

Roche presents new pivotal trial data across broad neuroimmunology portfolio at MSToronto2026

- Fenebrutinib FENTrepid and FENhance 1 & 2 late-breaking data demonstrate a therapeutic effect on chronic active lesions, addressing a primary driver of long-term disability progression in multiple sclerosis (MS)
- Fenebrutinib FENhance 1 & 2 Phase III pooled data show a 55% reduction in annualised relapse rate (ARR) vs active comparator
- Following European Commission paediatric approval on 15 October, new Ocrevus OPERETTA 2 Phase III data show 90% of children aged 10–17 remained relapse-free over two years
- Featured in "Best of MSToronto2026", Enspryng METEOROID Phase III data highlight significant attack reduction and improved functional recovery in MOGAD, an underserved autoimmune disease

Basel, 21 October 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today new Phase III data for investigational fenebrutinib in multiple sclerosis (MS), demonstrating reduced markers of chronic brain inflammation as well as more comprehensive disease control versus active comparators.¹⁻³ These findings, alongside new Ocrevus® (ocrelizumab) and Enspryng® (satralizumab) data, will be featured across more than 40 abstracts at MSToronto2026 (10th ACTRIMS-ECTRIMS Meeting), held 21 to 23 October in Toronto. Highlights include a fenebrutinib late-breaking presentation and an Enspryng presentation in the “Best of MSToronto2026.”⁴

“Addressing long-term disability progression to preserve people’s independence remains a critical challenge in neuroinflammatory diseases, and particularly in multiple sclerosis,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “Our recent data indicate that fenebrutinib can inhibit disease activity inside and outside the central nervous system, underscoring its potential to transform care for people living with relapsing and primary progressive forms of multiple sclerosis.”

Fenebrutinib targets progressive biology inside the brain

New data from the pivotal trials in RMS (FENhance 1 and 2) and PPMS (FENTrepid) support the potential of fenebrutinib as the first and only high-efficacy oral medicine for both forms of MS.

- **Reduction of chronic active lesions (Late-breaking oral #O137):** In the first prospective demonstration of a therapeutic effect on chronic active lesions in MS Phase III clinical trials, data show fenebrutinib reduced the volume of slowly

expanding lesions (SELs) by up to 30% ($p < 0.001$) in RMS (over 96 weeks) and PPMS (over 120 weeks), along with a 62% ($p = 0.001$) reduction in accumulation of paramagnetic rim lesions (PRLs) in RMS, versus active comparators. These findings demonstrate that fenebrutinib directly targets chronic neuroinflammation in the brain, a primary driver of disability progression in MS.¹

- **Comprehensive disease control (Poster #P1434):** In the pooled RMS trials, three quarters (75%) of fenebrutinib-treated patients showed no evidence of disease activity (NEDA-3) meaning zero relapses, zero MRI activity and zero worsening disability at nearly two years, a 70% reduction ($p < 0.001$) versus the comparator. These results show fenebrutinib's potential to suppress disease activity and delay progression.²
- **Preserving brain volume and function (Oral #0089):** Pooled RMS data show fenebrutinib reduced the annualised relapse rate (ARR) by 55% versus the comparator ($p < 0.001$) over 96 weeks. In addition, fenebrutinib reduced annual total brain volume loss by 23% ($p < 0.001$) and 12-week composite confirmed disability progression by 16% ($p = 0.04$). These findings demonstrate fenebrutinib's potential to control relapses, to slow brain tissue loss caused by neuronal cell death and to preserve function.³

Ocrevus provides consistent benefits across all age groups

New data show that Ocrevus provides significant and consistent efficacy across a broad MS patient population, from children 10 years of age to older adults.

- **Two-year data and immune function in paediatric MS (3 posters on the Phase III OPERETTA 2 study):** 90% of children with relapsing-remitting MS (RRMS) treated with Ocrevus, who were 10-17 years old at trial entry, remained free of relapses over two years (#P1439).⁵ Ocrevus selectively depleted target B cells with little to no effect on other immune cells (#P1407), while preserving pre-existing immunity to common childhood vaccines in 81-100% of patients (#P1415). The European Commission approved Ocrevus in this indication on 15 October, following FDA approval in May.^{6,7}
- **Two-year data in patients >55 years old (Poster #P1426 on the Phase IIIb CONSONANCE study):** 53% of participants over 55 years old treated with Ocrevus showed no disability progression after two years, similarly to younger participants (55%), showing Ocrevus maintains its effect on progression as people age.⁸
- **Switching from other treatments to Ocrevus:** Real-world data show progression was the leading reason for patients switching from ofatumumab to Ocrevus (ePoster #EP2733).⁹ A separate analysis of patients treated with Ocrevus or ofatumumab for one year show Ocrevus was associated with lower MRI lesion activity (Poster #P0305).¹⁰

Enspryng reduces risk of attack and is associated with improved recovery

Exploratory analyses of the pivotal METEOROID trial suggest that in addition to significantly

lowering the risk of relapse ([AAN 2026](#)), Enspryng was associated with improved recovery and reduced disability progression, which is critical to prevent permanent damage to the optic nerves, spinal cord or brain in myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). These findings reinforce Enspryng's potential to become the first FDA-approved treatment for MOGAD, with a decision in the U.S. expected in January 2027.^{4,11}

- **Relapse recovery (Oral #0035):** Patients treated with Enspryng achieved numerically superior recovery at 12 weeks post relapse versus placebo (median change in Expanded Disability Status Scale [EDSS] of -2 vs -0.5). Overall function was stable (median 0) with Enspryng, compared to worsening (median 0.5) with placebo, as measured with the EDSS at the end of the double-blind period or first relapse.⁴

About fenebrutinib

Fenebrutinib is an investigational oral, central nervous system (CNS)-penetrant, reversible and non-covalent Bruton's tyrosine kinase (BTK) inhibitor with an optimised pharmacokinetics (PK) profile. Fenebrutinib can act throughout the body and also cross the blood-brain barrier into the CNS to target chronic inflammation. It is uniquely designed to target relapsing and progressive biology by inhibiting cells in the immune system known as B cells and microglia. Targeting B cells helps control the acute inflammation that causes relapses, while targeting microglia inside the brain addresses the chronic damage that is thought to drive long-term disability progression.

While most current BTK inhibitors are covalent and irreversible, meaning they form a permanent chemical bond with the enzyme, fenebrutinib is non-covalent and reversible, meaning it binds and then eventually releases the enzyme.

About Ocrevus® (ocrelizumab)

Ocrevus is a humanised monoclonal antibody designed to target CD20-positive B cells, a specific type of immune cell thought to be a key contributor to myelin (nerve cell insulation and support) and axonal (nerve cell) damage. Ocrevus IV and Ocrevus subcutaneous (SC; marketed as Ocrevus Zunovo® [ocrelizumab hyaluronidase-ocsq] in the U.S.) are the only therapies approved for both RMS (including relapsing-remitting multiple sclerosis [RRMS] and active, secondary progressive multiple sclerosis [SPMS], as well as clinically isolated syndrome [CIS] in the U.S.) and primary progressive multiple sclerosis (PPMS). Both Ocrevus IV and SC are administered every six months. The initial IV dose is given as two 300 mg infusions two weeks apart with subsequent doses given as single 600 mg infusions. Ocrevus SC is given as a single 920 mg subcutaneous injection every six months.

About Enspryng® (satralizumab)

Enspryng, developed by Chugai, a member of the Roche Group, is a humanised monoclonal antibody that binds to both soluble and membrane-bound interleukin-6 receptors (IL-6R),

thereby inhibiting IL-6 mediated signalling, a 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.

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 U.S. and E.U., with a well-established safety profile in over 16,000 patients. Enspryng was also recently approved for the treatment of thyroid eye disease (TED) in the U.S.

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

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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