PRESS RELEASE

Stockholm, Sweden, 30 March 2026

EMA validates indication extension application for Tryngolza® (olezarsen) for the treatment of severe hypertriglyceridemia (sHTG)

Sobi® (STO: SOBI) today announced that the European Medicines Agency (EMA) has validated an indication extension application for Tryngolza® (olezarsen) for the treatment of adult patients with severe hypertriglyceridemia (sHTG) ≥880 mg/dL (≥10 mmol/L). Patients with elevated triglyceride levels have substantially higher risks of all-cause mortality, atherosclerotic cardiovascular events, and acute pancreatitis[1].

The submission is supported by results from the pivotal Phase 3 CORE and CORE2 studies, which were published in the *New England Journal of Medicine* in 2025[2].

"Tryngolza is the only pharmacological therapy to demonstrate a reduction in the risk of acute pancreatitis in patients with severe hypertriglyceridemia. If approved, it could offer an important therapeutic option to help prevent this life-threatening condition, which can place a significant burden on patients due to frequent hospitalisations, intensive treatment, persistent symptoms and reduced quality of life," said Lydia Abad-Franch, MD, Head of R&D and Medical Affairs and Chief Medical Officer at Sobi. "Sobi's marketing authorisation application reflects the growing body of clinical evidence supporting Tryngolza and our commitment to improving treatment options for people living with sHTG."

Olezarsen is developed by Ionis Pharmaceuticals. Sobi and Ionis entered into a licence agreement under which Sobi has exclusive rights to commercialise Tryngolza in ex-U.S. geographies except Canada and China. Tryngolza® (olezarsen) was approved in the European Union in September 2025 as an adjunct to diet for the treatment of adult patients with genetically confirmed familial chylomicronemia syndrome (FCS).

About Severe Hypertriglyceridemia (sHTG)

Severe hypertriglyceridemia (sHTG) is defined by severely high triglycerides ≥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 attack is key. Current standard of

[1] Ginsberg et al. *Eur Heart J*. 2021;42(47):4791-4806.
[2] Marston, Nicholas A et al. "Olezarsen for Managing Severe Hypertriglyceridemia and Pancreatitis Risk." *The New England journal of medicine* vol. 394,5 (2026): 429-441. doi:10.1056/NEJMoa2512761

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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, are Phase 3 global, multicentre, randomised, double-blind, placebo-controlled trials investigating the safety and efficacy of olezarsen for severe hypertriglyceridemia (sHTG). Participants aged 18 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 sHTG. 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., Canada, and the European Union as TRYNGOLZA® for adults with familial chylomicronemia syndrome (FCS).

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 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

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