FDA approves Roche’s Enspryng, a first-in-class IL-6R inhibitor, as the first and only at-home subcutaneous treatment option for thyroid eye disease (TED)

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FDA approval based on Phase III SatraGO-1 and -2 studies, with SatraGO-2 demonstrating a significant reduction in eye bulging (proptosis) and improvement in diplopia (double vision), with a favourable safety profile, regardless of TED activity or duration1,2 .

- **Enspryng (satralizumab) represents an important advance for people with TED, offering the first at-home SC treatment option every four weeks during maintenance phase, allowing for greater flexibility in how treatment is administered[1]**
- **Enspryng is an anti-IL-6R mAb using novel recycling antibody technology designed to inhibit IL-6 signalling upstream of autoantibody-driven pathology[2,3]**
- **TED is a rare autoimmune disease affecting approximately 155 out of every 100,000 people in the US that can lead to facial disfigurement and vision-threatening complications if left untreated[3-7]**

Basel, 16 October 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved Enspryng® (satralizumab) for the treatment of adults with thyroid eye disease (TED), providing patients with the first and only at-home subcutaneous treatment option. Enspryng can be administered by a person living with TED or a caregiver following training from a healthcare provider.[1]

“Today’s FDA approval of Enspryng provides an important new option for people with thyroid eye disease, who have long faced limited treatment choices,” said Levi Garraway, MD, PhD, Roche’s Chief Medical Officer and Head of Global Product Development. “As the first subcutaneous treatment for this condition, Enspryng offers a positive safety and efficacy profile and the potential for at-home administration.”

"Treating thyroid eye disease requires balancing efficacy, safety, and the practical realities of long-term treatment,” said César A. Briceño, MD, Clinical Trial Investigator and Associate Professor of

Ophthalmology at the Scheie Eye Institute, University of Pennsylvania. “As a clinical trial investigator, I have seen firsthand the potential of targeted therapies such as Enspryng. The availability of an effective subcutaneous treatment option could provide greater flexibility for both patients and physicians while reducing the logistical burden associated with infusion-based therapies. Enspryng has the potential to meaningfully expand our therapeutic options for patients with thyroid eye disease."

The totality of data from the pivotal Phase III SatraGO programme (SatraGO-1 and SatraGO-2) provided clinically meaningful improvements in patients with TED.[1,2] While SatraGO-1 did not meet its pre-specified primary efficacy endpoint at Week 24, SatraGO-2 achieved significant and clinically meaningful difference in proptosis response (52.9% in the Enspryng group compared to 23.4% in the placebo group) and in diplopia reduction (60.7% in the Enspryng group compared to 25.8% in the placebo group) in the active TED population.[1,2] Consistent results were achieved in the overall population (including both active and chronic patients) in SatraGO-2.[1,2] No new safety signals were identified in the SatraGO trials, with Enspryng’s safety profile consistent with its known profile in neuromyelitis optica spectrum disorder (NMOSD).[1,2] Full results were shared at the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) Fall Scientific Symposium in October 2025.[2]

“Thyroid eye disease not only affects a person’s eyes through bulging and vision problems, but it also takes a profound emotional toll on confidence, identity, relationships and daily life,” said Christine Gustafson, Chief Executive Officer of the TED Community Organization. “Until now, our community has had very limited choices. The approval of Enspryng represents a critical turning point through a convenient, targeted option.”

The approval in TED, following a priority review designation, marks the second indication for Enspryng, following an approval in neuromyelitis optica spectrum disorder (NMOSD) in 2020.[1,8,9] This follows a recent acceptance by the FDA for priority review in myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD).[10] Enspryng is also being studied in additional neurological autoimmune and inflammatory diseases that may benefit from inhibition of IL-6 mediated signalling.

About SatraGO-1 and -2
SatraGO-1 (NCT05987423) and -2 (NCT06106828) are identically designed, Phase III, randomised, placebo-controlled, multicentre studies to determine the efficacy, durability and tolerability of Enspryng for the treatment of adults with active, moderate-to-severe TED and chronic TED. The studies enrolled a total of 258 patients from 19 countries. Participants were randomised 1:1 to receive Enspryng or placebo. The primary endpoints were the proportion of participants with active, moderate-to-severe TED who achieved an at least 2 mm reduction in proptosis in the study eye from baseline at week 24.[2,3]

About thyroid eye disease (TED)
TED, also known as Graves’ ophthalmopathy, is a complex inflammatory autoimmune disease, affecting the area around the eyes and the eyes themselves, that can be sight-threatening, debilitating and disfiguring.[4,5] The most common symptoms are redness, swelling of the eyes, eyelid retraction, appearance of a stare, bulging of one or both eyes (proptosis), double vision (diplopia) and pain.[4,6]

TED is a progressive rare disease that affects approximately 155 people out of every 100,000.[3-5,7] It most commonly occurs in people with hyperthyroidism, approximately 50% of whom experience at least mild TED, but it can also affect people with hypothyroidism or normal thyroid function.[4,11]

Despite existing approved treatments for TED, a medical need remains for therapies that are effective, well-tolerated, and have a convenient route of administration.[3]

About Enspryng® (satralizumab)
Enspryng, developed by Chugai, a member of the Roche Group, is a humanised monoclonal antibody that is designed to bind to both soluble and membrane-bound interleukin-6 receptors (IL-6R), thereby inhibiting IL-6 mediated signalling, a known key pathway involved in inflammation. Enspryng incorporates Chugai's proprietary antibody recycling technology, which enables pH-dependent binding to IL-6R and repeated engagement of the target, extending antibody circulation and supporting sustained inhibition of IL-6 mediated signalling.[1-3,12]

Enspryng is the first and only IL-6R inhibitor treatment currently approved in approximately 90 countries for neuromyelitis optica spectrum disorder (NMOSD), including in the European Union and United States, with a well established safety profile in over 16,000 patients.[1,13]

Roche is committed to developing Enspryng in additional neurological autoimmune and inflammatory diseases that may benefit from inhibition of IL-6 mediated signalling, including autoimmune encephalitis (AIE) and myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). The FDA granted priority review of the Enspryng supplemental Biologics License Application (sBLA) for MOGAD in September 2026 with an approval decision expected in January 2027.[10]

Enspryng has orphan drug designation in the United States and European Union for NMOSD and MOGAD and in the United States for anti-NMDA receptor autoimmune encephalitis (anti-NMDAR AIE) and leucine-rich glioma-inactivated 1 autoimmune encephalitis (LGI1 AIE).

About Roche in Ophthalmology
At Roche, we are on a mission to save and restore eyesight. Over 330 million people around the world are blind, or living with vision loss, creating a profound personal and socioeconomic burden. With the broadest pipeline in Ophthalmology, we continue to invest at scale to redefine what is medically possible in eye care.

Our comprehensive ophthalmology pipeline integrates diverse targets, advanced delivery systems, cell and gene therapies, and AI-augmented imaging capabilities, targeting multiple vision-threatening conditions, including retinal vascular and diabetic eye diseases, geographic atrophy, and autoimmune conditions, such as thyroid eye disease and uveitic macular edema.

About Roche
Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody

market.

For more information, please visit www.roche.com.

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