Roche to present new data at AAN showing superior efficacy of investigational medicine ocrelizumab versus comparators on disease activity and progression in two forms of multiple sclerosis

- New analyses showing superior efficacy of ocrelizumab across clinical and subclinical outcomes compared with interferon beta-1a (Rebif®) in people with relapsing MS and compared with placebo in primary progressive MS will be presented

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that new data from three Phase III studies of the investigational medicine OCREVUS™ (ocrelizumab) will be presented during the 68th American Academy of Neurology (AAN) Annual Meeting from 15th to 21st April in Vancouver, Canada.

In addition, results of a novel endpoint, No Evidence of Disease Activity (NEDA) will be presented from the Phase III studies in relapsing multiple sclerosis at the Clinical Trials Plenary Session on Wednesday, 20th April. NEDA is a composite of key measures of disease activity that assesses level of disease control. Patients are considered to have achieved NEDA if they have no relapses, no disability progression and no new or enlarging MRI lesions over a specified time interval, for example, two years of a clinical trial.

“The data being presented at AAN show that ocrelizumab significantly reduced disability progression and brain tissue damage in both relapsing and primary progressive forms of MS,” said Sandra Horning, M.D., Roche’s Chief Medical Officer and Head of Global Product Development. “The analyses demonstrate ocrelizumab’s consistent effect across important measures of disease activity and provide further insights into the clinical effect of ocrelizumab in people with MS.”

Leading investigators will present the following oral and poster presentations:
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<th>Abstract Title</th>
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<td>Immunogenicity with Repeated Dosing of Ocrelizumab in Patients with Multiple Sclerosis</td>
<td>P2.087 (poster), Sunday, 17 April, 4:00 p.m. PDT</td>
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<td>Preferences for Multiple Sclerosis Treatments: Differences Across Subgroups of US Patients with RRMS</td>
<td>P3.108 (poster), Monday, 18 April, 5:30 p.m. PDT</td>
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<td>Myelin Damage in Relapsing Multiple Sclerosis Is Associated with Decreased N-Acetylaspartate and Creatine Concentrations</td>
<td>P4.181 (poster), Tuesday, 19 April, 5:30 p.m. PDT</td>
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<td>Ocrelizumab No Evidence of Disease Activity (NEDA) Status at 96 Weeks in Patients with Relapsing Multiple Sclerosis: Analysis of the Phase III Double-Blind, Double-Dummy, Interferon beta-1a-Controlled OPERA I and OPERA II Studies</td>
<td>PL02.004 (oral), Wednesday, 20 April, 9:00 a.m. PDT</td>
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<td>Efficacy and Safety of Ocrelizumab in Primary Progressive Multiple Sclerosis: Results of the Phase III Double-Blind, Placebo-Controlled ORATORIO Study</td>
<td>S49.001 (oral), Thursday, 21 April, 1:00 p.m. PDT</td>
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<td>Effect of Ocrelizumab on MRI Inflammatory and Neurodegenerative Markers of Disease in Patients with Relapsing Multiple Sclerosis: Analysis of the Phase III, Double-Blind, Double-Dummy, Interferon Beta-1a-Controlled OPERA I and OPERA II Studies</td>
<td>S49.002 (oral), Thursday, 21 April, 1:15 p.m. PDT</td>
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<td>Efficacy of Ocrelizumab in Patients with Relapsing Multiple Sclerosis: Pooled Analysis of Two Identical Phase III, Double-Blind, Double-Dummy, Interferon Beta-1a-Controlled Studies</td>
<td>S49.003 (oral), Thursday, 21 April, 1:30 p.m. PDT</td>
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<td>Effect of Ocrelizumab on Disability Progression in</td>
<td>S49.008 (oral), Thursday, 21 April, 2:45 p.m. PDT</td>
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Patients with Relapsing Multiple Sclerosis: Analysis of the Phase III, Double-Blind, Double-Dummy, Interferon Beta-1a-Controlled OPERA I and OPERA II Studies

Abstracts are available on the AAN website.
In addition, Genentech, a member of the Roche group, is sponsoring an Industry Therapeutic Update. Fred Lublin, M.D., Professor of Neurology and the Director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis at Mount Sinai Medical Center, will present “Evolving Perspectives on Disease Activity: What Is Lying Beneath the Surface?” on Tuesday, 19 April at 7:00 p.m. and 8:30 p.m. PDT at the Hyatt Regency Ballroom C in Vancouver.

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OCREVUS™ is the proprietary name submitted to global regulatory authorities for the investigational medicine ocrelizumab.

About ocrelizumab
Ocrelizumab is an investigational, humanised monoclonal antibody designed to selectively target CD20-positive B cells. CD20-positive B cells are a specific type of immune cell thought to be a key contributor to myelin (nerve cell insulation and support) and axonal (nerve cell) damage, which can result in disability in people with MS. Based on preclinical studies, ocrelizumab 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.

The Phase III clinical development programme for ocrelizumab (ORCHESTRA) includes three studies: OPERA I, OPERA II and ORATORIO. OPERA I and OPERA II are identical Phase III, randomised, double-blind, double-dummy, global multi-centre studies that evaluated the efficacy and safety of ocrelizumab (600 mg administered by intravenous infusion every six months) compared with interferon beta-1a (44 mcg administered by subcutaneous injection three times per week) in 1,656 people with relapsing forms of MS (i.e., relapsing-remitting MS and secondary-progressive MS with relapses). ORATORIO is a Phase III, randomised, double-
blind, global multi-centre study that evaluated the efficacy and safety of ocrelizumab (600 mg administered by intravenous infusion every six months; given as two 300 mg infusions two weeks apart) compared with placebo in 732 people with primary progressive MS (PPMS).2

In February 2016, the U.S. Food and Drug Administration granted Breakthrough Therapy Designation to ocrelizumab for the treatment of people with PPMS. Ocrelizumab is the first investigational medicine to receive Breakthrough Therapy Designation in multiple sclerosis.

**About multiple sclerosis**

Multiple sclerosis (MS) is a chronic disease that affects an estimated 2.3 million people around the world, for which there is currently no cure.3,4 MS occurs when the immune system abnormally attacks the insulation and support around nerve cells (myelin sheath) in the 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.5,6,7 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.8

Relapsing MS is the most common form of the disease. Disease activity and progression can occur even when people do not show signs or symptoms of MS, despite available relapsing MS treatments. 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.9 Approximately one in 10 people with MS are diagnosed with the primary progressive form of the disease. There are no approved treatments for PPMS.

**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, Down syndrome and autism.
About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives. 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. 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.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine 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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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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References

9. MS International Federation. Types of MS. Available at: http://www.msif.org/about-ms/types-of-ms/.