New data for Roche's OCREVUS (ocrelizumab) reinforce significant benefit on slowing disease progression in relapsing and primary progressive multiple sclerosis

- **85% of treatment-naïve, early-stage relapsing-remitting multiple sclerosis (RRMS) patients achieved no evidence of disease activity (NEDA) in open-label Phase IIIb ENSEMBLE study**
- **OCREVUS significantly slowed loss of brain tissue within T2 MRI lesions in primary progressive multiple sclerosis (PPMS) in post-hoc analysis of Phase III ORATORIO study**
- **OCREVUS-treated patients show highest adherence and persistence rates compared with other disease-modifying therapies (DMTs) in two-year U.S. claims analysis**

Basel, 16 April 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new OCREVUS® (ocrelizumab) analyses supporting its significant benefit on disease progression in early-stage relapsing-remitting multiple sclerosis (RRMS) and primary progressive MS (PPMS) as well as demonstrating high persistence and strong adherence to twice-yearly (six-monthly) dosing. These data are being presented virtually at the 73rd American Academy of Neurology (AAN) Annual Meeting from 17–22 April 2021. OCREVUS is the number one prescribed MS medication in the U.S. for patients starting a new treatment, and more than 200,000 people have now been treated with OCREVUS globally.

"All patients regardless of their form of MS experience disease progression from the start. Therefore, we are encouraged by these new analyses showing that early treatment with OCREVUS may significantly control disease progression in both relapsing-remitting MS and in primary progressive MS. Controlling progression can enable people with MS to maintain mobility and limit their disability," said Levi Garraway, M.D., Ph.D. Roche's Chief Medical Officer and Head of Global Product Development. "In addition, our data show that more people with MS are staying on OCREVUS, the only twice-yearly treatment for MS, compared with other therapies, which may translate to improved outcomes."

Interim analysis Phase IIIb ENSEMBLE: No evidence of disease progression in early-stage RRMS
OCREVUS treatment provided consistent benefit over one year in patients who were recently diagnosed with RRMS and had not received prior disease modifying treatment (DMT) in an interim analysis of open-label Phase IIIb study ENSEMBLE. After 48 weeks, 85% of OCREVUS-treated patients achieved no evidence of disease activity (NEDA; no relapses, worsening of disability or new or enlarging brain lesions with pre-specified MRI re-baselining at 8 weeks). The average annualised relapse rate across all patients was very low (0.005) and their mean change in Expanded Disability Status Scale score (EDSS) from baseline significantly improved from 1.71 to 1.55 (p=0.002). Additionally, neurofilament light chain (NfL), a marker of nerve cell damage, was reduced to nearly healthy control levels with OCREVUS treatment (10.5 pg/mL at baseline to 4.55 pg/mL at 48 weeks with OCREVUS vs. 4.12 pg/mL in healthy controls). The safety profile of OCREVUS in this trial was consistent with its overall favourable safety profile.

Post-hoc analysis Phase III ORATORIO: Slowed atrophied T2-lesion accumulation in PPMS

OCREVUS treatment significantly slowed accumulation of atrophied T2-lesion volume (aT2-LV) compared with placebo at 120 weeks in a post-hoc analysis of the ORATORIO study in PPMS (319 mm3 vs. 366 mm3 with placebo, p<0.015). AT2-LV is a measure that reflects the volume of T2 lesions in brain tissue that is replaced by cerebrospinal fluid, and is believed to be a marker of disease progression in MS. People with PPMS experience three to five times higher accumulation of aT2-LV than people with relapsing MS and these data suggest that OCREVUS may favourably impact the underlying progressive biology of MS.

Two-year US claims analysis: Highest adherence and persistence rates
Approximately 80% of patients adhered to twice-yearly (six-monthly) dosing of OCREVUS after their second year of treatment compared with other DMTs, which were grouped by administration route (35% adherence to injectables, 55% to orals and 54% to other infusions), in a new analysis of U.S. commercial and insurance claims databases. OCREVUS also had the highest proportion of patients (75%) persist with therapy at two years (33% with injectables, 54% with orals and 55% with other infusions).

With rapidly growing real-world experience and more than 200,000 people treated globally, OCREVUS is the first and only therapy approved for relapsing MS (RMS; including RRMS and active, or relapsing, secondary progressive MS [SPMS], in addition to clinically isolated syndrome [CIS] in the U.S.) and PPMS. At Roche, we are constantly striving to optimise the care for people with MS and a shorter two-hour OCREVUS infusion time, dosed twice yearly (six-monthly), is now approved for eligible people with RMS or PPMS in the U.S. and EU.

OCREVUS is approved in 95 countries across North America, South America, the Middle East, Eastern Europe, as well as in Australia, Switzerland, the United Kingdom and the European Union (EU).

About multiple sclerosis
Multiple sclerosis (MS) is a chronic disease that affects up to a million people in the U.S. and more than 2.8 million people worldwide. MS 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 muscle weakness, fatigue and difficulty seeing, and may eventually lead to disability. Most people with MS 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 MS experience disease progression – permanent loss of nerve cells in the central nervous system and gradual worsening of disability – at the beginning of their disease even if their clinical symptoms aren't apparent or don't appear to be getting worse. Delays in diagnosis and treatment can negatively impact people with MS, both in terms of their physical, mental and financial health. An important goal of treating MS is to slow the progression of disability as early as possible.

Relapsing-remitting MS (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 MS are initially diagnosed with RRMS. The majority of people who are diagnosed with RRMS will eventually transition to secondary progressive MS (SPMS), in which they experience steadily worsening disability over time. Relapsing forms of MS (RMS) include people with RRMS and people with SPMS who continue to experience relapses. Primary progressive MS (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 MS 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.

About OCREVUS (ocrelizumab)
OCREVUS is the first and only therapy approved for both RMS (including RRMS and active, or relapsing, SPMS) and PPMS, with six-month dosing. OCREVUS is a humanized 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 (MS). 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. OCREVUS is administered by intravenous infusion every six months. The initial dose is given as two 300 mg infusions given two weeks apart. Subsequent doses are given as single 600 mg infusions.

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 spinal muscular atrophy, multiple sclerosis, neuromyelitis optica spectrum disorder, Alzheimer's disease, Huntington's disease, Parkinson's disease, Duchenne muscular dystrophy and autism spectrum disorder. 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
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 billion. 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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