Media Release

New data for Roche's OCREVUS (ocrelizumab) show benefit in disability progression and cognitive decline in both secondary progressive and primary progressive multiple sclerosis

- **75% of patients with secondary progressive multiple sclerosis (SPMS) and primary progressive MS (PPMS) achieved no evidence of progression (NEP) in a one-year interim analysis of CONSONANCE study**
- **70% of patients with SPMS and PPMS demonstrated stable or improved cognition after one year of OCREVUS treatment in CONSONANCE**
- **Separate analysis on treatment disparities showed fewer Black and Hispanic patients with MS initiate high-efficacy treatments within two years of diagnosis**
- **Data at AAN support the body of evidence for OCREVUS more than 450,000 patient years and more than 225,000 patients treated globally**

Basel, 04 April 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new OCREVUS® (ocrelizumab) data that show its benefit on disease progression and cognitive outcomes in primary progressive multiple sclerosis (PPMS) and secondary progressive MS (SPMS). Separate analyses on treatment disparities among newly diagnosed patients with MS by race and ethnicity will be a platform presentation at the 74th American Academy of Neurology (AAN) Annual Meeting 02–07 April 2022 in Seattle. CONSONANCE data will be presented virtually at AAN 24-26 April 2022.

"We continue to work on closing treatment gaps for all people impacted by MS, as everyone living with this neurodegenerative condition experiences disease progression from the start. For people with progressive forms of MS and in some Black and Hispanic subpopulations, the disease may progress faster," said Levi Garraway, M.D., Ph.D. Roche's Chief Medical Officer and Head of Global Product Development. "We are encouraged by the low levels of disability progression and cognitive decline in OCREVUS-treated patients seen across the complete spectrum of progressive MS for the first time, since SPMS and PPMS often bring a substantial quality of life burden."

CONSONANCE interim analysis: low levels of disease progression in SPMS and PPMS patients

Treatment with OCREVUS resulted in a majority of patients experiencing no disease progression in a one-year analysis of CONSONANCE, a first-of-its-kind open-label Phase IIIb trial to evaluate the effect of OCREVUS in SPMS and PPMS patients. After one year, 75% of OCREVUS-treated patients with SPMS and PPMS achieved No Evidence of Progression (NEP; no evidence of confirmed disability progression as measured by an increase in Expanded Disability Status Score sustained for at least 24 weeks, and less than 20% worsening of

performance on the timed 25-foot walk [T25-FW] and Nine-Hole Peg Test [9-HPT]). NEP is a novel composite endpoint and reflects no evidence of worsening of a person's physical disability.

Additionally, 59% of OCREVUS-treated patients in the trial achieved No Evidence of Progression or Active Disease (NEPAD; NEP plus no protocol-defined relapses, new and/or enlarging T2 lesions or T1 gadolinium-enhancing lesions) over one year. NEPAD is another novel composite endpoint and reflects no evidence of clinical or MRI disease activity or worsening of a person's physical disability. Progression was primarily driven by T25-FW (16% of patients) and activity of new and/or enlarging T2 lesions (19% of patients), detected almost exclusively within the first 6 months of the trial.

The analysis also demonstrated the positive effects of OCREVUS on cognition, with 70% of patients having stable or improved cognition over one year, as measured with the Symbol Digit Modalities Test (SDMT). Clinically meaningful improvement (increase of ≥4 points on the SDMT) was observed in 34% of patients treated with OCREVUS and worsening (decrease of ≥4 points) in 30% of patients treated with OCREVUS. At enrolment, patients had moderate-to-severe dysfunction in information processing speed and visuospatial memory, which was stable or improved in a majority of patients after OCREVUS treatment.

After one year of participating in the trial, 75% of patients had one or more adverse events (AEs) and 7% experienced at least one serious AE. The interim analysis included 629 patients, and longer-term evaluation of OCREVUS will continue for four years with a target of 900 patients with PPMS or SPMS (in a 1:1 ratio) across 26 countries.

Continued research on the treatment patterns of minority populations living with MS

Current treatment guidelines recommend the initiation of high-efficacy disease modifying therapies (DMTs) for patients with highly active disease, as frequently seen with Black and Hispanic populations. However, a recent analysis of a U.S. commercial claims database found that only 30% of non-Hispanic Black, and 20% of Hispanic patients initiated any high-efficacy DMTs, in comparison to 39% of non-Hispanic white patients in the first two years after diagnosis.

These insights further support Roche's Phase IV 'Characterization of ocrelizumab in Minorities with Multiple Sclerosis' (CHIMES) trial in Black/African-American and Hispanic/Latino patients with relapsing MS (RMS). The results are expected to improve the current understanding of MS disease biology and treatment response to OCREVUS among these populations with MS, to improve standard of care in traditionally underserved communities and improve inclusivity in clinical research.

With rapidly growing real-world experience and more than 225,000 people treated globally, OCREVUS is the first and only therapy approved for relapsing MS (RMS; including relapsing-remitting MS [RRMS] and active 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 approved for eligible people with RMS or PPMS in the U.S. and European Union (EU).

OCREVUS is approved in 100 countries across North America, South America, the Middle East, Eastern Europe, as well as in Australia, Switzerland, the United Kingdom and the EU.

About multiple sclerosis

Multiple sclerosis (MS) is a chronic disease that affects 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, active SPMS and CIS in the U.S.) and PPMS, with six-month dosing. 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 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 multiple sclerosis, 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

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 recognizing our endeavor 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 thirteenth 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.

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