Media Release

New 6-year data for Roche's OCREVUS (ocrelizumab) show earlier treatment initiation nearly halves risk of needing walking aid in relapsing multiple sclerosis

- **Post-hoc analysis from 6 years of Phase III open-label extension studies showed OCREVUS treatment reduced the risk of needing a walking aid (EDSS≥6) by 49% in relapsing multiple sclerosis (RMS) patients compared with patients who switched from interferon beta-1a two years later**
- **Separate analysis showed OCREVUS slowed thalamic volume loss in patients with RMS and primary progressive MS (PPMS) vs. interferon beta-1a and placebo, respectively**
- **More than 150,000 people have been treated with OCREVUS globally, in clinical trial and real-world settings; data continue to show a consistent and favourable benefit-risk profile**

Basel, 28 April 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new analyses of Phase III OPERA I and OPERA II studies, as well as the open-label extensions, showing that OCREVUS® (ocrelizumab) treatment reduced the risk of disease and disability progression in RMS and PPMS. These new analyses add additional evidence to the benefit-risk profile of OCREVUS, including the impact of MS on people's daily lives. The data were selected for the 72nd American Academy of Neurology (AAN) Annual Meeting and will be made available online via virtual presentation in the coming weeks (in lieu of an in-person event).

"For people with MS, maintaining mobility for as long as possible is very important. We are encouraged by these new longer-term analyses showing that earlier initiation of OCREVUS treatment may reduce the risk of needing a walking aid by nearly 50 percent over six years," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Slowing MS progression earlier in the disease course – not just treating relapses – may bring additional clinically meaningful outcomes to people living with this disease."

Effect of OCREVUS on disability progression and risk of needing a walking aid in patients with RMS
Earlier treatment with OCREVUS may delay the risk of needing a walking aid compared to those who switched from interferon beta-1a two years later in a new post-hoc analysis from the open-label extension of the Phase III OPERA studies in RMS. 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. People treated with OCREVUS had a 49% reduction in the risk of needing a walking aid compared to those that received interferon beta-1a over 6 years of study (4.3% vs. 7.2%*; p=0.0042). Safety profiles in the double-blind period and open-label extension were generally consistent.

*Kaplan-Meier estimate at 288 weeks

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 www.roche.com

Effect of OCREVUS on disease progression measured by thalamic atrophy
OCREVUS progressively slowed thalamic atrophy (as measured by change in thalamic volume) in patients with RMS or PPMS. Results from the double-blind periods of the Phase III OPERA I, OPERA II and ORATORIO studies showed significantly less thalamic atrophy compared with interferon beta-1a and placebo, respectively (both $p<0.001$). The thalamus is a deep grey matter structure within the brain that acts as a relay and integrative centre, playing a key role in alertness, motor control and cognition, as well as sensory processing. It is affected by MS-related damage and its atrophy could be a useful marker of therapeutic efficacy.

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 (SPMS), in addition to clinically isolated syndrome in the U.S.) and 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.

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 the U.S.) and PPMS, with dosing every six months. 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 spectrum disorder.

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.

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: media.relations@roche.com
- Nicolas Dunant (Head)
- Patrick Barth
- Daniel Grotzky
- Karsten Kleine
- Nathalie Meetz
- Barbara von Schnurbein