Roche to present new data on OCREVUS in multiple sclerosis and ENSPRYNG in neuromyelitis optica spectrum disorder at ECTRIMS 2021

- **OCREVUS (ocrelizumab) data to show sustained reduction in disability progression through 8 years for primary progressive multiple sclerosis (PPMS) and 7.5 years for relapsing MS (RMS)**
- **Long-term safety analysis of all clinical trials will reinforce the consistently favourable benefit-risk profile of OCREVUS**
- **ENSPRYNG (satralizumab) data to show efficacy and safety sustained over four years of treatment for people living with neuromyelitis optica spectrum disorder (NMOSD)**
- **Study design for SAkuraBONSAI, a new study on disease activity and progression in ENSPRYNG patients, who are treatment naïve or where prior rituximab (or biosimilar) treatment has failed, will be presented**

Basel, 5 October 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new OCREVUS® (ocrelizumab) and ENSPRYNG® (satralizumab) data will be presented at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) from 13 - 15 October 2021. These data include 38 abstracts highlighting new longer-term efficacy and safety for both OCREVUS and ENSPRYNG, as well as our ongoing efforts to evaluate the impact of the COVID-19 pandemic for people living with MS. Additional data will show how a deeper scientific understanding of MS and NMOSD in diverse patient populations could help ensure access to treatment.

"The longer-term efficacy and safety data for both OCREVUS and ENSPRYNG reinforce the impact of these treatments - by significantly slowing disease progression in MS and by preventing debilitating relapses in NMOSD, respectively," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We continue to see that early and ongoing treatment markedly improves outcomes, and we'll continue to use scientific and real-world insights to improve our understanding and ways to support people living with these neurological disorders."

Multiple sclerosis (MS)
Roche will present 27 MS studies, including long-term data that show earlier treatment with OCREVUS continues to impact disability progression up to 8 years in people with primary progressive multiple sclerosis (PPMS) and up to 7.5 years in people with relapsing multiple sclerosis (RMS) in the Phase III open label extension studies. Additionally, updated long-term safety analysis of all clinical trials in patients with RMS and PPMS will reinforce the consistently favourable benefit-risk profile of OCREVUS.

Roche remains committed to addressing health disparities and we believe inclusive research can improve outcomes and derive insights that may address treatment barriers. A subgroup analysis of three studies (SaROD, CHORDS and NSEMBLE PLUS) in Black, African-American, Hispanic and Latino populations

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treated with a 2-hour OCREVUS infusion will be presented.

Neuromyelitis optica spectrum disorder (NMOSD)
New longer-term results from the SAkuraStar and SAkuraSky OLE studies for ENSPRYNG will show efficacy observed in the pivotal trials is sustained with high proportions of patients remaining free from relapse over four years of treatment. Similarly, safety data from the SAkuraStar and SAkuraSky OLE studies will show the favourable safety profile of ENSPRYNG is sustained with longer-term treatment. ENSPRYNG has been approved in 58 countries globally, including in the U.S. as the first and only subcutaneous treatment for adults with anti-aquaporin-4 antibody (AQP4-IgG) seropositive NMOSD. ENSPRYNG has also been approved for both adults and adolescents in the European Union, Japan, Canada and Switzerland.

Roche is dedicated to increasing scientific understanding of NMOSD and improving care for all people living with the condition. The study design will be presented for SAkuraBONSAI, a prospective, open-label study of ENSPRYNG to generate data to further the understanding of the disease activity and mechanism of action of ENSPRYNG in patients living with AQP4-IgG seropositive NMOSD who are treatment naïve or where prior rituximab (or biosimilar) treatment has failed. Other presentations will examine the development of new tools and techniques to identify patients with NMOSD and assess disability better.

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Medicine	**Abstract title**	**Presentation number (Type)**
		Presentations scheduled for 13 October, 12:00 – 9:00 PM CEST, unless indicated differently
OCREVUS for MS	Sustained Reduction in 48-week Confirmed Disability Progression in Patients with PPMS Treated with Ocrelizumab in the ORATORIO OLE: 8-Year Follow-up	158 (Oral) *15 October, 3:33 – 3:40 PM CEST*
	Long-term Reduction of Relapse Rate and Confirmed Disability Progression After 7.5 Years of Ocrelizumab Treatment in Patients with Relapsing Multiple Sclerosis in the OPERA OLE	P723 (ePoster) *14 October, 12:00 – 9:00 PM CEST*
	Safety of Ocrelizumab in Multiple Sclerosis: Updated Analysis in Patients with Relapsing and Primary Progressive Multiple Sclerosis	P724 (ePoster) *14 October, 12:00 – 9:00 PM CEST*

	Infusion-related Reactions in Black/African American and Hispanic/Latino Patients Treated with Ocrelizumab Administered as a Shorter Infusion	P690 (ePoster)
	Real-World Experience With Ocrelizumab in Relapsing Multiple Sclerosis: Insights From The MSOCR-R Cohort, a MSBase Registry Sub-Study	161 (Oral) *15 October, 3:19 – 3:26 PM CEST*
	Changes in Brain Metabolites Over 1 Year in Participants of the OBOE Trial for RMS and PPMS	029 (Oral) *13 October, 1:57 – 2:04 PM CEST*
	Long-term Suppression of MRI Disease Activity and Reduction of Global/Regional Volume Loss: Results From OPERA I/II and ORATORIO Open-label Extension	P407 (ePoster) *14 October 6:10 – 6:15 PM CEST*
	Slowly Evolving Lesions Showed Less Myelin Content than Non-slowly Evolving Lesions: Insights from a Sub-study of OPERA II	P480 (ePoster)
	A Broad Effect of Ocrelizumab on the Peripheral Immune Component in Patients with Early Relapsing-remitting Multiple sclerosis	P701 (ePoster)
	The Effectiveness of Ocrelizumab in Real-world Patients with Relapsing Multiple Sclerosis Over 18 months: a CONFIDENCE Interim Analysis	P828 (ePoster)
	Efficacy and Safety of Ocrelizumab in Patients with RRMS with Suboptimal Response to Prior Disease-modifying Therapies: 3-Year Data From CASTING and LIBERTO 1-Year Interim Results	P627 (ePoster) *14 October, 6:00 – 6:05 PM CEST*
	Recently Diagnosed Early-stage RRMS: NEDA, ARR, Disability Progression, Serum Neurofilament and Safety: Full Cohort 1-Year Data From the Ocrelizumab Phase IIIb ENSEMBLE Study	P628 (ePoster)
	A Brain White Matter Atlas of Probabilistic Lesion Distribution in All Forms of Multiple Sclerosis	P411 (ePoster)
	Demographic Features and Clinical Course of Pediatric-onset MS Patients on Newer Used Disease-modifying Treatments	P654 (ePoster)
	COVID-19 Infections and Vaccinations in the Swiss Multiple Sclerosis Cohort Study	P783 (ePoster)
	Pregnancy and Infant Outcomes in Women Receiving Ocrelizumab for the Treatment of Multiple Sclerosis	P641 (ePoster)
	Rationale and Design of a Phase 4 Study Exploring B-cell Levels and Immune Responses in Infants Born to Women with MS Who Were	P655 (ePoster)

	Exposed to Ocrelizumab up to 6 Months Before or During the First Trimester of Pregnancy (the MINORE Study)	
	B-cell Levels and Immunity in Breastfed Infants of Women with MS Treated with Ocrelizumab: Design of a Phase 4 Study (SOPRANINO)	P686 (ePoster)
	Real World Experience with Ocrelizumab in Patients with Primary Progressive Multiple Sclerosis: Insights From the German NeuroTransData Registry	P117 (ePoster)
	CELLO: A Phase IV, Multicenter, Randomized, Double-blind, Placebo-controlled Study Assessing Efficacy of Ocrelizumab in Radiologically Isolated Syndrome	P702 (ePoster)
	Impact of the COVID-19 Pandemic on Healthcare Utilisation in US People Living with MS: An Analysis of the FlywheelMS Cohort	P830 (ePoster)
Floodlight for MS	A Patient-focused Qualitative Study to Support Content Validity of Digital Performance Assessments in MS	P309 (ePoster)
	Novel Smartphone Sensor-based Scores for Remote Measurement of Gait and Hand Function Impairment in People with MS	P306 (ePoster)
	A Digital Remote Monitoring Assessment for Measuring Impairment in Information Processing Speed in People with MS	P303 (ePoster)
	Establishing Consensus Definitions of Smartphone-based Digital Outcome Measurements in Multiple Sclerosis	P308 (ePoster)
	The Importance of Quality Checks for Digital Health Studies Using Remote Unsupervised Assessments to Study Functional Impairment in MS	P305 (ePoster)
Fenebrutinib for MS	Fenebrutinib Reduces Disease Activity in a Mouse Model of Inflammatory Multiple Sclerosis, Which is Associated with Reduced Microglial Activation	P680 (ePoster)
ENSPRYNG for NMOSD	Long-Term Safety of Satralizumab in NMOSD: Results From the Open-Label Extension Periods of SAkuraSky and SAkuraStar	P023 (ePoster)
	Long-term Efficacy of Satralizumab in Aquaporin-4-IgG-Seropositive NMOSD: Results From the Open-Label Extension Periods of SAkuraSky and SAkuraStar	P024 (ePoster)
	SAkuraBONSAI: A Prospective, Open-Label Study of Satralizumab Investigating Novel Imaging, Biomarker, and Clinical Outcomes in Patients with AQP4-IgG Seropositive NMOSD	P039 (ePoster)

	Exploring Steroid Tapering in NMOSD Patients Treated with Satralizumab in the Open-Label Extension Period of SAkuraSky: a Case Series	P038 (ePoster)
	Characterization of a Neuromyelitis Optica Mice Model Induced by AQP4 Peptide Immunization	P321 (ePoster)
	Novel Assessment of Disability vs Cognition and Pain in NMOSD: a CIRCLES Cohort Study	P031 (ePoster)
	Novel Disability Assessment of NMOSD Derived From the CIRCLES Experience	P030 (ePoster)
	Using Cognitive Interviews to Develop a Conceptual Claims-Based Algorithm to Identify Patients with NMOSD	P049 (ePoster)
	Comparing Healthcare Resource Utilization and Costs of Active and Inactive Periods in NMOSD	P041 (ePoster)
	Evaluating the Economic and Healthcare Resource Burden Posed by NMOSD	P045 (ePoster)
	Multinomial Modeling Reveals Insights Into Disability in NMOSD: A CIRCLES Cohort Analysis	P984 (ePoster)

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. The cytokine IL-6 is believed to be a key driver in NMOSD disease processes, triggering the inflammation cascade and leading to damage and disability. ENSPRYNG was designed using novel recycling antibody technology. When compared to conventional antibodies, ENSPRYNG's recycling antibody technology enables the medicine to remain in the bloodstream

for a longer period of time and bind repeatedly to its target (the IL-6 receptor) - maximally sustaining IL-6 suppression in a chronic disease like NMOSD and enabling subcutaneous dosing every four weeks. Positive Phase III results for ENSPRYNG, as both monotherapy and in combination with baseline immunosuppressive therapy, suggest that IL-6 inhibition is an effective therapeutic approach for NMOSD. The Phase III clinical development programme for ENSPRYNG includes two studies: SAkuraStar and SAkuraSky.

ENSPRYNG is currently approved in 58 countries, including the United States, Canada, Japan, South Korea and the European Union.

ENSPRYNG has been designated as an orphan drug in the United States, Europe, Japan and Russia. In addition, it was granted Breakthrough Therapy Designation for the treatment of NMOSD by the FDA in December 2018, which is given to treatments that may demonstrate substantial improvement over other available options.

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

Roche is investigating more than a dozen medicines for neurological disorders, including multiple sclerosis, Alzheimer's disease, Huntington's disease, Parkinson's disease, Duchenne muscular dystrophy and autism spectrum disorder. 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
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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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 twelfth 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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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.

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