Data up to 8-years for Roche's OCREVUS (ocrelizumab) show early and ongoing treatment significantly reduced risk of requiring a walking aid in relapsing multiple sclerosis and disability progression in primary progressive multiple sclerosis

- **35% reduction in risk of needing a walking aid in relapsing multiple sclerosis (RMS) after 7.5 years vs. initiation 2 years later in Phase III open-label extension (OLE)**
- **29% reduction in 48-week confirmed disability progression in primary progressive MS (PPMS) after 8 years vs. initiation after double-blind period in Phase III OLE**
- **New 8-year safety data show consistent benefit-risk profile across all OCREVUS clinical trials**
- **Shorter 2-hour infusion of OCREVUS was equally well-tolerated in Black, African-American, Hispanic and Latino populations compared with overall study populations across three studies**
- **Roche and research partners will be presenting late-breaking data on COVID-19 in treated patients**

Basel, 13 October 2021 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new long-term data that reinforce the benefit of early initiation and ongoing treatment of OCREVUS® (ocrelizumab) on disability progression in relapsing multiple sclerosis (RMS) and primary progressive MS (PPMS), as well as safety outcomes for an analysis of shorter 2-hour infusion in minority populations. OCREVUS data from all clinical trials consistently show a favourable benefit-risk profile over eight years. Roche and research partners will also present four late-breaking abstracts to share the latest data regarding COVID-19 and vaccine response in patients treated with OCREVUS. These data are being presented virtually at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

"Many neurologists have had first-hand experience with OCREVUS over eight years in clinical trials and witnessed the consistently favourable efficacy and safety outcomes in RMS and PPMS, especially the reductions in progression to disability when given early in the disease," said Levi Garraway, M.D., Ph.D. Roche's Chief Medical Officer and Head of Global Product Development. "Additionally, the new safety analysis of the shorter two-hour OCREVUS infusion is encouraging particularly for groups that are often underrepresented in clinical trials. We continue our commitment to diversity and health equity in clinical trial participation and access to treatment."

Phase III OPERA I and OPERA II open-label extension (OLE): Sustained reduction in disability progression and low relapse rates in RMS

Long-term OCREVUS treatment continues to demonstrate sustained reduction in disability progression and suppression of disease activity in people with RMS. Earlier intervention with OCREVUS resulted in a 35% reduction in the risk of patients with RMS needing a walking aid over seven and a half years compared with

patients who switched from interferon beta-1a to OCREVUS after the 96-week double-blind period (5.2% vs 7.0%, respectively; 95% CI: 0.65 [0.44–0.97]; p=0.034). The risk was measured by the length of time until a person reached a score on the Expanded Disability Status Scale of 6 or greater (EDSS≥6) that was sustained for at least 48 weeks in a post-hoc analysis. Data also showed that switching from interferon beta-1a to OCREVUS at the start of the OLE period was associated with a rapid and robust reduction in annualised relapse rate (ARR) that was maintained through the 5.5-year OLE period. ARR was 0.2 pre-switch, 0.1 after 1 year of OCREVUS treatment and 0.03 after 5.5 years of OCREVUS treatment in the OLE. OCREVUS continuers maintained a low ARR of 0.03 after 7.5 years of OCREVUS treatment.

Phase III ORATORIO OLE: Sustained reduction in overall and upper limb disability progression in PPMS

After eight years, outcomes continue to favour early and ongoing treatment with OCREVUS to slow disability progression in people with PPMS. Earlier intervention with OCREVUS resulted in a 29% reduction in 48-week confirmed disability progression (CDP) in patients with PPMS over eight years compared with patients who switched to OCREVUS from placebo after the double-blind period of at least 120 weeks (95% CI: 0.71 [0.57–0.87]; p=0.001). A 24% (95% CI: 0.76 [0.62–0.92]; p=0.005) reduced risk of recurrent 48-week CDP (re-baselining EDSS after onset of CDP event) was seen in patients who were continuously treated with OCREVUS compared with those who switched from placebo. Many people with PPMS eventually transition into a wheelchair; therefore, maintaining the ability to use their hands and arms is important for these patients. Upper limb disability progression, measured by the nine-hole peg test (9-HPT), was also reduced in patients who were continuously treated with OCREVUS compared with those who switched from placebo (95% CI: 0.66 [0.50–0.86] respectively; p=0.002).

OCREVUS long-term safety data consistent over 8 years

New safety data as of November 2020 will be presented, representing 5,688 patients with RMS and PPMS and 21,675 patient-years of exposure to OCREVUS, across all OCREVUS clinical trials. These findings further demonstrate the consistently favourable benefit-risk profile of OCREVUS over eight years.

Three shorter infusion studies: subgroup analysis in minority populations

When treated with a shorter two-hour OCREVUS infusion, the rate and severity of infusion-related reactions in Black, African-American, Hispanic and Latino populations were similar to those reported in the overall patient population in a subgroup analysis of three studies (SaROD, CHORDS and ENSEMBLE PLUS). These patient populations may experience greater disease severity and faster progression, yet are vastly underrepresented in most clinical trials. A shorter infusion time may help reduce the burden on these patient populations and increase their access to treatment.

Late-breaking abstracts: COVID-19 in patients treated with OCREVUS

Patient safety is Roche's highest priority and we are closely monitoring the evolving COVID-19 situation. We are committed to working closely with the community to better understand the impact of COVID-19 on people who are treated with OCREVUS, and will continue to share new insights with the MS community as

they emerge.

Four late-breaking abstracts on COVID-19 in patients treated with OCREVUS, including vaccination response, will be presented by Roche and research partners.

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 European Union (EU).

OCREVUS is approved in 97 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 and active, or relapsing, 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
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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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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