Media Release

US FDA and EMA accept applications for Roche's OCREVUS (ocrelizumab) shorter 2-hour infusion time

- **Reduces infusion time to 2 hours from the current 3.5 hours for patients with relapsing or primary progressive multiple sclerosis, if approved**
- **Applications are based on data from the randomised, double-blind ENSEMBLE PLUS study, showing consistent safety to the currently approved OCREVUS dosing regimen**

Basel, 20 April 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) and the European Medicines Agency (EMA) has validated the application for a two-hour OCREVUS® (ocrelizumab) infusion time, dosed twice yearly for relapsing or primary progressive multiple sclerosis (MS).

"With more than 150,000 people treated with OCREVUS, the twice-yearly dosing schedule has benefited many MS patients and their physicians, as indicated by more than 90 percent* of patients continuing with treatment through one year," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We hope a shorter infusion time will further improve the experience for people living with MS while also increasing capacity in healthcare systems."

The regulatory applications are based on data from the randomised, double-blind ENSEMBLE PLUS study, which showed comparable frequency and severity of infusion-related reactions (IRRs) for a two-hour OCREVUS infusion time vs. the currently approved 3.5-hour time in patients with relapsing-remitting MS (RRMS). The first dose was administered per the approved dosing schedule (two 300 mg intravenous (IV) infusions separated by two weeks) and the second or later doses (600 mg IV infusion) were administered over a shorter, two-hour time. The primary endpoint of this study was the proportion of patients with IRRs following the first randomised 600 mg infusion (frequency/severity assessed during and 24-hours post infusion). No patients discontinued the study due to an IRR and no new safety signals were detected.

Detailed data will be presented at the earliest opportunity. The FDA and the European Commission are expected to make decisions on these applications by the end of 2020.

With rapidly growing real-world experience and more than 150,000 patients 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, in addition to clinically isolated syndrome in the U.S.) and primary progressive MS (PPMS). OCREVUS is approved in 90 countries across North America, South America, the Middle East, Eastern Europe, as well as in Australia, Switzerland and the European Union.

*Based on one-year analysis of U.S. PharMetrics Plus commercial claims database.

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About OCREVUS® (ocrelizumab)
OCREVUS is the first and only therapy approved for both RMS (including 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. The company's goal is to develop treatment options based on the biology of the nervous system to help improve the lives of people with chronic and potentially devastating diseases. Roche has more than a dozen investigational medicines in clinical development for diseases that include multiple sclerosis, spinal muscular atrophy, neuromyelitis optica spectrum disorder, Alzheimer's disease, Huntington's disease, Parkinson's disease and autism.

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.

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