Roche's ENSPRYNG approved by European Commission as first and only at-home subcutaneous treatment for neuromyelitis optica spectrum disorder (NMOSD)

- **ENSPRYNG is the first and only treatment approved for both adults and adolescents in the EU with AQP4-IgG seropositive NMOSD**
- **ENSPRYNG can be used as a monotherapy or in combination with immunosuppressive therapy to reduce relapses and prevent permanent disability**
- **In Phase III studies, ENSPRYNG significantly reduced the number and severity of relapses in people with AQP4-IgG seropositive NMOSD**

Basel, 28 June 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission (EC) has approved ENSPRYNG® (satralizumab) for the treatment of adults and adolescents from 12 years of age living with anti-aquaporin-4 antibody (AQP4-IgG) seropositive neuromyelitis optica spectrum disorder (NMOSD), as a monotherapy or in combination with immunosuppressive therapy (IST). ENSPRYNG is the first and only NMOSD treatment that is administered subcutaneously every four weeks, allowing home-dosing after appropriate training.

"An NMOSD relapse can be devastating, causing permanent neurological damage and disability that accumulates with subsequent relapses, which is why our goal is to prevent them," said Prof. Dr. Friedemann Paul, Professor of Clinical Neuroimmunology, Charité Universitätsmedizin Berlin. "With the approval of ENSPRYNG, we now have a treatment option with a favourable safety profile that significantly reduces relapses in AQP4-IgG seropositive adults and adolescents after their first NMOSD attack or in more advanced disease, either as a monotherapy or in combination with IST. Importantly, people with NMOSD now have the flexibility to administer treatment at home, which may alleviate the need to travel for hospital appointments."

The EC approval is supported by results from two Phase III studies, in which ENSPRYNG showed robust and sustained efficacy in reducing the risk of relapse in people with AQP4-IgG seropositive NMOSD. AQP4-IgG are present in around 70-80% of people with NMOSD, who tend to experience a more severe disease course compared to those not expressing AQP4-IgG antibodies.

"We thank the NMOSD community for their partnership and are delighted that ENSPRYNG will be available to people in the EU who until now had limited, accessible treatment options," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "Building on our growing scientific understanding of neuroimmunological conditions, we are confident ENSPRYNG can transform how people with NMOSD are treated by fitting into their day-to-day lives."

ENSPRYNG is the first and only approved medicine for NMOSD in the EU designed to bind to and block the interleukin-6 (IL-6) receptor, a central driver of the inflammation associated with NMOSD. The treatment

was designed by Chugai, a member of the Roche Group, 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.

Roche is working closely with reimbursement and health technology assessment bodies in EU member states to provide access to ENSPRYNG for people who may benefit from this treatment option as soon as possible.

About SAkuraStar and SAkuraSky in NMOSD
ENSPRYNG has been investigated in two pivotal Phase III studies in neuromyelitis optica spectrum disorder (NMOSD), with the primary endpoint of both studies being time to first protocol-defined relapse (PDR) adjudicated by an independent review committee in the double-blind period.

The Phase III SAkuraStar study evaluated the efficacy and safety of ENSPRYNG monotherapy administered to adults with NMOSD. In the anti-aquaporin-4 antibody (AQP4-IgG) seropositive subgroup, 83% treated with ENSPRYNG remained relapse free at 48 weeks, compared with 55% of those treated with placebo. At 96 weeks, 77% of those treated with ENSPRYNG remained relapse free, compared with 41% with placebo.

The Phase III SAkuraSky study evaluated the efficacy and safety of ENSPRYNG in combination with baseline immunosuppressive therapy in adults and adolescents with NMOSD. Overall, 92% of AQP4-IgG seropositive participants receiving ENSPRYNG in combination with IST remained relapse free at 48 and 96 weeks, compared with 60% and 53% with placebo, respectively.

ENSPRYNG showed a favourable safety and tolerability profile in the Phase III studies. The most common adverse reactions observed in the safety population were: headache, arthralgia, white blood cell count decrease, hyperlipidaemia and injection-related reactions.

About neuromyelitis optica spectrum disorder (NMOSD)
NMOSD is a rare, lifelong and debilitating autoimmune condition of the central nervous system that primarily damages the optic nerve(s) and spinal cord, causing permanent blindness, muscle weakness and paralysis. People with NMOSD experience unpredictable, severe relapses directly causing cumulative, permanent, neurological damage and disability. In some cases, relapse can result in death. NMOSD affects over 10,000 people in Europe, up to 15,000 people in the US and approximately 200,000 people worldwide. NMOSD can affect individuals of any age, race and gender, but is most common among women in their 30s and 40s, and appears to occur at higher rates in people of African or Asian background.

NMOSD is commonly associated with pathogenic antibodies (AQP4-IgG) that target and damage a specific cell type, called astrocytes, resulting in inflammatory lesions of the optic nerve(s), spinal cord and brain. AQP4-IgG antibodies are detectable in the blood serum of around 70-80% of people with NMOSD.

Although most cases of NMOSD can be confirmed through diagnostic tests, people living with the condition are still frequently misdiagnosed with multiple sclerosis. This is due to overlapping characteristics of the two disorders, including a higher prevalence in women, similar symptoms and the fact that people can experience relapses in both conditions.

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 included two studies: SAkuraStar and SAkuraSky.

ENSPRYNG is currently approved in 54 countries, including the United States, Canada, Japan, China and EMA territory countries.

ENSPRYNG has been designated as an orphan drug in the U.S., Europe and Japan. 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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