PRESS RELEASE

Stockholm, Sweden 25 July 2025

TRYNGOLZA® (olezarsen) recommended for EU approval by CHMP for familial chylomicronemia syndrome (FCS)

- *Recommendation based on Phase 3 Balance results, which showed a significant reduction of triglycerides and substantial reduction of acute pancreatitis events with TRYNGOLZA*
- *European Commission decision expected by Q4 2025*

Sobi® (STO: SOBI) and Ionis Pharmaceuticals, Inc. today announced that the Committee for Medicine Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion of TRYNGOLZA® (olezarsen) as an adjunct to diet in adult patients for the treatment of genetically confirmed familial chylomicronemia syndrome (FCS). The positive opinion is now referred to the European Commission (EC) for an approval decision, which is expected by Q4 2025.

Lydia Abad-Franch, MD, MBA, Head of Research, Development, and Medical Affairs (RDMA) and Chief Medical Officer at Sobi said "The approval recommendation brings us one step closer toward delivering TRYNGOLZA to people living with FCS in the EU and is a testament to our long-standing support for the FCS community. Patients with FCS suffer from complications such as acute pancreatitis. These are very severe events, often requiring intensive care and sometimes causing multiorgan failure as well as increasing morbidity and mortality. We believe TRYNGOLZA has the potential to be an important treatment for people living with this rare and serious disease, and we look forward to the final decision from the EC later this year."

"Building on the strong early launch of TRYNGOLZA in the U.S., the positive CHMP opinion advances our commitment to expand access to TRYNGOLZA globally," said Brett P. Monia, Ph.D., chief executive officer of Ionis. "TRYNGOLZA has demonstrated significant reductions in triglycerides and substantial reductions in acute pancreatitis events with favourable safety and tolerability. With this robust clinical profile, combined with Sobi's deep commercial market expertise in FCS, TRYNGOLZA has the potential to make a meaningful difference for people living with FCS in the EU."

The CHMP opinion is based on positive data from the Phase 3 Balance study, in which TRYNGOLZA demonstrated a statistically significant reduction in 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).

FCS is a rare and genetic form of severe hypertriglyceridemia (sHTG) that prevents the body from breaking down fats and severely impairs the ability to remove triglycerides from the bloodstream. People with FCS often have triglyceride levels of more than 880 mg/dL (10 mmol/L), compared to normal levels of <150 mg/dL (1.7 mmol/L), 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.

Sobi has exclusive rights to commercialize TRYNGOLZA in countries outside the U.S., Canada and China. As Ionis' European commercial partner for Waylivra (volanesorsen), the only medicine currently approved for FCS in the EU, Sobi will leverage existing market expertise and distribution channels to enable an effective TRYNGOLZA launch in FCS, if approved.

TRYNGOLZA was approved in the United States in December 2024 and granted orphan designation in the EU. Olezarsen is also being evaluated for severe hypertriglyceridemia (sHTG), a serious condition defined by dangerously high triglycerides (≥ 500 mg/dL), and data from the Phase 3 CORE and CORE2 studies are expected in Q3 2025.

About the Balance Study
Balance is a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy and safety of olezarsen in patients with FCS at six and 12 months. 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 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)
TRYNGOLZA® is an RNA-targeted medicine designed to lower the body's production of apoC-III, a protein produced in the liver that is a key regulator of triglyceride metabolism. TRYNGOLZA® (olezarsen) is approved in the United States as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). For more information about TRYNGOLZA, visit TRYNGOLZA.com. TRYNGOLZA is not yet approved for any indication in Europe.

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS
TRYNGOLZA is contraindicated in patients with a history of serious hypersensitivity to TRYNGOLZA or any of the excipients in TRYNGOLZA. Hypersensitivity reactions requiring medical treatment have occurred.

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
Hypersensitivity reactions (including symptoms of bronchospasm, diffuse erythema, facial swelling, urticaria, chills and myalgias) have been reported in patients treated with TRYNGOLZA. Advise patients on the signs and symptoms of hypersensitivity reactions and instruct patients to promptly seek medical attention and discontinue use of TRYNGOLZA if hypersensitivity reactions occur.

ADVERSE REACTIONS
The most common adverse reactions (incidence >5% of TRYNGOLZA-treated patients and >3% higher frequency than placebo) were injection site reactions, decreased platelet count and arthralgia.

Please see full Prescribing Information for TRYNGOLZA.

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.

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