Health Technology Briefing
August 2025

Satralizumab for treating thyroid eye disease

Company/Developer	Roche Products Ltd.

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 37732	NICE ID: Not Available	UKPS ID: 675070

Licensing and Market Availability Plans

Currently in phase III clinical development.

Summary

Satralizumab is being developed for the treatment of thyroid eye disease (TED). TED is a rare but potentially debilitating condition which occurs when the body's immune system attacks the tissue around and behind the eye, causing inflammation in the tissues. This can cause the eyes and eyelids to become red, swollen and uncomfortable and the eyes to be pushed forward. In some cases, there is swelling and stiffness of the muscles that move the eyes so that they no longer move in line with each other; this can cause double vision. Symptoms can severely affect daily functioning, self-esteem, and overall quality of life. Management of TED can be complex, and there is considerable variation in disease severity and response to treatments. There is still a need for better treatments for people whose disease comes back, who have significant side effects from current treatments, or who have long-term illness with no established treatment available.

Satralizumab is a monoclonal antibody, a type of protein that has been designed to block the action of interleukin-6 (IL-6). IL-6 is a protein in the body believed to play a key role in the inflammation occurring in people with TED. By blocking IL-6, satralizumab may help lower inflammation and prevent damage or changes to the tissues around the eye. Satralizumab is administered into the layer of fat beneath the skin (subcutaneously) once every four weeks. If approved (licensed), satralizumab could offer a novel, targeted approach to managing TED, especially for patients who experience inadequate responses or cannot tolerate existing therapies.

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

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Proposed Indication

Treatment of adult patients with thyroid eye disease (TED).[1,2]

Technology

Description

Satralizumab (Enspryng) is a humanised immunoglobulin G subclass 2 monoclonal antibody against IL-6 (interleukin 6) receptors; it specifically binds to both membrane-bound and soluble forms of IL-6 receptors and blockades IL-6 signaling pathways.[3] Elevated serum IL-6 levels have been shown to correlate with disease activity in patients with TED. IL-6 plays a pivotal role in the pathogenesis of TED through three key mechanisms that together may contribute to inflammation, tissue expansion, remodeling, and fibrosis within the orbit.[4] Satralizumab has been engineered to have pH-dependent binding to IL-6 receptors, increased affinity for the neonatal Fc (Fragment crystallisable) receptor, and a lower isoelectric point.[5,6] These modifications extend the elimination half-life of satralizumab in plasma by enhancing recycling and reducing clearance. By modulating IL-6 signalling, satralizumab aims to reduce tissue oedema and inflammation.[3]

Satralizumab is currently in clinical development for the treatment of patients with TED. In the ongoing phase III clinical trials (SatraGO-1, NCT05987423 and SatraGO-2, NCT06106828), satralizumab is administered subcutaneously every 4 weeks, with subsequent individualised treatment based on proptosis response.[1,2]

Key Innovation

The efficacy of current TED therapies commonly used to manage inflammation is often limited, underscoring the need for new treatments to improve patient outcomes.[7] There remains an unmet need in patients with active moderate-to severe TED for whom intravenous pulses of therapies such as corticosteroids are the mainstay of treatment but are not universally successful or available, and are associated with disease relapses and substantial side effects.[8] There also remains an unmet need in patients with chronic inactive TED for whom there is no established medical treatment, and surgery remains the only option. Evidence supports an important role of IL-6 and its receptor in the disease, suggesting the potential of satralizumab as a novel drug for treatment of TED.[4,8] Satralizumab is a subcutaneously administered, humanised monoclonal antibody that targets the interleukin-6 receptor (IL-6R). It is engineered with “antibody recycling” technology, which allows it to be reused in the body and gives it a longer half-life than typical IgG antibodies. As a result, it maintains effective IL-6 receptor blockade with dosing only once every four weeks—potentially reducing treatment burden for patients.[9]

If licensed, satralizumab would represent a new treatment option for patients with TED, particularly those who do not respond adequately to existing therapies. Its subcutaneous administration and engineered pharmacokinetics may also offer advantages in long-term management.

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Regulatory & Development Status

Satralizumab currently holds Marketing Authorisation in the EU/UK for the treatment of neuromyelitis optica spectrum disorders in adult and adolescent patients from 12 years of age who are anti–aquaporin-4 IgG (AQP4-IgG) seropositive.[10,11]

Satralizumab is currently in Phase II or III clinical development for the following indications:[12]

- Duchenne muscular dystrophy
- Neuromyelitis optica spectrum disorder
- Myelin oligodendrocyte glycoprotein antibody-associated disease
- N-methyl-D-aspartic acid receptor autoimmune encephalitis
- Leucine-rich glioma-inactivated 1 autoimmune encephalitis
- Neuromyelitis optica

Patient Group

Disease Area and Clinical Need

TED, also known as Graves' orbitopathy or ophthalmopathy, is an autoimmune condition in which the eye muscles, eyelids, tear glands and fatty tissues behind the eye become inflamed. It occurs when the body's immune system attacks the tissue around and behind the eye, causing inflammation in the tissues.[13] In most patients, the same autoimmune condition that causes TED also affects the thyroid gland, resulting in Graves' disease. TED can occur in people when their thyroid is overactive, underactive or functioning normally. It can also occur after treatment for Graves' disease.[13] Symptoms include pain, change in the appearance of the eyes (usually staring or bulging eyes), a feeling of grittiness in the eyes or excessive dryness, watery eyes, intolerance of bright lights, swelling or feeling of fullness in upper or lower eyelids, new bags under the eyes, redness of the lids and eyes, and difficulty moving the eyes. In some cases, there is swelling and stiffness of the muscles that move the eyes so that they no longer move in line with each other; this can cause double vision. Rarely TED can cause reduced vision from pressure on the nerve at the back of the eye or ulcers forming on the front of the eyes if the eyelids cannot close completely.[13]

TED affects approximately 50,000 people in the UK, with about 2,500 new cases every year.[14,15] The figures have declined over the past 10-20 years for reasons that are unclear.[14] In England 2023-24, there were 1,221 finished consultant episodes (FCEs) and 1,220 hospital admissions for Dysthyroid exophthalmos (ICD-10 code H06.2), resulting in 252 FCE bed days and 919 day-cases.[16]

Recommended Treatment Options

There are currently no approved pharmacological treatment options recommended by NICE for TED.

Teprotumumab has recently received UK Marketing Authorisation for the treatment of adult patients with moderate to severe TED. [17] NICE guidance is currently in development and expected to be published in August 2025.[18]

NICE currently recommends the following:[15,19]

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- radiation therapy for people with TED who do not respond adequately to other therapies or experience significant side effects from them. Radiation therapy directed towards the tissues behind the eyeball aims to reduce inflammation in the orbit. It can be applied either independently or alongside corticosteroids
- Surgical interventions, like orbital decompression, may be needed to relieve optic nerve pressure and correct proptosis

Clinical Trial Information	
Trial	**SatraGO-1;** NCT05987423, CTIS 2023-503309-13-00; A phase III, randomised, double-masked, placebo-controlled, multicentre study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of satralizumab in participants with moderate-to-severe Thyroid Eye Disease **Phase III** – Active, not recruiting **Location(s):** 4 EU countries, USA, and other countries **Primary completion date:** July 2025
Trial Design	Randomised, parallel assignment, quadruple-masked (participant, care provider, investigator, outcomes assessor)
Population	N=131 (actual); aged 18 years and older; patients with clinical diagnosis of TED
Intervention(s)	In Part I of the study, participants will receive satralizumab via subcutaneous (SC) injection every 4 weeks (q4w), followed by proptosis response-based individualised treatment in Part II of the study
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measure: Percentage of participants achieving ≥ 2mm reduction in proptosis from baseline (day 1) at week 24 in the study eye [Time frame: baseline, week 24] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	**SatraGO-2;** NCT06106828; CTIS 2023-503669-50-00; A phase III, randomised, double-masked, placebo-controlled, multicentre study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of satralizumab in participants with moderate-to-severe Thyroid Eye Disease **Phase III** – Active, not recruiting. **Location(s):** 4 EU countries, UK, USA, Canada, and other countries **Primary completion date:** July 2025

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Trial Design	Randomised, parallel assignment, quadruple-masked (participant, care provider, investigator, outcomes assessor)
Population	N=127 (actual); aged 18 years and older; patients with clinical diagnosis of TED
Intervention(s)	In Part I of the study, participants will receive satralizumab via SC injection q4w, followed by proptosis response-based individualised treatment in Part II of the study
Comparator(s)	Placebo will be administered by SC injection
Outcome(s)	Primary outcome measure: Percentage of participants achieving ≥ 2mm reduction in proptosis from baseline (day 1) at week 24 in the study eye [Time frame: baseline, week 24] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Estimated Cost

Satralizumab is already marketed in the UK; a 120mg/ml-pre-filled disposable injection costs £7,030.[20]

Relevant Guidance

NICE Guidance

- NICE technology appraisal in development. Teprotumumab for treating thyroid eye disease (ID6432). Expected August 2025.
- NICE clinical guideline: Thyroid disease. assessment and management (NG145). October 2023.
- NICE interventional procedure guidance. Retrobulbar irradiation for thyroid eye disease (IPG148). December 2005.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14 NHS Standard contract for specialised endocrinology services (Adults). A03/S/a.
- NHS England (2023). Prescribed specialised services manual (version 6) Chapter 12. Adult specialist ophthalmology services.

Other Guidance

- Bartalena L, Kahaly GJ, Baldeschi L, et al. 2021. European Group on Graves' Orbitopathy (EUGOGO) Clinical Practice Guidelines for the medical management of Graves' orbitopathy. European Journal of Endocrinology. 2021.[21]

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NB: This briefing presents independent research funded by the National Institute for Health and Care Research (NIHR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

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