Media & Investor Release

Roche to present data across broad and impactful neuroscience portfolio at 2022 AAN Annual Meeting

- **First data showing OCREVUS treatment effect on disability progression in non-active secondary progressive multiple sclerosis and further data in primary progressive MS will be presented**
- **Evrysdi data continue to demonstrate long-term efficacy and safety in a broad population of people with spinal muscular atrophy**
- **Longer-term efficacy and safety for Enspryng in neuromyelitis optica spectrum disorder reinforce previously seen results**
- **Additional data across neurological disorders, including Alzheimer's disease, help advance the scientific understanding of these conditions and the potential impact of early treatment**

Basel, 25 March 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced new data for its approved and investigational medicines across neurological disorders will be presented at the 74th American Academy of Neurology (AAN) Annual Meeting being held 02-07 April in Seattle and virtually 24-26 April 2022. These data include twenty-four abstracts highlighting Roche's expansive neuroscience portfolio across five therapeutic areas, including OCREVUS® (ocrelizumab) in relapsing, secondary and primary progressive multiple sclerosis (RMS, SPMS and PPMS), EVRYDSI™ (risdiplam) in spinal muscular atrophy (SMA), ENSPRYNG™ (satralizumab) in neuromyelitis optica spectrum disorder (NMOSD), along with data from investigational programs in Alzheimer's disease (AD) and Duchenne muscular dystrophy (DMD).

"The longer-term efficacy and safety data for OCREVUS, EVRYSDI and ENSPRYNG, as well as findings from diverse and underrepresented populations, demonstrate the significant impact of our expanding neuroscience portfolio," said Levi Garraway, M.D., Ph.D. Roche's Chief Medical Officer and Head of Global Product Development. "We remain committed to advancing the science and improving the lives of people living with neurological conditions."

Multiple Sclerosis

Roche will present 11 abstracts on MS and OCREVUS at AAN. New data from the one-year interim analysis of CONSONANCE, a first-of-its-kind open-label Phase III trial, will show the treatment effect of OCREVUS in the complete spectrum of progressive MS – SPMS and PPMS – with novel composite disability endpoints.

Additionally, an analysis of a U.S. claims database will highlight treatment disparities between Black and Hispanic/Latino-American patients and non-Hispanic white patients in the two years after diagnosis. Addressing health inequity and inclusion in research is central to

Roche's mission to improve patient health outcomes. The insights from the data presented at AAN reinforce the importance of Roche's CHIMES trial evaluating OCREVUS in Black and Hispanic patients with MS, which is now fully enrolled across sites in the U.S. and Kenya.

Spinal Muscular Atrophy

Roche will present encore data from the clinical development programme for EVRYSDI, including 3-year data from SUNFISH Part 1 and 2, highlighting the long-term efficacy and safety of EVRYSDI in people aged 2-25 years with Type 2 or Type 3 SMA. In addition, updated interim efficacy data from the RAINBOWFISH study in presymptomatic infants with SMA will be presented. The clinical development programme represents the broad real-world spectrum of people living with SMA from newborn babies to people aged 60 years old.

Roche will also share the design of the new MANATEE trial, a multi-centre, randomised, placebo-controlled, double-blind study studying GYM329, an investigational anti-myostatin, in combination with EVRYSDI.

Neuromyelitis Optica Spectrum Disorder

Roche will present encore long-term efficacy and safety data from the ENSPRYNG SAkuraSky and SAkuraStar studies. These data reinforce the previously observed efficacy and safety of ENSPRYNG, the first and only approved treatment designed to target and inhibit the IL-6 receptor activity, and that can be administered subcutaneously every four weeks at home after training from a healthcare provider.

To increase the scientific understanding of NMOSD and improve care for all people living with the condition, Roche has initiated SAkuraBONSAI, a multi-centre, Phase IIIb, international study evaluating ENSPRYNG treatment for people with AQP4-IgG seropositive NMOSD who are treatment naïve, or where prior rituximab (or biosimilar) treatment has failed*; SAkuraBONSAI will further evaluate disease activity and progression using comprehensive imaging, biomarker and clinical assessment.

Alzheimer's Disease

Roche will present updates from its AD clinical programme, including baseline characteristics of the Phase III GRADUATE studies in patients with early AD.

In addition, the design of the post-GRADUATE open label rollover study evaluating the long-term safety, tolerability and efficacy of gantenerumab in patients from the GRADUATE 1 and 2 studies will be presented.

*It is important to note, rituximab (or any biosimilar) is not approved by regulatory authorities for the treatment of NMOSD.

For more than two decades, Roche has been studying and developing gantenerumab, a late-stage investigational subcutaneously-administered monoclonal antibody, for the treatment of AD. Data from the pivotal GRADUATE trials are expected in the fourth quarter of 2022. Gantenerumab is also being evaluated in the Phase III SKYLINE prevention trial to better understand the potential of the investigational therapy to slow disease progression in people with the earliest biological signs of AD.

The full range of data from Roche's clinical development programme in neuroscience being presented at 2022 AAN include:

Medicine and/or Therapeutic Area	**Abstract Title**	**Presentation Number (type), Session Title** **Presentation Date + Time**
OCREVUS (ocrelizumab) for Multiple Sclerosis	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	P5: MS Clinical Trials and Therapeutics 1 Sunday, 3 April
	Long-Term Suppression of MRI Disease Activity and Reduction of Global/Regional Volume Loss: Results from Opera I/II and ORATORIO Open-Label Extension	P6: MS Clinical Trials and Therapeutics 2 Sunday, 3 April
	Repeated Confirmed Disability Progressions Analyses of the OPERA and ORATORIO Studies and their Open-Label Extensions	P7: MS Clinical Trials and Therapeutics 3 Monday, 4 April

	Evaluation of NEDA as a Predictor of Disease Progression in Patients with RMS and PPMS Treated with Ocrelizumab: Post-Hoc Analyses from the OPERA I/OPERA II and ORATORIO Trials	P16: MS Clinical Assessments and Outcome Measures Thursday, 7 April
	Demographics and Baseline Disease Characteristics of Black and Hispanic Patients with Multiple Sclerosis Enrolled in the CHIMES Trial	P4: MS Special Populations 1 Sunday, 3 April
	Treatment Patterns Among Newly Diagnosed Patients with Multiple Sclerosis by Race and Ethnicity	S40: MS Diversity and Epidemiology Thursday, 7 April
	A Multicentre, Open-Label, Single-Arm, Phase 3 Study (CONSONANCE) to Assess the Effectiveness and Safety of Ocrelizumab in Patients with Primary and Secondary Progressive Multiple Sclerosis: Year 1 Interim Analysis	Virtual Session 24-26 April
	A Multicenter, Open-Label, Single-Arm, Phase 3b Study (CONSONANCE) to Assess Efficacy of Ocrelizumab in Patients with Primary and Secondary Progressive Multiple Sclerosis: Year 1 Interim Analysis of Cognition Outcomes	Virtual Session 24-26 April

	Humoral and Cellular Responses to SARS-CoV-2 Vaccines in MS Patients on Ocrelizumab and other Disease-Modifying Therapies: A Prospective Study from NYU Multiple Sclerosis Care Center	Virtual Session 24-26 April
	Evaluating the Impact of Administration of Ocrelizumab via Home Infusion on Safety and Patient-Reported Outcomes	P16: MS Clinical Assessments and Outcome Measures, Thursday, 7 April
Gantenerumab for Alzheimer's Disease	Postgraduate Open-Label Rollover Study: Evaluation of Subcutaneous Gantenerumab Long-Term Safety, Tolerability, and Efficacy in Participants with Alzheimer's Disease	Session P6: Aging and Dementia: Clinical Trials 2 Sunday, 3 April
	Baseline Characteristics of the GRADUATE Studies: Phase III Randomized, Placebo-Controlled Studies Investigating Subcutaneous Gantenerumab in Participants with Early Alzheimer's Disease	Session P16: Aging And Dementia: Clinical Aspects 2 Thursday, 7 April

Alzheimer's Disease	Quantification of Cognitive Impairments in Preclinical and Early Alzheimer's Disease: A Proof of Concept Study to Investigate the Feasibility, Adherence and Preliminary Clinical Validity of Remote Smartphone Based Self-Assessments of Cognition, Function and Behavior	Session P14: Aging And Dementia: Neuropsychology and Remote Assessments 2 Wednesday, 6 April
EVRYSDI (risdiplam) for Spinal Muscular Atrophy	FIREFISH Parts 1 and 2: 24-month Efficacy and Safety of Risdiplam in Type1 SMA	S39: On-site Child and Developmental Neurology Thursday, 7 April
	SUNFISH: 3-year Efficacy and Safety of Risdiplam in Types 2 and 3 SMA	S39: On-site Child and Developmental Neurology Thursday, 7 April
	RAINBOWFISH: Preliminary Efficacy and Safety Data in Risdiplam-Treated Infants with Presymptomac SMA	P17: Child Neurology: SMA/DMD/Muscle 3 Thursday, 7 April
	JEWELFISH: Safety, Pharmacodynamic and Exploratory Efficacy Data in Non-Naïve Patients with Spinal Muscular Atrophy (SMA) Receiving Treatment with Risdiplam	P15: Poster session Monday, 4 April

	Pooled Safety Data from the Risdiplam Clinical Trial Development Program	P18: Child Neurology SMA/DMD/Muscle 3 Thursday, 7 April
	MANATEE: A Study of RO7204239 in Combination with Risdiplam Treatment in Pediatric Patients with SMA	P16: Poster Session Thursday, 7 April
ENSPRYNG (satralizumab) for Neuromyelitis Optica Spectrum Disorder	Long-Term Safety of Satralizumab in Neuromyelitis Optica Spectrum Disorder (NMOSD): Results from the Open-Label Extension Periods of SAkurasky and SAkurastar	Session S25: Autoimmune Neurology 2: Clinical Trials and Treatment (Presentation 010) Tuesday, 5 April
	Long-Term Efficacy of Satralizumab in Neuromyelitis Optica Spectrum Disorder: Results From The Open-Label Extension Periods of SAkurasky and SAkurastar	Session S25: Autoimmune Neurology 2: Clinical Trials and Treatment (Presentation 009) Tuesday, 5 April
	SAkurabonsai: A Prospective, Open-Label Study of Satralizumab Investigating Novel Imaging, Biomarker, and Clinical Outcomes in Patients with NMOSD	Session P15: Autoimmune Neurology: Neuromyelitis Optica Spectrum Disorder 2 Wednesday, 6 April
SRP-9001; Delandistrogenemoxeparvovec	Phase 1/2a Trial of SRP-9001 in Patients with Duchenne Muscular Dystrophy: 3-Year Safety and Functional Outcomes	S23: Therapeutics for Muscle Diseases Tuesday, 5 April

	A Phase 2 Clinical Trial Evaluating the Safety and Efficacy of SRP-9001 for Treating Patients with Duchenne Muscular Dystrophy	S23: Therapeutics for Muscle Diseases Tuesday, 5 April

About OCREVUS® (ocrelizumab)

OCREVUS is the first and only therapy approved for both RMS (including RRMS and active, or relapsing, SPMS and CIS in the U.S.) and PPMS, with six-month dosing. 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 EVRYSDI™ (risdiplam)

EVRYSDI is a survival of motor neuron 2 (SMN2) splicing modifier designed to treat SMA by increasing and sustaining the production of the survival motor neuron (SMN) protein in the central nervous system (CNS) and peripheral tissues. SMN protein is found throughout the body and is critical for maintaining healthy motor neurons and movement. EVRYSDI is administered daily at home in liquid form by mouth or by feeding tube.

The U.S. Food and Drug Administration (FDA) approved EVRYSDI for the treatment of SMA in adults and children 2 months of age and older. EVRYSDI was granted PRIME designation by the European Medicines Agency (EMA) in 2018 and Orphan Drug Designation by FDA and EMA in 2017 and 2019, respectively. At this time, EVRYSDI has been approved in 76 countries and submitted in a further 29 countries.

About ENSPRYNGTM (satralizumab)

ENSPRYNG, which was designed by Chugai, a member of the Roche Group, is a humanized 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, demonstrate that IL-6 inhibition is an effective therapeutic approach for patients with NMOSD who are AQP4-IgG seropositive. The Phase III clinical development program for ENSPRYNG includes two studies: SAkuraStar and SAkuraSky.

ENSPRYNG is currently approved in 63 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

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 recognizing 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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