Media & Investor Release

Roche's ENSPRYNG (satralizumab) reduces risk of relapses by 68% demonstrating potential to become first treatment for MOGAD

- **Phase III METEOROID study met its primary endpoint in patients with myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)**
- **MOGAD is a rare autoimmune disease of the central nervous system characterised by unpredictable attacks of the optic nerves, spinal cord or brain that are often severe and debilitating**
- **Data will be submitted to regulatory authorities**

Basel, 21 April 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today new data from the Phase III METEOROID study demonstrating that ENSPRYNG® (satralizumab) reduced the risk of a new relapse by 68% compared to placebo in adults and adolescents with myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD), meeting its primary endpoint. The primary endpoint was measured by the time from randomisation to the first MOGAD relapse during the double-blind treatment period (p=0.0025). The results were shared today at a late-breaking oral presentation in the Clinical Trials Plenary Session at the 2026 American Academy of Neurology (AAN) Annual Meeting in Chicago.

"MOGAD is a rare autoimmune disease that can attack the optic nerves, brain and spinal cord and cause severe and unpredictable relapses, resulting in accumulating neurological damage, vision loss and disability. Currently, there are no approved treatment options for this debilitating disease" said Michael Levy, MD, PhD, Associate Professor at Harvard School and Massachusetts General Hospital. "ENSPRYNG is the first medicine to show a meaningful clinical benefit for people with MOGAD in a pivotal trial, addressing the underlying neurological disability experienced by this patient population."

"The remarkable 68% reduction in relapses seen in the METEOROID study has the potential to redefine the standard of care and to deliver the first and only approved treatment for this debilitating rare disease," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "This milestone represents a breakthrough for the MOGAD community, and reinforces our commitment to developing new treatments that address the underlying biology of challenging neurological conditions."

The primary endpoint showed 87% of patients on ENSPRYNG were relapse free compared to 67% on placebo at 48 weeks, with onset of response observed as early as 8 weeks. A generally consistent treatment effect was observed across subgroups, including age, sex, race and background therapy use. ENSPRYNG also reduced the annualised relapse rate (ARR) by 66% (p=0.0030), a key secondary endpoint, as disability in MOGAD is related to acute relapses, and treatment aims to prevent subsequent relapses.

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Other key secondary endpoints that were statistically significant showed ENSPRYNG has the potential to reduce central nervous system (CNS) inflammation and use of rescue therapies such as steroids, plasma exchange or intravenous immunoglobulins. With ENSPRYNG, there was a 79% reduction in the annualised rate of active lesions on MRI across the optic nerves, brain and spinal cord and a 73% lower proportion of patients receiving rescue therapy compared to placebo (p=0.0026 and p=0.0024, respectively). In addition, a numerical 17% reduction in the annualised rate of inpatient hospitalisations was observed with ENSPRYNG compared to placebo (p=0.7528).

No new safety signals were reported with ENSPRYNG, and the safety profile was consistent with established data from more than a decade of ENSPRYNG clinical trial and post-approval experience in aquaporin-4 immunoglobulin (AQP4-IgG) seropositive neuromyelitis optica spectrum disorder (NMOSD). Adverse events (AEs) ≥5% and more commonly observed in patients receiving ENSPRYNG vs. placebo included injection-related reactions (16%), influenza (9%), arthralgia (9%), back pain (9%), sinusitis (7%) and diarrhoea (6%). There were low rates of AEs leading to temporary treatment interruption with ENSPRYNG (6%) and placebo (5%). There was one fatality not related to treatment, and none of the serious AEs were considered related to treatment.

The METEOROID data will be submitted to regulatory authorities globally.

About the METEOROID study

METEOROID is a Phase III, randomised, double-blind, placebo-controlled, multicentre study of ENSPRYNG® (satralizumab) in adults and adolescents 12 years and older with myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). Eligible participants were randomised 1:1 to receive treatment with either ENSPRYNG (60 mg, 120 mg or 180 mg based on body weight) or placebo, administered subcutaneously at 0, 2 and 4 weeks, then every 4 weeks thereafter. Patients continued background immunosuppressant therapy if they were on treatment at randomisation. The double-blind period was event-driven and ended after 28 adjudicated MOGAD relapses had been observed. Patients who experienced an adjudicated relapse or completed the double-blind period have the option to enter an open-label extension (OLE) period, in which all patients receive treatment with ENSPRYNG.

The primary endpoint is the time from randomisation to the first MOGAD relapse during the double-blind treatment period, as determined by an independent clinical adjudication committee. Secondary endpoints include the annualised rate of MOGAD relapses, the annualised rate of active lesions on MRI across the optic nerves, brain and spinal cord and the proportion of patients receiving rescue therapy (including oral or intravenous steroids, plasma exchange or intravenous immunoglobulins) and the annualised rate of inpatient hospitalisations.

About ENSPRYNG® (satralizumab)

ENSPRYNG, which was developed by Chugai, a member of the Roche Group, is a humanised monoclonal antibody that targets interleukin-6 (IL-6) receptor activity. ENSPRYNG was designed using novel recycling antibody technology which, compared to conventional technology, allows for sustained IL-6 inhibition.

People with MOGAD have elevated levels of IL-6 in cerebrospinal fluid (CSF) and serum, which promote T-cell-mediated inflammation, stimulate autoantibody production from plasma cells and disrupt the blood-brain barrier. By blocking IL-6 signalling, ENSPRYNG has the potential to lower disease-related antibody production, suppress inflammatory T cells and restore the integrity of the blood-brain barrier.

ENSPRYNG is the first and only IL-6 inhibitor treatment currently approved in approximately 90 countries for AQP4-IgG seropositive NMOSD, with more than 9,000 patients treated. ENSPRYNG offers the flexibility of at-home self-administration with subcutaneous injections, following training and approval from a healthcare provider. At initiation, a loading dose of ENSPRYNG 120 mg is administered every other week for a total of three injections. Maintenance doses are administered thereafter once every four weeks.

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). The U.S. Food and Drug Administration (FDA) has designated ENSPRYNG as an investigational orphan drug for MOGAD and anti-NMDA receptor autoimmune encephalitis (anti-NMDAR AIE). Roche recently announced positive Phase III results for ENSPRYNG in TED, with regulatory submissions planned this year.

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.

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