

## **New data further reinforce Roche's OCREVUS (ocrelizumab) as a highly effective treatment for people with multiple sclerosis**

- **75% of patients with relapsing-remitting multiple sclerosis (RRMS) and suboptimal response to prior treatment had no evidence of disease activity two years after switching to OCREVUS in open-label Phase IIIb CASTING study**
- **97% persistence and strong adherence to OCREVUS treatment and twice-yearly dosing schedule from real-world data**
- **OCREVUS is the first and only treatment approved for both relapsing MS (RMS) and primary progressive MS (PPMS) and now more than 170,000 people have been treated with OCREVUS globally in clinical trial and real-world settings; favourable benefit-risk profile remains consistent over 7 years**

Basel, 11 September 2020 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new data that show OCREVUS® (ocrelizumab) is a highly effective treatment option for people with relapsing-remitting multiple sclerosis (RRMS) who experienced a suboptimal response to their prior disease modifying therapy (DMT). Subgroup analysis from the two-year open-label Phase IIIb CASTING study also demonstrates that patients benefit across a wide range of disease related and demographic subgroups, regardless of prior treatment background. Findings will be presented at MSVirtual2020, the 8<sup>th</sup> Joint Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) and the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

“For a wide range of people with MS who experienced a suboptimal response to prior treatment, we continue to see evidence that OCREVUS provides significant benefit in slowing disease progression,” said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. “New real-world OCREVUS data show high persistence and adherence to the only B-cell therapy with a twice-yearly dosing schedule, which we know can be very important to both people with MS and their physicians.”

### **Phase IIIb open-label CASTING study**

Approximately 75% of RRMS patients (492/658) had no evidence of disease activity (NEDA; brain lesions, relapses and worsening of disability) two years after switching to twice-yearly OCREVUS treatment (with prespecified MRI re-baselining at 8 weeks) in the primary analysis of the CASTING study. Patients enrolled in the study had prior suboptimal response to at least six months of treatment with up to two DMTs. The analysis also showed the proportion of patients achieving NEDA remained consistently high across all measured patient subgroups, including baseline MRI activity, relapse activity, disability level, age and the number of prior DMTs. Further, 78% of patients treated with only one prior DMT compared with 70% of patients treated with two prior DMTs achieved NEDA.

Additionally, patients treated with OCREVUS experienced an improvement in the majority of symptoms measured by SymptoMScreen after two years. SymptoMScreen is a patient-reported outcome tool to assess

symptom severity across twelve domains. The most pronounced significant improvements ( $p < 0.001$ ) were seen in sensory symptoms, fatigue and vision, which are important for daily living.

### **CONFIDENCE real-world safety study**

A 97% treatment persistence for OCREVUS patients at 18 months, and strong adherence to infusions every six months, was seen in an interim analysis of more than 1,600 patients in the ongoing German CONFIDENCE study. Separate data from a U.S. commercial claims database that support high persistence and sustained adherence to OCREVUS treatment will also be presented.

### **OCREVUS longer-term safety data**

New safety data as of January 2020 will be presented, representing 5,680 patients with RMS and PPMS and 18,218 patient-years of exposure to OCREVUS, across all OCREVUS clinical trials. These findings further demonstrate the consistently favourable benefit-risk profile of OCREVUS over seven years.

With rapidly growing real-world experience and more than 170,000 people treated globally, OCREVUS has twice-yearly (six-monthly) dosing and is the first and only therapy approved for 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 primary progressive MS (PPMS). OCREVUS is approved in 92 countries across North America, South America, the Middle East, Eastern Europe, as well as in Australia, Switzerland and the European Union.

### **About multiple sclerosis**

Multiple sclerosis (MS) is a chronic disease that affects nearly 1 million people in the U.S. and more than 2.3 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 clinically isolated syndrome, RRMS and active, or relapsing, SPMS, in addition to 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 Roche in multiple sclerosis**

Roche is following the science in an effort to ultimately stop disease progression and preserve function in people living with multiple sclerosis (MS). As a company, we continue to advance the clinical understanding of MS and progression with the aim of bringing the most benefit to people living with MS.

### **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, neuromyelitis optica spectrum disorder, Alzheimer's disease, Huntington's disease, Parkinson's disease, Duchenne's 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 eleventh 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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](http://www.roche.com).

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