistically significant mean reduction of up to 73% in triglyceride levels at 6 months and a significant 83% reduction in the rate of acute pancreatitis events with Tryngolza compared with placebo**
- **Approximately 700,000 people in the EU5 are estimated to have triglyceride levels ≥880 mg/dL (≥10 mmol/L)[1], and therefore are at high risk of developing acute pancreatitis**

Sobi® today announced that the European Commission (EC) has approved Tryngolza™ (olezarsen) as an adjunct to diet, in combination with other lipid-lowering therapies, for the treatment of adult patients with severe hypertriglyceridaemia (sHTG, fasting triglyceride levels of ≥880 mg/dL [≥10 mmol/L]). Tryngolza is the first and only RNA-targeted therapy authorised in the EU for adults with sHTG ≥880 mg/dL (≥10 mmol/L). The approval follows an early positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in October and expands the marketing authorisation for Tryngolza which is already indicated for familial chylomicronemia syndrome (FCS) into a broader patient population.

The EU approval is based on results from the pivotal Phase 3 CORE and CORE2 studies, sponsored by Ionis Pharmaceuticals and conducted in collaboration with the TIMI Study Group. The approval is supported by a pre-specified analysis of adult patients with baseline triglyceride levels ≥880 mg/dL (≥10 mmol/L). In this population, Tryngolza demonstrated a statistically significant reduction in triglyceride levels of up to 73% at six months compared with placebo ($p<0.001$), with reductions sustained through 12 months.

At triglyceride levels ≥880 mg/dL (≥10 mmol/L), the risk of acute pancreatitis becomes clinically significant.[2] In a pooled analysis of the CORE and CORE2 studies, Tryngolza also demonstrated a significant 83% reduction in adjudicated acute pancreatitis events over 12 months compared with placebo ($p<0.001$).

“Acute pancreatitis is a potentially life-threatening medical emergency that may require intensive care admission and prolonged hospitalisation,” said Erik S.G. Stroes, MD, PhD, Professor of Vascular Medicine at Amsterdam UMC. “Some patients experience permanent organ damage and lasting effects on their quality of life. There is an unmet need for patients with sHTG for new, effective therapies to help reduce the risk of acute pancreatitis.”

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sHTG is the third most common cause of acute pancreatitis.[3] 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.[4]

“The European Commission’s approval of Tryngolza for the treatment of sHTG is an important step forward for patients in Europe who remain at increased risk of acute pancreatitis despite diet and existing lipid-lowering therapies,” said Lydia Abad-Franch, MD, Head of R&D and Medical Affairs and Chief Medical Officer at Sobi. “The EC decision marks meaningful progress for eligible patients living with sHTG.”

“This approval reflects the potential of RNA-targeted medicines to address serious conditions such as sHTG,” said Brett P. Monia, Ph.D., Chief Executive Officer of Ionis. “We are proud to work with our long-standing partner Sobi to bring Tryngolza to people in need across the EU.”

Tryngolza was discovered, developed and is commercialised in the U.S. 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 hypertriglyceridaemia (sHTG)
Severe hypertriglyceridaemia (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 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 (EU) and Canada for adults with familial chylomicronaemia syndrome (FCS) and in the United States and EU for severe hypertriglyceridaemia (sHTG). 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.

Contacts
For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here.

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