

Basel, 19 December 2014

Roche provides update on gantenerumab development programme

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the decision to discontinue SCarlet RoAD (WN25203), a phase III study of investigational anti-amyloid medicine gantenerumab in prodromal (pre-dementia) Alzheimer's disease, based on results of a pre-planned futility analysis and recommendation by the independent Data Monitoring Committee. No new safety signals for gantenerumab were observed in this analysis and the overall safety profile was similar to that seen in the phase I trial (NN19866).

Data from the SCarlet RoAD study will be shared with the medical community after full review and analysis. Findings from the trial will inform future research programmes, approaches and clinical trial design.

"We are disappointed with these study results because people with early stage Alzheimer's need new medicines that delay disease progression," said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development at Roche. "This is the first Phase III trial to evaluate a potential disease-modifying medicine in this early prodromal stage of Alzheimer's disease. We remain committed to investigating new medicines for this devastating illness."

Alzheimer's disease is a major focus of Roche neuroscience research and development. The company has a broad research programme that focuses on several pathways believed to play important roles in Alzheimer's disease. Its researchers are developing and investigating medicines designed to target these pathways in multiple ways and across different stages of the disease. Gantenerumab continues to be evaluated in the phase III Marguerite RoAD study (WN28745) in a later stage of Alzheimer's disease (mild dementia due to Alzheimer's). In addition, Roche has two investigational medicines for the disease in phase II development (crenezumab, an anti-amyloid antibody, and RG1577, a monoamine oxidase-B inhibitor).

About Alzheimer's disease

Alzheimer's disease is a progressive, fatal disease of the brain that gradually destroys memory and thinking skills and impairs basic daily functions such as the ability to manage one's own activities. Biological changes

are believed to start many years before clinical symptoms of Alzheimer's disease become evident. In the early stages (prodromal), people may have difficulty remembering things, but there are no signs of dementia. However, in the later stage of the disease people are often unable to communicate and increasingly become reliant on others for even simple day-to-day tasks. For people 65 and older, the disease typically progresses for four to eight years after diagnosis and eventually leads to death.ⁱ Dementia affects 44 million people worldwide with 7.7 million new cases each year, of which Alzheimer's disease is the most common form.ⁱⁱ There is no cure for Alzheimer's disease. Current treatments focus on alleviating symptoms and are unable to stop Alzheimer's from progressing because they do not affect the disease's underlying cause.ⁱⁱⁱ

About gantenerumab

Gantenerumab (RG1450) is an investigational, fully human, monoclonal antibody designed to decrease levels of beta amyloid, a protein that accumulates in the brains of people with Alzheimer's disease and is hypothesised to play a central role in disease development and progression.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 billion Swiss francs. 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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