Roche to present new data demonstrating the breadth and depth of its Alzheimer’s programme at the upcoming Alzheimer’s Association International Conference

- Late-breaking Phase II exploratory analysis of investigational crenezumab to show impact on amyloid beta oligomer levels in CSF
- Two year open-label extension updates for investigational gantenerumab will include data on effects of higher doses in reducing amyloid PET load and long-term safety

Basel, 20 July 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it will present 16 new data presentations from across its Alzheimer’s disease (AD) pipeline at this year’s Alzheimer’s Association International Conference (AAIC) from 22-26 July in Chicago, Illinois. Roche’s AD pipeline includes two late-stage investigational molecules, crenezumab and gantenerumab, which are both in Phase III clinical trials, and an anti-tau molecule in Phase II.

“The range of data that Roche is presenting at AAIC is a testament to our commitment to bring new treatments to help the many millions of people living with Alzheimer’s disease,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development.

In a late-breaking session, an exploratory analysis is being presented on crenezumab from the completed phase II BLAZE and ABBY clinical trials that will show the impact of crenezumab treatment over the whole trial duration on amyloid beta oligomer levels in cerebrospinal fluid (CSF) in people with mild to moderate AD. Baseline data from the CREAD 1 study in prodromal to mild AD will also be presented. Crenezumab is an investigational, monoclonal antibody designed to preferentially bind to and promote removal of oligomers, a form of amyloid beta.

Additionally, updates from open-label extension studies of gantenerumab, including data on the effects of higher doses of gantenerumab in reducing amyloid PET load at 24-months, as well as long-term safety data, will be presented. Data on the effects of low doses of gantenerumab on amyloid and tau biomarkers in cerebrospinal fluid will also be presented. Gantenerumab is an investigational, monoclonal antibody designed to bind to aggregated β-Amyloid and remove amyloid beta plaques. Two recently initiated Phase III GRADUATE clinical studies are evaluating the safety and efficacy of gantenerumab for the treatment of early AD.

The full range of data from Roche’s Alzheimer’s clinical development program, including investigational medicines and diagnostics, being presented at AAIC include:
<table>
<thead>
<tr>
<th>Investigational Medicine</th>
<th>Abstract Title</th>
<th>Abstract Number (type), Presentation Date, Time</th>
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<tbody>
<tr>
<td><strong>Crenezumab</strong></td>
<td>LATE BREAKER: Target Engagement in an AD Trial: Crenezumab Lowers Aβ Oligomer Levels in CSF</td>
<td><em>Selkoe D (oral)</em>&lt;br&gt;Session: DT-02-03 Developing Topics: Recent Developments in Biomarkers, Wednesday, July 25, 2018: 4:45-5:00 PM</td>
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<td></td>
<td>Baseline characteristics from a phase 3 trial of crenezumab in prodromal to mild Alzheimer’s disease (CREAD) Lin H, et al.</td>
<td><em>Lin H (oral)</em>&lt;br&gt;Session: 01-02 Clinical Prevention and Early Alzheimer’s Disease Trials, Sunday, July 22, 2018: 8:45 AM - 9:00 AM</td>
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<td><strong>Gantenerumab</strong></td>
<td>The Effect of Low Doses of Gantenerumab on Amyloid and Tau Biomarkers in Cerebrospinal Fluid (CSF) in the Marguerite Road Study</td>
<td><em>Voyle N (oral)</em>&lt;br&gt;Session: O1-09 Clinical: Clinical Investigations in Symptomatic AD Using Abeta Targeted Therapeutics, Sunday, July 22, 2018: 2:15 - 2:30 PM</td>
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<td>24-Month Amyloid PET Results of the Gantenerumab High-Dose Open Label Extension Studies</td>
<td><em>Klein G (oral)</em>&lt;br&gt;Session: O1-09 Clinical: Clinical Investigations in Symptomatic AD Using Abeta Targeted Therapeutics, Sunday, July 22, 2018: 2:30 – 2:45 PM</td>
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<td>Update on the Safety and Tolerability of Gantenerumab in the Ongoing Open-Label Extension (OLE) of the Marguerite Road Study in Patients with Mild Alzheimer’s Disease (AD) after Approximately Two Years of Study Duration</td>
<td><em>Abi-Saab D (oral)</em>&lt;br&gt;Session: O1-09 Clinical: Clinical Investigations in Symptomatic AD Using Abeta Targeted Therapeutics, Sunday, July 22, 2018: 2:45 – 3:00 PM</td>
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<td>Update on the Safety and Tolerability of Gantenerumab in the Ongoing Open-Label Extension of the Scarlet Road Study in Patients with Prodomal Alzheimer’s Disease after Approximately 2 Years of Study Duration</td>
<td><em>Andjelkovic M (oral)</em>&lt;br&gt;Session: O1-09 Clinical: Clinical Investigations in Symptomatic AD Using A-Beta Targeted Therapeutics, Sunday, July 22, 2018: 3:00 – 3:15 PM</td>
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<td>CSF Biomarkers</td>
<td>LATE BREAKER: Detecting brain amyloid status using fully automated plasma Aβ biomarker assays</td>
<td>Hansson O (oral) Session: DT-02-04 Developing Topics: Recent Developments in Biomarkers, Wednesday, July 25, 2018: 5:00-5:15 PM</td>
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<td>Analysis of cerebrospinal fluid (CSF) biomarkers to predict risk of clinical decline and progression to dementia in patients with mild cognitive impairment and mild cognitive symptoms</td>
<td>Shaw LM (poster) Session: P3-06 Diagnosis and Prognosis: Biomarkers (non-neuroimaging) Tuesday, July 24, 2018: 9:30 AM - 4:15 PM, McCormick Place, Hall F1</td>
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<td>Multicenter evaluation of the analytical characteristics of the Elecsys® Total-Tau cerebrospinal fluid (CSF) and Elecsys® Phospho-Tau (181P) CSF immunoassays</td>
<td>Kollmorgen G (poster) Session: P1-07 Diagnosis and Prognosis: Biomarkers (non-neuroimaging) Sunday, July 22, 2018: 9:30 AM - 4:15 PM, McCormick Place, Hall F1</td>
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<td>Technical validation and multicenter evaluation of the Elecsys® β-Amyloid 1-40 prototype immunoassay for quantitation in cerebrospinal fluid (CSF)</td>
<td>Wiegers AK (poster) Session: P1-07 Diagnosis and Prognosis: Biomarkers (non-neuroimaging) Sunday, July 22, 2018: 9:30 AM - 4:15 PM, McCormick Place, Hall F1</td>
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<td>A Unified Pre-Analytical Protocol for Handling of CSF Samples before Analyses of AD Biomarker Levels</td>
<td>Hansson O (oral) Session: O2-09 Biomarkers: Methods and Quality, Monday, July 23, 2018: 2:00 PM - 3:30 PM</td>
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<td>CSF biomarkers in the general population: associations with demographics and APOE genotype</td>
<td>Van Harten AC (oral) 02-04 Biomarkers: Longitudinal Changes: Monday, July 23, 2018: 9:00 AM - 9:15 AM,</td>
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<td>Diagnostic performance of Elecsys® immunoassays for cerebrospinal fluid Alzheimer’s disease biomarkers in a non-academic multicentre memory clinic cohort: the ABIDE project</td>
<td>Willemse E (oral) Session: O2-09 Biomarkers: Methods and Quality, Monday, July 23, 2018: 2:00 PM - 3:30 PM</td>
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PET Tau Tracers

**Abstract Title**: Tau Burden Measured Using [18F]GTP1 Correlates with CSF Tau Phosphorylation at Sites T217 and T205 More Closely Than T181

**Abstract Number (type), Presentation Date, Time**: Wildsmith K (oral)
Session: O3-14 Biomarkers: Novel Biomarkers in Cerebrospinal Fluid (CSF), Tuesday, July 24, 2018: 4:30 PM - 4:45 PM

**Abstract Title**: Baseline Tau Burden Measured By [18f]GTP1 Imaging Is Associated with Subsequent Cognitive Decline in Prodromal to Mild Alzheimer’s Disease

**Abstract Number (type), Presentation Date, Time**: Teng E (poster)
Session: P4-17 Developing Topics, Wednesday, July 25, 2018: 9:30 AM - 4:15 PM, McCormick Place, Hall F1

Non-molecule

**Abstract Title**: P# 25259 Estimand in Early Alzheimer’s Disease: Progress Update from the International Alzheimer’s Disease Scientific Working Group (AD SWG) Substream.

**Abstract Number (type), Presentation Date, Time**: Delmar P (poster)
Session: P4-01 [Posters Wed] Therapeutics: Clinical, Wednesday, July 25, 2018: 9:30 AM - 4:15 PM, Hall F1

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**About crenezumab**

Crenezumab is an investigational, monoclonal antibody designed to preferentially bind to and promote removal of neurotoxic oligomers, a form of amyloid beta. Crenezumab has an antibody backbone (IgG4) designed to minimize the inflammatory response in the brain, which may result in a lower risk of MRI abnormalities. It is currently being studied in two phase III, two-year, randomized, double-blind, placebo-controlled, multicenter clinical trials (CREAD 1 and 2) in early AD. Based on the learnings from two completed phase II trials, the CREAD studies are using higher doses of crenezumab and have enrolled people with early AD who have confirmed AD pathology. These studies are now fully enrolled. Crenezumab is also being studied in a landmark Alzheimer’s Prevention Initiative (API) trial of cognitively healthy individuals in Colombia with an autosomal dominant mutation who are at risk to develop early-onset AD. Crenezumab is being developed by Roche and Genentech and was discovered by Swiss biotechnology company AC Immune SA.

**About gantenerumab**

Gantenerumab is an investigational, monoclonal antibody designed to bind to aggregated amyloid beta and remove amyloid beta plaques. It is being investigated in two phase III studies (GRADUATE 1 and 2) for the treatment of early AD. In completed phase III clinical studies, gantenerumab removed beta amyloid plaques, which have been shown to be toxic to the brain. Ongoing open-label extension studies have informed the design of the GRADUATE program. The new studies, which are enrolling people with early AD with confirmed AD brain pathology, include higher doses of gantenerumab. The target dose is achieved through a titration regimen to optimize safety.
Gantenerumab is also being studied as part of the DIAN-TU trial, a worldwide clinical study evaluating multiple compounds in individuals at risk for or with a type of early-onset AD caused by a genetic mutation. Gantenerumab is being developed by Roche and Genentech and was identified and optimized by phage display technology in cooperation with MorphoSys AG, a Munich-based Biotech.

About Alzheimer’s disease
Alzheimer’s disease is a progressive, fatal disease of the brain that gradually destroys memory, thinking skills and problem solving and impairs daily functioning such as the ability to manage one’s own activities. Biological changes are believed to start decades before clinical symptoms of Alzheimer’s disease become evident. In the early stages (prodromal to mild dementia), people may have difficulty remembering things, but daily function may or may not be impaired. In the later stage of the disease, people increasingly become reliant on others for even simple day-to-day tasks. Dementia affects 44 million people worldwide with 7.7 million new cases each year, of which Alzheimer’s disease is the most common form. 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 causes.

About Roche in neuroscience
Neuroscience is a major focus of research and development at Roche. The company’s goal is to develop treatment options based on the biology of the nervous system to help improve the lives of people with chronic and potentially devastating diseases. Roche has more than a dozen investigational medicines in clinical development for diseases that include multiple sclerosis, Alzheimer’s disease, spinal muscular atrophy, Parkinson’s disease, Huntington’s disease and autism spectrum disorder.

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. 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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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