Media Release

Roche's OCREVUS subcutaneous administration approved by European Commission, as first and only twice-a-year injection for relapsing and primary progressive multiple sclerosis

- **OCREVUS subcutaneous (SC) injection offers a new, 10-minute administration of OCREVUS with comparable efficacy and safety to intravenous infusion (IV)**
- **OCREVUS SC provides an additional treatment option without the need for IV facilities, expanding accessibility for patients**
- **Roche is working closely with national health systems in Europe to ensure people with multiple sclerosis can access OCREVUS SC as quickly as possible**

Basel, 25 June 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has granted marketing authorisation for OCREVUS® (ocrelizumab) subcutaneous (SC) for the treatment of relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS). OCREVUS SC is a 10-minute injection that maintains the same twice-yearly schedule as the previously approved intravenous (IV) infusion. More than 350,000 people with multiple sclerosis have been treated with OCREVUS IV globally.

"OCREVUS transformed the way multiple sclerosis is treated as the first anti-CD20 therapy approved in this disease. Now, people in the EU with multiple sclerosis can have their medicine administered in just 10 minutes twice per year without needing an IV facility," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "This makes it easier for more people with multiple sclerosis to access their treatment, while also saving time for providers."

The approval is based on pivotal data from the Phase III OCARINA II trial, which showed non-inferior levels of OCREVUS in the blood, when administered subcutaneously, and a safety and efficacy profile comparable to the IV formulation in patients with RMS and PPMS. OCREVUS SC was well tolerated and no new safety concerns were identified. More than 92% of patients who were surveyed as part of the study reported being satisfied or very satisfied with the SC administration of OCREVUS.

OCREVUS SC was developed to provide an alternative twice-a-year treatment option, in addition to IV, so that the administration of OCREVUS can be matched to the individual needs of patients and healthcare professionals (HCPs). The SC injection was designed to be HCP administered, with the flexibility to administer either in the clinic or in settings outside the clinic. Roche is committed to advancing innovative clinical research programmes to broaden the scientific understanding of multiple sclerosis, further reduce disability progression in RMS and PPMS and improve the treatment experiences for those living with multiple sclerosis.

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About OCREVUS SC

OCREVUS SC combines OCREVUS with Halozyme Therapeutics' ENHANZE® drug delivery technology.

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. This nerve cell damage can lead to disability in people with multiple sclerosis. Based on preclinical studies, OCREVUS binds to CD20 cell surface proteins expressed on certain B cells, but not on stem cells or plasma cells, suggesting that important functions of the immune system may be preserved.

The ENHANZE® drug delivery technology is based on a proprietary recombinant human hyaluronidase PH20 (rHuPH20), an enzyme that locally and temporarily degrades hyaluronan – a glycosaminoglycan or chain of natural sugars in the body – in the subcutaneous space. This increases the permeability of the tissue under the skin, allowing space for OCREVUS to enter, and enabling it to be rapidly dispersed and absorbed into the bloodstream.

OCREVUS is the first and only therapy approved for both RMS (including relapsing-remitting multiple sclerosis [RRMS] and active, or relapsing secondary progressive multiple sclerosis [SPMS], as well as clinically isolated syndrome [CIS] in the U.S.) and PPMS.

About the OCARINA II study

OCARINA II (NCT05232825) was a Phase III, global, multicentre, randomised study that evaluated the pharmacokinetics, safety and clinical and radiological efficacy of the subcutaneous (SC) formulation of OCREVUS compared with OCREVUS intravenous (IV) infusion in 236 patients with relapsing multiple sclerosis (RMS) or primary progressive multiple sclerosis (PPMS).

The trial met its primary and secondary endpoints, demonstrating SC injection was non-inferior to IV infusion based on OCREVUS levels in the blood, and comparable control of clinical (relapses) and radiological (MRI lesions) disease activity. The safety profile of OCREVUS SC was also consistent with the well-established safety profile of OCREVUS IV.

About multiple sclerosis

Multiple sclerosis is a chronic disease that affects more than 2.9 million people worldwide. Multiple sclerosis occurs when the immune system abnormally attacks the insulation and support around nerve cells (myelin sheath) in the central nervous system (brain, spinal cord and optic nerves), causing inflammation and consequent damage. This damage can cause a wide range of symptoms, including weakness, fatigue and difficulty seeing, and may eventually lead to disability. Most people with multiple sclerosis experience their first symptom between 20 and 40 years of age, making the disease the leading cause of non-traumatic disability in younger adults.

People with all forms of multiple sclerosis experience disease progression – permanent loss of nerve cells in the central nervous system – from the beginning of their disease even if their symptoms aren't apparent or don't appear to be getting worse. Delays in diagnosis and treatment can negatively impact people with multiple sclerosis, in terms of their physical and mental health, and contribute to the negative financial impact on the individual and society. An important goal of treating multiple sclerosis is to slow, stop and ideally prevent progression as early as possible.

Relapsing-remitting multiple sclerosis (RRMS) is the most common form of the disease and is characterised by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. Approximately 85% of people with multiple sclerosis are initially diagnosed with RRMS. The majority of people who are diagnosed with RRMS will eventually transition to secondary progressive multiple sclerosis (SPMS), in which they experience steadily worsening disability over time. Relapsing forms of multiple sclerosis (RMS) include people with RRMS and people with SPMS who continue to experience relapses. 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.

About Roche in Neuroscience

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

Roche is investigating more than a dozen medicines for neurological disorders, including neuromuscular diseases: Duchenne muscular dystrophy, facioscapulohumeral muscular dystrophy and spinal muscular atrophy; neuro immune diseases: multiple sclerosis and neuromyelitis optica spectrum disorder; and neurodegenerative diseases: Alzheimer's disease, Huntington's disease and Parkinson's disease. Together with our partners, we are committed to pushing the boundaries of scientific understanding to solve some of the most difficult challenges in neuroscience today.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each

person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

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