

Ad hoc announcement pursuant to Art. 53 LR

Roche's anti-amyloid beta antibody gantenerumab granted FDA Breakthrough Therapy Designation in Alzheimer's disease

- **Gantenerumab is an investigational antibody in Phase III development for early Alzheimer's disease (AD)**
- **Gantenerumab is the first and only anti-amyloid antibody being investigated for subcutaneous administration in late-stage trials for the treatment of AD**
- **Ongoing Phase III GRADUATE programme with gantenerumab is anticipated to deliver a comprehensive data set with expected readout in the second half of 2022**

Basel, 8 October 2021 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that gantenerumab, an anti-amyloid beta antibody developed for subcutaneous administration, has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of people living with Alzheimer's disease (AD). This designation is based on data showing that gantenerumab significantly reduced brain amyloid plaque, a pathological hallmark of AD, in the ongoing SCarlet RoAD and Marguerite RoAD open-label extension trials, as well as other studies. Learnings from these studies have been incorporated into the optimised design of two ongoing parallel, global, placebo-controlled and randomised Phase III trials, GRADUATE 1 and 2. The pivotal trials are evaluating gantenerumab in more than 2,000 participants for more than two years and are expected to be completed in the second half of 2022.

“For more than a decade, we've been committed to advancing the science of Alzheimer's as well as our investigational medicine gantenerumab, and we look forward to delivering a comprehensive and robust data set that furthers our collective understanding of this devastating disease,” said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. “This Breakthrough Therapy Designation reinforces our confidence in gantenerumab, which would be the first subcutaneous medicine for the treatment of Alzheimer's disease with the potential for at-home administration.”

Breakthrough Therapy Designation is designed to accelerate the development and review of medicines intended to treat serious or life-threatening conditions with preliminary evidence that indicates they may demonstrate a substantial improvement over available therapies that have received full FDA approval. This designation for gantenerumab marks the 39th Breakthrough Therapy Designation for Roche's portfolio of medicines.

AD is a progressive, fatal disease of the brain characterised by a decline in memory, language and other thinking skills, as well as changes in mood and behavior. Biological changes in the brain are believed to start decades before clinical symptoms of AD become evident. Alzheimer's is the most common form of dementia, which currently affects more than 55 million people worldwide, and is projected to reach 78 million by 2030.

An enormous and growing public health challenge, it is predicted to cost the global economy a cumulative \$20 trillion over the next decade, or US \$2.8 trillion per year by 2030. Approximately 10 million people globally are diagnosed with AD each year. Given the medical and societal complexities of AD, several tools and treatment options will likely be required to meet the multiple and diverse needs of people living with the disease.

Roche and Genentech are continuing to explore multiple approaches and molecules that may address key pathways of AD, including beta amyloid and tau, as well as innovative tools designed to more effectively diagnose AD and support clinicians in monitoring disease progression.

About gantenerumab and its clinical program

Gantenerumab is an investigational IgG1 antibody designed to bind to aggregated forms of beta-amyloid and remove brain amyloid plaques, a pathological hallmark of Alzheimer's disease (AD). Gantenerumab significantly lowered amyloid plaque in patients with sporadic AD in the SCarlet RoAD and Marguerite RoAD open-label extension studies, and with dominantly inherited AD in the DIAN-TU-001 study. Learnings from these studies have been incorporated into the optimised design of two ongoing parallel, global, placebo-controlled and randomised Phase III trials, GRADUATE 1 and 2.

The pivotal GRADUATE trials are investigating the effect of gantenerumab on amyloid load and downstream biomarkers of disease progression as well as the safety and efficacy of gantenerumab in people with early (prodromal-to-mild) AD. The studies include more than 2,000 patients treated for more than two years in up to 350 study centers in more than 30 countries worldwide. It is evaluating a monthly target dose of 1,020 mg with an optimised titration, aimed at maximizing exposure and minimising dose interruption throughout the study period for better detection of a potential clinical benefit. Both trials are expected to be completed in the second half of 2022.

Other studies evaluating gantenerumab in AD include:

- Open RoAD, a rollover open-label study for the former SCarlet RoAD and Marguerite RoAD OLEs to continue to evaluate the safety and tolerability of long-term administration of gantenerumab in participants with AD.
- GRADUATION, an open-label study to evaluate the pharmacodynamic (PD) effects of once weekly administration of gantenerumab in participants with early AD. The study design is similar to the GRADUATE studies and includes the option of home administration by a caregiver.
- An exploratory OLE of DIAN-TU-001, aiming to build on learnings from DIAN-TU-001 and further investigating the relationship of biomarker changes with cognitive and clinical findings in people with autosomal dominant AD (ADAD).

About Roche in Alzheimer's disease

For decades, advocacy groups, academia, industry and the broader healthcare community have collectively progressed our understanding of Alzheimer's disease (AD) – with the hope that every step would help lead to advancements in treating this devastating disease. Given the complexity of Alzheimer's on a disease and societal level, we anticipate the need for several treatment options to meet the multiple and diverse needs of all people living with Alzheimer's and their caregivers. As both a pharmaceutical and diagnostics company, we're in the unique position to contribute to this progress through our ongoing research and studies of investigational medicines for different targets, types and stages of Alzheimer's and delivering tests to detect, diagnose and monitor the disease. We are hopeful that our ongoing research will lead to scientific progress that could impact millions of people. We are also working in over 70 partnerships with organizations from across the healthcare sector to accelerate progress and improve care for people with AD.

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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