Media & Investor Release

U.S. FDA grants Priority Review for Roche's Enspryng for MOGAD, an autoimmune disease with no approved treatments

- **If approved, Enspryng would be the first and only disease-modifying therapy for MOGAD (myelin oligodendrocyte glycoprotein antibody-associated disease)**
- **Filing acceptance is based on the Phase III METEOROID study showing that Enspryng reduced the risk of relapses by 68%[1]**
- **MOGAD is a rare disease of the central nervous system characterised by unpredictable attacks of the optic nerves, spinal cord or brain[2,3]**

Basel, 10 September 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review to a supplemental Biologics License Application (sBLA) for Enspryng® (satralizumab) for the treatment of myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). The filing acceptance is based on positive results from the Phase III METEOROID study, which showed that Enspryng provided consistent, clinically meaningful improvements for people living with MOGAD.[1] This marks the second FDA Priority Review for Enspryng, following the one granted for thyroid eye disease (TED) in June 2026. The FDA is expected to make a decision on approval in MOGAD by 10 January 2027.

Additionally, the European Medicines Agency (EMA) has validated the application for Enspryng for MOGAD in Europe. The decision by the European Commission is expected in the third quarter of 2027.

"MOGAD can be unpredictable and debilitating, with each relapse carrying the potential for lasting neurological damage, yet there are currently no approved treatments," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "Enspryng has the potential to transform care for people living with MOGAD, significantly reducing serious attacks and decreasing the reliance on high-dose steroids and immunosuppressants."

The METEOROID study, presented at the American Academy of Neurology (AAN) Annual Meeting in April 2026, met its primary endpoint of time from randomisation to the first MOGAD relapse during the double-blind treatment period. Enspryng significantly reduced the risk of a new relapse by 68% compared to placebo (p=0.0025), with 87% of Enspryng-treated patients remaining relapse-free at 48 weeks compared to 67% in the placebo arm. Enspryng also provided significant improvements across key secondary measures, including annualised relapse rate, MRI lesion activity and rescue therapy use.[1]

The safety profile in the METEOROID study was consistent with data from more than a decade of Enspryng clinical trial and post-approval experience in neuromyelitis optica spectrum disorder (NMOSD).[1]

MOGAD is a rare autoimmune disease where the immune system mistakenly attacks parts of the central nervous system.[2,3] It can cause sudden attacks on the optic nerves, brain and spinal cord, which can lead to vision loss, confusion, muscle weakness and disability.[2-6]

About Enspryng (satralizumab)

Enspryng was developed by Chugai, a member of the Roche Group, and is a humanised monoclonal antibody that targets interleukin-6 (IL-6), a key chemical messenger involved in the body's inflammatory response, receptor activity. 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.

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 U.S. and E.U., with a well-established safety profile in over 10,000 patients.

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 thyroid eye disease (TED).

Enspryng has orphan drug designation in the U.S. and E.U. for NMOSD and MOGAD and in the U.S. for anti-NMDA receptor autoimmune encephalitis (anti-NMDAR AIE) and leucine-rich glioma-inactivated 1 autoimmune encephalitis (LGI1 AIE). The FDA granted Priority Review of the Enspryng supplemental Biologics License Application (sBLA) for TED in June 2026 with an approval decision expected in October 2026.

About myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)

MOGAD is a rare autoimmune disease of the central nervous system (CNS) that preferentially affects the optic nerves but can also affect the brain and spinal cord. The prevalence of MOGAD is estimated to range from 0.51 to 3.42 per 100,000 people. The disease can affect people of all ages, and the symptoms are often severe and debilitating, including loss of vision, pain, fatigue, numbness, bladder/bowel or erectile dysfunction, impaired ambulation and cognitive dysfunction. Relapsing MOGAD is characterised by multiple, unpredictable attacks of worsening neurological symptoms. Symptoms may not fully resolve after an attack, leading to accumulating, permanent, neurological damage, vision loss and disability. Currently, there are no approved treatment options available for MOGAD.

About Roche in Neurology

Neurology is a major focus of research and development at Roche. Our goal is to pursue groundbreaking science to develop new diagnostics and treatments that help improve the lives of people with chronic and potentially devastating diseases globally.

Roche is investigating more than a dozen medicines for neurological conditions, including multiple sclerosis, spinal muscular atrophy, neuromyelitis optica spectrum disorder, Alzheimer's disease, Huntington's disease, Parkinson's disease and Duchenne muscular dystrophy. Roche Diagnostics has developed a broad range of approved and investigational tools, including digital and blood-based tests and cerebrospinal fluid (CSF) assays, aiming to more effectively detect, diagnose and monitor neurological conditions. Together with our partners, we are committed to pushing the boundaries of scientific understanding to solve some of the most difficult challenges in neurology today.

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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