Media & Investor Release

FDA grants Priority Review to Roche's Enspryng, the first and only at-home subcutaneous treatment option for thyroid eye disease (TED)

- **The filing application is based on improvements seen across key efficacy endpoints from the global phase III SatraGO-1 and SatraGO-2 studies, including proptosis (bulging eyes) and diplopia (double vision) in active TED**
- **Enspryng (satralizumab) has the potential to become the first at-home subcutaneous disease-modifying standard of care for TED**
- **TED is an autoimmune disease affecting approximately 155 out of every 100,000 people that can lead to facial disfigurement and vision threatening complications if left untreated**

Basel, 30 June 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has accepted and granted priority review to a supplemental Biologics License Application (sBLA) for Enspryng® (satralizumab) for the treatment of thyroid eye disease (TED). The filing acceptance is based on results from the two randomised, placebo-controlled global phase III SatraGO studies assessing the safety and efficacy of Enspryng in patients with moderate to severe TED. The data were presented at the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) in October 2025.[1] The FDA is expected to make a decision on approval by 15 October 2026.

"The FDA's decision to grant priority review to Enspryng is an important step toward expanding treatment options for people living with thyroid eye disease," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "By targeting the underlying disease biology with a novel mechanism of action, this subcutaneous therapy has the potential to introduce a new treatment approach that combines clinical efficacy and a favourable safety profile with the convenience of at-home administration."

The totality of data from the pivotal phase III SatraGO programme demonstrated that Enspryng provided consistent, clinically meaningful improvements across key TED signs and symptoms, with a favourable and differentiated safety profile compared to currently available treatments.[1,2] For the primary endpoint of proptosis (bulging eyes) response at week 24, 53% of patients treated with Enspryng in SatraGO-2 achieved a proptosis reduction compared to 23% of patients treated with placebo, meeting statistical significance.[1] Similarly, in the SatraGO-1 trial, 49% of patients achieved a proptosis response compared to 31% in the placebo arm.[1] While this numerical improvement did not meet statistical significance, SatraGO-1 offers additional confirmatory evidence regarding the potential benefit of satralizumab in this setting.[1] Enspryng also drove notable improvements in secondary measures across both studies, achieving reductions in clinical activity score (CAS)

for 78% to 90% of patients with active TED and improving double vision (diplopia) for 44% to 61% of patients with active TED in SatraGO-1 and SatraGO-2 respectively.[1]

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]

About SatraGO-1 and -2

SatraGO-1 (NCT05987423) and -2 (NCT06106828) are identically designed, phase III, randomised, placebo-controlled, multicenter studies to determine the efficacy, durability and tolerability of Enspryng for the treatment of adults with active, moderate-to-severe TED and chronic inactive TED.[3] The studies enrolled a total of 258 patients from 19 countries.[1,3] Participants were randomised 1:1 to receive Enspryng or placebo.[1,3] 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.[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.[3,4,5,7] 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.[4,8]

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 was developed by Chugai, a member of the Roche Group, and is a humanised monoclonal antibody that targets IL-6, a key chemical messenger involved in the body's inflammatory response, receptor activity.[3,9] Enspryng was designed using novel recycling antibody technology which, compared to conventional technology, allows for sustained IL-6 inhibition by binding strongly and repeatedly to the IL-6 receptor enabling rapid and sustained suppression of inflammatory pathways.[3,10]

Enspryng is the first and only IL-6 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 10,000 patients.[1,2,9,11]

Roche is committed to developing Enspryng in additional neurological autoimmune and inflammatory diseases that may benefit from inhibition of IL-6 signalling, including autoimmune encephalitis (AIE) and myelin oligodendrocyte glycoprotein antibody-associated

disease (MOGAD). Roche recently announced positive phase III results for Enspryng in MOGAD, with regulatory submissions planned this year.[12]

Enspryng has orphan drug designation in the United States and European Union for treatment of NMOSD, and investigational orphan drug designation in the US for MOGAD, anti-NMDA receptor autoimmune encephalitis (anti-NMDAR AIE), and leucine-rich glioma-inactivated 1 autoimmune encephalitis (LGI1 AIE).[2]

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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Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Lorena Corfas
Phone: +41 79 568 24 95

Simon Goldsborough
Phone: +44 797 32 72 915

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +41 79 398 38 53

Yvette Petillon
Phone: +41 79 961 92 50

Dr Rebekka Schnell
Phone: +41 79 205 27 03

Irène Stephan
Phone: +41 79 377 83 75

Roche Investor Relations

Dr Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com