Media & Investor Release

Roche to present new OCREVUS (ocrelizumab) data in multiple sclerosis and continued research into neuromyelitis optica spectrum disorder at ECTRIMS 2022

- **OCREVUS data will show significant benefit on slowing disease activity and progression in patients with treatment-naive early-stage relapsing-remitting multiple sclerosis (RRMS)**
- **Largest pregnancy safety data across anti-CD20 medicines for OCREVUS in multiple sclerosis (MS)**
- **Nine-year safety data for OCREVUS reinforces its favourable benefit-risk profile**
- **New research demonstrates impact of misdiagnosis and delay of starting treatment in NMOSD**

Basel, 19 October 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new OCREVUS® (ocrelizumab) data and continued research into neuromyelitis optica spectrum disorder (NMOSD) will be presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) from 26-28 October 2022. These data include 35 abstracts, highlighting disease activity and progression results in early-stage RRMS, pregnancy outcomes from more than 2,000 women with MS and long-term safety data for OCREVUS, as well as global NMOSD data exploring impact of delayed treatment, clinical characterization of disease severity and stability, and accurate identification of people living with NMOSD through healthcare claims-based algorithms. Finally, the design of a Phase III study evaluating the efficacy and safety of satralizumab in Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease (MOGAD), a rare, chronic and debilitating autoimmune disease primarily affecting the optic nerve, brain and spinal cord, will be presented.

“Our aim is to enable people living with MS and NMOSD to maintain life to the fullest. With over 250,000 people treated with OCREVUS, we continue to see significant reductions in MS disease progression balanced with favourable safety,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “We are also focused on remaining unmet needs – such as earlier diagnosis and treatment – which is critical to ensure patients are receiving the most appropriate treatment.”

Multiple sclerosis (MS)

Roche will present 29 MS abstracts, including data from a two-year interim analysis of treatment-naive, early-stage patients with RRMS from the open label Phase IIIb ENSEMBLE study that will show the positive impact on disease activity and progression when newly diagnosed patients are treated with OCREVUS, and outcomes from the largest cumulative

pregnancy dataset for an anti-CD20 MS medicine in more than 2,000 women treated with OCREVUS. Long-term data from all OCREVUS clinical trials in relapsing MS (RMS) and primary progressive MS (PPMS) over nine years will reinforce the consistently favourable benefit-risk profile of OCREVUS.

Neuromyelitis optica spectrum disorder (NMOSD)

Roche will present five NMOSD abstracts, including the development and testing of a healthcare claims-based algorithm to identify people living with NMOSD. Misdiagnosis of NMOSD is common and associated with a delay in initiating maintenance therapy. This was highlighted in a study looking to develop a clearer understanding of patient characteristics, relapse severity and other drivers of treatment choice.

The development of validated consensus statements on AQP4-IgG seropositive NMOSD management will also be presented with a focus on treatment recommendations including satralizumab; these statements aim to optimise patient outcomes through informed treatment decision making. The characterisation of disease severity and stability in NMOSD will also be presented, with the aim of integrating these in worldwide NMOSD clinical practice.

Roche will also present the study design from a Phase III study that will evaluate the efficacy and safety of satralizumab in MOGAD.

Follow Roche on Twitter via @Roche and keep up to date with ECTRIMS 2022 news and updates by using the hashtag #ECTRIMS2022.

Medicine	**Abstract title**	**Presentation number (Type)** **Presentation date** **Time**
e-Posters available from 26 October at 8:00 CEST **Poster presentations scheduled for 26 October at 16:30-18:30 CEST unless indicated differently**		
OCREVUS for MS	Pregnancy and Infant Outcomes in Women Receiving Ocrelizumab for the Treatment of Multiple Sclerosis	0038 (Oral) 26 October 14:49-14:56 CEST
	Treatment-Naive Patients With Early-Stage Relapsing-Remitting Multiple Sclerosis Showed Low Disease	P285 (Poster) 27 October

	Activity After 2-Year Ocrelizumab Therapy, With No New Safety Signals; The Phase IIIb ENSEMBLE Study	13:20-13:25 CEST
	Safety of Ocrelizumab in Multiple Sclerosis: Updated Analysis in Patients With Relapsing and Primary Progressive Multiple Sclerosis	P326 (Poster)
	An Interim Analysis of Efficacy and Safety Data in Black and Hispanic Patients With Multiple Sclerosis Receiving Ocrelizumab Treatment in the CHIMES Trial	P686 (Poster)
	Demographics and Baseline Disease Characteristics of Patients With Relapsing Multiple Sclerosis From Kenya Participating in the CHIMES Trial	EP1049 (e-Poster)
	The Patient Perspective on Family Planning Needs and Priorities in Multiple Sclerosis: a Combined Quantitative and Qualitative Research Study	P077 (Poster)
	Blood Neurofilament Light Levels Predict Non-Relapsing Progression Following Anti-CD20 Therapy in Relapsing and Primary Progressive Multiple Sclerosis: Findings From the Ocrelizumab Randomised, Double-Blind Phase 3 Clinical Trials	P256 (Poster)
	Identification of Novel CSF Measures of Disease Activity and Chronic Progressive Biology in MS: Results of the Ocrelizumab Biomarker Outcome Evaluation Study (OBOE): A Randomised, Open-Label Clinical Trial	P449 (Poster) 27 October 13:34-13:40 CEST
	Real-World Clinical and Economic Outcomes Among Persons With Multiple Sclerosis Initiating First- vs. Second-Line Treatment With Ocrelizumab	EP1127 (e-Poster)
	Trends in the Use of Disease-Modifying Therapies in Pre-Pregnant Women With Multiple Sclerosis in the United States: a Claims Database Analysis	P479 (Poster) 27 October 17:00-19:00 CEST
	COVID-19 Vaccination Patterns and Outcomes Among Persons With Multiple Sclerosis in the FlywheelMS Cohort	EP1100 (e-Poster)

	Ocrelizumab in Patients With Early-Stage RRMS – Results From the Phase IIIb ENSEMBLE Trial and the Matched Real-World NTD MS Registry Cohort	P771 (Poster) 27 October 17:00-19:00 CEST
	Safety of Shorter Ocrelizumab Infusion Confirmed Over Multiple Administrations: Results of the ENSEMBLE PLUS Substudy	P739 (Poster) 27 October 17:00-19:00 CEST
	Efficacy and Safety of Ocrelizumab is Maintained in Patients with RRMS with Suboptimal Response to Prior Disease-Modifying Therapies: 4-Year NEDA Data from CASTING-LIBERTO	P289 (Poster)
	Employment and Cognitive Improvements in Ocrelizumab-Treated Patients With Relapsing-Remitting Multiple Sclerosis: 96-Week CASTING Study Data	P776 (Poster) 27 October 17:00-19:00 CEST
	Cognitive Improvements in Ocrelizumab-Treated Patients with Relapsing-Remitting Multiple Sclerosis: 96-Week CASTING Study Data	P377 (Poster)
	Long-Term Efficacy and Safety of Ocrelizumab in Treatment-Naive Patients With Early Relapsing Multiple Sclerosis: 7-year Data From the OPERA Open-Label Extension Trials	P723 (Poster) 27 October 13:30-13:35
	Eight-Year Analyses of Repeated Confirmed Disability Progressions in the OPERA and ORATORIO Studies and Their Open-Label Extensions	P050 (Poster)
	Ocrelizumab Dose Selection for Treatment of Relapsing-Remitting Multiple Sclerosis in Children and Adolescents: Preliminary Pharmacokinetic, Safety and Efficacy Results From the OPERETTA 1 Study	P444 (Poster) 27 October 17:00-19:00 CEST
	Infusion-Related Reactions With Ocrelizumab in Relapsing Multiple Sclerosis: Over 9 Years of Data From OPERA OLE	P725 (Poster) 27 October 17:00-19:00 CEST
	SARS-CoV-2 Vaccination and COVID-19 Infections in People With Multiple Sclerosis Treated With	P562 (Poster)

	Ocrelizumab in the Prospective, Multicenter, Noninterventional MuSicalE and CONFIDENCE Studies	27 October 17:00-19:00 CEST
	SARS-CoV-2 vaccine-induced immune responses and breakthrough infections in people with multiple sclerosis treated with ocrelizumab	P553 (Poster) 27 October 17:00-19:00 CEST
	Severe COVID-19 Outcomes Following Vaccination in Persons With Multiple Sclerosis: a Real-World Evidence Study	P747 (Poster) 27 October 17:00-19:00 CEST
	Longitudinal Study of Humoral and Cellular Responses to COVID-19 mRNA Vaccines With and Without 3rd ("Booster") Dose in MS Patients on Ocrelizumab: 24-Week Results From VIOLA (NCT04843774)	EP1052 (e-Poster)
	Clinical and MRI Outcomes in Pediatric-Onset MS Patients on Ocrelizumab and Fingolimod	EP0995 (e-Poster)
Floodlight in MS	Assessment of Upper Extremity Function and Performance Fatigability in Multiple Sclerosis Using Sensor-Based Features Derived From the Smartphone-Based Pinching Test	O144 (Oral) 28 October 10:49-10:56 CEST
	Identification of Distinct Adherence Profiles for Smartphone Sensor-Based Tests (Floodlight) in a Study of People With Progressive Multiple Sclerosis (CONSONANCE)	P123 (Poster)
	Remote Passive Monitoring in People Living With Progressive Multiple Sclerosis During the COVID-19 Pandemic Shows a Measurable Reduction in Daily Activity	P522 (Poster) 27 October 17:00-19:00 CEST
	A Prospective Study of the Feasibility of Smartphone-Based Self-Monitoring to Characterise Cognitive and Neurological Impairment in People With Multiple Sclerosis: Floodlight MS MoreActive	EP0886 (e-Poster)

ENSPRYNG for NMOSD	International, evidence-based Delphi consensus on the management of AQP4-IgG seropositive NMOSD, with a focus on treatment recommendations for eculizumab, inebilizumab and satralizumab	P008 (Poster)
	Understanding treatment decisions in neuromyelitis optica spectrum disorder: a global clinical record review with patient interviews	P412 (Poster) 27 October 17:00-19:00 CEST
	Characterisation of disease severity and stability in neuromyelitis optica spectrum disorder: a global clinical record review with patient interviews	P417 (Poster) 27 October 17:00-19:00 CEST
	Development and Validation of a Claims-Based Algorithm to Identify Patients with Neuromyelitis Optica Spectrum Disorder	EP0911 (e-Poster)
	Baseline Characteristics of Initial Patients in the CorEvitas SPHERES Registry for NMOSD	P408 (Poster) 27 October 17:00-19:00 CEST
satralizumab for MOGAD	METEOROID: A Randomised, Double-Blind, Placebo-controlled, Multicentre Phase 3 Study of Satralizumab in Patients with Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease	EP1040 (e-Poster)

About OCREVUS (ocrelizumab)

OCREVUS is the first and only therapy approved for both RMS (including RRMS and active, or relapsing, secondary progressive MS [SPMS], in addition to clinically isolated syndrome [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 ENSPRYNG (satralizumab)

ENSPRYNG, which was designed by Chugai, a member of the Roche Group, is a humanised monoclonal antibody that targets interleukin-6 (IL-6) receptor activity. ENSPRYNG was designed using novel recycling antibody technology which, compared to conventional technology, allows for longer duration of the antibody and subcutaneous dosing every four weeks.

Positive Phase III results for ENSPRYNG, as both monotherapy and in combination with baseline immunosuppressive therapy, demonstrate that IL-6 inhibition is an effective therapeutic approach for neuromyelitis optica spectrum disorder (NMOSD). ENSPRYNG is currently approved for NMOSD in 72 countries with further applications under review with numerous regulators. Roche continues to investigate ENSPRYNG in further indications including generalised myasthenia gravis (gMG), Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease (MOGAD) and Autoimmune Encephalitis (AIE).

ENSPRYNG was granted Breakthrough Therapy Designation for the treatment of NMOSD by the FDA in December 2018 and designated as an orphan drug for NMOSD in the United States, Europe, Russia and Japan.

In addition, it has been designated as an orphan drug for gMG, MOGAD and AIE (NMDAR).

About Roche in neuroscience

Neuroscience is a major focus of research and development at Roche. Our goal is to pursue ground-breaking science to develop new treatments that help improve the lives of people with chronic and potentially devastating diseases.

Roche has both approved and investigational medicines across multiple sclerosis, spinal muscular atrophy, neuromyelitis optica spectrum disorder, myasthenia gravis, Alzheimer's disease, Huntington's disease, Parkinson's disease and Duchenne muscular dystrophy. Together with our partners, we are committed to pushing the boundaries of scientific understanding to solve some of the most difficult challenges in neuroscience today.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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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