Roche to present new data in multiple sclerosis and neuromyelitis optica spectrum disorder at MSVirtual2020

- **New data further reinforce OCREVUS (ocrelizumab) as a highly effective treatment option offering a favourable and consistent benefit:risk profile, with high treatment persistence and adherence**
- **Initiation of Phase IIIb OCREVUS higher dose clinical trial programme and Phase IV study evaluating OCREVUS in minority populations**
- **Initiation of Phase III clinical trial programme for fenebrutinib, an investigational medicine designed to be a highly selective and reversible Bruton's tyrosine kinase (BTK) inhibitor, which may offer novel approach to suppress disease activity and slow disease progression in MS**
- **New Phase III data from SAkuraStar and SAkuraSky studies demonstrate reduced severity of relapses with ENSPRYNG (satralizumab), recently FDA-approved as the first and only subcutaneous treatment for adults living with anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD)**

Basel, 3 September 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new multiple sclerosis (MS) and neuromyelitis optica spectrum disorder (NMOSD) data will be presented at MSVirtual2020, the 8th Joint Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) - European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Meeting from 11-13 September 2020.

"While conditions of the nervous system are some of the most complex to understand and treat, we are committed to following the science to reduce relapses in NMOSD and slow and eventually stop disease progression in MS," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "From the success of our first-in-class B-cell MS therapy OCREVUS, we are poised to continue advancing the science in MS with our new investigational BTK inhibitor fenebrutinib, and in NMOSD with the recent FDA approval of ENSPRYNG."

Multiple Sclerosis (MS)
New analyses from the two-year open-label Phase IIIb CASTING study will show patients with relapsing-remitting MS (RRMS) who experienced a prior suboptimal response to one or more disease-modifying therapies (DMTs) achieved a high rate of no evidence of disease activity (NEDA) after switching to OCREVUS. Other data to be presented will show high treatment persistence and strong adherence for patients treated with OCREVUS compared to other DMTs in real-world settings. Additionally, new longer-term safety data will reinforce the consistently favourable benefit:risk profile of OCREVUS.

We are exploring potential optimisation of OCREVUS, our first-in-class B-cell therapy, in a large Phase IIIb clinical trial programme to evaluate the impact of higher dose OCREVUS on reducing disability progression in relapsing MS (RMS) and primary progressive MS (PPMS). This decision was based on analyses from the

pivotal RMS and PPMS studies presented at the American Academy of Neurology Annual Meeting 2019, which showed higher OCREVUS exposure was associated with lower B-cell levels and with greater control of disability progression, without impacting safety.

Roche is also deeply committed to addressing barriers to clinical trial participation and advancing inclusive research. The study design of the recently initiated CHIMES (CHaracterisation of ocrelizumab In Minorities with multiplE Sclerosis) trial, an open-label, multi-centre Phase IV study evaluating disease activity and neurological biomarkers in African-American and Hispanic- and Latinx-American people with RMS treated with OCREVUS, will be presented.

Roche's commitment to potentially slow or stop disease progression continues with the Phase III clinical trial programme initiation of fenebrutinib, an investigational Bruton's tyrosine kinase (BTK) inhibitor in RMS and PPMS. Fenebrutinib is designed to be a highly selective small molecule and is the only reversible (non-covalent) BTK inhibitor currently in Phase III development in MS.

Neuromyelitis Optica Spectrum Disorder (NMOSD)
New data show ENSPRYNG lowered relapse severity in people with NMOSD in double-blind periods of SAkura Phase III studies. Pooled data from SAkura open-label extension (OLE) studies also showed ENSPRYNG significantly reduced risk of relapse, further reinforcing the findings from the double-blind period. Preventing relapses, the most severe of which cause cumulative, irreversible neurological damage and disability, is the primary goal for NMOSD disease management.

On 14 August, ENSPRYNG was approved by the US Food and Drug Administration (FDA) as the first and only subcutaneous treatment for adults living with anti-aquaporin-4 (AQP4) antibody positive NMOSD, a rare disabling neurological disorder often mistaken for MS. ENSPRYNG can be self-administered every four weeks by a person living with NMOSD or a caregiver, after an initial loading dose and following training by a healthcare provider.

Until recently, people living with NMOSD did not have medicines specifically tested and designed to treat the condition. Many people with NMOSD remain misdiagnosed and untreated.

New data from the double-blind and OLE trials continue to build on one of the largest pivotal clinical trial programmes undertaken for this rare neurological disease, further demonstrating ENSPRYNG's sustained efficacy and favourable safety profile in adults with NMOSD.

Follow Roche on Twitter via @Roche and keep up to date with MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS Meeting news and updates by using the hashtag #MSVIRTUAL2020.

A full list of Roche presentations can be found at:
https://cslide.ctimeetingtech.com/msdc2020/attendee/confcal/session

Presentations at MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS Meeting include:

Medicine	Abstract Title	Presentation Number (type) Presentation Date Time
OCREVUS (ocrelizumab) for Multiple Sclerosis	Safety of Ocrelizumab in Multiple Sclerosis: Updated Analysis in Patients with Relapsing and Primary Progressive Multiple Sclerosis	#P0389 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Rationale and Design of Two Phase IIIb Studies of Ocrelizumab at Higher Than the Approved Dose in Patients with RMS and with PPMS	#P0230 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Ocrelizumab Phase IIIb Efficacy from CASTING: 2-Year NEDA (MRI Re-baselined) Subgroup Rates in RRMS Patients with a Suboptimal Response to Prior DMTs	#P0219 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Improvements in Patient-reported SymptoMScreen Scores Among Ocrelizumab-treated Patients with RRMS: 2-year Results from the CASTING Clinical Trial	#P1039 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Ocrelizumab Treatment in Patients with RRMS Who Had a Suboptimal Response on One or More Prior Disease-modifying Therapies: CHORDS 2-year Results	#P0221 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Ocrelizumab Phase IIIb Efficacy: 1-year NEDA Rates (with MRI Re-baselining) from the ENSEMBLE Study in Early-stage Relapsing-remitting MS Patients	#P0220 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Change in Serum Neurofilament Light Chain Levels: ENSEMBLE 1-year Interim Results	#P0037 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET

	Shorter Infusion Time of Ocrelizumab: Results from the ENSEMBLE PLUS Study in Patients with Relapsing-remitting Multiple Sclerosis	#P0392 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	FlywheelMS: The Prevalence of Multiple Sclerosis Subtypes in Digitized Health Records	#P0875 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Treating Minority Patients with Multiple Sclerosis: Development of the CHIMES Trial	#P0242 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Characteristics and Patient Reported Outcomes of Patients Initiating Ocrelizumab in the NARCOMS Registry from 2017 to 2019	#P1009 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Ocrelizumab Treatment Induces a Sustained Blood NfL Reduction in Patients with PPMS and RMS	#P0125 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Modulation of Cerebrospinal Fluid Immunoglobulins by Ocrelizumab Treatment	#P0110 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Long-term Reduction of Relapse Rate and 48-week Confirmed Disability Progression After 6.5 Years of Ocrelizumab Treatment in Patients with RMS	#P0216 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Sustained Reduction in 48-week Confirmed Disability Progression in Patients with Ocrelizumab in the ORATORIO OLE: 7-year Follow-up	#P0237 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET

	Ocrelizumab Reduces Thalamic Volume Loss and Clinical Progression in PPMS and RMS Independent of Baseline NfL and Other Measures of Disease Severity	#P0123 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Treatment Persistence and Adherence to Ocrelizumab in the Real-world Setting- an Ad-hoc Analysis of the CONFIDENCE Study	#P1063 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Persistence and Adherence to Ocrelizumab Compared with Other Disease-modifying Therapies for Multiple Sclerosis for up to 18 Months in the US	#P0897 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Characteristics of Patients Initiating Ocrelizumab vs Other Disease-modifying Therapies in a US National Multiple Sclerosis Registry	#P0845 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Collecting Real-world MRI Data in Patients with MS: Preliminary Results from FlywheelMS	#P0856 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Pregnancy Outcomes in Patients Treated with Ocrelizumab	#P1132 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Reduced Thalamic Atrophy in Patients Initiating Earlier versus Delayed Ocrelizumab Therapy: Results from the OLE of OPERA I/II and ORATORIO	#FC03.05 (oral presentation) Sunday, 13 September 7:48 – 8:00 PM CEST / 1:48 – 2:00 PM ET
Fenebrutinib for Multiple Sclerosis	Examination of Fenebrutinib, a Highly Selective BTKi, on Disease Progression of Multiple Sclerosis	#P0211 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Fenebrutinib, a Noncovalent, Highly Selective, Long Residence Time Investigational BTK Inhibitor for the Treatment of MS	#P0338 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET

ENSPRYNG (satralizumab-mwge) for Neuromyelitis Optica Spectrum Disorder	Satralizumab in First Incident Treatment-Naive AQP4-IgG Seropostive NMOSD Patients enrolled to SAkuraStar: A Case Series	#P0754 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Safety of Satralizumab Based on Pooled Data from Phase 3 Studies in Patients with Neuromyelitis Optica Spectrum Disorder	#P0753 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Infection Rates with Satralizumab in Patients with Neuromyelitis Optica Spectrum Disorder (NMOSD): Results from the Phase 3 SAkura Studies	#P0721 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Efficacy of Satralizumab in Neuromyelitis Optica Spectrum Disorder (NMOSD): Results from Open-Label Extension Periods of SAkuraSky and SAkuraStar	#P0711 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Estimating the Cost of Illness for Patients with Neuromyelitis Optica Spectrum Disorder from US Commercial Claims	#P0712 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Psychometric Validation of the Expanded Disability Status Scale in Neuromyelitis Optica Spectrum Disorder	#P1046 (on-demand e-poster) Friday, 11 September 2:00 PM CEST / 8:00 AM ET
	Autoimmune Comorbidity Increases Healthcare Cost Burden in Patients with NMOSD in the United States: A Retrospective Commercial Claims Analysis	#P0689 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Cost of Illness for Patients with NMOSD and Nonautoimmune Disease Estimated from Claims Databases in the United States	#P0705 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Burden of Autoimmune Comorbidity in Patients with NMOSD in the United States Revealed by Retrospective Commercial Claims Analysis	#P0694 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET

	Treatment Patterns in Patients with Neuromyelitis Optica Spectrum Disorder	#P0759 (on-demand e-poster) Friday, 11 September 2:20 PM CEST / 8:20 AM ET
	Effect of Satralizumab on Relapse Severity in Neuromyelitis Optica Spectrum Disorder (NMOSD): Results from the Phase III SAkura Studies	#FC01.03 (oral presentation) Sunday, 13 September 7:24 – 7:36 PM CEST / 1:24 - 1:36 PM ET

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 US) 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 IL-6 receptor activity. The cytokine IL-6 is believed to be a key driver in NMOSD, triggering the inflammation cascade and leading to damage and disability. 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 used concurrently with baseline immunosuppressant 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 approved in the US, Canada, Japan and Switzerland. Applications are under review with numerous regulators, including in the EU and China.

ENSPRYNG has been designated as an orphan drug in the US, Europe and Japan. In addition, it was granted Breakthrough Therapy Designation for the treatment of NMOSD by the FDA in December 2018.

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, neuromyelitis optica spectrum disorder, Alzheimer's disease, Huntington's disease, Parkinson's disease, Duchenne's 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 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. 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 eleventh 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Dr. Daniel Grotzky
Phone: +41 61 688 31 10

Nina Mählitz

Patrick Barth
Phone: +41 61 688 44 86

Karsten Kleine
Phone: +41 61 682 28 31

Nathalie Meetz

Phone: +41 79 327 54 74

Phone: +41 61 687 43 05

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com

Dr. Lisa Tuomi
Phone: +1 650 467 8737
e-mail: tuomi.lisa@gene.com