Media & Investor Release

Roche presents new data at CTAD, demonstrating its growing momentum in diagnostics for Alzheimer's disease

- **New data highlight the potential of the Roche Elecsys® Amyloid Plasma Panel and Elecsys ptau181 for ruling out Alzheimer's disease related amyloid pathology with very good accuracy.**
- **In the largest worldwide clinical trial of its kind, the blood-based test showed very good accuracy in ruling out Alzheimer's pathology in those being investigated for the disease, potentially avoiding the need for further invasive and unnecessary tests.**
- **Results further demonstrate Roche's commitment to bringing diagnostic clarity for Alzheimer's disease to people at an early stage of cognitive decline.**

Basel, 31 October 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today new late-breaking data on its Elecsys Amyloid Plasma Panel (combination of pTau181 and ApoE4), for Alzheimer's disease, at the 17th Clinical Trials in Alzheimer's Disease congress (CTAD) in Madrid, Spain. Results show that the test, currently in development, could accurately rule out amyloid pathology – a hallmark of Alzheimer's disease – in a broad population with varying cognitive impairment, as seen in routine clinical practice.[1] This could allow clinicians to rule out Alzheimer's disease as a possible cause of cognitive symptoms with a simple blood test, offering certainty and reassurance.

In the prospective, multicentre study, which included 492 patients across the US and Europe, the Roche Elecsys Amyloid Plasma Panel was able to rule out Alzheimer's disease with a high negative predictive value (NPV) of 96.2% based on a 23.4% prevalence of amyloid positivity according to positron emission tomography (PET) scans, with 91.0% sensitivity and 69.8% specificity. The performance of the test was only minimally impacted by the patients' age, sex, body mass index or impaired kidney function. Roche's pTau181 biomarker performed similarly as a standalone assay.

"The data from this large-scale study in cognitively impaired individuals suggests that a fast and simple blood test could reliably rule out amyloid pathology, offering much-needed reassurance to patients and their families," commented Matt Sause, CEO of Roche Diagnostics. "Alzheimer's disease is one of the most challenging health issues of our time, and its impact on society is growing as the world's population ages. For many people, getting a clear and timely diagnosis remains challenging. This test could help patients to receive the right care at the earliest opportunity."

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The Elecsys Amyloid Plasma Panel, which received FDA Breakthrough Device Designation in July 2023, is a minimally invasive blood test that measures phosphorylated Tau (pTau) 181 protein and apolipoprotein (APOE) E4 in plasma. This is the first industry trial of its kind (globally prospectively collected diagnostic registrational clinical trial) to investigate the test's clinical performance in a patient population that reflects as closely as possible the patients who could benefit from the test. It involved a subset of patients from a wider trial looking at a highly diverse set of patients with broad inclusion criteria, to ensure the test could be used effectively across different geographies and ethnicities. Further potential uses for the test are being explored with the rich patient population.

In addition to data on the Elecsys Amyloid Plasma Panel and pTau181, Roche also presented data for its Elecsys pTau 217 assay which is currently in development and also received FDA Breakthrough Device Designation earlier this year. The results from this latest study demonstrate high accuracy of amyloid pathology detection in comparison with another available pTau 217 test.

Today, barriers to early and accurate diagnosis of Alzheimer's disease exist across the globe, with up to 75% of people living with the symptoms of Alzheimer's but without a diagnosis. Those who have received a diagnosis waited, on average, 2.8 years after symptom onset.[2] To address the growing strain that Alzheimer's disease is putting on healthcare systems, it will be essential to make a person's journey to diagnosis faster and more accessible. This will ultimately enable access to appropriate new therapies as they become available. With an unmatched base of installed solutions worldwide, Roche is uniquely placed to rapidly scale testing once approved, ensuring that patients can benefit from the test as soon as it has been cleared for use.

Roche is committed to using its diagnostic and pharmaceutical capabilities in an effort to better detect and treat Alzheimer's disease as early as possible, and working toward preventing the disease altogether. To achieve this, the company is developing and delivering solutions to more effectively detect, diagnose, and monitor the disease and progressing research into investigational medicines for different targets, types, and stages of the disease. This includes trontinemab, a novel Brainshuttle™ Aβ antibody that is currently in development and is specifically engineered for enhanced access to the brain to enable rapid reduction of amyloid in people with Alzheimer's disease. Further data on progress in the Alzheimer's disease pipeline will be shared with investors. Click here to access the investor presentation.

About the Elecsys Amyloid Plasma Panel

This product is currently under development and not commercially available. The below information reflects Roche's plans for these products if they are approved by regulatory bodies for clinical use in the future:

The Elecsys Amyloid Plasma Panel measures phosphorylated Tau (pTau) 181 protein assay and apolipoprotein (APOE) E4 assay in human blood plasma. Elevations in pTau181 occur in the early stages of Alzheimer's disease, while the presence of APOE4 constitutes the most common genetic risk factor for Alzheimer's disease. The result is intended for consideration in conjunction with other clinical information to advise for further confirmatory testing with amyloid positron emission tomography (PET) or cerebrospinal fluid (CSF) testing. Patients testing negative with the Elecsys Amyloid Plasma Panel are unlikely to be amyloid positive and should be investigated for other causes of cognitive decline.

About Elecsys pTau217

This product is currently under development and not commercially available. The below information reflects Roche's plans for these products if they are approved by regulatory bodies for clinical use in the future:

Elecsys Phospho-Tau (217P) is intended to be an in-vitro diagnostic immunoassay for the quantitative determination of the protein Phospho-Tau (217P) (pTau217) in human plasma from individuals aged 60 years and older. The test is intended for use as an aid in identifying amyloid pathology, a pathological feature of Alzheimer's disease.

- A positive Elecsys pTau217 result indicates a high likelihood of having a positive amyloid PET/CSF result.
- A negative Elecsys pTau217 result indicates a high likelihood of having a negative amyloid PET/ CSF result.
- An indeterminate pTau217 result indicates uncertainty on the amyloid PET/CSF result. The pTau217 result should be used in the diagnostic pathway in conjunction with other clinical information.

About Roche in Alzheimer's disease

With more than two decades of scientific research in Alzheimer's disease, Roche is working towards a day when we can detect and treat the disease early, in order to stop or even prevent its progression to preserve what makes people who they are. Today, the company's Alzheimer's disease portfolio spans investigational medicines for different targets, types and stages of the disease, including trontinemab. On the diagnostics side, it also includes approved and investigational tools, including digital and blood-based tests and CSF assays, aiming to more effectively detect, diagnose and monitor the disease. Yet the global challenges of Alzheimer's

disease go well beyond the capabilities of science, and making a meaningful impact requires collaboration both within the Alzheimer's community and outside of healthcare. Roche will continue to work together with numerous partners with the hope to transform millions of lives.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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.

References

[1] Kirste I, et al, Revamping Alzheimer's Disease Diagnostics: Evaluating Future IVD Plasma p-Tau 181 and ApoE4 Immunoassays for Amyloid Detection in a Multi-Center Study Reflective of Routine Clinical Practice, presented at CTAD, October 2024.
[2] Life Expectancy Following Diagnosis Of Alzheimer's Disease Depends On Age At Diagnosis, Johns Hopkins Bloomberg School of Public Health, November 18, 2002, https://publichealth.jhu.edu/2002/alzheimer-age

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