Roche’s OCREVUS (ocrelizumab) approved in Switzerland for primary progressive and relapsing forms of multiple sclerosis

- OCREVUS is the first and only approved treatment for people with primary progressive MS, a highly disabling form of MS
- An important new treatment option for people with relapsing forms of MS demonstrating superior efficacy on the three major markers of disease activity compared with Rebif
- Authorisation in Switzerland marks the first for OCREVUS in Europe following approvals in North America, South America, the Middle East, Ukraine and Australia

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the Swiss agency for the authorisation and supervision of therapeutic products (Swissmedic) has granted authorisation of OCREVUS® (ocrelizumab) for the treatment of adult patients with active relapsing forms of multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS). MS, which affects almost 15,000 people in Switzerland, is the leading cause of non-traumatic disability in young adults and often results in serious and permanent disabilities.

“The approval of OCREVUS in Switzerland, the first in Europe, is a significant moment for the Swiss MS community, and we are pleased that the regulators have recognised how the clinically meaningful results for OCREVUS may benefit people with active relapsing forms of MS and primary progressive MS,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Despite available therapies, some people with relapsing forms of MS continue to experience disease activity and disability progression, and people with primary progressive MS, who have never had an approved treatment, experience a faster accumulation of disability. OCREVUS, given every six months, has the potential to transform the treatment of both relapsing forms of MS and primary progressive MS.”
OCREVUS is the first medicine to be approved in Switzerland for PPMS, which affects approximately 15 percent of people with MS. PPMS is a debilitating form of the disease marked by steadily worsening symptoms, but typically without distinct relapses or periods of remission. Additionally, disability accumulates twice as fast in PPMS as in RMS, meaning that people with PPMS may have to rely on mobility aids or become wheelchair bound, are unable to work, and need carers to look after them sooner. In contrast, RMS, the most common form, is characterised by episodes of new or worsening signs or symptoms (relapses) followed by periods of complete or incomplete recovery.

“The approval of OCREVUS for both active relapsing forms of MS and primary progressive MS in Switzerland is much welcomed news for people with one of these two forms of MS that can radically alter the lives of those affected and their families,” said Professor Ludwig Kappos, Head Physician of the Department of Neurology and Outpatient Clinic at the University Hospital of Basel. “OCREVUS offers people with active relapsing forms of MS a treatment with a favourable benefit/risk profile and is the first medicine demonstrating efficacy and delaying the progression of disability in people with primary progressive MS.”

In the Phase III ORATORIO study for PPMS, OCREVUS significantly slowed disability progression and reduced signs of disease activity in the brain (MRI lesions) compared with placebo. In the Phase III OPERA I and OPERA II studies for RMS, OCREVUS demonstrated superior efficacy on the three major markers of disease activity, slowing the worsening of disability and significantly reducing MRI lesions compared with Rebif® (high-dose interferon beta-1a). The most common side effects associated with OCREVUS in all Phase III studies were infusion reactions and upper respiratory tract infections, which were mostly mild to moderate in severity.

OCREVUS has been approved for use in countries across North America, South America, the Middle East, Eastern Europe, and in Australia. Marketing applications for OCREVUS are currently under review in over 50 countries across the world.

About OCREVUS (ocrelizumab)
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 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 the OPERA I and OPERA II studies in relapsing forms of MS

OPERA I and OPERA II are Phase III, randomised, double-blind, double-dummy, global multi-centre studies evaluating the efficacy and safety of OCREVUS (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. In these studies, relapsing MS (RMS) was defined as relapsing-remitting MS (RRMS) and secondary progressive MS (SPMS) with relapses. A similar proportion of patients in the OCREVUS group experienced serious adverse events and serious infections compared with patients in the high-dose interferon beta-1a group in the RMS studies.

About the ORATORIO study in primary progressive MS

ORATORIO is a Phase III, randomised, double-blind, global multi-centre study evaluating the efficacy and safety of OCREVUS (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). The blinded treatment period of the ORATORIO study continued until all patients had received at least 120 weeks of either OCREVUS or placebo and a predefined number of confirmed disability progression (CDP) events was reached overall in the study. A similar proportion of patients in the OCREVUS group experienced adverse events and serious adverse events compared with patients in the placebo group in the PPMS study.

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.1,2 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.3,4,5 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.6
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. 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 percent of people with MS are diagnosed with the primary progressive form of the disease.

People with all forms of MS experience disease activity – inflammation in the nervous system and permanent loss of nerve cells in the brain – even when their clinical symptoms aren’t apparent or don’t appear to be getting worse. An important goal of treating MS is to reduce disease activity as soon as possible to slow how quickly a person’s disability progresses. Despite available disease-modifying treatments (DMTs), some people with RMS continue to experience disease activity and disability progression.

**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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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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Roche Group Media Relations
Phone: +41 -61 688 8888 / e-mail: media.relations@roche-global.com
- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Simone Oeschger
- Anja von Treskow
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