Media Release

CHMP recommends EU approval of Roche's Ocrevus for children and adolescents with relapsing multiple sclerosis

- **Ocrevus addresses a critical need in paediatric neurology as the first high-efficacy anti-CD20 treatment option for people with MS as young as 10 years old**
- **In the Phase III OPERETTA 2 study, Ocrevus demonstrated non-inferiority in relapse control and superiority over fingolimod in suppressing brain lesions[1]**
- **Safety in children and adolescents was aligned with the established safety profile of Ocrevus across more than 525,000 adult patients globally[1]**

Basel, 18 September 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Ocrevus® (ocrelizumab) intravenous (IV) infusion for the treatment of paediatric patients aged 10 years and older with relapsing forms of multiple sclerosis (RMS). The U.S. FDA approved Ocrevus for paediatric RMS patients in May 2026. A final decision from the European Commission is expected in the near future.

"Children and teens living with multiple sclerosis experience more frequent and severe relapses than adults, yet their treatment options have lagged behind," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "The positive CHMP opinion brings us closer to bridging a longstanding gap in Europe, offering young people with MS a high-efficacy therapy backed by a decade of adult experience."

"Living with a paediatric MS diagnosis means that children and adolescents must navigate a complex condition with unpredictable relapses that require hospital admission and acute therapies, lead to missed days of school and social activities, and face the potential for future disability," said Dr. Brenda Banwell, MD, Chair of Pediatrics, Johns Hopkins Medicine, Pediatrician-in-Chief and Co-Director, Johns Hopkins Children's Center. "Extending Ocrevus, a proven treatment for adults, to younger patients is an important step forward to suppress disease activity early on, with the goal of preserving their physical and cognitive health."

The CHMP's positive opinion is based on the Phase III OPERETTA 2 study, which showed that Ocrevus was non-inferior to fingolimod (the current standard treatment in paediatric MS) at controlling relapses, reducing the risk of relapses by 48% compared with fingolimod. In OPERETTA 2, Ocrevus was superior at reducing brain inflammation, showing significant reductions in new or enlarging T2 lesions (-48%) and gadolinium-enhancing active T1 lesions (-87%). Ocrevus demonstrated a consistent safety profile in children and teens similar to that seen in adults, with no patients stopping treatment due to side effects.[1]

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At least 40,000 children and adolescents are living with MS worldwide, with roughly one-third in Europe, emphasising the need for early high-efficacy MS treatment.[2]

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 multiple sclerosis

Multiple sclerosis is a chronic disease that affects more than 3 million people worldwide. People with all forms of multiple sclerosis experience disease progression from the beginning of their disease. Therefore, an important goal of treating multiple sclerosis is to slow, stop and ideally prevent progression as early as possible.

Approximately 85% of people with multiple sclerosis are initially diagnosed with relapsing-remitting multiple sclerosis (RRMS). Relapsing forms of the disease (RMS) include RRMS and active secondary progressive MS, and people with RMS experience relapses and worsening disability over time. Primary progressive multiple sclerosis (PPMS) is a debilitating form of the disease marked by steadily worsening symptoms but typically without distinct relapses or periods of remission. Approximately 15% of people with multiple sclerosis are diagnosed with the primary progressive form of the disease. Until the FDA approval of Ocrevus®, there had been no FDA-approved treatments for PPMS, and Ocrevus is still the only approved treatment for PPMS. Despite the availability of high-efficacy therapies, over a third of MS patients remain on lower-efficacy therapy today. Slowing or stopping progression while simultaneously stopping relapses remains a high unmet need in MS.

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.

References

[1] Banwell B, et al. Efficacy and Safety of Ocrelizumab Compared With Fingolimod in Paediatric Relapsing-Remitting MS: Results of the Phase III OPERETTA 2 Study. Presented at the 2025 Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS); 26 September 2025; Barcelona, Spain.
[2] MS International Federation. The Atlas of MS 2026: A global update on MS prevalence, incidence, and the gaps that remain. September 2026. Available from: http://www.msif.org/wp-content/uploads/2026/09/Atlas-Epidemiology-report-text-core-data-2026-FINAL.pdf

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