Media Release

Roche to present five-year OCREVUS (ocrelizumab) efficacy and safety data in relapsing and primary progressive multiple sclerosis (MS) at ECTRIMS

- **Data reinforce importance of early initiation and continuation of OCREVUS treatment**
- **New analyses highlight the need for active treatment in underrepresented populations, such as primary progressive MS (PPMS) patients with more advanced disability and relapsing MS (RMS) patients of African descent**
- **Roche continues to advance the clinical understanding of MS with new studies incorporating novel clinical endpoints and digital tools**

Basel, 2 October 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that new data on OCREVUS® (ocrelizumab) in people with relapsing and primary progressive forms of MS will be presented during the 34th Congress of the European Committee for the Treatment and Research in Multiple Sclerosis (ECTRIMS) meeting in Berlin, Germany, 10 to 12 October. Fifteen abstracts will be presented throughout the congress, including five-year efficacy and safety OCREVUS data and post-hoc analyses of the Phase III studies that evaluate OCREVUS in underrepresented MS patient populations.

A new analysis of the Phase III ORATORIO study shows OCREVUS treatment reduced upper limb disability progression similarly in PPMS patients with or without advanced overall disability (Expanded Disability Status Scale <6.0 and ≥6.0 and nine-hole peg test (9-HPT) times ≤25 seconds and >25 seconds). These analyses informed the ORATORIO-HAND trial, which for the first time ever will use the 9-HPT as the primary outcome to evaluate the long-term efficacy and safety of OCREVUS in people with PPMS including those later in their disease course.

A subgroup analysis of the Phase III OPERA I and OPERA II studies in RMS patients of African-descent, who usually have faster MS disease progression than other populations, showed OCREVUS treatment benefit on MRI and composite efficacy outcomes versus interferon beta-1α. A greater proportion of patients of African descent treated with OCREVUS achieved no evidence of disease progression (NEDA) compared with interferon beta-1α (46 percent vs. 10 percent, respectively; p=0.002).

“We continue our commitment to people with MS by evaluating OCREVUS in groups that are often overlooked in clinical trials,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “In addition to now having five years of consistent efficacy and safety data results for OCREVUS, other data will be presented at ECTRIMS that advance the clinical understanding of MS. Our goal is to help the MS community better understand and manage their disease.”

New tools to rapidly assess the severity of MS symptoms are crucial to improving patient outcomes and optimising care. SymptoMScreen, a novel patient-reported outcome tool to assess symptom severity across twelve domains (walking, hand function/dexterity, spasticity, bodily pain, sensation, bladder control, fatigue, vision, dizziness, cognitive function, depression and anxiety), will be used in two Phase IIIb OCREVUS trials

(ENSEMBLE and CASTING). Baseline data from these studies show differences in disease severity on all domains, for example, 31 percent of patients in ENSEMBLE (treatment-naïve relapsing-remitting MS (RRMS) patients) and 41 percent of patients in CASTING (RRMS patients who have had a prior suboptimal response to a disease-modifying therapy) experienced moderate to severe fatigue.

Roche will also present final primary endpoint data for the FLOODLIGHT proof-of-concept study evaluating an innovative smartphone-based self-monitoring technology. The data show FLOODLIGHT may be more sensitive than periodic in-clinic disability assessments. There was also high adherence to the technology, with 76 percent adherence to active tests and 71 percent adherence to passive monitoring. Results also showed that satisfaction amongst patients with MS who completed the study was good to excellent (patient-reported 75 average score out of a possible 100 at the last visit).

Based on initial results from the FLOODLIGHT proof-of-concept study, Roche has initiated a new, global study called FLOODLIGHT Open with plans to enrol 10,000 people in five years. FLOODLIGHT Open will assess the feasibility of monitoring disease activity and disability progression over the 365 days in a year that someone lives with MS, versus the two or three days they visit with their neurologist. It is an open access study, which means anyone can join and the anonymous data collected through the study is freely available to doctors and scientists to help accelerate research and collaboration. FLOODLIGHT Open is currently enrolling in the United States and Canada and will open in other countries later this year. To learn more and enrol, visit https://floodlightopen.com or download the FLOODLIGHT app on iTunes for iPhone or Google Play for Android.

OCREVUS is now approved in 67 countries across North America, South America, the Middle East, Eastern Europe, as well as in Australia, Switzerland and the European Union. Marketing applications are currently under review in more than 20 countries across the world.

Additionally, Roche is sponsoring two symposia: “Disease activity: Can starting early with effective treatment offer better outcomes in MS?” on Wednesday, 10 October at 18:15 CEST in Hall A and “Disease progression: Changing how we think about MS” on Thursday, 11 October at 07:30 CEST in Hall B.

Follow Roche on Twitter via @Roche and keep up to date with ECTRIMS 2018 news and updates by using the hashtag #ECTRIMS2018.

Roche presentations at ECTRIMS 2018
A full list of Roche presentations can be found at: https://www.ectrims-congress.eu/2018/scientific-programme/scientific-programme.html. Select poster presentations at ECTRIMS 2018 include:

Abstract Title	**Presentation Number (type), Presentation Date, Time**
Long-Term Reduction of Relapse Rate and Confirmed Disability Progression After 5 Years of Ocrelizumab Treatment in Patients With Relapsing Multiple Sclerosis	#P590 (poster presentation), Wednesday, 10 October, 17:00 – 19:00 CEST
Long-term Reduction in Brain MRI Disease Activity and Atrophy After 5 Years of Ocrelizumab Treatment in Patients With Relapsing Multiple Sclerosis	#P588 (poster presentation), Wednesday, 10 October, 17:00 – 19:00 CEST
Ocrelizumab Treatment Effect on Upper Limb Function in PPMS Patients With Disability: Subgroup Results of the ORATORIO Study to Inform the ORATORIO-HAND Study Design	#P619 (poster presentation), Wednesday, 10 October, 17:00 – 19:00 CEST
FLOODLIGHT: Smartphone-Based Self-Monitoring is Accepted by Patients and Provides Meaningful, Continuous Digital Outcomes Augmenting Conventional In-Clinic Multiple Sclerosis Measures	#P624 (poster presentation), Wednesday, 10 October, 17:00 – 19:00 CEST
Subgroup Analysis to Evaluate the Efficacy of Ocrelizumab Versus Interferon β-1a in African-Descended Patients With Relapsing Multiple Sclerosis in the OPERA I and OPERA II Studies	#P639 (poster presentation), Wednesday, 10 October, 17:00 – 19:00 CEST
Year One Interim Analysis Results of the Phase IIIb CHORDS Study Evaluating Ocrelizumab Effectiveness and Safety in Patients With Relapsing-Remitting Multiple Sclerosis Who Had Suboptimal Response With Prior Disease-Modifying Treatments	#P635 (poster presentation), Wednesday, 10 October, 17:00 – 19:00 CEST
Sustained Reduction in Confirmed Disability Progression in Patients With Primary Progressive Multiple Sclerosis Treated With Ocrelizumab in the Open-Label Extension Period of the Phase III ORATORIO trial	#P910 (poster presentation), Thursday, 11 October, 17:15 – 19:15 CEST
Patient-Reported SymptoMScreen Baseline Scores in Patients with Relapsing-Remitting Multiple Sclerosis Enrolled in Phase IIIb Studies of Ocrelizumab (ENSEMBLE and CASTING)	#P943 (poster presentation), Thursday, 11 October, 17:15 – 19:15 CEST
Safety of Ocrelizumab in Multiple Sclerosis: Updated Analysis in Patients with Relapsing and Primary Progressive Multiple Sclerosis	#P1229 (poster presentation), Friday, 12 October, 12:15 – 14:15 CEST

About OCREVUS® (ocrelizumab)
OCREVUS is a humanised monoclonal antibody designed to selectively 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 multiple sclerosis (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, and therefore 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. 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, Alzheimer's disease, spinal muscular atrophy, 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. 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 tenth consecutive year, Roche has been recognised as the most sustainable company 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 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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.

Roche Group Media Relations

Phone: +41 -61 688 8888 / e-mail: media.relations@roche.com

- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Simone Oeschger
- Anja von Treskow