PRESS RELEASE

Stockholm, Sweden 19 September 2025

Tryngolza ® (olezarsen) approved in the European Union for familial chylomicronemia syndrome (FCS)

Sobi® (STO: SOBI), a global biopharmaceutical company dedicated to delivering innovative treatments for patients with rare diseases, and Ionis Pharmaceuticals, Inc. today announced that Tryngolza® (olezarsen) has been approved in the European Union (EU) as an adjunct to diet in adult patients for the treatment of genetically confirmed familial chylomicronemia syndrome (FCS). The approval follows the positive opinion of the Committee for Medicinal Products for Human Use.

The approval is based on positive data from the Phase 3 Balance study, in which Tryngolza 80 mg demonstrated a statistically significant reduction in fasting triglyceride levels at six months that was sustained through 12 months. Additionally, Tryngolza demonstrated a substantial and clinically meaningful reduction in acute pancreatitis events over 12 months. Tryngolza showed a favourable safety and tolerability profile. Study results were published in *The New England Journal of Medicine (NEJM).*

Lydia Abad-Franch, MD, MBA, Head of Research, Development, and Medical Affairs (RDMA) and Chief Medical Officer at Sobi said "Tryngolza is the next step in our support for the FCS community in Europe. It has a strong safety and efficacy profile, with significant reductions in triglyceride levels and a notable decrease in acute pancreatitis events, which impact morbidity, mortality, and quality of life. This builds on our commitment to FCS that began with Waylivra (volanesorsen), the only approved treatment for FCS in Europe until now. With the European Commission's approval of Tryngolza for FCS, we are looking forward to providing this therapy to eligible patients with this rare and debilitating condition across the EU."

FCS is a rare and genetic form of severe hypertriglyceridemia (sHTG). People with FCS often have extremely high levels triglyceride levels, and are at high risk of developing acute pancreatitis, which can be life-threatening. In the EU, FCS is estimated to impact up to 13 people per million.

"The EU approval of Tryngolza is a significant advance for the treatment of FCS," said Brett P. Monia, Ph.D., chief executive officer, Ionis. "Tryngolza has the potential to be a transformative treatment option for FCS patients in the EU who are at risk of debilitating and life-threatening acute pancreatitis attacks. We are proud to work with Sobi, a long-standing partner of Ionis and the FCS community, to make Tryngolza available to people with FCS in the EU."

Sobi has exclusive rights to commercialize Tryngolza in countries outside the U.S., Canada and China. Tryngolza is also being evaluated in patients with sHTG with triglyceride levels ≥500 mg/dL (5.65 mmol/L), and positive topline results from the Phase 3 studies were announced in September 2025.

About the Balance Study

Balance was global, multicenter, randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy and safety of olezarsen in patients with FCS with 12-month duration. The primary endpoint was the percent change from baseline in fasting triglyceride levels at six months compared to placebo. Secondary endpoints included percent changes in triglyceride levels at 12 months, percent changes in other lipid parameters at six and 12 months and adjudicated acute

pancreatitis event rates over the treatment period. Following treatment and the end-of-trial assessments, patients were eligible to enter an open-label extension study to continue receiving olezarsen once every four weeks.

About Familial Chylomicronemia Syndrome (FCS)
FCS is a rare, genetic disease characterized by extremely elevated triglyceride levels. It is caused by impaired function of the enzyme lipoprotein lipase (LPL). Because of limited LPL production or function, people with FCS cannot effectively break down chylomicrons, lipoprotein particles that are 90% triglycerides. People living with FCS are at high risk of acute pancreatitis in addition to other chronic health issues such as fatigue and severe, recurrent abdominal pain. People living with FCS are sometimes unable to work, adding to the burden of disease.

About TRYNGOLZA® (olezarsen)
Trynglolza® 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 (olezarsen) is approved in the United States and the European Union for adults with familial chylomicronemia syndrome (FCS). Tryngolza is administered as an 80 mg subcutaneous injection once monthly using a pre-filled autoinjector. Olezarsen is also being evaluated for severe hypertriglyceridemia (sHTG), defined by high fasting triglyceride levels ≥500 mg/dL.

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.

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