TRYNGOLZA™ (olezarsen)

PRODUCT FACT SHEET

TRYNGOLZA™ (olezarsen) is approved by the U.S. Food and Drug Administration (FDA) as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).[1]

TRYNGOLZA is the first-ever FDA-approved prescription treatment that is proven to reduce triglyceride levels in adults with FCS when used with an appropriate diet, and showed a reduction in acute pancreatitis (AP) events.[1]

FCS is a rare, genetic, potentially life-threatening form of severe hypertriglyceridemia (sHTG) that prevents the body from breaking down fats and impairs the body's ability to remove triglycerides from the bloodstream due to impaired function of the enzyme lipoprotein lipase (LPL).[2]

- Those living with FCS have a high risk of potentially life-threatening AP, which is a painful inflammation of the pancreas, and experience chronic health issues such as fatigue and severe, recurrent abdominal pain.[3]

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 in the blood.[1,4] It is the first-ever treatment currently indicated in the U.S. for adults with FCS, a potentially life-threatening disease.[2]

The most common side effects of TRYNGOLZA include injection site reactions, decreased platelet count and arthralgia.[1]

TRYNGOLZA is self-administered via an auto-injector monthly.[1]

Please see Important Safety Information on page 2. Please see full Prescribing Information for TRYNGOLZA, also available at TRYNGOLZA.com.

TRYNGOLZA Research at a Glance

The **FDA approval of TRYNGOLZA** was based on positive data from the global, multicenter, randomized, placebo-controlled, double-blind **Phase 3 clinical trial (Balance)** in adults with FCS and fasting triglyceride levels ≥880 mg/dL.[1]

In the Balance trial, the **efficacy** of TRYNGOLZA was evaluated in 45 adult patients with FCS.[1] The primary endpoint evaluated an 80 mg dose at six months, with additional endpoints including an evaluation at 12 months.

In the 80 mg group, TRYNGOLZA demonstrated a statistically significant placebo-adjusted mean reduction in triglyceride levels of 42.5% from baseline to six months (p=0.0084).[1] Median percent change from baseline over the 12-month treatment period demonstrated a consistent lowering effect.[1]

Select secondary endpoints include:

- **Fewer AP events were observed over 12 months in the 80 mg TRYNGOLZA group;** one patient (5%) in the TRYNGOLZA 80 mg group experienced AP compared with seven patients (30%) in the placebo group.[1]

TRYNGOLZA demonstrated a favorable safety profile versus placebo.[1] The most common adverse reactions (incidence >5% of TRYNGOLZA-treated patients and at a >3% higher frequency than placebo) were injection site reactions (19% and 9%, respectively), decreased platelet count (12% and 4%, respectively) and arthralgia (9% and 0%, respectively).[1]

Tryngolza™ (olezarsen) 80 mg injection

Access to TRYNGOLZA: Ionis Every Step™

Ionis is committed to helping people access the medicines they are prescribed and will offer a suite of services for people prescribed TRYNGOLZA through Ionis Every Step. In addition to insurance support and financial assistance programs, Ionis Every Step offers personal support for patients and their doctors. Ionis Patient Education Managers are dedicated partners for patients through every step of the treatment journey.

Visit TRYNGOLZA.com for more information.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

TRYNGOLZA™ (olezarsen) is indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

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, also available at TRYNGOLZA.com

References

1. TRYNGOLZA [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.
2. Moulin P, Dufour R, Averna M, et al. Identification and diagnosis of patients with familial chylomicronaemia syndrome (FCS): Expert panel recommendations and proposal of an "FCS score". *Atherosclerosis*. 2018;275:265-272.
3. Davidson M, Stevenson M, Hsieh A, et al. The burden of familial chylomicronemia syndrome: Results from the global IN-FOCUS study. *J Clin Lipidol*. 2018;12(4):898-907.e2.
4. Chyzhyk V, Brown AS. Familial chylomicronemia syndrome: A rare but devastating autosomal recessive disorder characterized by refractory hypertriglyceridemia and recurrent pancreatitis. *Trends Cardiovasc Med*. 2020;30(2):80-85.

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Tryngolza™ (olezarsen) 80 mg injection