Media & Investor Release

New data for Roche's OCREVUS show that after 10 years of treatment 77% of people with relapsing multiple sclerosis were free from disability progression and 92% continue to walk unaided

- **10-year efficacy data highlight OCREVUS' impact on preventing disability progression and maintaining mobility in both relapsing and progressive forms of multiple sclerosis (MS)**
- **More than 3,200 women with MS treated with OCREVUS reported no increased risk in adverse pregnancy and infant outcomes with real-world analyses showing low risk of relapse during and after pregnancy**
- **OCREVUS controlled disease activity and progression over one year in Black and Hispanic / Latinx people with MS**

Basel, 12 October 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new clinical and real-world data for OCREVUS® (ocrelizumab), demonstrating its role in continuing to transform care for people living with relapsing or primary progressive multiple sclerosis (RMS or PPMS) presented at the 9th Joint ECTRIMS-ACTRIMS Meeting (European and Americas Committees for Treatment and Research in Multiple Sclerosis). OCREVUS is the first and only disease-modifying treatment (DMT) in MS to benefit both people with RMS and PPMS and now has 10 years of follow-up data from its three Phase III trials.

"OCREVUS is the first B-cell therapy approved for RMS and PPMS and it's remarkable to see that after 10 years of treatment, a great majority of RMS patients remain free from disease progression," said Stephen Hauser, M.D., chair of the Scientific Steering Committee of the OPERA studies and director of the Weill Institute for Neurosciences at the University of California, San Francisco. "These results signify that people with both RMS and PPMS have more years to spend their days living independently without the need for walking aids or wheelchairs."

10-year disability outcomes from Phase III OCREVUS open-label extension (OLE) trials

After 10 years of continuous OCREVUS treatment, 77% were free from disability progression based on 48-week confirmed disability progression (CDP) events and 92% of patients with RMS were still walking unassisted. In patients with PPMS, 36% were free from disability progression based on 48-week CDP events and 80% of those patients treated continuously with OCREVUS over 10 years were still able to walk. The long-term data reinforce the critical importance of early treatment in preserving function across the MS spectrum, showing a

lower risk of reaching disability events in patients with RMS and PPMS who initiated OCREVUS treatment earlier (initiating at the start of the double-blind studies vs. the start of the OLEs).

10-year safety profile of OCREVUS

New safety data from 6,155 patients with 28,269 patient-years of exposure to OCREVUS across 12 clinical trials further support the medicine's favourable benefit-risk profile, which has remained consistent over 10 years. The risk characteristics of OCREVUS in the all-exposure population (RMS and PMS) remained consistent with the characteristics observed during the controlled treatment periods. Serious infections and malignancy rates remain within the range reported for patients with MS in real-world registries. Longer exposure to OCREVUS did not lead to an increased risk of serious infections regardless of the immunoglobulin G (IgG) status of the patients (normal levels or levels below the lower limit of normal). No new or unexpected safety signals were seen in patients treated with OCREVUS in ongoing clinical trials.

"Some women affected by MS may be thinking about starting a family, so it is important to understand how their treatment prior to pregnancy may impact them and their unborn child," said Levi Garraway. "With more than 300,000 people treated globally and 30 ongoing trials, we continue to accrue robust evidence for how OCREVUS may benefit many underrepresented groups including pregnant women and people of Black or Hispanic heritage."

Real-world analyses on pregnancy & infant outcomes and postpartum relapses

Family planning is an essential aspect in the care of women living with MS, many of whom are of child-bearing age. Roche safety data from 3,253 cumulative pregnancies in women with MS do not suggest an increased risk of adverse pregnancy or infant outcomes in women with MS treated with OCREVUS. Outcomes were known for 1,145 prospectively reported pregnancies and 512 of these had *in utero* exposure to OCREVUS. Respective outcomes from these two groups were: 83.6% and 84.2% live births (1.3% and 1.6% with major congenital anomalies); 1.2% and 0.8% ectopic pregnancy; 5.1% and 7.4% elective terminations; 10.0% and 7.4% spontaneous abortions; <0.1% and 0.2% still birth. *In utero* exposure to OCREVUS did not increase the risk of adverse pregnancy or infant outcomes compared with epidemiological background of both the MS and general populations.

Furthermore, a real-world analysis from the international MSBase registry based on data from 1,722 women living with MS receiving different DMTs suggests that women who conceived during OCREVUS treatment or soon after their last dose are at low risk for relapse during pregnancy and postpartum. During pregnancy, the annualised relapse rate (ARR) was 0.00 for women previously treated with OCREVUS vs. 0.05 to 0.32 for other DMTs. The postpartum ARR was 0.09 for women treated with OCREVUS vs. 0.10 to 0.74 for other DMTs. Roche is committed to generating further data on family planning priorities by assessing pregnancy and infant outcomes including infant B cell levels through routine pharmacovigilance activities, post-marketing commitments and two ongoing Phase IV studies, MINORE (placental transfer and infant outcomes) and SOPRANINO (breastmilk transfer and infant outcomes).

One-year efficacy and safety outcomes from Phase IV CHIMES study

Black and Hispanic / Latinx people with MS experience more severe disease, faster disease progression and greater disability than white people living with MS. CHIMES is the first-ever clinical trial focused exclusively on broadening understanding of MS disease biology among Black and Hispanic / Latinx people with MS. One-year data from the trial show that OCREVUS controlled disease activity and disability progression in these populations, demonstrating a safety and efficacy profile consistent with the large body of clinical evidence from other OCREVUS trials. Approximately half of 182 patients enrolled in the CHIMES trial achieved no evidence of disease activity (NEDA) at one year (46% of Black patients and 58% of Hispanic / Latinx patients at 48 weeks), with approximately 95% of patients experiencing no relapses (95% of Black patients and 96% of Hispanic / Latinx patients), no 24-week CDP (95% of Black patients and 94% of Hispanic / Latinx patients) and no T1 gadolinium-enhancing (T1-Gd+) lesions (95% of Black patients and 97% of Hispanic / Latinx patients). No new or enlarging T2 lesions were observed in about half of Black patients (46%) and more than half of Hispanic / Latinx patients (64%). No new safety signals were observed. The results also provide new insight into the role of social determinants of health in the recruitment and retention of diverse patient populations for clinical research, a critical first step in breaking the cycle of inequity.

More than 300,000 people with MS have been treated with OCREVUS globally. OCREVUS is approved in more than 100 countries across North America, South America, the Middle East, Eastern Europe, Asia as well as in Australia, Switzerland, the United Kingdom and the EU.

Roche is committed to advancing innovative clinical research programmes to broaden the scientific understanding of MS, further reduce disability worsening in RMS and PPMS and improve the treatment experiences for those living with the disease. There are more than 30 ongoing OCREVUS clinical trials designed to help us better understand MS and its progression.

About OCREVUS (ocrelizumab)

OCREVUS is the first and only therapy approved for both RMS (including relapsing-remitting MS [RRMS] and active, or relapsing secondary progressive MS [SPMS], in addition to clinically isolated syndrome [CIS] in the U.S.) and PPMS. 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 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 – from 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, 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 MS is to slow, stop and ideally prevent disease activity and progression 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 Roche in Neuroscience

Neuroscience is a major focus of research and development at Roche. Our goal is to pursue ground-breaking science to develop new treatments that help improve the lives of people with chronic and potentially devastating diseases. Roche and Genentech are investigating more than a dozen medicines for neurological disorders, including MS, spinal muscular atrophy, neuromyelitis optica spectrum disorder, Alzheimer's disease, Huntington's disease, Parkinson's disease, acute ischemic stroke, Duchenne muscular dystrophy and Angelman syndrome. 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 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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